S. HRG. 113–361

JUSTICE DENIED: RULES DELAYED ON AUTO SAFETY AND MENTAL HEALTH

HEARING

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT,
FEDERAL RIGHTS AND AGENCY ACTION

OF THE

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UNITED STATES SENATE

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JUSTICE DENIED: RULES DELAYED ON AUTO SAFETY AND MENTAL HEALTH

THURSDAY, NOVEMBER 7, 2013

U.S. SENATE,
SUBCOMMITTEE ON OVERSIGHT, FEDERAL RIGHTS, AND AGENCY ACTION,
COMMITTEE ON THE JUDICIARY,
Washington, DC.

The Subcommittee met, pursuant to notice, at 1:34 p.m., in Room SD–226, Dirksen Senate Office Building, Hon. Richard Blumenthal, Chairman of the Subcommittee, presiding.

Present: Senators Blumenthal, Whitehouse, Klobuchar, Franken, and Hatch.

OPENING STATEMENT OF HON. RICHARD BLUMENTHAL, A U.S. SENATOR FROM THE STATE OF CONNECTICUT

Chairman BLUMENTHAL. We will be joined shortly, I am told, by Senator Hatch, the Ranking Member, and as sometimes happens, we are going to be interrupted by a vote at 1:45. That is what has been scheduled. Then we will take a brief break and return to this very, very important hearing, "Justice Denied: Rules Delayed in Auto Safety and Mental Health." And as some of you may know, this hearing is a continuing effort to expose the costs and damage done by regulations that are delayed and thereby cause justice to be denied.

When elected officials talk about regulation, the stakes can be tremendously high even if the public does not always understand and even may not be aware of what the consequences are. Regulatory agencies have authority to act through official rulemaking and the notice and comment process created in 1946 through the Rules of Administrative Procedure, but they should do so openly and transparently, and they should be held accountable for meeting deadlines for those rules. Without the rules, very often the law is simply dead letter. Regulations are essential to making laws enforceable, and that is really why we are here, because too many laws have been made essentially less effective or even unenforceable as a result of delays or non-issuance of such regulations.

In the case of mental health parity, the cost has been clarity and certainty. Congress passed the Mental Health Parity and Addiction Equity Act in 2008. Congressman Kennedy and Senator Ted Kennedy were instrumental in its passage. They have led the Nation in appreciating and acting on the importance of treating as well as diagnosing mental health issues.

Nothing I say can really do justice to the work that they have done, along with others, and I want to applaud the Ranking Member, Senator Hatch, who was an original cosponsor of that legislation and is a champion in this fight. And he knows personally how grateful many people are to his leadership and to others who have worked on this issue. I have done so as a State official, as a State Attorney General, and very proudly with a number of my colleagues who have been State officials.

The Act required that implementing agencies write a rule within a year. Pretty simple. Two years later—2 years after the Act, 1 year after the statutory deadline—the agencies released an interim final rule. But the rule essentially left a lot of questions unanswered. Even worse, it left the industry wondering whether to change its policies or to wait until a final rule brought certainty and a clear path forward. And the regulators also hesitated to change rules, leaving the industry essentially free to delay compliance with the law.

Five years after the Act was passed, this promise remains unfulfilled. I am told that issuance of final rules is imminent, 5 years after the Act was passed, 4 years after the statutory deadline, but the costs have been tremendous.

In mental health, uncertainty kills. If an individual poses a threat to himself or others, he cannot be told he will get the care he needs as soon as his insurance company decides the meaning of "parity." He cannot win access to needed care only after resorting to the courts or to a long administrative process. In a very specific, concrete, practical way, justice delayed is justice denied. And that fact is particularly true of veterans who need mental health care. This issue is particularly pertinent at this point in our history because of the large number of veterans who will be coming from the wars that they have fought, combat that has exacted a toll on their mental health through post-traumatic stress and traumatic brain injury. They need this treatment for their invisible wounds. And as we approach Veterans Day, we should be especially mindful about the searing, destructive impact of this delay on our veterans.

In the auto safety realm, the National Highway Traffic Safety Administration, known as NHTSA, struggled early in its history to release rules in a timely fashion. The result was twofold. On the one hand, important NHTSA rules have been delayed even when Congress has expressly demanded them. One good example is the rear visibility rule. We held a hearing that dealt in part with it last time, and it was discussed at that hearing as a prime example of rule delay meaning justice and safety denied.

On the other hand, NHTSA has had to do by recall what it should have been able to do by rule. Clarence Ditlow, one of our witnesses, a very distinguished safety expert, will tell the story of rules that were suggested to NHTSA by automobile safety advocates but went nowhere, only to arise again when defective automobiles have been removed from the road, not because they were bad-looking or because they were the wrong color, but because they were unsafe—in fact, defective.

These are tragic situations for people who are injured or killed in a car that never should have been sold in the first place. And they are also bad for the car companies. Quite bluntly, their con-

sumers, their customers, want to know exactly what they are getting, and the companies want to know what the law requires of them to give those customers.

When I talk to businessmen, they tell me they make money in a heavily regulated industry. They need to know what the rules are and have certainty about what those rules will be. The great enemy is uncertainty. When the policy is made by adjudication because rulemaking is too difficult, these businessmen cannot get the certainty and clarity they need to invest, grow jobs, and grow their companies.

Now, I said at the beginning the story we are telling here should be common ground. Both industry and consumers want clear rules. Everybody wants certainty. Anybody who has watched a high school civics class, if you have not taken one lately, knows that students learn the laws are made by the Congress, they are executed by the President and the executive branch, and adjudication takes place in the courts. But Congress cannot make laws that are effective if those laws are not accompanied by regulations necessary to enforce them. And representatives of both private interests and the public interest should want bad behavior to be prevented before it occurs as well as punished afterward.

The problem that we face is to make sure the rules are promulgated and enforced, and enforced effectively, and that is why we are here today.

I want to again thank everyone, particularly Ranking Member Hatch, who will join us shortly, if not before the vote, then afterward. And I am now going to ask for the witnesses to be sworn in so that we can proceed with your testimony.

If you would please stand, raise your right hand: Do you affirm that the testimony you are about to give before the Committee will be the truth, the whole truth, and nothing but the truth, so help you God?

Mr. KENNEDY. I do.

Ms. MORELLI. I do.

Chairman BLUMENTHAL. Thank you. Let me introduce the witnesses to the Committee.

Representative Patrick Kennedy of Rhode Island is the co-founder of One Mind for Research. He has been an active and steadfast advocate of not only research but treatment of all neurological and psychiatric disorders, and he has been an advocate not only as a Member of Congress but afterward, and is the winner of numerous awards for the work that he has done in this area. And I know how busy you are. We thank you for being here today, Congressman.

Cathy Morelli works full-time as a casualty claim adjuster. Her 15-year-old daughter suffers from a mental illness, and she advocates for her and others who have to fight for insurance benefits for the treatment of mental illness. She likewise, in Southington, Connecticut, where she lives, as well as the State and the Nation, has been a very vigorous and effective advocate for treatment of mental health issues and better understanding of those issues.

So we thank you both for being here today, and, Congressman Kennedy, if you could please begin.

STATEMENT OF THE HONORABLE PATRICK J. KENNEDY, A FORMER REPRESENTATIVE IN CONGRESS FROM THE STATE OF RHODE ISLAND, AND FOUNDER, THE KENNEDY FORUM, BRIGANTINE, NEW JERSEY

Mr. KENNEDY. Thank you, Mr. Chairman, and it is an honor to be here with Cathy. It is good to see you again, Cathy.

Thank you, Mr. Chairman, for your leadership on this issue and for calling this hearing. As you pointed out, we have been waiting 5 years for the final rule on a piece of legislation that my late father, who sat just where you are sitting today, who sat in this chamber of the Senate for nearly 50 years, helped me pass. And it was the last major piece of legislation that my father and I worked on together, and I recall President George W. Bush signing it into law, again reaffirming the fact that these are not Republican or Democratic issues. Pete Domenici and Jim Ramstad were our able cosponsors on that piece of legislation, and it is important for us to reflect on that today in a very partisan environment that we live in.

I think it is also important to reflect, as you have stated at the outset, that there are huge consequences to this lack of clarification and implementation of the final rule—specifically, as you mentioned, Mr. Chairman, our veterans. So when most people think about the Mental Health Parity and Addiction Equity Act, they do not often think about who those people are that are going to be impacted. Particularly they do not think about it when they think about our veterans, who, of course, have suffered what is known as the signature wound of the war: traumatic brain injury and post-traumatic stress disorder.

Frankly, however, most of our veterans will never go to the VA for their care. That is because most of our veterans are State guard and reservists, like the Connecticut Guard, like the Rhode Island Guard. And they will go back to their places of employment. And if you cannot see the injury on the outside, then it does not exist. But as they go back to work and they are trying to deal with the confusion, with the emotional swings, with the impact and the symptoms of their signature wound of war, they need to be assured by all of us that they are not going to be left behind.

This is not the job of just an insurance company. This is not the job of just the Federal Government. This is not the job of the mental health profession. It is the job of all of us. And the subject of this hearing, which is this delay in rulemaking and how that impacts the end result, well, as you know, Mr. Chairman, having been a top cop in Connecticut as Attorney General, you need clarity, you need rules in order for those to know what they are going to be held accountable to.

Now, I will tell you that one of the reasons I believe we have had a delayed rule is not an unhappy coincidence, and that is, the passage of the ACA. Frankly, the Health Care Affordability Act has done more to extend parity than we ever were able to do in our parity bill. So I give the administration great credit for taking that next step and really taking parity and bringing it across our health care system.

However, as you pointed out, Chairman, the notion that we have had to wait this long for clarity means that people have fallen

through the cracks, and specifically we have seen them fall through the cracks by those inscrutable insurance companies who do not always follow the best of what the intentions and what the spirit of the law says, but who wait for clarification before they know to do the right thing.

Some insurance companies have gotten it right. Many have gotten it wrong, and the reason is because they felt they could because the Federal Government was not there to clarify where their actions would be in violation.

I just want to conclude, because I know most of the good work that this Committee does is in the questions and answers, but let me conclude with this: We just had a case in New York that was dismissed by a judge under the Mental Health Parity and Addiction Equity Act for two reasons:

One, the judge said that the plaintiff had to be a consumer, could not be someone suing on behalf of a consumer. Now, that has got a whole set of implications with it, particularly for our community of the mentally ill who have a tough time fighting for their own survival and health, let alone having to take a case to court, as Cathy did on behalf of her daughter.

Number two, the court dismissed the case because they said the defendant was not the insurance company, and, Mr. Chairman, I would think that this would spark a lot of interest in Washington, particularly amongst the Chamber of Commerce. They said the defendant had to be the employer themselves; in other words, if United or Anthem or any of the insurance companies make a medical necessity determination, decide to impose higher treatment limitations or financial limitations to those seeking mental health/substance abuse disorder care, then they can do so now with impunity, according to this judge and their ruling. And the right of recourse now is for employees, not someone who represents them, not a doctor or someone who can help them; it is up to the employees to bring the case against their own employer. Well, Cathy can speak about the role of stigma in this whole issue. You can only imagine what it would be like for someone to try to fight for recourse and to know that they have to do it against the person that is giving them a job.

Mr. Chairman, all due respect, my message to this Committee is that the final rule is not the final word on this issue. And as you pointed out—and I think in large part due to your scheduling this hearing—we are going to get a final rule, and I understand it is going to be tomorrow. But this is not the final rule. It is the first step, because it is going to be the beginning whereby we begin to understand how we implement this thing called the Mental Health Parity and Addiction Equity Act, which, Mr. Chairman, you and I both know when we wrote the law—and Senator Hatch, Chairman Hatch, was a big part of this—we were crystal clear about what we meant. Parity, equality. If you treat diabetes, whether it is inpatient, outpatient, in-network, out-of-network, pharmacy benefits, emergency room services, you must do the same for a diabetic as you would an alcoholic as you would an asthmatic. If you treat someone with a stroke and you give them, you know, inpatient emergency room care and then you give them partial hospitalization, you have got to do that for someone who has had a psychotic

break and has psychosis, you have got to treat them the same. And the services must be the same.

And what we have not had in the final rule is a description of what are the services. We have it in the law, Mr. Chairman. The law is very clear: Across all six categories of services there must be parity.

But without the rule, then we have this confusion, and when there is a vacuum, Mr. Chairman, you know what happens in a vacuum. People do not always behave the way we would like them to behave because they do not know where the lines are drawn. Hopefully tomorrow the administration will draw some pretty bright lines outlawing discrimination, and I will conclude with this.

Why? Not only for Cathy Morelli's daughter, not only for people who are average Americans who suffer from a substance abuse disorder like I do, or a mental illness like I do, but most importantly, for our Nation's heroes, our veterans, because through no fault of their own they came home from war, signature wound was traumatic brain injury and post-traumatic stress. And when they go to their insurance company, whether it be Anthem Blue Cross or United Optimum, or whatever, guess what? We need to make sure that that insurance company does not impose any higher treatment limitations, does not impose any of these "non-quantitative treatment limit" kind of barriers, like fail first, as they are doing today on the rest of America. I will tell you, Mr. Chairman, the day one of our veterans gets denied treatment for their wounds of war, I will tell you maybe that is going to be the day that our CEOs in America realize that they have a responsibility for what insurance company they hire to manage their benefits, and that maybe personally they might be liable, and that is really the decision of a judge this last week in New York. So if that is the case, I would hope that they are telling their legal counsels right now to get ready, because if Cathy has anything to say about it, just like she has done so persuasively in your State of Connecticut, Mr. Chairman, we are going to go around the country, and we are going to show up in places where there are consumers being denied. And just like in the rest of the civil rights movement, we are going to stand with others so that they do not have to do this alone and do not have to fight for dignity and quality of insurance coverage just as if they were to have any other physical health issue.

Thank you for letting me share.

[The prepared statement of Mr. Kennedy appears as a submission for the record.]

Chairman BLUMENTHAL. Thank you very much, Congressman, for that very powerful and insightful testimony.

I am told that a vote has been called. I do not have anyone who can take the gavel for me here, so I am going to be gone for just a few minutes, and then rush back. Hopefully I will have Senator Hatch with me, if I can grab him, but I just want to thank you for focusing on veterans who are so often, unfortunately and tragically, denied the treatment they deserve. Even with the supposed availability of the VA as a source of treatment, we had in Connecticut just within the past week a marine who came back from Afghanistan and tragically took his own life after seeking treatment for PTS, and with better treatment maybe he could have been saved.

Justin Eldridge was, in fact, a brave hero, and I had occasion to know him and to try to help him gain treatment. But, unfortunately, that treatment was not as available as it should have been, and as a result, the tragedy has consumed him and his family, and I thank you for focusing on veterans. Many of them are getting treatment, but parity is absolutely necessary.

Mr. KENNEDY. Well, as you go, Mr. Chairman, let me point out that 72 percent of all veterans will never go to the VA in their lifetime. That is a fact most Americans do not realize. They are going to get their care through their employer-sponsored health plan. That is why this issue is more than just a consumer rights issue. It is an issue for our patriots. It is our veterans' issue.

Thank you, Mr. Chairman.

Chairman BLUMENTHAL. That is a very, very important fact. The other is that 30 percent of veterans leaving the military today, or more, according to the armed forces themselves, suffer from PTS or traumatic brain injury. So we are not talking about a scattered few here and there. We are talking about a major part of our veteran population.

So I am going to go. I apologize, Ms. Morelli, but our fellow residents of Connecticut will hold me very responsible if I miss this vote. Thank you. I will be right back.

[Recess 1:57 p.m. to 2:14 p.m.]

Chairman BLUMENTHAL. Thank you very much for your patience. We will now return, beginning with—Senator Hatch has an opening statement that he would like to make, and I am very glad that he does and that he is here. And so with your indulgence, let us proceed with that. Thank you.

OPENING STATEMENT OF HON. ORRIN G. HATCH, A U.S. SENATOR FROM THE STATE OF UTAH

Senator HATCH. Well, thank you, Mr. Chairman, and I apologize for not being here initially. I certainly welcome our witnesses here today, especially Patrick, whom I have known for a long time, and we are friends.

I will just make a couple of points for the record so that we can hear from the witnesses who have come here today.

The subject of the first panel is the regulatory delay following enactment of mental health parity legislation in 2008. Now, I cosponsored legislation addressing the issue of mental health parity in the 107th Congress, the 108th, Congress, and the 110th Congress. Those bills were introduced by my friend Pete Domenici of New Mexico in the Senate. The Mental Health Parity Act passed the Senate by unanimous consent in 2008. One of the witnesses today, former Representative Patrick Kennedy, also a friend, introduced the legislation to address this issue that was enacted into law in October 2008. And so it concerns me greatly that the agencies required by that law to issue final regulations have still not done so. The best they could do was to issue interim final regulations, and even that was nearly 4 years ago.

I want to make clear that I view the issue before us as separate from how the Affordable Care Act addresses mental health insurance coverage. The Mental Health Parity Act has bipartisan support in 2008. The Affordable Care Act did not in 2010. I do not

want the ongoing controversies about the Affordable Care Act to confuse or distract attention from the issue of mental health parity regulations that we are examining here today.

The Affordable Care Act is, however, connected to this overall topic in a different way. At this Subcommittee's previous hearing on August 1, I said that rushing regulations can also have serious costs. One of the witnesses of that hearing was from the Mercatus Center at George Mason University. Another of their scholars, Jerry Ellig, wrote an op-ed published just last week in *The Hill* about how rushing regulations contributed to the widespread and growing problem of insurance companies canceling health insurance policies for millions of Americans. I ask consent to put that op-ed into the record, Mr. Chairman.

Chairman BLUMENTHAL. Without objection.

[The op-ed appears as a submission for the record.]

Senator HATCH. The second panel today is on auto safety and how the National Highway Traffic Safety Administration affects traffic accidents or fatalities. I confess that I am not entirely clear about how the substance of auto safety regulation fits within the Judiciary Committee's purview. I think we must resist the temptation to think that federal regulators can account for and control everything around us.

It is my understanding, for example, that more than 90 percent of traffic crashes involve human error; more than 10,000 annual traffic deaths are caused by drunk drivers; and more than half of all those killed in crashes are not wearing seat belts.

At the same time, this particular agency has been very active with what sounds to me like positive results. Just in the last decade, NHTSA has issued hundreds of proposed and final regulatory actions.

It is safe to say that automobiles are one of the most highly regulated consumer products in America today, and while the number of licensed drivers has more than doubled and the number of miles they drive has more than quadrupled since 1960, NHTSA's estimate of the rate of traffic deaths per miles driven for the first half of this year happens to be the lowest in history.

Mr. Chairman, we have before us distinguished experts on this subject, and I really look forward to hearing what they have to say, and I want to congratulate you for holding these hearings.

Chairman BLUMENTHAL. Thank you, Senator Hatch. And you were not here, but I paid tribute to the leadership that you demonstrated in gaining the mental health parity law at the time working with Senator Ted Kennedy as well as with Congressman Patrick Kennedy, who is a friend of both of us, and we thank you for your leadership.

Senator HATCH. I thank you. Well, Ted got me into lots of problems from time to time, but——

[Laughter.]

Senator HATCH. I think it was all worth it. I will put it that way. We did some very, very important things together, and we were and still are very dear friends.

Chairman BLUMENTHAL. And I also want to welcome Senator Franken, who has also been a real champion and leader on this issue and with this rule.

I am informed, by the way, Senator Hatch, that the mental health parity regulation will be issued tomorrow. Congressman Kennedy mentioned it in his opening statement, as did I, and this rule has been in the works for too long, but we are glad that it will be issued shortly, and it may well be, as Congressman Kennedy suggested, that the prospect of this hearing, which was made known to the administration, helped to expedite it. But whatever the cause, we are glad for the result.

Ms. Morelli, you have been very, very patient and understanding, and please go ahead. We welcome you here, and I am particularly admiring and grateful for your courage and your strength as a parent as well as an advocate. Thank you for being here today.

STATEMENT OF CATHY MORELLI, SOUTHINGTON, CONNECTICUT

Ms. MORELLI. Well, thank you for giving me this opportunity to tell my story.

I am here today to talk about the difficult battle I had with my health insurer, Anthem, in my attempt to get my teenage daughter the treatment she needed for her mental illness. I was completely blindsided by my health insurer's constant denials for mental health treatment that my daughter so desperately needed. It was a battle I had never previously experienced whenever I sought coverage for treatment of medical conditions. Unfortunately, I discovered in a very difficult way that coverage for the treatment of a mental illness would not be as easily accessible as it is for a medical condition.

Early in 2012, my then 13-year-old daughter was struggling with an eating disorder and began engaging in self-harming behaviors and suicidal attempts. Her first inpatient hospitalization began in March 2012 due to a suicide attempt and cutting herself. Within 6 days of this hospitalization, our health insurer denied her continued stay in this hospital advising that they felt she could be managed on an outpatient basis and that the treatment was not medically necessary. The hospital disagreed with my insurer and filed an expedited appeal, but my insurer maintained their denial.

Within a day of being released from that first hospital, she again attempted suicide and engaged in serious self-harming behaviors that involved cutting so deeply into her thigh that it required sutures to close the wound. She spent the next 14 days in the emergency department, and during her stay there she began her aggression toward people and spent most of her days in restraints and under heavy sedation. Within just 6 hours of being released from the emergency department, she again attempted suicide and struggled significantly with an eating disorder and spent the next 8 days medically admitted to a hospital on a feeding tube. Once she was stabilized, she was transferred to Vermont to yet another psychiatric hospital.

Over the course of just 5 months, she was in and out of numerous psychiatric hospitals with each stay being cut prematurely short by my health insurer's refusal to pay for the treatment that every doctor and therapist said she needed.

I had applied for voluntary services through the Department of Children and Families through the State of Connecticut. I did this

very early on to get help in managing her illness because it was very clear to me that my health insurer was not going to pay for the treatment she really needed. Every denial was based on my health insurer's contention that inpatient treatment was not medically necessary and that she could be managed on an outpatient basis. DCF provided us with intensive in-home psychiatric services, known as IICAPS, in between these hospital admissions. She was also being seen by an outpatient provider.

But despite IICAPS' and the outpatient provider's best efforts, my daughter's illness continued to spiral out of control; but without health insurance to cover the necessary inpatient treatment and the inability to pay out of my own pocket, I had no choice but to rely on outpatient treatment.

Things really escalated in June 2012 when my daughter brought a knife to school and revealed this along with extensive fresh cuts on her body to the staff. She was taken to the hospital and then was admitted to yet another psychiatric hospital. This was the turning point for my daughter because, despite my health insurer's denial, this hospital would not release her as she was a danger not only to herself but to others.

While inpatient and under the care of professionals who treat mental illness, my daughter attempted and nearly succeeded at suicide. She was then placed on what is called "one-to-one supervision," meaning staff was within arm's reach of her at all hours of the day and night. I fail to see how my family could have provided this level of care that my health insurer claimed was possible. I will read an excerpt from a letter addressed personally to my 14-year-old daughter for her inpatient stay where she attempted and nearly succeeded at ending her life. This letter is dated July 16, 2012. I quote: "We cannot approve the request for hospital admission as of July 16, 2012. The hospital gave us information about you. This did not show that hospital care is medically necessary. You have recently been in the psychiatric hospital for about 1 month due to behavior problems and trying to hurt yourself. You have had these problems for a long time. You had to go into the medical hospital for a few days and now the medical hospital wants you back in the psychiatric program. You had not been getting better in any significant way for at least the last 30 days. There is no plan to do anything different. It does not seem likely that doing the same thing will help you get better. You need treatment that will likely help you get better . . ." Interestingly, my insurer paid for only 1 day of the 30 days they speak about in that letter. They acknowledge she needs the treatment, but they make it very clear they are not going to pay for it.

So along with DCF and the Office of the Healthcare Advocate, who also became involved in my daughter's case, we applied for Husky Health, which is the State-funded insurance plan, and coverage began at some point during her last admission. With the help from the State, my daughter was finally able to get the long-term treatment that was necessary to stabilize her condition and allow her to return home and be managed on an outpatient basis.

With the help of the OHA, we began appealing the 13 denials issued by my health insurer in just those 5 months. At first, we went through the insurer's two-step internal appeal process, but

the denials were upheld. We then filed external appeals through the insurance department, and every single denial issued by my health insurer was overturned. But it never had to get to the level it did considering the mental health parity laws in place. With a lack of regulations, these health insurers will not stop their discriminatory practices toward the treatment of mental illness.

[The prepared statement of Ms. Morelli appears as a submission for the record.]

Chairman BLUMENTHAL. Thank you, Ms. Morelli. Thank you very, very much for that really powerful example of the effect of the denial of coverage resulting from the lack of regulation. And you have been very objective and factual in your presentation. Let me ask you what the effect of those denials was on your family's emotional state and possibly also on your daughter as she sought to recover from this life-changing illness.

Ms. MORELLI. It was a very rough time. I often look back and wonder how we got through it. I am not really sure I can tell you how we did it. Perseverance. We had a lot of support from family, her school, the State, DCF, the Office of the Healthcare Advocate especially. I think without the resources that our State offers, I would never have gotten through it. But there was clearly an emotional toll for me as well as my husband and my other two daughters. At times, her sisters did not want to sleep in their own bed at night for fear that their sister would harm them. So it was pretty—it was a pretty rough time.

Chairman BLUMENTHAL. Thank you.

Congressman Kennedy, I guess this story is, again, an example of why you fought so hard, along with your dad, for a law which guarantees better parity, better insurance coverage. And we are not here to embarrass any particular insurer. I know the name of Ms. Morelli's insurer. But this kind of intransigence and insensitivity seems all too common.

Mr. KENNEDY. So the irony is this: This hearing is process equals substance. The process you have calculates the answer you are going to get. So if the process is not right, you are not going to get the right answer. In her case, as in the case with this rule, we do not have the right process, and that means for insurance companies, we need public disclosure requirements so that we know when someone like Cathy is facing a situation of discrimination.

By the way, insurance companies need that. You know, for them to know when they have crossed the line, they need the same kinds of case law much like you would have with the IRS given certain situations which describe what is legal, what is illegal. Cathy paints the most glaring story of illegality, but, frankly, the real rub for the next few years is that gray area, and how do even insurance companies know when they are crossing the line?

What we need from you is to help us bring transparency so that we have a better idea—because Cathy mentioned one of the things that helped her get through is the Office of Public Advocacy. Well, guess what? Who is out there looking at all the Cathy Morelli's in the country and making sure that ERISA-insured plans are not, you know, subscribing to a pattern and practice of discrimination across State lines—like we do not know, but under the law the HHS Secretary has the authority to require from insurance compa-

nies how they make medical necessity decisions, and they also can de-identify that data and make it clear who is in violation. I mean, this is a process, Mr. Chairman, and I would just encourage you to not look at this hearing as, like I said, the end of the final rule but really the beginning of this long process. You thought the process of getting a final rule was long. Wait until it takes us the time—and the sooner we get at it, Mr. Chairman, is the sooner we save lives, not only like Cathy Morelli's family's life was saved but the veterans that we talked about earlier, as I said, many of whom are going to get their insurance through their employer-sponsored health insurance.

So I do not think employers will be very keen on knowing that their insurance carrier is denying a legitimate American hero from getting treatment for the signature wound of the war. But that is going to be the implication, Mr. Chairman, of us not doing what you are starting here with this hearing, and that is, implement a rule protecting people from discrimination against their brain illness.

Chairman BLUMENTHAL. Thank you. I am going to defer to my colleagues at this point. I really agree strongly that this regulation will be a final rule but not the final word, and we need to pursue that better word or rule even as we have this one.

I am going to, with the permission of our Ranking Member, go a little bit out of order just to ask Senator Whitehouse of Rhode Island, since a former fellow colleague is here, to do his welcome. And he would have been here earlier, but as I mentioned to everyone here, we had a vote, and thank you for being here.

Senator WHITEHOUSE. Thank you, Chairman, and I also thank the Ranking Member for his courtesy. I just want to take a moment and welcome my colleague from Rhode Island, Representative Patrick Kennedy. It is terrific to have him back here, and it makes me very proud to see what a continuing good effect he is having. I know this is a passion for him.

Patrick, we miss you around here, but clearly you are flourishing and doing exemplary work. So thank you so much.

And, Mr. Chairman, let me just thank you and the Ranking Member for this hearing. It has been said that the oversight function of Congress is sometimes even to be preferred to its legislating function, and I think that without the attention that you both have brought to this issue with this hearing, we would not have received the news we did today that the rule is finally going to be announced. It was an exemplary effort in legislative oversight by Senator Blumenthal and Senator Hatch, and I am grateful to both of you.

Chairman BLUMENTHAL. Thank you. Thank you, Senator Whitehouse. And I thanked Senator Hatch earlier, but I thank him again and now defer to him for his questions.

Senator HATCH. Well, I want to thank you, Mr. Chairman. I think you have shown a great deal of interest in this subject matter and are moving in an appropriate way—in appropriate ways, I should say.

I also want to thank you, Ms. Morelli, for being here today and for your article in the *New York Times*. You know, as a parent of a child with mental illness, you add a very, very important voice

to these problems and to our understanding of these issues and how they affect individuals and families. So your being here today is very, very important, and I concur with my dear friend and colleague from Rhode Island in his comments, and also the Chairman as well.

Representative Kennedy—I am going to call you "Patrick." I have known you since you were a little boy.

[Laughter.]

Senator HATCH. You have certainly grown much bigger than I thought——

[Laughter.]

Senator HATCH. But I cannot thank you enough for the leadership of you and your family and that you continue to exercise and provide on this issue as well as other issues, and I am very grateful to you.

In your written testimony, you described how the administration's continuing failure to issue this final rule creates uncertainty. In your experience, how does this delay and the uncertainty it causes affect insurers and employers? You have alluded to that already, but how is the private sector responding to this lack of clarity?

Mr. KENNEDY. Well, as was the case in other laws that were passed, it is left to the court system to ultimately interpret the federal law. Well, part of the problem, even with the interpretation of the federal law, as we saw with this notable case against an insurance carrier, dismissed last week in New York, was that they did not even have the terms who is a plaintiff, who is a defendant. Ironically, Mr. Chairman, they say that insurance carriers are not the defendants, employers are the defendants.

So, Mr. Chairman, let me just say that I think for the Chamber of Commerce in Washington, D.C., who now represents not only insurer CEOs but every other CEO, they are going to be interested in this latest federal judge's decision, because it now says they cannot just pass the buck and give the Heisman to whoever their benefit manager is in an ERISA-sponsored health plan, where an insurance company acts as the intermediary. They are going to be the ultimate arbiter and final person with responsibility.

So I mention that, Mr. Chairman, because I think these decisions that are being made today, in lieu of a failed clarity on a final rule, are going to create a lot of not only confusion for families like Cathy Morelli's, but it is going to create a lot of confusion for employers who may want to do the right thing, Mr. Chairman, and need that guidance to know when they have crossed the line and when they have not. And, you know, I think that is the real challenge for us now, is the oversight process.

So the process of issuing a final rule was not very pretty. We understand what were some of the implications. Of course, the administration had health care reform to add to this mix, which is putting a lot on the table, so we give them that. But the question now is: As Cathy mentioned, is her situation going to be repeated in the future? We are going to get the rule tomorrow. The question is: Are we going to have it in our ability to ensure that, to the best of our ability—granted, it is not going to be perfect—that this situation no longer happens?

What I am saying to you, Mr. Chairman, what you just heard echoed by my good friend and colleague from Rhode Island, is that this is going to require constant oversight. And to the extent that this Committee can help inform the administration as to where within their existing authority they have that oversight capacity, to require information by insurance companies as to how they make medical necessity decisions, my feeling, frankly, is—and I know this will be music to Chairman Hatch's views as a conservative—we do not need to mandate new rules on them. We just need them to be more transparent with adhering to the rules that we have put before them, because I think the light of day and the public at large is going to keep them honest if they know that if they have a deliberate discriminatory practice, they are going to be called out on it.

I do not begrudge them if they make bad decisions that were within the margins, provided we have a way of expeditiously correcting those bad decisions. Again, all this comes back to a process, Mr. Chairman, and oversight is the key to that process. And that oversight can only take place if there is transparency of the situations that allowed for Ms. Morelli's situation to take place.

Senator HATCH. In many cases, when Congress enacts a law, a single agency or department is responsible for issuing the rules or regulations to implement it. Now, this complex area of insurance regulation involved multiple agencies and departments at the same time. The Department of Health and Human Services, Labor, and Treasury are all involved in the rulemaking that we are looking forward to today.

In your opinion, has this involvement by multiple departments affected the development of this final rule, or has it contributed to its delay?

Mr. KENNEDY. We have to think in some sense that that kind of multiple jurisdiction would contribute to the level of complexity. But here is another level of complexity. As I understand, the rules can indicate that States have a big responsibility in implementation, so now the question is: Where do States take their call? It would be a lot easier, like in civil rights, if we define the parameters on the federal level and not leave it to be squishy amongst the 50 States as to whether you are treated in one State versus another. That kind of harkens back to a day where, you know, justice depended on geography whether you had different colored skin or not.

Now, in this day and age, we cannot have it where people as Americans, as our veterans from our country, are treated one way where their signature wounds of war are covered in one State but their signature wounds of war, TBI and post-traumatic stress, are not covered in another State, Mr. Chairman.

So I think that for clarity we are going to need to make sure that it exists on the federal level so that these States are not having to kind of reinterpret what is meant by a rule that delegates a lot of this to the States. So I think to answer your question, there was complexity. I think there is going to be even more complexity if we are not, you know, more vigilant, if you will.

Senator HATCH. Well, thanks to both of you. I appreciate your testimony.

Chairman BLUMENTHAL. Thank you, Senator Hatch.

We are fortunate to be joined today by two of my colleagues who have been real leaders in this area, as I mentioned earlier, and I am going to call on them in the order of their arrival. Senator Franken, if you would please proceed.

Senator FRANKEN. Thank you, Mr. Chairman, for convening this very important hearing. Paul Wellstone was a friend of mine, and I hold the seat that Paul once held. David Wellstone is not here today, but as Patrick well knows, David has been coming to D.C. time and time again to fight for these regs to be issued.

I have focused, been focused from day one, on the implementation of the Mental Health Parity and Addiction Equity Act, really from day one, and I have led six Senate letters to the Obama administration since then requesting the timely release of the final rules. It is a little too late now for a timely release, but I am very happy that we——

Mr. KENNEDY. We were glad you were on our side, Senator.

Senator FRANKEN. Believe me, I was so glad to be on your side on this one, and I am relieved that the final rules appear to be coming out tomorrow.

Patrick—I am sorry—Congressman Kennedy, you know, we have been through this together. The last time I saw you was at a mental health policy conference at the White House. It was a couple days after my grandson was born, and I told you that I had held him in my arms after he was born and said, "No one expects you to know anything. There is no pressure on you." And you said, "That is not how it goes in my family."

[Laughter.]

Mr. KENNEDY. That is right.

Senator FRANKEN. And you said this, you said, "They say, 'You are going to file for Congress, and then run for President.'"

[Laughter.]

Senator FRANKEN. So I just have to say that of all the accomplishments of all the members of the Kennedy family, you, sir, have been a Profile in Courage.

Mr. KENNEDY. Thank you.

Senator FRANKEN. And I want to thank you for that.

Okay. So now we think these rules are going to be released tomorrow. What do you want to see in them in terms of their scope and transparency?

Mr. KENNEDY. Well, the transparency is what we want to see because we have the authority to require public disclosure of the way an insurance company makes medical necessity determinations, and we have a way of reporting how Patient X with a mental illness, an eating disorder, and so forth is treated versus Patient Y with cardiovascular disease, with a stroke, with diabetes, with asthma. And if those patients with asthma and diabetes are treated inpatient and outpatient and in-network and out-of-network and in the pharmacy with coverage and with the ER, then guess what? The other chronic illness that happens to be above their neck needs to be covered, too, and it needs to be covered equally so you have a total scope of services. So we cover if diabetes means that you lose your sight or your legs, but we do not wait until you have to lose your legs to diabetes. We treat it in advance of that. But in

mental illness, we wait until you need your legs amputated. In mental illness, if it were like cancer, we would wait until it was State IV cancer before we would pay for it. So——

Senator FRANKEN. So what you are looking for are the transparency, the rules and regs regarding transparency.

Mr. KENNEDY. Because I believe, Senator, that otherwise we are going to constantly be trying to litigate this thing to get disclosure about an insurance company as to why they made the decision they did. They may have a good reason. They just need to be up front about it and let the chips fall where they may, because at the end of the day, we are all going to have to do something in terms of keeping costs down. Frankly, mental health, as most economists recognize, is the saver of health care dollars because you think of someone with diabetes, if they have untreated alcoholism, you are in a real pickle. If you think of someone with heart disease with depression, guess what? Your heart disease is going to be in real trouble, too. You are four times more likely to have a heart attack.

The point is that we need integration and we need transparency in the way we manage patients so that we can understand whether there is an overt discrimination. Now, we get it that the advancement of this science of mental health still needs to go a great deal further in its advancement. But we still know enough now to know, like in Cathy's situation, where it is blatant discrimination, and we should at least be able to tell that and enforce that.

Senator FRANKEN. And, Ms. Morelli, I just want to thank you for your testimony today. You and I know that one in five children and one in four adults faces mental illness, but for families that are going through this, they can feel pretty alone, as I imagine you did. And your willingness to speak out about your daughter's experience and your experience is just very courageous, and I want to thank you.

You know firsthand, obviously, why it is so important that behavioral health services be covered to the same extent as medical and surgical services by insurers. Can you just tell us how you think your life would have been different and how your daughter's life would have been different if these regs had been issued and that you had gotten the proper treatment then?

Ms. MORELLI. I can tell you that in between hospital admissions, when she was home and we were not able to manage her, and she did the extreme cutting and the behavior was so extreme, I can tell you my daughter will have less scars—would have less scars had she gotten the treatment initially and not done this back and forth to the hospital routine that we seemed to do, because that is where the significant cutting was happening, was at home, unfortunately, because I do not have the ability to childproof my house to a 14-year-old child who will even use her braces to cut herself. So——

Senator FRANKEN. And what was the effect of that on your other children, on your two other daughters?

Ms. MORELLI. They were absolutely terrified of their sister, afraid to go to bed at night for fear that she would harm them, because at one point she had threatened to harm us. So they no longer trusted her because they saw what she was capable of.

Senator FRANKEN. And this has an ongoing toll for your family.

Ms. MORELLI. It does.

Senator FRANKEN. I see that I am out of time here, but I again want to thank you for your courageous testimony and, Congressman, thank you for yours.

Mr. KENNEDY. Thank you, Senator Franken, for carrying on your late colleague's work. Senator Paul Wellstone was a hero to all of us.

Senator FRANKEN. And I want to recognize Jim Ramstad, too, from Minnesota, who worked with you.

Mr. KENNEDY. Yes. Thank you.

Chairman BLUMENTHAL. Thanks, Senator Franken.

Senator Klobuchar.

Senator KLOBUCHAR. Thank you very much, and thank you, Congressman Kennedy, for being here and for all your work, as Senator Franken mentioned. I know you were in Minnesota recently.

Mr. KENNEDY. Yes.

Senator KLOBUCHAR. And thank you for that. And I know any friend of Jim Ramstad's is a friend of ours, so thank you, and you have an incredibly special friendship, that means a lot to everyone in our State, so thank you.

Al already mentioned the work that Paul did on this bill, which was incredible, and thank you for helping carry on his torch over in the House and getting this done. I was there when that happened, and it took a lot of work on all sides.

So my questions are more about what has been happening in terms of the big picture. You talked in your testimony about the problems of the delayed regulatory process, how it goes beyond the Mental Health Parity Act, and that it has stalled efforts to end discrimination in multiple other settings. Could you elaborate on that and what that means?

Mr. KENNEDY. Well, if we had had a final rule earlier, we would have begun the process of really crystallizing the spirit of the law, which is that we do not want unequal treatment. But, of course, as you know, we have unequal treatment in a lot of other areas of federal insurance: in the VA, in the Department of Defense, in Medicare, and in Medicaid.

So I just say that to give some insurers a little pause that I am not just beating up on them today, because, frankly, we are not setting a very good example as a Federal Government, because we do not treat mental illness equally to other physical illnesses within our own Federal Government. So Medicare does not reimburse it the same way. Medicaid does not. There are many, many examples of disparity in the availability of treatment and the extent of treatment available to people that is reimbursable by the Federal Government.

So I would have said that with the final rule, there is a lot more work to be done. For Jim Ramstad's work that he started and Paul Wellstone's, that can continue, but we need to take that next step. You cannot literally jump ahead when you do not have the biggest step of all, which is laying the framework for equality. Because once we do that, now we can do the other things so that the Cathy Morelli's who are senior citizens in Minnesota who are getting denied geriatric psychiatry because it is not treated the same as some other specialty service with Medicare, that they are not denied.

But we cannot even do that until we first get this. So what I am saying is this kind of held up everything until now. What I am saying is the dam is going to break tomorrow. I am glad you two are here carrying on the great Minnesota tradition, because there is going to be a lot of work to really make this a reality in the future.

Senator KLOBUCHAR. The *New York Times* article many have talked about here quotes an insurance representative suggesting that the industry would welcome final rules. I think sometimes people do not think about it, but when there is no guidance or unclear guidance, it affects everyone, businesses and health insurers as well. Do you want to comment about that?

Mr. KENNEDY. I think insurance would welcome it. Why? Because they would have clarity that they are playing on the same level playing field as everyone else. Even the problem of insurance for all was that community rating. It is so that everybody is not competing on who can be denied care but is competing on who can most effectively treat the illnesses at the most cost-effective way.

This should not be a game of who can cherry-pick and who can deny. And all I would say is that is the real challenge for us going forward. And I think insurance companies like that clarity. They are in the business of clarity. They need clarity to know how they are going to make their decisions, and the clearer that we can be with them, I think the more they will welcome it, because now they are not going to be at a competitive disadvantage.

Let us say one insurance company decides, well, we are just going to knock it out for Cathy and her family from here on out. They cannot be at a competitive disadvantage with their thinking that, well, but if my competitor does not do that, maybe I might be at a financial loss.

We need to make it clear that, no, you are all in this together, we are all in this together, and it is important for you to do that, to get this final rule, be very clear, and the implementation of it be very clear.

I would point to the many reviews that Cathy had to go through to get her claim addressed—internal review and external review. So, Mr. Chairman, I would also commend to you that you should take this up, because this is within your jurisdiction, to oversee how, much like the Banking Committee dealt with whether banks could self-deal. Right? We had 2008—the irony is that parity passed on the banking reform, the TARP legislation.

Senator KLOBUCHAR. Right.

Mr. KENNEDY. So what did we put in place to try to fix this problem of these shady investments? Well, we said you cannot behave in this way, you cannot self-deal; you know, you cannot have these rating agencies be the ones you hired tell you that you are okay. Right? So they are all saying, oh, keep doing it, keep doing it, keep doing it. Well, of course, everybody knew that it was suspect, but why didn't the rating agencies say, hey, fellows, this is not kosher, you have got to stop this? Why? Because they were being paid by the banks to tell them what they wanted to hear.

So here is the point: The insurance industry hires reviewers to tell them how they are doing. Now, what reviewer is going to tell their employer, hey, fellows, you are really not acting too well, and you better scale back that whole process of medical management

overtly for and oppressively against the mentally ill because it is just not according to law? They are going to say, good-bye, we will get someone else who can come in and tell us that we are not doing such a bad job.

I would just say, again, Mr. Chairman, it is process equals substance. If you get a good process, you are going to have a better chance of getting a better outcome.

Senator KLOBUCHAR. Ms. Morelli, have you thought through, if this law was properly implemented, the rules were in place, how that would have made you and your daughter's life different?

Ms. MORELLI. Yes, perhaps the first hospital I brought her to would have been the only hospital she had to go to and get the long-term treatment she needed to stabilize. It would have been a huge difference. I mean, it got to the point where I had to send my daughter from Connecticut—I had to send her down to Virginia. She had been to all the psychiatric hospitals, and I do not know why they turned her away, but I am guessing, you know, they were not able to help her the first time with Anthem denials, and we ended up having to send her down to Virginia for long-term treatment. And, fortunately, the State of Connecticut paid for it.

Senator KLOBUCHAR. Thank you.

Chairman BLUMENTHAL. Thank you, Senator Klobuchar.

I want to again thank both of you for being here today. Congressman Kennedy, I assure you that these regulations will not be the last word. We are going to continue to be vigilant, as you have suggested we must be, and make sure that the promise of this landmark historic legislation is fulfilled. I will tell you I join in thanking you for your leadership, but also I can tell you the voice and spirit of your father is very much with us——

Mr. KENNEDY. Thank you.

Chairman BLUMENTHAL [continuing]. On this issue, as so many others. In this hearing room, in the halls of the Senate, on the floor, I continue to hear his voice, and I think that his warrior fighting spirit for justice is one of the principles and the reasons that I and so many others feel so strongly about this issue. So thank you, and thank you, Ms. Morelli, again for your being here, but also your insistence as a parent that your child and your family be given what it is due. This story really is about justice, fundamentally. parity is about justice. And I very much admire your bravery and your strength. So thank you very much for being here, and we will proceed to our next panel.

If I could ask the next panel to please stand so I can administer the oath. That is, as you may know, our practice here in the Committee. We are not singling you out for special treatment. Do you affirm that the testimony that you are about to give to this Committee is the truth, the whole truth, and nothing but the truth, so help you God?

Mr. MCGARITY. I do.

Mr. DITLOW. I do.

Mr. COGLIANESE. I do.

Chairman BLUMENTHAL. Let me introduce each of the witnesses to the Committee.

Professor McGarity holds the Joe R. and Teresa Lozano Long Endowed Chair in Administrative Law at the University of Texas Law

School. He has taught environmental law, administrative law, and torts at the law school since 1980. Prior to then, prior to this job, he taught at the University of Kansas School of Law. Professor McGarity has written widely in the areas of environmental law and administrative law. He is the immediate past president and member of the Board of Directors of the Center for Progressive Reform, and we are very, very privileged to have you here today given your extensive knowledge of the administrative law issues that so concern us in this hearing.

Clarence Ditlow, well known and renowned as executive director of the Center for Auto Safety, a consumer group founded by Consumers Union. He directs the Center for Auto Safety to improve auto safety, reliability, and he has played a major role in initiating major reforms and recalls, and he has testified more than 50 times before congressional committees on auto safety, warranties, air pollution, consumer protection, fuel economy, emergency conservation, patents, and inventions. I could go on about your abundant expertise, sir, but we appreciate your being here today as well.

And Professor Cary Coglianese is the Edward B. Shils Professor of Law and Political Science at the University of Pennsylvania, where he currently also serves at the Penn Program on Regulation, and he served as the law school's Deputy Dean for Academic Affairs. He specializes in the study of regulation and regulatory processes with an emphasis on the empirical evaluation of alternative regulation and regulatory strategies. I know that you bring a very, very valuable perspective to these hearings today, Professor, and I really thank you for being here today.

I thank all of our witnesses for your patience and indulgence in waiting for us to begin this panel. We are a little bit behind, partly because of the vote and other factors, but I very much appreciate your being here today.

If we could start with you, Professor McGarity.

STATEMENT OF THOMAS O. McGARITY, JOE R. AND TERESA LOZANO LONG ENDOWED CHAIR IN ADMINISTRATIVE LAW, UNIVERSITY OF TEXAS SCHOOL OF LAW, AUSTIN, TEXAS

Mr. MCGARITY. Thank you, Chairman Blumenthal, Ranking Member Hatch. I am very pleased to be here to testify on——

Chairman BLUMENTHAL. Are you sure your microphone is on?

Mr. MCGARITY. Sorry. I am very pleased to be here to testify on a broken rulemaking system.

The authors of the original Administrative Procedure Act envisioned rulemaking as a relatively straightforward process for making agency policy through open procedures that relied heavily on agency expertise and invited the public to participate in the policymaking process.

The APA also provided for judicial review under a lenient arbitrary and capricious test. Informal rulemaking has not, however, evolved into the flexible and efficient policymaking tool that its supporters envisioned.

During the 1980s and 1990s, the rulemaking process became increasingly rigid and burdensome as Presidents, courts, and Congress added an assortment of analytical requirements to the simple rulemaking model and as evolving judicial doctrines obliged agen-

cies to take great pains to ensure that the technical bases for their rules were capable of withstanding judicial scrutiny under what is now called the "hard look" doctrine of judicial review. Professor Don Elliott referred to this phenomenon in the late 1980s as the "ossification" of the rulemaking process.

It is fair to say that the problem has become even worse during the 21st century, at least in the case—and I want to limit myself perhaps to the case of "high stakes" rulemaking where the outcome really matters to the stakeholders, not just to everyday rulemaking process of relatively non-consequential rules.

Along with many other scholars, I am convinced that the rulemaking process is not merely ossified. It is broken. In my written testimony, I describe several of the causes of the broken rulemaking model, including the business community's deregulatory agenda, burdensome procedural and analytical requirements imposed by courts and various executive orders, centralized White House review, and overly aggressive judicial review. This has had unfortunate side effects, including inefficiency in implementation, reduced incentives to revise existing rules, reduced incentives to innovate, and an overall inability of agencies to attain their statutory goals.

The ossification of the rulemaking process has also yielded perverse unintended consequences. Agencies committed to fulfilling their statutory missions have sought out policymaking vehicles outside of the broken informal rulemaking process. These alternative rulemaking tools, however, often lack transparency, provide regulated industries and the public with little notice of the agency's position on critical issues, and offer few, if any, opportunities for the public to participate in the rulemaking process.

Some agencies have become so frustrated with the hurdles that informal rulemaking must overcome that they have attempted to make policy on a case-by-case basis through adjudications, directives, and recalls, that sort of thing.

More troublesome from the standpoint of open government is the increasing tendency of agencies to engage in "nonrule rulemaking" through less formal policymaking tools. Informal guidance from technical manuals, guidance documents, guidelines in general are a necessary part of a complex administrative process. But these are typically promulgated without the benefit of comments by an interested public. These less formal policymaking vehicles render regulatory agencies much less accountable to the public and pave the way to arbitrary decisionmaking. They may also lack sufficient gravitas and permanence to allow companies to rely on them in making important investment decisions.

The increase in agency use of "interim final" rules is especially worrisome. The agencies typically agree to accept public comment on interim final rules and prepare statements of basis and purpose for the final rules that are supposed to follow. One serious problem with this tool, though, is the fact that the agency need never promulgate a final rule. And when they do promulgate them, they are often greatly delayed, as we have seen earlier this afternoon. Interim final rules have a tendency to achieve a permanence that belies the agency's expressed willingness to consider public comments.

I mention in my testimony several possible solutions, and all directed toward taking away the incentive to use rulemaking avoidance devices by relieving the agencies of many of the burdensome aspects of the existing informal rulemaking process. Among these are greater oversight by Congress, which we have talked about this afternoon as well; eliminating procedural and analytical mandates in statutes; requiring agencies to finalize interim final rules within a set period of time, say 3 years; cutting back on White House oversight; a softer judicial look at the substance of rules.

This Committee is in an ideal position to begin the lengthy process of repairing this broken but extremely valuable rulemaking tool. I applaud the members of the Committee for holding these hearings, and I welcome your questions.

[The prepared statement of Mr. McGarity appears as a submission for the record.]

Chairman BLUMENTHAL. Thank you very much, Professor.

Mr. Ditlow.

STATEMENT OF CLARENCE M. DITLOW, EXECUTIVE DIRECTOR, CENTER FOR AUTO SAFETY, WASHINGTON, DC

Mr. DITLOW. Mr. Chairman and members of the Subcommittee, thank you for the opportunity to testify on delays in rulemaking at NHTSA. The Center for Auto Safety has followed NHTSA for over 40 years, and I would like to put a little flesh to some of the arguments that have been expressed from academia.

NHTSA is a wonderful agency. It has a vital mission. If we had not had a NHTSA, traffic deaths in this country today would be 200,000 versus 50,000 when the Safety Act was passed. But, unfortunately, it is woefully underfunded; it does not even have a laboratory to do its own research for rulemaking and enforcement actions. Instead, it has to rent space from Honda, a company that it regulates.

During the first 5 years after its creation, NHTSA issued almost 50 standards, and in the 40 years since then, it has issued very few standards. And with rare exception, the revision of the original standards came from congressional mandates. So Congress told NHTSA to upgrade the fuel tanks integrity standard, to upgrade the airbag standard, to set a standard for head injury, for tire standards, for roof crush, for pole tests. And I have put the bills in my written testimony where this has been done.

But when you take a look at the defects and the lack of rules, whether it is the Pinto, whether it is Firestone tires, whether it is Jeeps today, whether it is sudden acceleration, there is a lack of a rule. And because of the lack of a rule, we have defects in the real world which lead to recalls. And recalls cost the auto companies a lot of money. They cost consumers a lot of lives. And we would have been much better off if we had an effective rule in place, and I have a number of examples in my full testimony, and I will just go into a couple of them.

Take a look at tires. The original tire standard was issued in 1970. It became quickly out of date as we had higher speed travel, as we had heavier vehicles. Congress in 1978, after the first Firestone recall, told NHTSA we ought to upgrade the standard. NHTSA did not do it, so in 2000, we had the Ford Firestone series

of recalls, and this time Congress passed the TREAD Act, and it mandated that the tire standard be upgraded, and today we have a good tire standard.

Another real simple example is fused circuits. Two of the largest recalls ever are ignition switches in Fords and cruise control deactivation switches in Fords, both of which would short out and start fires in a vehicle, even if the vehicle was parked, turned off, and in the garage at night. And in some instances, a house burned down and people died.

We at the Center for—the Public Interest Research Group had petitioned NHTSA to fuse electrical circuits, but they never issued that standard. There was a lot of industry opposition. It cost money. Well, how much did these recalls cost Ford? How many lives were lost?

Another instance which we take a look at is electronics. In 1975, NHTSA commissioned the Department of Commerce to do some evaluation of electronics in cars, and Commerce said electronics are coming, you need to set standards for electronics in cars. Instead, what happened, NHTSA did not issue standards. We had acceleration with Toyota, we had acceleration in other vehicles. Today we have dozens of software recalls in vehicles. And what we need is a system validity check for software and electronics in cars. This is not setting a standard for what kind of electronics you used, but make sure that whatever you use goes through a verification test, a validity test that shows you have been putting good software and good electronics in the vehicles.

Another, you know, just airbags, the standard—everyone likes this cite about NHTSA. There is one single standard that there have been 91 final rules in that standard, tweaking this, tweaking that, changing course. And today we have airbags that really work well, but it took us 40 years to get there, and if we had been there in 10 years instead of 40 years, we would have saved a lot more lives.

What I would like to do is suggest that this hearing really provides a unique opportunity to examine the failings of the Motor Vehicle Safety Program at NHTSA in the rulemaking area. And if we have a better program, we will have fewer deaths. And we can do it, but we just have to decide how to do it, and I will leave the Committee with one final example.

Maybe we need a performance standard with a deadline. When I started out in government regulation, I worked on two major rules: one was the Clean Air Act, which required catalysts; one was the Safety Act, which was going to require airbags. We got catalysts on cars in 5 years to reduce emissions and clean the air. Why did we do it? Because Congress set a statutory deadline to reduce emissions by 95 percent by 1975. The Safety Act has no performance standard. It just said go out and set standards and consider passive restraints. But nothing specific, and we had 30 years of additional delay, which cost us thousands of lives, and if we had had a better rulemaking process, we would not have had that delay, and we would have saved the lives.

Thank you.

[The prepared statement of Mr. Ditlow appears as a submission for the record.]

Chairman BLUMENTHAL. Thank you, Mr. Ditlow.
Professor.

STATEMENT OF CARY COGLIANESE, EDWARD B. SHILS PROFESSOR OF LAW, AND DIRECTOR, PENN PROGRAM ON REGULATION, UNIVERSITY OF PENNSYLVANIA, PHILADELPHIA, PENNSYLVANIA

Mr. COGLIANESE. Chairman Blumenthal, Ranking Member Hatch, I very much appreciate the invitation to testify today, and I want to thank you both for your valuable public service to our Nation.

The idea that our regulatory system is broken is perhaps one of the few ideas that almost everyone agrees with today. Of course, that agreement runs out fairly quickly. The ways that different people perceive the regulatory system to be broken vary considerably. Some think the system is out of control. Others believe it provides too little control of harmful business conduct. And disagreement obviously also exists over what to do to fix the broken system.

My testimony today focuses on one widely perceived problem with the regulatory system: the ossification of rulemaking. Administrative law scholars point to the National Highway Traffic Safety Administration as evidence for ossification, as well as to support their belief that its source lies with judicial review.

Now, my testimony is that the evidentiary basis for this widespread belief disappears on closer scrutiny. This is not to say that every rule is adopted as swiftly as everyone would like. Today's hearing obviously shows that that does not happen. Nor is my testimony that rulemaking is always easy to do. I take note of Representative Kennedy's statement that developing a final rule is "not pretty," in his words.

But if we are to look at the general policy about the structure of our regulatory process and think about creating or modifying rules with respect to judicial review or other general standards of administrative law, then it is a general account of the rulemaking process that we need to focus on. And the conventional story about that general account is that NHTSA enjoyed no more than about 10 good years from the standpoint of using regulations to improve the safety of automobiles, and that after the mid-1970s, the agency, in the face of some losses in the courts, retreated from rulemaking and shifted its efforts instead to issuing recalls on defective cars, which is thought to be a weaker strategy for protecting the driving public rather than issuing more proactive regulations.

And the villain in the story, the conventional story, is principally the judiciary. A 1972 decision by the Sixth Circuit is often thought to be the case that led to the shock to the system and led NHTSA to retreat and, in the words of some administrative law scholars, to abandon the process of rulemaking.

My testimony in detail is in my written comments, but let me briefly summarize the findings of my research.

First, NHTSA has not abandoned rulemaking. The 2013 draft report to Congress from the Office of Information and Regulatory Affairs estimates that over the last 10 years NHTSA's rules have imposed as much as $10 billion in annual costs on the economy as

well as delivered about $22 billion in annual benefits, or at least as much as that.

Now, it may be that there is still not enough regulation from a normative standpoint, but it certainly is not the case that there is no rulemaking. Nor should one be misled to think that the number of rules issued in NHTSA's first decade were all that substantial. In fact, a 2004 study by NHTSA showed that during the agency's first decade, NHTSA's rules imposed about $250 in costs on automobiles; whereas, in the 1990s, the rules adopted then imposed even greater costs, up to about $760 per car.

Second point, NHTSA did not shift in the mid-1970s to a strategy of recalls. The conventional wisdom is based upon looking at data on total recalls, and if one looks at just the recalls initiated by NHTSA, you get a much different pattern.

A third point is that the impact of judicial review in explaining the pattern of NHTSA's rulemaking and recalls has been overstated. First of all, most of NHTSA's rules are not resulting in litigated court decisions. The agency does win a substantial majority of its cases that do reach a decision. And the pattern of rules did not drop immediately after the Sixth Circuit decision in 1972. The pattern of recalls did not suddenly pick up either, as you would expect from the conventional story.

Fourth, and finally, other explanations I think offer more plausible alternative accounts of the historical patterns in NHTSA's rules, one being if you look at the overall budget that NHTSA has had for operations and research, you find that the pattern in its budget tracks fairly closely the pattern in its number of rules.

Let me just conclude by saying that even though many thoughtful scholars, many of whom are my colleagues and friends who I respect, even though they hold fervently to the belief that, as a general matter, the threat of judicial review has ossified rulemaking, the well-cited account that we read in the literature is not very well supported on further examination. Other studies are beginning to show this with respect to other agencies as well.

In the end, there may be many problems that lead people to conclude the U.S. regulatory system is broken. There is just no systematic evidence that the ossifying impact of judicial review is one of those.

Thank you.

[The prepared statement of Mr. Coglianese appears as a submission for the record.]

Chairman BLUMENTHAL. Thank you. I want to thank all of our witnesses, and if there is no objection, I am going to make sure that all of your written testimony and the previous panel's as well be included in the record. But thank you for keeping your remarks within the 5-minute time limit.

I am going to defer to Senator Hatch for his questions at this point.

Senator HATCH. Well, thank you, Mr. Chairman. This has been a very interesting hearing on what many would think would be a boring set of subjects. But they are not to me.

Dr. Coglianese, let me just start with you and start out with a very basic question whether the National Highway Traffic Safety Administration, NHTSA, is in the regulatory game at all. In his

testimony, Professor McGarity says that NHTSA has given up on rulemaking and focuses instead on recalls. Do you agree with that?

Mr. COGLIANESE. No, Senator, I would not agree with that. The evidence in the *Federal Register* is that there are rules still coming out of NHTSA, and one sees that both from looking at the regulatory impact analyses that are filed in these rules, that these rules deliver substantial benefits to society, and they also impose substantial costs to society.

NHTSA itself did an ex post evaluation of its regulations in 2004 and found that these regulations that NHTSA is adopting are saving a lot of lives. So there is no evidence of a systematic abandonment of rulemaking at NHTSA.

Senator HATCH. Some scholars have written that judicial decisions in the 1970s have led NHTSA to effectively abandon rulemaking. If that were even partially true decades ago, do you think that this still has a paralyzing effect on NHTSA today?

Mr. COGLIANESE. Well, when it comes to judicial review, first of all, with a closer look at the evidence, you do not see the dramatic shift away from rulemaking that is consistent with a conventional account.

Second, the standard for judicial review, arbitrary and capricious standard that was enunciated in that Sixth Circuit decision in 1972, was basically adopted by the U.S. Supreme Court in the case of *State Farm* in the early 1980s and has been continuing to this day. So if it were judicial review that was really ossifying the rulemaking process, it would be striking that NHTSA has been adopting additional rules even though it is doing so under the existing standard.

Senator HATCH. Well, in my opening statement, I noted that NHTSA has issued literally hundreds of regulatory actions in just the past decade. On its face, does that not seem consistent with the accusations that there is so-called ossification, as you have mentioned, in NHTSA rulemaking? Do you agree with that or——

Mr. COGLIANESE. Right, I think the evidence is that NHTSA is engaging in rulemaking. It is doing so even in the face of the arbitrary capricious test and the prospect of judicial review.

Senator HATCH. Okay. Professor McGarity, I appreciate all you folks testifying here today. It is very important to us. Your written testimony states that those being regulated are "no longer put on notice of the standards of conduct that the agency is applying to them . . ." Now, this makes it sound like actual rulemaking is the only way that an agency like NHTSA communicates such standards or regulations. But as I understand it, NHTSA issues what it calls a "Rulemaking and Research Priority Plan," if I have that right.

Now, this document, which appears in the *Federal Register*, addresses its anticipated rulemaking and research activities based on current science and data.

Now, Mr. Chairman, I ask consent that NHTSA's Rulemaking and Research Priority Plan for 2011–13 be made part of this record.

Chairman BLUMENTHAL. Without objection.

[The information referred to appears as a submission for the record, however, due to the voluminous nature will not be included in the printed version of this hearing.]

Senator HATCH. Now, I do not know how many agencies have a regulatory road map like this, but it seems to me this supplements the actual rulemaking. Now, doesn't this prove that NHTSA is, in fact, communicating standards of conduct for those being regulated?

Mr. MCGARITY. My thought on that is that, yes, other agencies do the same, maybe not as extensively as NHTSA does, but what this—if I am thinking about the document that you are mentioning correctly, it puts the regulatees on notice of what rules NHTSA plans in the future. What I was alluding to in my testimony is when agencies engage in alternatives to rulemaking, they do not do this sort of plan when they issue just a guidance document or, for that matter, when NHTSA issues a recall, it is not pursuant to some preannounced criteria that it applies to this particular thing. It's done on a case-by-case basis.

NHTSA does not use as many of the informal policy guidance, interpretative rules and that sort of thing as other agencies, and I would say that my testimony was aimed more at those sorts of things. That it is not something that NHTSA does.

If I could have a moment, I could respond to Professor Coglianese's point.

Senator HATCH. Sure.

Mr. MCGARITY. NHTSA does promulgate lots of rules, but most of these, I think, are not the major rules that stakeholders really care about. There are lots of minor modifications, as Mr. Ditlow pointed out, and I think that sometimes Professor Coglianese and I and other scholars talk across each other a little bit, because those scholars that talk about the ossification of the rulemaking process, we are talking about major important rules, not just day-to-day rules that get promulgated, like pesticide tolerances which come out by the hundreds. So that studies that focus on just total output are kind of missing the important impact of judicial review—and I do not limit myself just to judicial review—and Presidential review and all these regulatory analysis requirements are having on the agencies as they try to implement important rules like the ones we heard about earlier today.

Senator HATCH. Okay. If I could ask one more question, in your testimony you say that NHTSA prefers recalls to rulemaking. Now, I noted in my opening statement that NHTSA has, in fact, issued hundreds of regulatory actions in the last decade; but it also seems to me that the increase in recalls over the last decade is at least as much due to Congress as it is to NHTSA. The so-called TREAD Act, which was enacted in 2000, requires that companies identify potential problems and promptly notify NHTSA. As a result, virtually all recalls are voluntary rather than initiated by NHTSA, so I am a little confused by your testimony that NHTSA has given up on rulemaking in favor of recalls.

Could you just explain that a little bit more?

Mr. MCGARITY. Sure. In fact, I think that you are exactly right that in recent years a lot of the recalls have been spawned by the reports that are made by the companies. In fact, I think that has

been the case for most of NHTSA's history, and here we have to look a little bit behind the scenes.

A company does not want to have NHTSA declare a recall and tell the world that this automobile is bad. And what they will do is when NHTSA has a problem with a car, they go and they talk to the company about it and they negotiate about it, and very often that results in a negotiated recall initiated by the company but, really, if you go beneath the surface of it, initiated by NHTSA who came to the company with the problem.

In more recent years, after the TREAD Act, I think it is true that the companies have been coming to NHTSA and initiating the negotiations about what is going to happen to protect the public. But I do not exclude those company-initiated recalls from the basic pattern of NHTSA working through recalls as much as or more so then through rules. It has not promulgated that many important rules that have not been required by Congress.

So, once again, one of the solutions I suggest is that Congress require more of these rules, as they have, with respect to NHTSA.

Senator HATCH. Both of you gentlemen have been great. Mr. Ditlow, I appreciate personally the work that you do, and I just want to compliment you for hanging in there and doing what you do.

Mr. Chairman, I am grateful you have had this hearing. I have got to be excused, but I appreciate all three of you being here as well as the prior panel. This has been a good hearing.

Chairman BLUMENTHAL. Thank you, Senator Hatch.

Senator HATCH. Thank you so much.

Chairman BLUMENTHAL. Thank you.

I have some questions, not lengthy, but I want to express my appreciation to you for being here.

Mr. Ditlow, perhaps you could comment on the comments made by Professor Coglianese. I noted in your testimony toward the end you cited an oil industry executive telling you at one point that he once asked his counterparts in the automobile industry why they opposed virtually every NHTSA rule or regulation, no matter how big or small, and he told you that their strategy was to focus on the little things so they never got to the big things. And I suspect that these numbers about rules and regulations or the numbers of pages in the *Federal Register* perhaps are not fully reflective of what is happening with rulemaking. And maybe you could just comment.

Mr. DITLOW. That is certainly true and——

Chairman BLUMENTHAL. And if you could turn on your microphone.

Mr. DITLOW. That is certainly true, and what is happening is the industry knows that NHTSA has limited resources, and they only have so many lawyers to work on so many rules. So if they oppose every single rule, no matter how big or how small, then that is one less lawyer, one less rulemaking that they may be able to do that is important. And taking a look at what has happened recently, there have been two really good standards to come out of NHTSA in the last 5 years: one is electronic stability control, and one is side curtain airbags. And both of those were performance stand-

ards, but they resulted in these systems, and they are saving a lot of lives. But it was Congress that mandated that NHTSA do this.

And so what I would suggest is that the premise that NHTSA is not issuing rules is correct. I mean, what is happening is Congress is dictating to NHTSA to issue rules in the face of NHTSA's inaction. And NHTSA's inaction is in large part due to the amount of resistance that comes from the auto industry.

And we can look at rules getting tied up at OMB. Well, the industry lobbyists are over at OMB opposing that and submitting information on the costs of a new regulation, and it gets delayed. And if there was one failing on backup cameras, it was not setting a hard and fast deadline. You know, give the industry—give NHTSA the ability to make one, maybe two extensions, but not a perpetual extension where all they have to do is come to the Congress and say we need another year.

Chairman BLUMENTHAL. I noted particularly your reference to the absence of any safety standard for electronic controls and computer processing units in cars, which now have become so reliant on electronic devices and controls, and yet there is no safety standard. Perhaps you could talk about the implications.

Mr. DITLOW. Yes, well, modern cars have 50 to 100 electronic processors in them, and there is no standard for these electronic processors. And organizations like IEEE have standards where you can validate the computer software, the electronic devices themselves, that you can determine how complex they are, what is the likelihood that the code will be wrong in them. And NHTSA has not set any standard whatsoever in that area. And to the extent that they have standards, what they are trying to do is apply mechanical concepts to electronic systems so that if you have a key fob that starts a car, their standard says inserting the code into the ignition via the key fob is the same as inserting a key into the dash. Well, it is not the same, and the code can be flawed, and there is no test of the code. And that is what NHTSA needs to focus on, and we have an agency that is under—required to do a study for Congress as a result of the legislation that was passed in MAP–21. But there is no standard that is forthcoming. We have not seen the study yet, and I am afraid that we are headed into something like was discussed in the first panel: Where is the regulation? Is the regulation going to be coming? No. We are going to get a study. And what is the study going to say? It is going to say we need more time. And it is going to be a long time coming before we see an electronic standard from this agency.

Chairman BLUMENTHAL. And the absence of these regulations has real-world consequences in imperiling lives and perhaps causing crashes and imperiling people.

Mr. DITLOW. Absolutely. What we are seeing with the unintended acceleration and the litigation that is arising is that the electronics and software experts are coming in, they are examining the source code in the Toyotas, and they are finding bugs and glitches in it that can cause and did cause sudden acceleration, and these cases are now being upheld by a jury. And it is just tragic. We should not have—one of our objectives at the Center for Auto Safety is to eliminate these causative accidents and eliminate the product liability cases, because they are failures in society. You

have a victim who has been injured, and we need to have fewer victims and better regulations.

Chairman BLUMENTHAL. Let me ask you, Professor Coglianese, I am sure you are familiar with this area: What do you think about the need for standards relating to electronic controls and computer devices in cars?

Mr. COGLIANESE. I am not an auto safety engineer so I am not—you know, I am not going to opine on that. So I really would like to, if I may, just take one moment to reply to Professor McGarity's point earlier, if that would be permitted.

Chairman BLUMENTHAL. Sure.

Mr. COGLIANESE. Thank you very much.

I just wanted to note that the rulemaking that I am talking about, that I observe at NHTSA, are not all these little technical amendments. Every year the Office of Information and Regulatory Affairs files a report to Congress on regulations, and there is a table in it, and OIRA puts the agencies that have the most significant rules in it. And out of hundreds and hundreds of agencies for the last 20 years, NHTSA has appeared in that report, and the dollar amounts for the benefits are incredible from NHTSA rules. And, of course, the costs are very high, too. So there is significant rulemaking that is taking place at NHTSA.

Thank you.

Chairman BLUMENTHAL. I am going to give Professor McGarity an opportunity to respond, but you would not dispute that, at least on its face, there seems to be a need for some regulatory effort in regard to the electronic devices and computers that are now more and more present in cars.

Mr. COGLIANESE. Certainly to the extent that those systems are part of cars and they could pose safety hazard, a responsible regulator definitely should be looking at them.

Chairman BLUMENTHAL. And is there any dispute—I would ask this of all the panelists—that NHTSA presently has authority to issue such regulations or rules?

Mr. COGLIANESE. I do not have a dispute with that.

Chairman BLUMENTHAL. Professor McGarity, do you wish to respond?

Mr. MCGARITY. Just briefly, I would simply say that those huge benefits, although I have not looked at it in detail, my guess would be are coming from rules that Congress mandated by a deadline so as to avoid the ossification problem. So I would make that point, that my guess is that most of those, the benefits are attributable to major rules that Congress required, which is one of the solutions I suggest.

Chairman BLUMENTHAL. Let me ask all three of you, you have been here for the earlier testimony. You heard about this delay in the issuance of mental health parity regulations. You have experienced with respect to NHTSA and more generally in terms of the regulatory governance area delays and so forth. What is the best way to prevent such delays? And who would have standing to challenge an agency that simply fails to comply with a deadline for issuance of regulation? We are not talking about disagreements with the regulations, challenges to their substantive merit, which could be, in effect, questioned by someone aggrieved by them, some-

one subject to the regulations if they were harmed, but simply the delay, who has standing to challenge?

Mr. MCGARITY. Well, to the extent that there is a statutory deadline—I think Professor Coglianese will agree with me—the beneficiaries of the regulation, the erstwhile beneficiaries of the regulation or groups representing those beneficiaries, should be able to challenge agency action not taken under the Administrative Procedure Act or sometimes under the individual statutes, to the extent that they have standing, which still the test is that they are aggrieved and are arguably within the zone of interest protected by the statute.

Chairman BLUMENTHAL. But the statute in question may or may not apply to them, depending on what the regulations provide. And since the regulations are not final, it is kind of a Catch–22. I would argue that there is standing under a correct and I think legal interpretation of the standing doctrines. But I wonder how common those challenges are. Maybe, Professor Coglianese, you have some——

Mr. COGLIANESE. Well, in areas such as environmental law, where many statutes contain very specific deadlines, the deadlines are quite frequently not met. But they are not always subjected to any judicial challenge. Those who might bring the lawsuits have—you know, have resource constraints as well. But the remedy is there.

Of course, once one gets into court after an agency has missed a statutory deadline, the ultimate remedy is for the court then to impose its own schedule or timetable. You know, obviously the court will not be able to grant the remedy of meeting a deadline that has already passed.

I think, though, from the standpoint of overall public policy, the question is: Are we getting ultimately enough benefits from delay to justify the lost opportunities that we would gain from acting sooner? There may be many cases in which delay is valuable and needed if it means creating a regulation that will be more effective or that could avoid a very counterproductive result. And in the case of automobile safety, it seems at least, just as much as a responsible regulator needs to look into some of the problems, a responsible regulator also needs to make sure that their regulations do no harm and that they are not going to put in place something that in the complex engineering of an automobile creates an additional hazard that had not been anticipated.

Mr. DITLOW. Senator Blumenthal, standing is something that really concerns public interest organizations. The Center for Auto Safety won a lawsuit against the Department of Transportation on fuel economy standards, but we lost it on a rehearing en banc on standing. So we won on the merits, but we lost on the issue of standing.

And even in the area of safety, the way the courts have looked at standing in recent years gives us qualms about whether or not they will restrict the access to the courts for the citizens' groups trying to even enforce a deadline.

So we would like to see a citizen suit provision put into the Safety Act, just like we have in the Clean Water Act. I mean, that would help.

Chairman BLUMENTHAL. Excellent idea. Let me ask, then, perhaps all of you: How common are challenges based on delays in rulemaking? And do they succeed ever? Do you know of any?

Mr. COGLIANESE. Oh, sure. I mean, there was a major one under the Clean Water Act that led—often these lead to settlements because the factual issue is pretty clear. One looks at the calendar and one looks at the *Federal Register*, and there is no need for a lot of depositions or such. So they settle out of court. Most of the toxic water pollutant regulations were adopted, for example, under a decree that was issued as a settlement of a deadline suit.

Mr. DITLOW. Consumers Union and Public Citizen and some parents are in a challenge in the Second Circuit over the backup camera, failure to issue the backup camera rule. But there is no firm deadline, and so they waited 2 years to file that lawsuit.

I would like to point out one thing in terms of recalls and standards. Some standards, like the backup camera standard, there is no—you will not see a recall for failure to install a backup camera. But you will see a recall for things like a defective cruise control circuit, the lack of a fuse. So I would take what Professor McGarity does and refine it just a little bit and say that recalls do, in fact, become a substitute for good rules in certain areas, but in other areas it is a totally ineffective tool.

Chairman BLUMENTHAL. Did you have anything to add, Professor McGarity?

Mr. MCGARITY. Only just a slight thing, and that is that Professor Coglianese is right that we have many suits in the environmental area that have resulted in settlements in which the agency has established its own deadline. Sometimes it goes back to court and asks for an extension of it, but there are many of these.

There is, however, in the other House a movement afoot to stop these settlements from happening, so one needs to be aware of those as well.

Chairman BLUMENTHAL. Thank you. Well, again, I really express my gratitude to all of you. You have greatly informed the Committee, and I hope that perhaps we will take some of your ideas and implement them in ways that will be helpful to agencies meeting the deadlines that are established by this Congress, but also enabling better compliance, swifter promulgation of these rules so that the public can benefit from the laws that we make. So I thank you very much and adjourn this hearing.

[Whereupon, at 3:47 p.m., the Subcommittee was adjourned.]

[Questions and answers and submissions for the record follow.]

APPENDIX

ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

Witness List

Hearing before the
Senate Committee on the Judiciary
Subcommittee on Oversight, Federal Rights, and Agency Action

On

"Justice Denied: Rules Delayed on Auto Safety and Mental Health"

Thursday, November 7, 2013
Dirksen Senate Office Building, Room 226
1:30 p.m.

Panel I

The Honorable Patrick J. Kennedy
Former United States Representative (D-RI-1)
Founder, The Kennedy Forum
Brigantine, NJ

Cathy Morelli
Southington, CT

Panel II

Thomas O. McGarity
Joe R. and Teresa Lozano Long Chair in Administrative Law
University of Texas School of Law
Austin, Texas

Clarence M. Ditlow
Executive Director
Center for Auto Safety
Washington, DC

Cary Coglianese
Edward B. Shils Professor of Law
University of Pennsylvania
Philadelphia, Pennsylvania

PREPARED STATEMENT OF HON. RICHARD BLUMENTHAL

INTRODUCTORY REMARKS

JUSTICE DENIED: RULES DELAYED IN AUTO SAFETY AND MENTAL HEALTH

November 7, 2013

When elected officials talk about regulations, there is a lot to disagree on. The stakes in this area can be very high, and people disagree in good faith about the appropriate scope of regulation.

What we are discussing here today should not lead to disagreement.

First, let's start with the facts. Regulatory agencies generally have the authority to act through official rulemaking—the notice and comment process created in 1946 and developed throughout the years. This process is relatively open and transparent, and it tends to produce rules that—whatever we might think of them—are at least clear and unambiguous.

Agencies also have the authority to act in other ways. They can put out guidance documents interpreting their rules or a statute. They can put out temporary rules as stopgap measures. They can enforce the law through adjudication and use agency precedent instead of a rule. All of these measures are, to some degree, less transparent than the notice and comment process. Most produce less clarity.

When an agency has the duty to protect the public, it will tend to do so in a way that requires the least time, energy, and resources. That's just commonsense.

In the context of administrative law, this means that the massive delays in the rulemaking process are going to push agencies—in fact, force agencies—to use tools other than rulemaking.

Of course, there are cases where agencies should rely on alternatives to official rulemaking. Sometimes adjudication is a more flexible and appropriate tool than rulemaking. Sometimes a new program requires a series of temporary rules to get up and running quickly.

But when agencies rely on alternatives to official rulemaking, there is a cost. The case studies we are going to consider here today show how high that cost can be.

In the case of mental health parity, the cost has been clarity and certainty. Congress passed the landmark Mental Health Parity and Addiction Equity Act in 2008. And I want to applaud the Ranking Member, Senator Hatch, who was an original cosponsor of that legislation and is a champion in this fight.

However, the devil was in the details. To clarify those details, the Act required the implementing agencies to write a rule within one year. Two years later, the agencies released an interim final rule. But the rule left too many questions unanswered. Even worse, it left industry wondering whether to change its policies or to wait until a final rule brought certainty on the path forward. Regulators also

hesitated to change their rules, leaving industry free to delay compliance with the law. Five years after the Act was passed, its promise remains unfulfilled.

In mental health, uncertainty kills. If an individual poses a threat to himself or others, he cannot be told he will get the care he needs as soon as his insurance company decides what "parity" means. He cannot win access to needed care only after resorting to the courts or to a long administrative process. In a very concrete way, justice delayed is justice denied.

In the auto safety realm, the National Highway Traffic Safety Administration (NHTSA, pronounced nitz-ah) struggled early in its history to release rules in a timely fashion. The result was two-fold. On the one hand, important NHTSA rules have been delayed even when Congress has expressly demanded them. The rear visibility rule that was discussed at the last hearing of this subcommittee is a prime example.

On the other hand, NHTSA has had to do by recall what it should have been able to do by rule. Clarence Ditlow will tell the story of rules that were suggested to NHTSA by automobile safety advocates but went nowhere, only to come up again when defective automobiles have had to be removed from the road. These are tragic situations for those who are injured or killed in a car that never should have been sold in the first place. They are also bad for those car companies who want to

know exactly what is required of them by the law. When I talk to businessmen, they tell me that they can make money in a heavily regulated industry. They just need to know what the rules are and to have certainty about what the rules will be. When policy is made by adjudication because rulemaking is too difficult, these businessmen cannot get the certainty they need.

As I said at the beginning, the story we are telling here today should be common ground. Both industry and consumers should want clear rules. Both employers and workers should want rules that are developed with public input and public scrutiny. Representatives of both private interests and the public interest should want bad behavior to be prevented before it occurs, rather than simply punished after.

And if we can all agree on the problem we face, maybe we can start to work together to find solutions we can agree on.

I want to thank everybody who came out today—particularly Ranking Member Hatch and our witnesses.

PREPARED STATEMENT OF HON. PATRICK J. KENNEDY

No Parity without Clarity: The Challenge of Laws without Rules

Testimony of
Patrick J. Kennedy
Member of Congress, 1st District, Rhode Island, 1995-2011

Senate Judiciary Committee
Subcommittee on Oversight, Federal Rights, and Agency Action

November 7, 2013

Mr. Chairman, thank you for inviting me here today to testify on the consequences of delay in the rulemaking process. It is my understanding that you have asked me to come before you because of my experiences in sponsoring the Mental Health Parity and Addiction Equity Act, MHPAEA, in 2008, while I was still a member of Congress, and, since then, in seeking implementation of that law, still a central focus of my activities as a private citizen.

Five years ago, when my father and I sponsored the Mental Health Parity and Addiction Equity Act (MHPAEA) and shepherded it through the House and Senate, we thought its signing by President Bush was the end of a process. In fact, it was barely the beginning.

As the theme of this Judiciary Committee Hearing indicates, a lot of ambitious laws get passed without anyone really being sure how they will be enforced—and, worse, without a clear roadmap for how those underlying rules will be researched and written and overseen in a reasonable amount of time. But the five-year wait for clarity on mental health parity is a particularly good—or particularly bad—example of the problem and the challenge. And I'm pleased to have the opportunity to share what has happened to this historic law, which also

turned out to be the last one my father worked on—and my father and I worked on together—before he died.

The concept of parity began to emerge more than twenty years ago, when people with mental health diagnoses found themselves paying higher copays for mental health treatment and routinely facing arbitrary limits on such basic provisions of their policies as the dollar amounts of their coverage or the number of visits they could make to certain treatment settings. Many found their insurance cancelled after they reached those limits. It was evident that these limits were grossly out of line with the standards applied to coverage for other conditions. The quest for parity was seen as a simple question of fairness; it was an attempt to bring a halt to blatant discrimination against people with mental illnesses or substance use disorders.

As you know, parity laws of some sort were ultimately passed in over thirty states, and President Clinton signed a symbolically important federal law in 1996. These were all real advances that improved the lives of some people with mental health diagnoses and substance use disorders, but they were only incremental steps. The largest plans were not affected by the state laws, and the 1996 federal law was very limited in its scope. It took another dozen years to arrive at the law we ultimately passed in 2008. One reason for this was the need for legislators to reconcile different visions of what parity meant. On the House side, where I sat, and here in the Senate, those of us working on the bill heard a steady stream of stories – from the tales of individuals and families left with high bills and no access to the treatments they needed to the fears of insurers and employers that the costs of parity would be unbearably high. As frustrating as it was for a dozen years to go by before MHPAEA was passed and signed, I believe the final product reflected the best of the legislative process; it is a thoughtful and fair policy solution to a

real inequity in our system that recognizes the different perspectives of the full "community of mental health."

As I say, those of us who had worked long and hard on this legislation felt pretty good about our ability to balance competing interests and draft language that could be supported by members of both chambers and both parties. Naively, it turns out, we believed we had done the heavy lifting and thought the regulatory process would simply operationalize the solution we had achieved. In truth, the Mental Health Parity and Addiction Equity Act instead entered a kind of twilight zone in which everyone with an interest in it was left to imagine what it meant. The prolonged regulatory process created an environment in which competing visions of parity could flourish with little guidance from the controlling authorities.

At best, insurance regulation is confusing, given the distribution of responsibilities among various state and federal agencies, depending on the types of policies, among other things. This parity law complicates matters even more. The Departments of Health and Human Services, Labor, and the Treasury all have authority over parts of the law. And MHPAEA even includes an important provision giving stronger areas of state law precedence over the federal statute. There's no question that developing regulations and enforcement mechanisms for the law is not easy. But this is the job of the executive branch of government, and it is not unreasonable to expect it to be done in a timely manner.

As I mentioned, parity laws have been passed in the majority of states over the past 20 years. Not only are these laws highly variable in the provisions they include, but regulatory and enforcement efforts in those states have largely been governed by a wait-and-see attitude. Few states have wanted to get out ahead of the federal government, especially when the largest plans – those with the greatest influence in the market – are regulated at the federal level.

Finally, it is important to understand that regulation of MHPAEA also has implications for the actions of unrelated departments and agencies and the programs they run. For example, we want to make sure that the VA's health programs for the veterans it serves are incompliance with parity. And, although outside of the scope of MHPAEA, Medicare still has a distance to cover in its journey to parity.

The big picture, then, is that the regulatory delay has held up not just the definitive implementation of MHPAEA, but it has stalled similar but unrelated efforts to end discrimination in multiple other settings. MHPAEA is the law, but parity is a concept that is advancing in the same way that other concepts of justice have advanced. The law is meant to guarantee non-discrimination in covered insurance policies, but behavior change occurs in many settings that are technically beyond the reach of the law.

Just to recap, MHPAEA was passed and signed into law on October 3, 2008, and its provisions became effective exactly one year later. Many insurance plans follow the calendar year; the effective date for them was January 1, 2010. The Interim Final Rule for MHPAEA was issued on February 2, 2010, effective April 5, 2010, and applicable to plan years beginning on or after July 1, 2010. We have been waiting for the Final Rule ever since then – over three years. We hear it is due out at any moment. But we've heard that a lot of times already.

What has happened during that period? The answer isn't pretty. The insurance industry has struggled to understand its obligations, and its response has been patchy. Some carriers have understood that parity provides opportunities for them to provide better service to their members and the employers who purchase much of the coverage they provide. They have tried earnestly to look ahead at the changes in the field wrought by the Affordable Care Act and have adjusted

their practices to ensure access to comprehensive care that complies with both laws, as best they can determine.

At the same time, other carriers have taken this delay as an opportunity to continue or, indeed, institute practices that meet neither the spirit nor the letter of the law. But with the rule still not final, they appear to have reasoned, who's to tell them not to. The result is that some families have faced the very discriminatory practices the law was meant to end.

Nature abhors a vacuum, the saying goes, and in this instance an unfiltered mix has swirled into the void left by the unfinished rule. Clearly, this is a situation that holds the potential to harm individuals and families not receiving the coverage they believe the law has guaranteed them, but it also contains many perils for insurers and the businesses that purchase their products. How can they formulate a reliable business plan without a firm understanding of their industry's future obligations under the parity law? How can they assemble insurance plans providing coverage for an appropriate range of services if they don't know what parameters the rule will place around those services?

We are also seeing cases brought to court in several states in which individuals are claiming they were denied benefits they believe the parity law should have guaranteed them. I can't say whether private legal action would have been taken if the final rule had come out. But I do know that we are already seeing different courts head in several directions. I have to believe that clear guidance on the federal law would have put judges on firmer legal ground when hearing such claims.

I want to stop here and acknowledge that achieving parity is proving to be a process. I've already alluded to the long legislative journey that brought us to passage on October 3, 2008. We don't have time today to detail the many twists and turns in that journey, but I will say that we

were on a continuous learning curve throughout. I believe that, at its best, the regulatory and enforcement process should also be one of regular information sharing and improvement, as well. The truth is that we are moving into waters no one has navigated before us, and we'll have to be vigilant about taking soundings and recalibrating our course as we move forward. But we must move forward, and the chief concern I want to express to this committee is that the failure to provide firm guidance – the lack of a final rule – has allowed us to drift off course. My father's memoir was titled, "True Compass," referring to his inner sense of direction in the causes of greatest importance to him. Having a rule sooner in the process would have given us a mark on which to set our compass in this important leg of the parity voyage.

I hope we all can learn from the experiences we have had with the parity law and its delayed rule. But I also want to express the view that the journey will continue even after the rule is issued – which, incidentally, could be any time. We have to be clear that implementation and enforcement of even a "final" rule will require constant vigilance. All the stakeholders must come together and figure out exactly what parity can be and must be, and to create a roadmap to equality in coverage of disease of all the organs of the body.

I should point out, however, one aspect of the wait for this final rule that is unique. Since the passage of the Mental Health Parity act in 2008, we have also lived through the passage of the Patient Protection and Affordable Care Act (ACA) in March 2010. That law offers its own unique version of establishing mental health parity, and it may very well be that the endless delays over the final rule for the 2008 law grow out of the endless controversies over the 2010 law. The ACA guarantees that pre-existing conditions won't be used to prevent us from insurance coverage, and also goes further in guaranteeing parity than our bill did. The ACA also

expands coverage for early intervention and prevention, which dares us to confront our strategies and evidence deficits in both of these areas.

In the meantime, we are anxiously awaiting the crucial "final rule" on mental health parity. The protections of that final rule, along with those in the ACA, can provide a new kind of safety net for those with mental illnesses, addictions and intellectual disabilities. Then we have to start testing just how safe that net is.

Yet both laws come with the same challenge. Both dare us to define what parity is and should be: how it will be operationalized and, perhaps more important, how it will be enforced, especially for patients with severe mental illnesses who, like victims of cancer, could have permanent, life-threatening and unnecessary setbacks because of restricted or refused care.

This year, we are celebrating the 50th anniversary of President Kennedy's Community Mental Health Act of 1963. It has provided the vision for recent mental health policy in this country, and for that is to be applauded. But the anniversary also gives us pause and forces us to face up to the fact that, in many places, President Kennedy's vision was never realized.

What we know about the aftermath of the Community Mental Health Act of 1963 is that many of its well-meaning goals were underfunded and ultimately undermined—and, just two years later, when Medicare and Medicaid offered healthcare to the first time to many older and disabled Americans, it was a form of healthcare that treated certain diseases of the brain differently than all others. Just as "separate but equal" was being rejected as a formula for educating our children, a form of it was being embraced so that treatment for mental illness was made separate and not even equal.

The confluence of the Affordable Care Act and the Mental Health Parity Act represents a second chance to fulfill the promise of JFK's plea that Americans with mental illnesses,

addictions and developmental disabilities "no longer be alien to our affections or beyond the help of our communities." But this will only happen if we come together to help make these laws work for us. Because, as I urge the committee to keep in mind, the reason to have these interim and final rules written faster, but also with more information gathered, is because so much needs to happen *after* the rules are published.

Because this coming Monday is Veterans' Day, I want to make sure I stress one other extremely important reason for us to get implementation of the parity law right, and that is that no one stands to gain more from true parity than the men and women who have served our country and now need treatment for the invisible wounds they have brought home from Iraq and Afghanistan. Only some of our veterans receive services in the VA system. Many have come back to work for employers who provide their health coverage. We owe it to the men and women who have given so much for our country to guarantee they have access to the services that will enable them to flourish in our society. We need to make sure they are able to receive the best, evidence-based rehabilitation and services, just as we do for their brothers in arms with mangled limbs or other obvious wounds. When I think of the parity law, I always think of it as the best welcome home we can offer to our returning warriors.

Without actually seeing the final rules on Mental Health Parity, we already have a pretty good idea of what is still missing from them. Even with MHPAEA and ACA in place, we will still need more language, real-world scenarios, case law and perhaps additional regulations to guarantee the two most basic medical rights for those with brain diseases:

1) Patients must have access to the services they need in the setting that is most appropriate to their symptoms and situation, in a way that is no better than, but no worse than medical/surgical care. This means equal access to evidence-based treatments (medication,

psychotherapy, etc), equal access to inpatient, outpatient and intermediate care, and the elimination of "fail first" requirements that do not exist in the treatment of any other illnesses.

2) The process by which cases can be reviewed for compliance must be fully transparent, and a consistent level of enforcement must be maintained at the federal, state and local levels.

We believe the current laws already require both of these, but with little action to date to make them a reality, we can't be certain the laws will be observed.

We call upon the federal government to finally create operative definitions of three concepts that are crucial to the future of care of brain diseases. They are:

1) "Parity"

2) "Essential Health Services" as they apply to brain health, with a definition symmetrical to all other illnesses for both treatment and preventive care

3) "Discrimination" as it pertains to the failure to provide parity in treatment of mental illness, addiction and developmental disorders.

Without modern, useful definitions of these three concepts, the new laws will never allow for proper oversight at the federal and state level. We must begin, immediately, a process to get to them—a process that all major stakeholders are part of, so none have an incentive to undermine or game it, as has happened in the past.

First, we need more information on current practice in mental health and addictions care, both in what is being covered and what isn't and why. To that end, I'd like to suggest that the GAO look more closely into existing use of mental health services—including how it has changed over the five years since the parity law went into effect—and also into existing enforcement of mental health parity in the Department of Health and Human Services and the Department of Labor. We must make sure that the letter of the law is observed as

implementation proceeds, and that is GAO's task. But we also need to know that the right data is being collected for us to see whether the new policy embodied by the law is changing practice – in other words, whether people with mental health and substance use conditions are gaining access to the services they need at the same cost people with any other conditions would bear. We must have evidence that the experiences of the 1 out of 5 Americans with a mental health diagnosis prove the law is working.

Specifically, we must be able to know what people with mental health problems are spending out of pocket, and whether they have to go out of network or travel long distances to find the providers they need. If they do, is their experience different from that of someone with, say, diabetes who is covered by the same insurance plan?

As preventive care and early intervention are now required and covered as never before, can we make sure that a "checkup from the neck-up" is routinely done, and "mental health first aid" is taught like all other first aid?

And if there is a difference between the experiences of people with mental health or substance use problems and those of people with other conditions, we must be able to say, "That's not parity."

We are, of course, sensitive to the privacy needs of people with mental illnesses, addictions and intellectual disabilities. But we are also mindful that the new laws are supposed to protect them from their illnesses affecting the quality and equality of their care. The need for confidentiality at the federal, state and local levels when investigating alleged parity violations is important to fairness in the process. However, the current lack of transparency prevents others from learning from the experience. Perhaps the departments of Labor, Health and Human Services, and the Treasury could develop a system like the one used by the Internal Revenue

Service and the Department of Justice where tax opinions and antitrust opinions are provided based on a set of facts without names and made public so that the industry benefits from a common understanding of what is and is not acceptable conduct. We need some kind of system to create true "de-identified transparency" so that everyone can see and understand the emerging picture of parity under these new laws.

It is not the government's job to bring together all the different stakeholders who will need to help interpret and agree on definitions that allow for the real-world challenges of care to be addressed. That is up to us.

To that end, over the past year, my former congressional colleague, Jim Ramstad, and I held our own local hearings on how parity was playing out in the real world. And two weeks ago, we held a historic meeting at the JFK Library to celebrate the 50th Anniversary of my uncle, President Kennedy's signing of the Community Mental Health act, and to jumpstart a new collaboration between *all* the stakeholders in the "community of mental health." It is called, appropriately, The Kennedy Forum. We engaged a large and varied group, including Vice President Biden, Secretary Sebelius, and many local, state, and federal officials, along with insurers, business leaders, researchers, providers, and, most of all, people who every day live with mental illnesses, addictions, and intellectual disabilities – all in all, a group of people who don't often meet together.

My goal with the Kennedy Forum was to assemble all parts of the community and help them to recognize their common interest in being involved at this critical point in time so that we can be sure we do all we can to pave the way for access to and provision of effective and equitable services for the foreseeable future. As with implementation of the parity law itself, we won't have such an opportunity again in our lifetimes.

It was inspiring to hear the directors of the Department of Health and Human Services, the National Institute of Mental Health, the National Institute of Drug Addiction, the Administrator of the Substance Abuse and Mental Health Services Administration, the president of the American Psychiatric Association, even the medical director of one of the more open-minded health insurance companies and one of the top attorneys challenging them, sit together in small conferences to try to find common ground. This is the beginning of a process by which all the people affected by the final rule on Mental Health Parity will try to work together to actually achieve that parity. It is the kind of consensus building that you would like to see come of the process of post-law rule writing, but seldom does.

For example, in the aftermath of the Kennedy Forum, the leaders of the top caregiver organizations involved in the conditions covered by the law—the American Psychiatric Association, American Psychological Association, American Medical Association, National Association of Social Workers, the National Council for Behavioral Health and the National Association of State Mental Health Program Directors—have agreed to attend an historic meeting to put aside their parochial interests and find common ground on how to make the most of this opportunity to provide accessible quality mental health care in the post-parity and affordable-caring world. In the words of APA President Dr. Jeffrey Lieberman, "true mental health care is not just the job of psychiatrists and psychologists, or mental health providers, but all health care professionals working in diverse settings ranging from hospitals and offices to student health services in schools and universities."

Over the next year, in partnership with our sister organization, One Mind for Research, we plan to convene additional events. Their goal will be to provide an easy conduit of communication between groups often barricaded in their own silos.

None of this will be easy. We have been grappling with these challenges and prejudices for centuries, ever since founding father Dr. Benjamin Rush wrote the first American textbook on mental illness as medical disease in 1812. But, just as the Civil Rights Act of the 1960s gave our nation a process of confronting long-held racial prejudice, the confluence of the ACA and the Mental Health Parity Act offer a process of confronting our long-held medical prejudices, and the damage they cause to patients, families and caregivers every day. And I remain hopeful that what we have done during our five-year wait for a final rule on parity can be a model both for how to best use the time between law and final rule, and how to shorten it.

PREPARED STATEMENT OF CATHY MORELLI

Testimony of Cathy Morelli, Southington, Connecticut

Before the Senate Judiciary Committee

"Justice Denied: Rules Delayed on Auto Safety and Mental Health"

November 7, 2013

I'm here today to talk about the difficult battle I had with my health insurer in my attempt to get my teenage daughter the treatment she needed for her mental illness. I was completely blindsided by my health insurer's constant denials for mental health treatment my daughter so desperately needed. It was a battle I had never previously experienced whenever I sought treatment for medical conditions. Unfortunately, I discovered in a very difficult way that coverage for treatment of a mental illness would not be as easily accessible as treatment for a medical condition.

Early in 2012, my then 13 year old daughter was struggling with an eating disorder and began engaging in self-harming behaviors and suicidal attempts. Her first inpatient hospitalization began on March of 2012 due to a suicide attempt and cutting herself. Within 6 days of this hospitalization our health insurer denied her continued stay in this hospital advising that they felt she could be managed on an outpatient basis and inpatient treatment was not medically necessary. The hospital disagreed with my insurer and filed an expedited appeal but my insurer maintained their denial.

Within a day of being released from that first hospital she again attempted suicide and engaged in serious self-harming behaviors including cutting into her thigh so deeply that sutures were required to close the wound. She spent the next 14 days in the emergency department and during her stay there she began her aggression towards people and spent most of her days in restraints and under heavy sedation. Within 6 hours of being released from this emergency department, she again attempted suicide and was struggling significantly with an eating disorder and spent the next 8 days medically admitted to the hospital on a feeding tube. Once stabilized, she was transferred to VT to yet another psychiatric hospital.

Over the course of 5 months she was in and out of numerous psychiatric hospitals with each stay being prematurely cut short due to my health insurer's refusal to pay for the treatment that every doctor and therapist said she needed.

I had applied for voluntary services through the Department of Children and Families very early on to get help in managing my daughter's mental illness as it was becoming very clear that my health insurer was not going to pay for the treatment she really needed. Every denial was based on my health insurer's contention that inpatient treatment was not medically necessary and that she could be managed on an outpatient basis. DCF provided us with intensive in-home psychiatric services, known as IICAPS, in between hospital admissions. She was also being seen by an outpatient provider.

Despite IICAPS' and her outpatient provider's best efforts, my daughter's illness continued to spiral out of control, but without health insurance to cover the necessary inpatient treatment and the inability to pay out of my own pocket, I had no choice but to rely on outpatient treatment.

Things really escalated in June of 2012 when my daughter brought a knife to school and revealed this along with extensive fresh cuts on her body to staff. She was taken to the hospital and then was admitted to yet another psychiatric hospital. This was a turning point for my daughter because despite my health insurer's denial, this hospital would not release her as she was a danger not only to herself, but to others as well.

While inpatient and under the care of professionals who treat mental illness, my daughter attempted and nearly succeeded at suicide. She was placed on what is called one-to-one supervision meaning staff was within arm's reach of her at all hours of the day and night. I fail to see how my family could have provided this level of care in our own home as our health insurer claimed was possible. I'll read an excerpt from a letter addressed personally to my then 14 year old daughter for her inpatient stay where she attempted and nearly succeeded at ending her life. The letter is dated July 16, 2012. I quote "We cannot approve the request for hospital admission as of July 16, 2012. The hospital gave us information about you. This did not show that hospital care is medically necessary. You have recently been in the psychiatric hospital for about one month due to behavior problems and trying to hurt yourself. You have had these problems for a long time. You had to go into the medical hospital for a few days and now the medical hospital wants you back in the psychiatric program. You had not been getting better in a significant way for at least the last 30 days. There is no plan to do anything different. It does not seem likely that doing the same thing will help you get better. You need treatment that will likely help you get better..." Interestingly, the insurer paid for only one day of the 30 days they spoke about in their letter. They acknowledge she needs treatment but they make it very clear they are not going to pay for it.

Along with DCF, The Office of the Healthcare Advocate became involved in my daughter's case. We applied for Husky Health which is the state funded insurance plan and coverage began at some point during this latest hospital admission. With the help from the state my daughter was finally able to get the long term treatment that was necessary to stabilize her condition and allow her to return home and be managed on an outpatient basis.

With the help of the OHA we began appealing the 13 denials issued by my health insurer in those 5 months. At first, we went through the insurer's two-step internal appeal process but the denials were upheld. We then filed external appeals through the insurance dept. and every single denial ever issued by my health insurer was overturned. It never had to get to the level it did considering the Mental Health Parity Laws in place. With a lack of regulations these health insurers will not stop their discriminatory practices towards the treatment of mental illness.

Cathy Morelli
Southington, CT

PREPARED STATEMENT OF THOMAS O. MCGARITY

TESTIMONY OF

THOMAS O. MCGARITY
Joe R. and Teresa Lozano Long Endowed Chair in Administrative Law
University of Texas School of Law

on

"Justice Denied: Rules Delayed on Auto Safety and Mental Health"

United States Senate
Committee on the Judiciary
Subcommittee on Oversight, Federal Rights, and Agency Action

November 7, 2013

My name is Tom McGarity. I hold the Joe R. and Teresa Lozano Long Endowed Chair in Administrative Law at the University of Texas School of Law, where I teach courses in Administrative Law, Torts and Environmental Law. I am also a member of the Board and immediate past president of the Center for Progressive Reform. I began writing about the ossification of informal rulemaking more than twenty years ago when I published the first thoroughgoing analysis of the ossification problem while serving as a consultant to the Carnegie Commission on Science, Technology and Government.[1] My most recent article on the pathologies of informal rulemaking in the twenty-first century, entitled "Administrative Law as Blood Sport," was published in 2012.[2] I am very pleased to be here to testify on the topic of the broken federal rulemaking process. Please note that I am expressing my own views and not necessarily those of the University of Texas or the Center for Progressive Reform.

A Broken Rulemaking Model.

The authors of the original Administrative Procedure Act (APA) envisioned rulemaking as a relatively straightforward process for making agency policy through open procedures that relied heavily on agency expertise and invited the public to participate in the policymaking process. Under the original model, the agency was obliged to provide a "general notice" of proposed rulemaking containing: "(1) a statement of the time, place, and nature of public rulemaking proceedings; (2) reference to the legal authority under which the rule is proposed; and (3) either the terms of substance of the proposed rule or a description of the subjects and issues involved."[3] After issuing the notice of proposed rulemaking, the agency had to "give interested persons an opportunity to participate in the rulemaking through submissions of written data, views, or arguments with or without opportunity for oral presentation."[4] After considering the comments, the agency was required to "incorporate in the rules adopted a concise general statement of their basis and purpose." The APA also provided for judicial review of rulemaking under which the reviewing court was to "hold unlawful and set aside agency action, findings and conclusions found to be . . . arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with law."[5]

The basic model prescribed by the APA remains in effect. It has the great virtue of allowing affected members of the public to participate directly in the policymaking process by submitting information and views during the comment phase of the rulemaking and by challenging final rules in court under the "arbitrary and capricious" test. It also ensures that the agency explains the rule's basis and purpose to the

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[1] Thomas O. McGarity, Some Thoughts on Deossifying the Rulemaking Process, 41 Duke L. J. 1385 (1992).

[2] Thomas O. McGarity, Administrative Law as Blood Sport, 61 Duke L. J. 1671 (2012).

[3] 5 U.S.C. § 553(b).

[4] 5 U.S.C. § 553(c).

[5] 5 U.S.C. § 706(2)(A).

satisfaction of a reviewing court. Informal rulemaking has not, however, evolved into the flexible and efficient process that its supporters originally envisioned.

During the 1980s and 1990s, the rulemaking process became increasingly rigid and burdensome as presidents, courts and Congress added an assortment of analytical requirements to the simple rulemaking model and as evolving judicial doctrines obliged agencies to take great pains to ensure that the technical bases for rules were capable of withstanding judicial scrutiny under what is now called the "hard look" doctrine of judicial review. Professor E. Donald Elliott, himself a former General Counsel of the Environmental Protection Agency, referred to this phenomenon as the "ossification" of the rulemaking process, and I wrote an article based on my study for the Carnegie Commission describing the ossification phenomenon, identifying some of its causes, and suggesting some ways to "deossify" the rulemaking process.

It is fair to say that the problem has become even worse during the twenty-first century, at least in the case of "high stakes" rulemaking where the outcome of the rulemaking process really matters to the stakeholders.[6] First, the rulemaking battles have spread to arenas that are far less structured and far more political than the agency hearing rooms and appellate courtrooms of the past. Second, the roster of players has expanded beyond the relevant government officials, the advocates for the regulated industry and beneficiary groups, and the occasional congressional aide to include advocacy organizations with broad policy agendas, think tanks, grass roots organizations, media pundits, and internet bloggers. Third, because rulemaking battles are fought by many players in multiple arenas, they have become far more strategic, and the range of allowable tactics has broadened rather dramatically. Finally, in today's deeply divided political economy, the players no longer make a pretense of separation between the domains of politics and administrative law, and they are far less restrained in the rhetoric they employ in their attempts to influence agency policymaking.

My 2012 article on "blood sport" rulemaking highlights many of the tactics that stakeholders now use for slowing down or influencing the outcome of high-stakes

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[6] Several empirical and quasi-empirical studies claim to demonstrate that federal rulemaking is not as ossified as I and others have suggested. *See* Jason Webb Yackee & Susan Webb Yackee, *Testing the Ossification Thesis: An Empirical Examination of Federal Regulatory Volume and Speed, 1950–1990*, 80 GEO. WASH. L. REV. 1414 (2012); William S. Jordan, *Ossification Revisited: Does Arbitrary and Capricious Review Significantly Interfere With Agency Ability to Achieve Regulatory Goals Through Informal Rulemaking?*, 94 NW. U. L. REV. 393 (2000). Although this is not the place for a detailed response to those studies, they generally look at all rulemaking activities of a single agency or a group of agencies. I am willing to concede that the rulemaking process is functioning reasonably effectively for rules of little consequence, like the hundreds of pesticide tolerances and state implementation plan approvals that the Environmental Protection Agency (EPA) undertakes every year. It even works reasonably well for many rules designated "major" because of their impact on the economy. For rules that really matter and to which regulatees are prepared to devote substantial resources, however, the existing rulemaking model is not working. I am happy to limit my observations in this testimony to "high stakes" rulemakings, which I define as major rulemaking exercises in which the stakes are especially high, the agency is attempting to implement a new regulatory program or major expansion of an existing program, or the proceedings have the potential to establish an important precedent with large economic consequences for the regulated industries or the beneficiaries of the regulatory program.

rulemaking proceedings, many of which are employed outside the APA's notice-and-comment process.[7] Under the pressure of constant opposition from the regulated industries and with only sporadic countervailing pressure from beneficiaries of the regulated programs, statutory deadlines are missed, ambitious policy goals remain unachieved, and the protections envisioned by the authors of the statute gradually erode away.

Along with many other scholars, I am convinced that the current rulemaking process is not merely ossified -- it is broken.

Not surprisingly, agencies that are committed to fulfilling their statutory missions have sought out policymaking vehicles outside of the broken informal rulemaking process. These alternative policymaking tools often lack transparency, provide regulated entities with little notice of the agency's position on critical issues, and offer few, if any, opportunities for the public to participate in the policymaking process.

Congress can play an important role in fixing the APA's broken rulemaking model. And these hearings offer a welcome opportunity to shine a spotlight on the broken rulemaking process and to consider rulemaking vehicles that allow agencies to implement statutory policies in a timely, effective and transparent fashion.

The Unfortunate Side Effects of a Broken Rulemaking Model.

The fact that the rulemaking model is broken has yielded several unfortunate side effects, including the inability of agencies to attain the goals of their statutes, inefficiency in implementation, reduced incentives to revise existing rules, and reduced incentives to innovate.

Frustrating the Attainment of Statutory Goals.

The first, and most obvious, consequence of the broken rulemaking model is the negative impact on the agencies' attempts to implement their statutory goals. Most regulatory statutes were enacted to accomplish broad public policy goals, and they rely on the agencies to achieve those goals by filling in the implementation details through rulemaking or, in some instances, through rules articulated in individual adjudications. As informal rulemaking has become increasingly burdensome, some agencies have effectively given up on meeting their statutory goals in some important areas of their responsibilities.

The experience of the Occupational Safety and Health Administration (OSHA) in promulgating occupational health standards is a good example of this phenomenon. The goal of occupational health safety and health standards is to "assure so far as possible

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[7] I elaborate on these points at some length in Thomas O. McGarity, Administrative Law as Blood Sport, 61 Duke L. J. 1671 (2012).

every working man and woman in the Nation safe and healthful working conditions."[8] OSHA is to achieve that goal by promulgating occupational health standards that "assure, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life."[9]

OSHA got off to a good start in its early years by promulgating occupational health standards for asbestos, vinyl chloride, 14 carcinogens, benzene, cotton dust, and a number of other chemicals. As the rulemaking process became more burdensome during the 1980s and 1990s, the agency's rulemaking output dramatically dropped. These standards provided important health protections to thousands of American workers and, in the case of the cotton dust standard, benefitted the industry as well.[10] Standard setting for the many hazardous chemicals to which employees are exposed in many workplaces came to a complete halt in 2001. During the George W. Bush Administration, OSHA did not promulgate a single occupational health standard of any consequence. The agency's output remained unchanged under the Obama Administration, until OSHA published a notice of proposed rulemaking for silica dust, a notorious workplace contaminant, last August. OSHA predicts that the proposed rule, should it ever go into effect, will save nearly 700 lives and prevent 1,600 new cases of silicosis annually. That rulemaking is just underway, and I predict that it will be years before the agency brings it to a successful completion. In the interim, the lives of hundreds of workers will be needlessly lost to this entirely preventable disease.

Inefficiency.

In addition to frustrating congressional policy goals, the current broken state of the informal rulemaking process deprives the government of one of rulemaking's greatest virtues -- administrative efficiency. Informal rulemaking allows agencies to resolve highly technical issues generically in a single proceeding, rather than addressing the same issues over and over again in individual adjudications. By allowing agencies to resolve recurring issues generically, informal rulemaking contributes to the overall efficiency of the implementation process. But when generic rulemaking becomes too resource-intensive for the agency to consider, the taxpayer is the ultimate loser.

Reduced Incentives to Revise Existing Rules.

Nearly every president since President Carter has ordered the regulatory agencies to revisit their existing rules with a view toward revising or eliminating outdated or ineffective rules. Yet once an agency has endured the considerable expense and turmoil of writing a rule, it has every incentive to leave well enough alone. Even when forced by

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[8] 29 U.S.C. § 651(b).

[9] 29 U.S.C. § 655(b)(5).

[10] See Sidney A. Shapiro, Ruth Ruttenberg & James Goodwin, Saving Lives, Preserving the Environment, Growing the Economy: The Truth About Regulation (Center for Progressive Reform 2011)

statute to revisit existing rules, agencies are very reluctant to change them, because that would involve a new rulemaking initiative. For example, the Environmental Protection Agency (EPA) has a statutory obligation to reexamine its national ambient air quality standards (NAAQS) every five years, but it has rarely completed the process without the additional incentive of an agency-forcing lawsuit. In recent years, it has revised several of the standards, but the revisions have entailed a major expenditure of agency resources, and all have been challenged in court. By the time the agency completes the rulemaking for one NAAQS revision, the process of reconsidering that revision is already well underway.

Reduced Incentives to Innovate.

The ossification of the informal rulemaking process reduces agency incentives to experiment with flexible or temporary rules. Experiments are welcome in an atmosphere in which rules can be undone if they do not produce the anticipated changes or if they cause unanticipated side effects. But experimentation is riskier in an atmosphere in which any change is likely to be very costly and most likely irreversible.

Perverse Effects of the Broken Rulemaking Model.

The interventions that resulted in a broken approach to making rules have had two unanticipated consequences. Agencies that have the authority to do so have begun to make policy in individual adjudications, and agencies have resorted to less formal policymaking techniques such as policy statements, interpretative rules, manuals, and interim final rules that are never finalized. Both of these perverse effects come at considerable cost to the policymaking process.

Increased Incentives to Avoid Rulemaking by Adjudicating.

Some agencies have become so frustrated with the hurdles that informal rulemaking must overcome that they have attempted to make policy through case-by-case adjudication when they have the authority to take that route. The Federal Trade Commission, for example, has rulemaking authority, but it rarely exercises that authority unless Congress specifically orders it to do so. Instead, the agency makes policy in individual enforcement actions. Similarly, the National Highway Traffic Safety Administration has effectively given up on rulemaking unless specifically required by statute, focusing instead on its statutory power to force the recall of motor vehicles that contain "defects" related to safety performance. The move away from rulemaking to adjudication gives the agency the flexibility to allow policies to evolve through the gradual process of stare decisis. So long as the adjudicatory record supports the specific action, the agency can avoid explaining the factual and policy underpinnings for broad rules that it articulates in adjudications.

When agencies resort to articulating rules in adjudications as a vehicle for avoiding informal rulemaking, however, regulatees are no longer put on notice of the standards of conduct that the agency is applying to them and both regulatee and beneficiary groups are

deprived of the opportunity that informal rulemaking provides to influence the agency's thinking on the rule through the comment process. Moreover, the agency is not as accountable to Congress and the public when it makes regulatory policy through adjudication, because the policymaking process in an adjudication is generally limited to the parties to the particular proceeding.

Increased Incentives to Avoid Rulemaking Through Less Formal Policymaking Tools.

More troublesome, perhaps, from the standpoint of open government is the increasing tendency of agencies to engage in "nonrule rulemaking" through less formal devices, such as guidance documents and technical manuals. Although informal guidance documents and technical manuals are a necessary part of a complex administrative regime, they are typically promulgated without the benefit of comments by an interested public. Adopting these less formal devices as a way to avoid burdensome and intrusive rulemaking requirements would therefore render regulatory agencies much less accountable to the public and pave the way to arbitrary decisionmaking. Since these informal devices can often be employed by officials at relatively low levels in the agency, they may lack sufficient gravitas and permanence to allow companies to rely upon them in making important investment decisions.

The increase in agency use of "interim final" rules is especially worrisome. Often employed because the agency feels that it is necessary to get a rule on the books as rapidly as possible because of some urgent need, interim final rules become effective immediately without the benefit of public comment and remain in effect until the agency finalizes them. Agencies usually invoke the vague "good cause" exception to the notice and comment requirements in section 553(b)(3)(B) to justify interim final rulemaking. The agency typically agrees to accept public comment on an interim final rule and prepare a statement of basis and purpose for the final rule that is supposed to follow. One serious problem with this tool for evading notice-and-comment rulemaking is the fact that the agency need not ever promulgate a final rule. Interim final rules have a tendency to achieve a permanence that belies the agency's expressed willingness to consider public comments.[11] Agencies that do not want to go to the trouble of a burdensome rulemaking proceeding can avoid it by promulgating an interim final rule and hoping that no stakeholder goes to the trouble of challenging it in court.

The Causes of the Broken Rulemaking Model.

The informal rulemaking process did not become broken out of chance or neglect. It was the result of vigorous efforts by the regulated community to avoid the strictures of federal regulation and the sometimes well-intentioned efforts of regulatory reformers and judges to fit informal rulemaking to a (largely extra-statutory) synoptic model of regulation under which agencies are not supposed to intrude into private markets unless they can

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[11] See Michael Asimow, Interim-Final Rules: Making Haste Slowly, 51 Ad. L. Rev. 703 (1999).

identify an apparent market failure and demonstrate that the benefits of the proposed regulatory intervention outweigh its costs.

The Business Community's Deregulatory Agenda.

In the early years, informal rulemaking became a victim of its own success. Because the original model allowed agencies to impose regulatory requirements so efficiently, the affected industries were initially taken by surprise. By the end of the 1970s, however, the business community had launched an aggressive campaign to "reform" federal regulation. Although their attempts to change the substance of the regulatory statutes were largely unsuccessful, they were successful in larding up the informal rulemaking process with procedural, structural and analytical trappings that had the predictable effect of slowing down the agencies. My book *Freedom to Harm* describes in some detail this thirty-year regulatory reform effort as it affected many agencies administering federal statutes enacted to protect consumers, workers, and the environment.[12]

Burdensome Analytical Requirements.

Congress, presidents and the courts have added to the minimal procedural protections of section 553 of the APA various requirements that agencies provide support for scientific and technical conclusions in a "rulemaking record," respond to public comments that pass a threshold of materiality, and prepare various analyses of the impact of proposed regulations on the economy, small businesses, families, and federalism, most of which were ostensibly designed to make agency rulemaking more transparent and less arbitrary. These procedural and analytical accretia, however, have made the rulemaking process far more burdensome and expensive for all of the participants in the policymaking process, including, most importantly, the agencies.

For example, the modest APA requirement that the agency provide a "concise general statement of basis and purpose" for final rules has blossomed into requirements that agencies provide a "reasoned explanation" for rules and that they rationally respond to outside comments that pass a "threshold of materiality." These additional analytical requirements invite abuse by well-heeled participants who hire consultants and lawyers to pick apart the agencies' preambles and background documents and launch "blunderbuss" attacks on every detail of the legal and technical bases for the agency rules. The agency cannot afford to allow any of the multifaceted attacks to go unanswered for fear that a court will remand the entire rule to the agency to respond to that comment.

Congress has also enacted statutes specifying broad analytical requirements for all agency rulemaking. The Regulatory Flexibility Act requires agencies to prepare a series of Regulatory Flexibility Analyses for all rules that have a "significant" effect on a "substantial number" of small businesses describing the impact of proposed and final rules on small businesses and exploring less burdensome alternatives.[13] After enactment of the Small Business Regulatory

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[12] Thomas O. McGarity, Freedom to Harm (2013)

[13] 5 U.S.C. § 601 et seq. (1982).

Enforcement Fairness Act in 1996, an agency's failure to prepare Regulatory Flexibility Analyses is subject to judicial review.[14] The Unfunded Mandates Reform Act of 1995 requires agencies to prepare a detailed cost-benefit analysis for all rules that may result in the expenditure of more than $100 million by state governments, local governments, or the private sector.[15]

Presidents have also imposed burdensome regulatory impact analysis requirements on executive branch agencies. Executive Orders issued by Presidents Ford and Carter required agencies to prepare "Inflation Impact Statements" and "Regulatory Analyses" for major rules. The scope of the required analysis increased dramatically during the Reagan Administration with the promulgation of Executive Order 12291, which required agencies to prepare extensive "Regulatory Impact Analyses" (RIAs) detailing the costs and benefits of all major rules, defined to be those with an impact on the economy of more than $100 million.[16] President Clinton modified the requirements to some extent in Executive Order 12866, but not in a way that reduced the burden on the agencies of preparing lengthy and detailed analyses of the costs and benefits of major rules.[17] President Obama left Executive Order 12866 in place, but he supplemented it with Executive Order 13563, which did not affect the nature and content of the required RIAs.[18] An agency's failure to prepare an RIA is not judicially reviewable, but the RIA can play a role in substantive judicial review of the underlying regulation under the "arbitrary and capricious" test.[19]

The process of preparing an RIA involves an information-intense examination of the costs and benefits of the agency's preferred proposal and of numerous alternatives. For important rulemaking efforts the agencies usually employ numerous consultants and devote one or more person-years of agency staff to the RIA preparation process. A comprehensive RIA for a major rulemaking exercise can cost more than a million dollars. Although RIAs often provide very useful information to decisionmakers and the public about how various regulatory options will affect regulatees and beneficiaries, it is not always clear that the benefits of a lengthy RIA outweigh the costs of preparing it.

Centralized White House Review.

Executive orders signed by every president since President Johnson have required major rules to undergo some form of centralized interagency review. During most of that period, the reviews were administered by the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget. In part, this increase in presidential supervision is the result of a determined insistence by the presidents to maintain control over the regulatory bureaucracy. But it has also represented an attempt by the White House and OIRA to redirect the substantive policies of the agencies away from interventionist "command and control" approaches and

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[14] Pub. L. No. 104-121 § 605(a)(1)

[15] Unfunded Mandates Reform Act of 1995, Pub. L. 104-4 (1995).

[16] Executive Order No. 12291, 3 C. F. R. 127 (1982).

[17] Executive Order 12866, 3 C.F.R. 638 (1993)

[18] Executive Order 13563, 3 C.F.R. 215 (2011).

[19] See Thomas O. McGarity, Regulatory Analysis and Regulatory Reform, 65 Tex. L. Rev. 1243, 1317-30 (1987).

toward less intrusive market-oriented approaches. Since deregulatory policies can often be implemented by doing nothing at all, ossification can be a useful tool for advancing deregulatory policies while avoiding public accountability for those policies. When the White House has wanted to slow down the rulemaking process for particular rules, often at the behest of the regulated entities, the OIRA review process has been the primary vehicle for accomplishing that goal.

Perhaps more than any other aspect of the current regulatory process, the desire to avoid the OIRA review process induces agencies to find alternatives to informal rulemaking for regulating private conduct. Over the years agency officials have complained that the prospect of OIRA review exerts a powerful disincentive to issue protective regulations that also increase regulatory burdens. Even if most rules sail through the OIRA review process untouched, OIRA review may nevertheless have a chilling effect on agency attempts to implement statutory commands through rulemaking.

Overly Aggressive Judicial Review.

The courts have played a prominent role in rendering rulemaking unattractive through aggressive application of the "hard look" doctrine, under which the courts carefully examine the administrative record and the agency's explanation to determine whether the agency applied the correct analytical methodology, applied the right criteria, considered the relevant factors, chose from among the available range of regulatory options, relied upon appropriate policies, and pointed to adequate support in the record for material empirical conclusions. The Supreme Court in 1983 summarized the hard look doctrine in a four-part test that remains the keystone of judicial review under the "arbitrary and capricious" test for judicial review under the APA and many agency statutes. Under this test, the court must set aside an agency rule if: "the agency has relied on factors which Congress has not intended it to consider; entirely failed to consider an important aspect of the problem; offered an explanation for its decision that runs counter to the evidence before the agency; or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise."[20]

Although judicial application of the hard look doctrine has varied widely from circuit to circuit and from case to case within circuits, it has had a profound effect on the way that agencies go about writing major rules that are likely to be challenged in court. The branch of hard look review under which the court sets aside a rule if the agency "entirely failed to consider an important aspect of the problem" has inspired the agencies to write preambles to final rules and supplementary explanations that go on for hundreds of pages as the agency staffs engage in herculean efforts to leave no stone unturned. The requirement that the agency respond to comments that cross a "threshold of materiality" has resulted in equally vigorous attempts by agency staffs to characterize, segregate and respond to the thousands of comments that agencies engaged in high stakes rulemaking typically receive.

There is a genuine risk of judicial overreaching when courts undertake this review of the agency's explanations, because remanding for failure to consider an important aspect of the

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[20] Motor Vehicle Manufacturers Ass'n v. State Farm Mutual Auto Ins. Co., 463 U.S. 29, 42 (1983).

problem or failure to respond to a relevant comment is an easy way for a court to dispose of a rulemaking challenge without appearing to extend itself beyond the range of its institutional competence. In remanding for further analysis, the court is not ruling that the agency is wrong or irrational; it is merely holding that the agency's analysis is incomplete. Yet the message that the agencies hear is that their explanations must be exceedingly thoroughgoing in every regard, or the courts may send their rulemaking initiatives back to the drawing board.

Savvy program managers know that in the complex and constantly shifting institutional environment of modern rulemaking, a trip back to the drawing board can send the project spinning off in odd directions or, worse, can be a consignment to oblivion as the agency commits limited staff resources to other projects, institutional memory fades, and more immediate priorities press old rulemaking initiatives to the bottom of the agenda. The key to successful rulemaking is therefore to make every effort to render the rule capable of withstanding the most strenuous possible judicial scrutiny the first time around. As a result, the process of assimilating the record and drafting the preambles to proposed and final rules may well be the most time-consuming aspect of informal rulemaking. I have even seen instances in which the agency elicited a separate round of public comment on the staff-prepared summary of the previous comments to be sure that the agency correctly understood them. It is easy to see how notice-and-comment rulemaking can degenerate into an endless process of public comment and analysis. The prospect of having to go through the immense effort of assembling and digesting the record and drafting a preamble capable of meeting judicial requirements for reasoned justification provides a strong incentive for agencies to seek out ways to avoid rulemaking.

Possible Solutions.

Agencies that are conscientiously committed to carrying out their statutory missions will continue to employ informal rulemaking with all of its burdensome accoutrements if they have no other alternative. For example, EPA's statutes typically require it to use informal rulemaking to fill in the necessary implementation details, and they often specify precise deadlines for EPA action. Its heavy rulemaking output during the past few years is a testament to the ability of a very determined agency to employ even a broken system to achieve important statutory goals. But those efforts consumed scarce resources that are unlikely to be available in such quantities in the future. The agency has on many occasions made policy through less formal devices like guidance documents that are not subject to many of the requirements that afflict informal rulemaking. And it will no doubt continue to do so as the resources available to the agency dwindle.

There are two ways to address the predictable efforts of agencies to avoid the burdens and vicissitudes of informal rulemaking. One approach, much preferred among regulatees, is to extend the reach of centralized review, judicial review, and extra-statutory analytical requirements to less formal policymaking vehicles like policy statements, guidance documents, and interim final rules that are never finalized. For example, both Presidents George W. Bush and Barack Obama took steps to ensure that,

during their administrations, OIRA would have an opportunity to review important guidance documents, policy statements, and the like.[21]

The other approach is to take away the incentive to use rulemaking avoidance devices by relieving the agencies of many of the burdensome aspects of the existing informal rulemaking process. Rather than giving up on informal rulemaking, the agencies and Congress should be attempting to extract it from the morass that currently envelops it.

Greater Oversight of the Real-World Rulemaking Process.

The first thing that Congress can do to fix the broken informal rulemaking model is to step up its oversight of the rulemaking process and of the roles that agency staffs, OIRA desk officers, lobbyists for regulatees and beneficiary groups, think tanks, trade associations, and ordinary citizens play in that process. Congressional oversight of rulemaking should be systemic and not limited to inquiries into particular rulemaking exercises. This subcommittee is taking an important step in the right direction by holding these hearings. It should continue to probe the rulemaking process, perhaps with the aid of the Congressional Research Service and the Government Accountability Office, to build the legislative record necessary to support legislation addressing the failures of the current rulemaking model.

Eliminating Procedural and Analytical Mandates in Statutes.

Some agencies like OSHA believe that their statutes mandate a more formal rulemaking process than the notice-and-comment process envisioned by section 553. Congress could amend those statutes to make its intent clear that formal hearings and other formal procedures are not necessary in particular contexts.

Congress could enact legislation to reduce or eliminate one or more of the many analytical requirements in statutes and executive orders. An agency is most interested in analyzing issues that are directly relevant to the success or failure of the rulemaking initiative in the relevant judicial and political arenas. Eliminating marginally useful analytical requirements would probably not reduce the intensity of the agency's analysis of the pertinent issues. Since the process of producing analytical paperwork is both time-consuming and expensive, the rulemaking process would probably move along more expeditiously after Congress removed unnecessary analytical hurdles.

Since intense analysis of the costs and benefits of proposed and final regulations is more useful in some areas than in others, Congress (and the president) might usefully explore the possibility

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[21] See Executive Order 13422, 3 C.F.R. 191 (2007) (extending OIRA review to "significant" guidance documents, which it generally defined to include guidance documents that would have an annual economic effect of $100 million or more or some other large economic or policy effect); Memorandum from Peter Orszag, Director, White House Office of Management and Budget, to the Heads and Acting Heads of Executive Departments and Agencies (Mar. 4, 2009), *available at* http://www.whitehouse.gov/sites/default/files/omb/assets/memoranda_fy2009/m09-13.pdf (clarifying that even though President Obama had revoked Executive Order 13422, significant guidance documents would still remain the subject of OIRA review during the Obama Administration).

of reducing or eliminating some aspects of the analytical requirements in some regulatory areas. For example, whether the benefits of analyzing the impact of regulations on small entities are outweighed by the negative impact of such analytical requirements on the flexibility of rulemaking is an open question. Congress might revisit the Regulatory Flexibility Act to form some conclusions as to whether that statute is reducing flexibility, rather than enhancing it.

Finalizing Interim Final Rules.

If interim final rules never have to be finalized, the comments that the agency accepts can be a waste of time and effort. More importantly, the agency never gets the benefit of input from outsiders, a result that is entirely inconsistent with purpose of notice and comment rulemaking. Congress could solve this problem by amending the APA to provide that when an agency issues an interim final rule, it must also issue it as a proposed rule and that the interim final rule automatically expires after three years if the agency does not promulgate a final rule during the interim. Congress has already adopted this approach in the context of "temporary regulations" issued by the Internal Revenue Service.[22]

Cutting Back on White House Oversight.

The primary objection to OIRA review of rulemaking is that OIRA's input often goes beyond comments on the agency's analysis to demands that the agency change the substance of the rules. Unidentified White House officials can use the OIRA review process to advance policies that run counter to the agencies' statutes. Agencies are understandably reluctant to cede decisionmaking authority to OIRA, and Congress should be equally concerned about the White House's de facto exercise of unconstrained power over the agencies' implementation of congressional goals. Much of what motivates the agencies to attempt to circumvent the rulemaking process is the prospect of dealing with the acrimonious and time-consuming process of OIRA review.

Abuse of the OIRA review process can be limited and its accountability enhanced by increasing its transparency. OIRA review is not governed by the Administrative Procedure Act, and the transparency of that review process has waxed and waned over the years. OIRA review remains far from transparent, because the rules of engagement with agencies are often ignored in practice. Moreover, the content of conversations between outside lobbyists and White House and OIRA officials concerning particular rulemaking initiatives are not generally disclosed. Still another round of conversations between industry and interest group representatives and government officials can take place after the rule is challenged in court, as the parties negotiate about the content of the regulations as part of an overall effort to settle the litigation. These negotiations are not bound by any rules or procedures, and the contents of the discussions are rarely disclosed voluntarily.

OIRA review will be much less intrusive if the contents of OIRA-agency communications and communications between outside interests and OIRA or other White House officials regarding particular rulemaking initiatives are spread on the public record for all to see. When OIRA staffers know that the time consumed in the review process and the extent to which they attempt to substitute their policy preferences for those of the appointed agency heads and Congress will

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[22] 26 U.S.C. § 7805(e).

become publicly available, they may be less likely to use the review process as a vehicle for affecting substantive agency policy.

A Softer Judicial Look at the Substance of Rules.

Reducing the intensity of substantive judicial review would probably enhance rulemaking flexibility, but it would also leave more room for administrative arbitrariness. We are therefore left with a delicate balance between the increased accountability afforded by judicial review and the risk of overly intrusive judicial interventions as courts strive to perfect an inherently imperfect process through the "hard look" doctrine. I have suggested that a better metaphor for this evaluative function may be that of the "pass-fail prof" who must determine whether a research paper on a topic about which he is vaguely familiar meets the minimum standards for passable work. His disagreement with the paper's conclusions will certainly not cause him to flunk the student. Even a poor analysis will not cause the paper to fail, if the analysis is at least plausible. A check of the citations may reveal that the student could have found more sources or that he may have mischaracterized one of the cited sources, and still the paper may pass. Only where there is an inexcusable gap in the analysis, an obvious misquote, or evidence of intellectual dishonesty will the pass-fail prof put an "F" on the paper and send the student back to try again. When the courts engage in substantive judicial review, they should, like the pass-fail prof, see their role as that of screening out bad decisions, rather than ensuring that agencies reach the "best" decisions.

Congress might think about enacting legislation designed to signal to the courts its intention that they reduce the intensity of judicial review of informal rulemaking. It could, for example, amend the APA to change the scope of review for informal rulemaking. That being said, it is hard to imagine words that could specify less intensive review than the words "arbitrary and capricious." At the end of the day, the scope of rulemaking review may be an issue that is best worked out by the courts with the aid of outside criticism from administrative law scholars.

Conclusion.

In my view, the venerable informal rulemaking process established by section 553 of the Administrative Procedure Act is broken. This committee is in an ideal position to begin the lengthy process of repairing this broken, but extremely valuable policymaking tool. I applaud the members of the committee for their willingness to initiate an ongoing dialogue on the virtues and limitations of informal rulemaking as a vehicle for implementing federal regulatory statutes.

PREPARED STATEMENT OF CLARENCE M. DITLOW

Statement of Clarence M. Ditlow
Executive Director, Center for Auto Safety
On Delays in National Highway Traffic Safety Administration (NHTSA) Rulemaking
Before the Subcommittee on Oversight, Federal Rights and Agency Actions
Senate Judiciary Committee
November 7, 2013

Mr. Chairman, members of the Subcommittee, thank you for the opportunity to testify on delays in rulemaking at NHTSA. I am Clarence Ditlow, Executive Director of the Center for Auto Safety (CAS) founded by Consumers Union and Ralph Nader in 1970 to be a voice for consumers on auto safety. The Center has watch dogged NHTSA and the auto industry for 40 years. NHTSA is a wonderful agency with a vital mission but it is woefully underfunded, understaffed and outgunned by the industry it regulates. Unlike FDA, EPA and other agencies, it doesn't even have its own research lab on which to base it actions; instead it rents space from Honda.

During first five years after its creation in 1966, NHTSA issued more safety standards than it did in the next forty years. Many of the original standards such as seat back strength and head restraints are woefully out of date. With rare exception, revision of the original standards or issuance of major new standards came from Congressional mandates. Today, standards issued by NHTSA on its own tend to be relatively minor or without significant industry opposition such as low-speed vehicles, wheel chair lifts, and alternative fuel systems.

After the seminal rulemaking by NHTSA, the history of the agency has been one of an agency where Congress has to intervene as a major safety issue emerges that the agency is unable to resolve or lacks authority. Some examples of Congressional intervention are:

1974 Amendments, Pub Law No. 93-492 - Required Recall Repairs to Be Free, Mandated FMVSS 301 Fuel System Integrity Take Effect, Required 8 Schoolbus Safety Standards, Upgraded Defect Notices, Provided Right of Public to File Defect Petitions, Doubled Civil Penalty

1991 ISTEA, Pub Law No. 102-240, Required Full Front Seat Airbags, Revised Head Injury Rule

1998 TEA-21, Pub Law No. 105-178, Required Improved Airbag Rule

2000 TREAD Act, Pub Law No. 106-414, Required Revised Tire Safety Standard, Tire Pressure Monitoring, Early Warning Reporting System, Increased Civil Penalty to $15 Million

2002 Anton's Law, Pub Law No. 107-318, Required Booster Seat, Lap & Shoulder Belt Rules

2005 SAFETEA-LU, Pub Law No.109-59, Required Rollover Prevention, Side Impact, Roof Crush, Occupant Ejection, Power Window Switch Rulemakings, Crashworthiness Ratings & 15-Passenger Van Safety

2007 Cameron Gulbransen Act, Pub Law No. 110-189 - Required Backover, Power Window, Brake Shift Interlock Rules.

2010 Pedestrian Safety Enhancement Act - Alert Sound from Electric/Hybrid Vehicles

2012 MAP-21, Required Child Side Impact & Better Anchors Rules, Required Rear Seat Belt Reminder and Seat Specification Rules, Increased Civil Penalty to $35 Million

Whether it's the Chevrolet Corvair in the 1960's, the Ford Pinto and the Firestone 500 tire in the 1970's, the Audi 5000, Chrysler minivan tail gate and GM pickups with side saddle gas tanks in the 1980's, the Ford Explorer and Firestone Wilderness & ATX tires in the 1990's, Toyota sudden acceleration in the 2000's, or Jeep fuel tanks today, there's a common thread: Out-of-date and inadequate safety standards coupled with enforcement efforts playing catch up to an industry

striving to run out the statute of limitations. If the industry wins the bet and the agency never catches up, individual companies can save hundreds of millions of dollars in avoided recalls as Toyota bragged about in sudden acceleration. If they lose and contain the loss at NHTSA, the worst case scenario is a fine of $35 million. If the defect goes public, the cost to the auto companies is far greater in lost sales and reputation. But as history has shown, only one or two defects go public every decade. What goes unsaid is that the innocent bystanders, the consumers, pay with their lives.

As shown by the above examples, failure to issue effective rules result in large recalls that cost the auto industry lost profits and the public lost lives. Take the following examples:

Electronics: In the mid-1970's NHTSA anticipated the increased use of electronics in vehicles and potential hazards associated with their use beginning with the use of electronic ignitions in 1975. Lacking resources and personnel to adequately evaluate electronic controls, the agency contracted with the Institute for Telecommunications Sciences to assess the potential and methods for electronic magnetic interference (EMI) to cause malfunctions in the electronic controls in vehicles.[1] In a second research phase, the Institute produced Guidelines for Electromagnetic Compatability (EMC).[2] Although the agency intended to develop safety standards for electronic controls, no standards were issued.

With the advent of electronic ignition systems and cruise control systems in the late 1970's and early 1980's sudden acceleration complaints without clear mechanical failures began to appear. NHTSA opened more and more sudden acceleration investigation. Some resulted in recalls for electronic control failures. The first two Toyota sudden acceleration recalls were for replacement of the cruise control computer which could cause sudden acceleration on start up (86V-132, 90V-040). Even though NHTSA determined the cruise control computers caused the sudden acceleration, it had to give the computers to Toyota to find the failure mode, a short in the printed circuit board.

Today we still have no safety standard for electronic controls and computer processing units (CPU's) using embedded software in motor vehicles even though vehicles employ 50 or more CPU's. Although NHTSA turned to NASA during the Toyota unintended acceleration (UA) investigations, NASA concluded: Due to system complexity . . . and the many possible electronic hardware and software systems interactions, it is not realistic to attempt to 'prove' that the ETCS-I cannot cause UA's. Today's vehicles are sufficiently complex that no reasonable amount of analysis or testing can prove electronics and software have no errors. Therefore, absence of proof

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[1]NHTSA Study: "Investigation of Electromagnetic Interference Effects on Motor Vehicle Electronic Control and Safety Devices" - Oct. 1975

[2]NHTSA Study: "Electromagnetic Interference Effects on Motor Vehicle Electronic Control and Safety Devices, Volume I - Summary" ; NHTSA Study: "Electromagnetic Interference Effects on Motor Vehicle Electronic Control and Safety Devices, Volume II - Measurements, Analysis and Testing"; NHTSA Study: "Electromagnetic Interference Effects on Motor Vehicle Electronic Control and Safety Devices, Volume III - Automotive EMC Guidelines" - Nov. 1976.

that the ETCS-I has caused a UA does not vindicate the system. " A team of 4 software engineers from the Barr Group spent 18 months examining the Toyota electronic throttle source code using the NASA analysis as a starting point and found what NASSA would have found had it not been shut down – Toyota's source code "is defective and contains bugs" and the electronic throttle control system (ETCS) fail safes are defective and inadequate.

What NHTSA does not have in the way of safety standards which FAA has and which voluntary standards organizations like IEEE has is a process safety standard to ensure the validity and safety of computer code used in electronic systems with safety critical functions. The increasing number of NHTSA safety recalls for software changes indicates the need for a software verification standard.

Fused Circuits: In 1972, Dr Carl E Nash of the Public Interest Research Group petitioned NHTSA to require electrical circuits in vehicles to be fused but NHTSA took no action. In the years, NHTSA defect investigations led to some of the largest recalls ever including 9 million Fords for ignition switches that shorted out and caused dash fires. Just five years later, NHTSA forced Ford to recall 16 million more vehicles for defective cruise control deactivation switches that shorted out and caused fires. Tragically in both cases, the fires could start when the vehicles were parked in garages and burned houses down.

BTSI: In the 1980's and 1990's, there were many hundreds of deaths caused by rollaway vehicles where an unattended car shifted out of park and rolled away or where a driver shifted into gear and mistakenly pushed the gas pedal instead. These lead to numerous investigations and recalls such as 23 million Fords for failing to hold in Park and 251,000 Audi's and 185,000 Nissans for sudden acceleration. Chrysler avoided a safety recall only by doing a service campaign to install a BTSI on its 1993-95 Grand Cherokees. Ultimately Congress required BTSI installation in all vehicles by September 1, 2010.

Airbag Deaths: In 1998, Congress required NHTSA to issue a revised airbag standard that protected small women and children in low speed airbag deployments. In the 1970's when NHTSA was issuing the first airbag rule, the agency proposed a no-deploy at 12 mph requirement and CAS proposed testing for all size occupants. The auto industry vigorously opposed both requirements which were dropped. Indeed, in upholding the airbag rule, a unanimous Supreme Court pointed out: "For nearly a decade, the automobile industry waged the regulatory equivalent of war against the airbag and lost - the inflatable restraint was proved sufficiently effective." [3]

Tires: One of the original safety standards issued by NHTSA regulated passenger vehicle tires. In 1978, Congress held extensive hearings on what became the largest tire recall ever, the Firestone 500 steel-belted tires when CAS successfully campaigned to get 19.5 million Firestone tires recalled. Unfortunately, one of the key recommendations of the Committee to upgrade Federal Motor Vehicle Safety Standard 109 was never acted on by NHTSA. FMVSS 109 which sets performance standards for tire strength, endurance and high speed performance was developed in

[3] *State Farm Mutual Automobile Insurance Co. v. DOT*, 463 US 29, 49 (1983).

the late 1960's and early 1970's when there were very few radial tires and no SUVs on the road. NHTSA withdrew the only enforcement action it ever brought under the standard because it was so vague and difficult to enforce.

On August 9, 2000, Bridgestone/Firestone (Firestone) and Ford announced jointly that Firestone would recall approximately 14.4 million ATX, ATX II and Wilderness AT tires that were original equipment on Ford vehicles. The recall came after only after intense public scrutiny and an estimated $2 billion cost to Ford and Firestone. Although there are many similarities between the Firestone 500 and the Firestone/Ford tire failures, there is a key difference -- the role of the vehicle on which the tires are mounted. In the Firestone 500 recall, there were more tires and complaints (14,000 then versus 2,400 in the ATX/Wilderness) but fewer deaths (41 then versus 240). The primary vehicle in which Firestone ATX, ATX II and Wilderness tire tread separations and deaths have been associated was an SUV which is far more likely to roll over than a passenger car, and when it rolls over, its occupants are likely to be injured.

As a result of Ford/Firestone, Congress passed the TREAD Act in 2000 and did what it didn't do in 1978, mandated NHTSA to issue revised Federal Motor Vehicle Safety Standards for tires.

Conclusion: An oil industry executive once told me that he asked his counterparts at the auto industry why they opposed virtually every NHTSA regulatory proposal when so many were so minor. The answer was that we tie them up in so many little things, they never get to the big ones.

This hearing provides a unique opportunity to examine the regulatory process at NHTSA and ask how the rulemaking process can be improved to not only reduce the unacceptable toll of death and injuries on the nation's roads but also provide stability to the auto industry which suffers from lack of public confidence and sales when preventable defects such as Ford Explorers that roll over when Firestone tires fails, Toyota unintended acceleration and exploding Jeep fuel tanks occur. The federal government through the National Highway Traffic Safety Administration should lead the way to vehicle safety and not clean up afterwards.

PREPARED STATEMENT OF CARY COGLIANESE

Testimony of Cary Coglianese
Edward B. Shils Professor of Law
Director, Penn Program on Regulation
University of Pennsylvania

Before the
U.S. Senate
Committee on the Judiciary
Subcommittee on Oversight, Federal Rights, and Agency Action

Hearing on "Justice Denied: Rules Delayed on Auto Safety and Mental Health"

November 7, 2013

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November 7, 2013

Chairman Blumenthal, Ranking Member Hatch, and Members of the Subcommittee, I appreciate your invitation to appear before you today to testify on trends in rulemaking by the National Highway Traffic Safety Administration (NHTSA). By way of background, I am the Edward B. Shils Professor of Law and former Deputy Dean for Academic Affairs at the University of Pennsylvania Law School, as well as a Professor of Political Science and the Director of the Penn Program on Regulation at the University of Pennsylvania. The focus of my research and teaching has been on administrative law and government regulation, with a particular emphasis on the empirical study of regulatory policymaking. My recent books include *Does Regulation Kill Jobs?* (with Adam Finkel and Christopher Carrigan, forthcoming 2013), *Regulatory Breakdown: The Crisis of Confidence in U.S. Regulation* (2012), and *Import Safety: Regulatory Governance in the Global Economy* (with Adam Finkel and David Zaring, 2009).

Summary

For more than two decades, administrative law scholars have perpetuated claims about how the threat of judicial review has effectively "paralyzed" NHTSA in the exercise of its rulemaking authority. Specifically, the claim is that judicial review under the arbitrary and capricious standard has prompted NHTSA all but to abandon rulemaking and shift instead to issuing individual recalls on defective automobiles. Yet these claims of NHTSA's abandonment of rulemaking in the face of judicial review simply do not bear up under close scrutiny. NHTSA has continued to undertake substantial rulemaking, notwithstanding the persistent threat of judicial review. The agency's purported shift to recalls has been neither dominant nor as discernible as has been typically supposed. The trends that do exist in NHTSA rulemakings over several decades do not appear well explained by judicial decisions. Other explanations – such as the life cycle of regulatory implementation, decreases in public support for auto safety regulation, and changes in budgetary resources – appear more plausible. Members of Congress would do well to consider carefully other highly plausible alternatives before making policy decisions based on claims that have little empirical support, however widely accepted they may be among legal scholars.

Claims of NHTSA's Retreat from Rulemaking

The Administrative Procedure Act of 1946 (APA) authorizes courts to invalidate government regulations deemed to be "arbitrary and capricious." Many scholars and practitioners believe that, to minimize the risk of judicial rejection, government officials overcompensate by taking excessive care to develop extensive rulemaking records and draft lengthy *Federal Register* documents, resulting in what has become known as the "ossification of rulemaking."

Claims of ossification are made about regulation generally, but they are most frequently supported by reference to a detailed and elegant case study on NHTSA completed in the 1980s by Jerry Mashaw, a thoughtful and distinguished professor of administrative law at Yale University, and his co-author, David Harfst, a lawyer.[1] Mashaw and Harfst examined NHTSA's record of rulemaking during the two decades following the enactment of the National Traffic and Motor Vehicle Safety Act of 1966 ("Motor Vehicle Safety Act"). Like other new regulatory initiatives of the late 1960s and early 1970s, the Motor Vehicle Safety Act called for the government to provide for the protection of public health and safety by issuing general rules or standards. This power to issue general rules was viewed at the time as one of the "greatest inventions of modern government"[2] because it offered a procedure for governmental correction of market failures thought to be easier than the traditional case-by-case adjudication that characterized older regulatory agencies. Yet rather than finding rulemaking easier, NHTSA purportedly retreated from rulemaking in the face of judicial losses in the early 1970s. According to Mashaw and Harfst, NHTSA's losses under the arbitrary and capricious standard "burdened, dislocated, and ultimately paralyzed its rule making efforts."[3] Instead of seeking to protect the driving public by issuing rules, the agency shifted to vehicle defect recalls, a form of the old-style, adjudicatory approach.

Although Mashaw and Harfst's underlying research is now itself more than a quarter-century old, their findings continue to reinforce widespread agreement that judicial review has hampered administrative agencies' regulatory efforts and has led some agencies – like NHTSA – to retreat from rulemaking altogether. Discussion and concern about ossification persist throughout contemporary administrative law scholarship, as well as in discussions by legal and policy decision makers.[4] Citing Mashaw and Harfst's work, Professor Richard Pierce has written that "NHTSA has abandoned almost completely its efforts to establish policy through

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1 Jerry L. Mashaw & David Harfst, Regulation and Legal Culture, 4 Yale J. Regn. 257 (1987) (hereinafter "Legal Culture"); Jerry L. Mashaw & David Harfst, Inside the National Highway Traffic Safety Administration: Legal Determinants of Bureaucratic Organization and Performance, 57 U. Chi. L. Rev. 443 (1990) (hereinafter "Legal Determinants"); Jerry L. Mashaw & David Harfst, The Struggle for Auto Safety (1990) (hereinafter "Struggle").

2 Kenneth Culp Davis, Administrative Law Treatise 283 (1970).

3 Mashaw & Harfst, Legal Determinants, supra note 1, at 444.

4 See, e.g., American Radio Relay League, Inc. v. FCC, 524 F.3d 227 (2008) (J. Kavanaugh opinion concurring and dissenting in part) (lamenting that judicial application of the arbitrary and capricious standard has "gradually transformed rulemaking -- whether regulatory or deregulatory rulemaking -- from the simple and speedy practice contemplated by the APA into a laborious, seemingly never-ending process.").

rulemaking."[5] In his widely cited article on rulemaking ossification, Professor Thomas McGarity has noted that "[i]n an exhaustive study of rulemaking in the NHTSA, Professors Mashaw and Harfst found that stringent judicial review is largely responsible for that agency's virtual abandonment of rulemaking in favor of case-by-case recalls."[6] Professors Cass Sunstein and Adrian Vermeule have cited Mashaw and Harfst's research to support their claim that:

> It is now well-documented that [judicial] review has contributed to the "ossification" of notice-and-comment rulemaking ... In light of the risk of invalidation, many agencies have turned away from notice-and-comment rulemaking altogether – with the National Highway Traffic Safety Administration ("NHTSA"), for example, attempting to promote automobile safety through ex post recalls.[7]

Chronicling how NHTSA has "stalled" as an agency, Professors Rena Steinzor and Sidney Shapiro rely on Mashaw and Harfst's work to argue that, following a loss in the Sixth Circuit in 1972, NHTSA "dropped prospective standard setting as the centerpiece of its regulatory efforts" and "[i]nstead...turned to recalls as its weapon of choice."[8] Dean Elizabeth Magill has written that "NHTSA shifted to a strategy of recalls, all but abandoning its standard-setting efforts."[9]

The Mashaw and Harfst Account

In their influential study of NHTSA, Mashaw and Harfst called attention to the fact that in the first eight to ten years following passage of the Motor Vehicle Safety Act of 1966, NHTSA and its predecessor agencies put into place a basic regulatory framework -- one that exists largely to the present day. By 1976, NHTSA had put in place about 50 different safety "standards" governing different parts of the vehicle. As Mashaw and Harfst described it, "[v]irtually no aspect of motor vehicle safety was ignored. From brakes, windshield wipers, and seat belts to fuel tanks, rearview mirrors, and energy-absorbing steering assemblies, NHTSA cast an intricate net of minutely detailed regulatory requirements over a vast array of motor vehicle components and equipment."[10]

However, in these early years, NHTSA also faced resistance by firms within the automobile industry, including legal challenges to some of its new standards. In 1972, NHTSA lost three major cases in a row. Mashaw and Harfst singled out one of these three cases,

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[5] Richard Pierce, Two Problems in Administrative Law: Political Polarity on the District of Columbia Circuit and Judicial Deterrence of Agency Rulemaking, 1988 Duke L.J. 300 (1988).

[6] Thomas O. McGarity, Some Thoughts on "Deossifying" the Rulemaking Process, 41 Duke L.J. 1385 (1992).

[7] Cass R. Sunstein & Adrian Vermeule, Interpretation and Institutions, 101 Mich. L. Rev. 885, 932 (2003).

[8] Rena Steinzor & Sidney Shapiro, The People's Agents and the Battle to Protect the American Public: Special Interests, Government, and Threats to Health, Safety, and the Environment (2010).

[9] M. Elizabeth Magill, Agency Choice of Policymaking Form, 71 U. Chi. L. Rev. 1383, 1447 n. 132 (2004)

[10] Mashaw & Harfst, Struggle, supra note 1, at 69.

Chrysler v. Department of Transportation,[11] for its dramatic impact on the agency. In *Chrysler*, the Sixth Circuit reviewed a challenge to the agency's attempt to develop a passive restraints standard. Although the court upheld NHTSA's standard against a series of objections, it ultimately sent the rule back for failing the APA's arbitrary and capricious test because the agency had not adequately specified the dimensions and criteria for the anthropomorphic dummies used in the crash tests called for under the standard. NHTSA apparently had little reason in advance to suspect that the rule would be rejected for failure to state adequately a few parameters for test dummies. For this reason, the *Chrysler* decision[12] -- not to mention the losses in the other cases that same year[13] -- apparently came as a shock and placed "a stranglehold on the regulatory process" at NHTSA.[14] For Mashaw and Harfst, "it was this case, more than any other, that taught the agency how precarious its legal position in rulemaking really was."[15] Mashaw and Harfst argued that "ninety percent of [NHTSA's] total rulemaking output occurred prior to 1974. Indeed, none of its current safety rules was first issued after 1976"; after the *Chrysler* decision, NHTSA "fail[ed] almost completely to promulgate any new safety rules."[16]

Why did judicial review under the arbitrary and capricious standard allegedly result in NHTSA's abandonment of rulemaking? According to the conventional account, the chief problem lies with the uncertainty over how any given court will interpret the standard. Because courts may inflate the importance of marginal issues, agencies cannot anticipate the depth of analysis that may be required. Regulators either spend their time attempting to respond to every conceivable challenge in advance, or they turn to other actions that are not as vulnerable to judicial rejection.

In contrast to the judiciary's posture in *Chrysler* and other rulemaking cases, the courts had purportedly tread much more lightly on agency decision making when industry challenged NHTSA's recall decisions in court. The courts permitted NHTSA to pursue defect claims based on identified problems with the mechanical operation of a vehicle even if the agency could not show that the defect caused an unreasonable risk or created a sufficient safety problem to justify the cost of the recall action. Due in large part to this "green light from the courts," NHTSA apparently "produced an orgy of recall activity in the latter half of the 1970s."[17] Losses in court over rulemakings combined with wins over recalls led NHTSA to "shift from rules to recalls."[18]

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[11] 472 F.2d 659 (6th Cir.).

[12] Mashaw & Harfst, Struggle, supra note 1, at 87-88.

[13] Mashaw & Harfst, Legal Determinants, supra note 1, 457.

[14] Jerry L. Mashaw, Greed, Chaos, & Governance: Using Public Choice to Improve Public Law 181 (1997). Mashaw also described judicial review's effects on NHTSA as "debilitating," id. at 165, and "crippling," Mashaw & Harfst, Struggle, supra note 1, at 147. To be sure, he does not claim that judicial review is the only factor that may affect the production of rules, though it is the dominant one discussed in his work and certainly in the larger literature on administrative law.

[15] Mashaw & Harfst, Struggle, supra note 1, at 87-88

[16] Mashaw & Harfst, Legal Determinants, supra note 1, at 445.

[17] Mashaw & Harfst, Struggle, supra note 1, at 164.

[18] Mashaw & Harfst, Legal Culture, at 312.

Reconsidering NHTSA's "Retreat" from Rulemaking

Those unfamiliar with the work of administrative law scholars might be forgiven for finding the ossification thesis somewhat surprising. After all, government regulation overall has clearly not disappeared. Quite the contrary, today regulation occupies a space that is high on the policy agenda. The *Federal Register* continues to be published each business day, with more pages appearing nearly every year. In 1970, the *Federal Register* contained 20,036 pages, while in 2002 it contained 80,332 pages. To be sure, the *Federal Register* contains much more than just binding regulations, but the government publication that contains just the binding language of agency rules – the *Code of Federal Regulations* (CFR) – has also grown significantly over the years, doubling in the overall number of pages during the period from 1976 to 2002.[19]

When social scientists have looked systematically for ossification in rulemaking across the federal government, they have failed to find much evidence that this effect exists. In a comprehensive study of rulemaking across the federal government from 1983-2003, Professor Anne Joseph O'Connell reported that her "results suggest that the administrative state is not significantly ossified."[20] A statistical analysis of federal rulemaking from 1983-2006 by Professors Jason Webb Yackee and Susan Webb Yackee indicated that agencies that experience a high volume of litigation actually produce rules somewhat more quickly than other agencies.[21] As I have noted elsewhere, "[t]he empirical evidence for a retreat from rulemaking in the face of stringent judicial review is not nearly as clear as has been generally supposed."[22]

A rulemaking retreat is also far from clear at NHTSA. On the contrary, we can see today more clearly than ever before that NHTSA has definitely not abandoned rulemaking. The part of the CFR containing NHTSA's auto safety rules more than doubled during the period from 1976 to 2002 – an increase greater than that for the CFR overall during the same period.[23] To find further evidence of substantial NHTSA rulemaking activity, one needs to look no further than the Office of Management and Budget's (OMB) annual reports on federal regulation. The pages of the *Regulatory Program of the United States Government* that OMB issued annually from 1986 through 1992 contain list after list of NHTSA rulemaking proceedings. Since the late 1990s, OMB's Office of Information and Regulatory Affairs has published an annual report to Congress which details the estimated costs and benefits of regulations adopted across the federal government. Out of the hundreds of federal agencies and offices issuing regulations each year, OMB has consistently singled out NHTSA, along with a small number of other major-rulemaking agencies such as the Environmental Protection Agency, for issuing rules with

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[19] Cary Coglianese, Empirical Analysis and Administrative Law, 2002 Univ. Ill. L. Rev. 1111, 1128 (2002) (noting that in 1976 the CFR spanned 72,740 pages, but by 1996, it had grown to 132,112 pages -- or an increase of 1.8 times). By 2002, the CFR had increased to 145,099 pages, or a doubling since 1976.

[20] Anne Joseph O'Connell, Political Cycles of Rulemaking: An Empirical Portrait of the Modern Administrative State, 94 Va. L. Rev. 889 (2008).

[21] Jason Webb Yackee and Susan Webb Yackee, Administrative Procedures and Bureaucratic Performance: Is Federal Rule-making "Ossified"? 20 J. Pub. Admin. Res. & Theory 261 (2010).

[22] Coglianese, supra note 19, at 1127.

[23] NHTSA's auto safety regulations took up 218 pages in the CFR in 1976 and 572 pages in 2002 (or 2.6 times more pages).

substantial economic impacts. The 2013 draft report to Congress, for example, estimates that NHTSA's major rules from 2002-2012 imposed between $5.2 – $10.1 billion in annual costs and yielded $13.1 – $22.3 billion in annual benefits.[24]

Since the 1980s, NHTSA has published cost estimates in the Federal Register for some of its most significant rules. In 1983, for example, NHTSA required the installation of single-centered stop lamps on the rear of cars, at an estimated cost to the industry of $40-70 million per year. In 1989, it issued new head restraint standards estimated to cost $12.4 million. In 1991 and 1992, it issued new standards for reflectorized school bus stop arms and school bus mirrors, at an annual estimated cost respectively of $3.3 million and $1 million. Its trailer lamps rule imposed an estimated $17 million in annual costs beginning in 1992. Fuel system integrity standards for alcohol fuel cars were added in 1993, at an estimated cost of $10 million a year. Some of NHTSA's most costly actions included standards in 1995 for antilock brakes on medium to heavy trucks, estimated to cost $400 million annually plus an additional $232 million for operating costs; standards for child restraint anchorage systems in 1999, costing an estimated $152 million per year; and head impact protection standards in 1995, costing an estimated $641 million annually.[25]

According to a 1996 Department of Commerce study of the auto manufacturing sector, "safety regulations have added about $1,000 to the average selling price of passenger cars since 1980."[26] In 2004, NHTSA released an extensive *ex post* evaluation of the economic impacts associated with its auto safety regulations. During the period 1968-1978 – which roughly corresponds with the period that Mashaw and Harfst (and others) have considered the height of NHTSA rulemaking – the annual costs associated with federal auto safety standards averaged $268 per car; by contrast, in the decade following the publication of Mashaw and Harfst's work (1991-2001), NHTSA computed the comparable annual costs to be $760 per car (both periods in 2002 dollars).[27]

In the several decades since the passage of the 1966 Act, fatalities from automobile accidents have declined in the United States, even as vehicle-miles-traveled have increased dramatically. According to National Safety Council data, in 1966 there were 5.7 fatalities per 100 million vehicle miles traveled; by 2009, this rate was down to 1.2, or a decrease of over 75

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[24] OMB, 2013 Draft Report to Congress on the Benefits and Costs of Federal Regulations and Agency Compliance with the Unfunded Mandates Reform Act (April 2013), http://www.whitehouse.gov/sites/default/-files/omb/inforeg/2013_cb/draft_2013_cost_benefit_report.pdf.

[25] For the rules referenced in this paragraph, see: 48 Fed. Reg. 48235 (1983); 54 Fed. Reg. 39183 (1989); 56 Fed. Reg. 20363 (1991); 57 Fed. Reg. 57000 (1992); 57 Fed. Reg. 58406 (1992); 58 Fed. Reg. 5633 (1993); 60 Fed. Reg. 13216 (1995); 64 Fed. Reg. 10786 (1999); 60 Fed. Reg. 43031 (1995).

[26] Charles Fine et al., The U.S. Automobile Manufacturing Industry 77 (1996) (published the U.S. Department of Commerce, Office of Technology Policy, available online at http://www.ta.doc.gov/Reports/-autos/auto.pdf. *See also* Robert W. Crandall et al, Regulating the Automobile (1986) (referring to Bureau of Labor Statistics reports indicating that while auto safety standards added no more than $200 to the cost of the average car in 1972, these regulations had imposed costs of nearly $900 per car by 1984).

[27] NHTSA, Cost and Weight Added by the Federal Motor Vehicle Safety Standards for Model Years 1968-2001 in Passenger Cars and Light Trucks, DOT-HS-809-834 (December 2004).

percent.[28] NHTSA has estimated that more than 325,000 lives have been saved due to auto safety standards; as the costs associated with auto safety standards have increased, so too have the number of lives saved annually from required technologies: from 1,373 lives saved per year during 1968 -1978 to 14,142 per year from 1991-2001.[29]

Reconsidering NHTSA's "Shift" to Recalls

Although it is clear that NHTSA has not abandoned rulemaking, perhaps the agency has nevertheless shifted disproportionately to vehicle recalls. According to Mashaw and Harfst, NHTSA's shift to recalls can be documented by data contained in agency reports showing an increase in the number of recalled vehicles during the period between 1966 to 1980: "[M]otor vehicle recalls have increased from about fifteen million motor vehicles between 1966 and 1970 to some thirty-three million vehicles from 1971 to 1975, to over thirty-nine million vehicles between 1976 and 1980."[30] NHTSA experienced, in Mashaw and Harfst's words, "an orgy of recall activity in the latter half of the 1970s. During some of the Carter years, 1977 through 1980, more cars were recalled for repair than were sold new in the United States."[31] This increased recall activity became, according to their account, a substitute for rulemaking: "[I]t was only mildly hyperbolic to characterize vehicle safety regulation as synonymous with NHTSA's recall program."[32]

The source on which Mashaw and Harfst relied -- NHTSA's report of annual recalls -- probably gives an inflated view of the agency's recall activity. The *total* recalls reported annually by the agency include not only recalls initiated by the agency, but also manufacturer-initiated recalls, which actually make up a substantial portion of the number of recalls issued in any given year. Under the 1966 Act, manufacturers are required to notify consumers if they find a defect or a violation of a safety standard on their own. In addition to these manufacturer-initiated recalls, the Act also provides separately for NHTSA to initiate its own recall investigations in response to consumer complaints about alleged defects or safety standard violations. NHTSA-initiated recall investigations often result in the manufacturer agreeing to take action without any order from NHTSA or the courts, but these investigations are prompted by NHTSA in response to complaints or on the basis of its own analysis of accident data. As a result, this subset of recalls initiated by NHTSA, as opposed to those initiated by manufacturers, probably more purely reflects *the agency's* behavior.

Furthermore, since NHTSA can initiate its recalls in response to complaints of both defects and violations of safety standards, it is important to distinguish further even within the category of NHTSA-initiated recalls. Those agency recalls arising out of alleged violations of safety standards serve to *complement* rather than *substitute* for the agency's rulemaking, namely by enforcing the standards imposed by rulemaking. Any examination purporting to show that

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28 National Safety Council, Injury Facts 104 (1999); National Safety Council, Injury Facts 94 (2011).

29 NHTSA, Lives Saved by the Federal Motor Vehicle Safety Standards and Other Vehicle Safety Technologies, 1960-2003, DOT-HS-809-833 (October 2004).

30 Mashaw & Harfst, Struggle, supra note 1, at 12.

31 Id. at 164.

32 Id. at 166.

NHTSA recalls have become a true substitute for rulemaking should be based on the subset of NHTSA-initiated defect recalls, as they do not stem from any existing safety standards.

NHTSA's recall database permits an examination of recall activity back to 1967. Each recall in the database is coded according to whether it was reported manufacturer-initiated or NHTSA-initiated, as well as whether it was a defect or a standard violation recall. For each recall campaign, the database provides the estimated number of vehicles affected. Figure 1 (appendix) compares the data reported by Mashaw and Harfst on *total* recalled vehicles with the number of vehicles coded in NHTSA's database as *NHTSA-initiated defect* investigations. As shown in Figure 1, the NHTSA database lists very few agency-initiated recalls before 1970 – incidentally the same year the agency was established. Given that the agency was created in 1970, it should be unremarkable that an increase occurred in both NHTSA-initiated recalls as well as total recalls after 1970.[33] However, contrary to the impression created within the administrative law literature, the subsequent five-year period saw no corresponding increase in recalls coded as NHTSA-initiated. It would appear that NHTSA initiated no steady "orgy" of defect recalls.

This is not to say that NHTSA-initiated defect recalls have not increased over the span of the past four decades. To the contrary, both the number of such recall campaigns and the number of vehicles affected have increased over the years, albeit with notable fluctuation from year to year. The recalls and the vehicles affected by them, however, have occurred at a rate positively correlated with the number of vehicles on the roads, which has risen quite steadily over the same period.

What Can Judicial Review Explain?

Given the time period when Mashaw and Harfst conducted their research, they could understandably only observe NHTSA activity through the mid-1980s. Relative to NHTSA's rulemaking output up through the mid-1970s, rulemaking did fall in the subsequent decade. Mashaw and Harfst correctly observed a decline in the number of NHTSA final rules issued after 1976.[34] Between 1967-1976, NHTSA and its predecessor agencies issued an annual average of 49 final rule documents in the *Federal Register*, while between 1977-1986 NHTSA issued an annual average of only 19. (The average annual output of rules during NHTSA's first decade is also significantly higher than the annual average from 1977-2003.)

Might judicial review explain this decline in the annual number of rules issued after 1976? Most administrative law scholars believe it does. Although NHTSA's rulemakings survived their first two encounters in court in 1968 and 1969, the agency received three losses in a row in the next round of court decisions in 1972.[35] According to Mashaw and Harfst, the judicial losses NHTSA suffered in 1972 – and particularly the *Chrysler* decision – "beleaguered"

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[33] Figure 1 reports the data in graphical form exactly as Mashaw and Harfst report them in the text of their book, namely in the three five-year periods shown. See supra note 30 and accompanying text.

[34] Mashaw & Harfst, Struggle, supra note 1, at 13 (noting that "total rulemaking issuances in NHTSA's second decade are less than half those of its first").

[35] Wagner Elec. Corp. v. Volpe, 466 F.2d 1013 (3rd Cir. 1972); H & H Tire Co. v. U. S. Dept. of Transp., 471 F.2d 350 (7th Cir. 1972); Chrysler Corp. v. Department of Transp., 472 F.2d 659 (6th Cir. 1972).

the agency.[36] NHTSA suffered from a "hypersensitivity to judicial review in the aftermath of the *Chrysler* decision."[37] As a result, the pace of rulemaking "dramatically" slowed down.[38] The resulting "slowdown" prompted a series of legislative hearings beginning in February 1974, at which "agency officials repeatedly defended the pace of NHTSA's rulemaking activity on the grounds that the agency was likely to be sued on almost every rule and that even greater delay in standard setting would result from judicial determinations that the rulemaking record had been inadequately developed and analyzed."[39]

Notwithstanding this widely-held understanding among administrative law scholars, judicial review does not provide a satisfactory explanation of the pattern of rulemaking at NHTSA over time. First, given that NHTSA's major litigation losses occurred in 1972 (and that legislators' apparent complaints about a rulemaking slowdown began to be aired in early 1974), we should presumably expect to see a decline in the number of final rules beginning in 1973. What is striking, however, is that NHTSA continued to issue an average of 56 new rules each year for the following *four* years, 1973-1976. As shown in Figure 2 (appendix), this average number of rules issued in the four years *following* the agency's key court losses is slightly higher than the average for the four years preceding 1972. If *Chrysler* and the other judicial losses in 1972 had debilitated the agency, as Mashaw and Harfst and others have claimed, then it took the agency four years before it began exhibiting a downturn in its issuance of final rules – the very actions that subjected the agency to the risk of a judicial challenge. Yet there is no clear theoretical reason why the effects of judicial review should exhibit a four-year lag, especially if the *Chrysler* decision had the kind of dramatic shock to NHTSA's rulemaking system that is commonly supposed. The 1972 court losses certainly did not appear to have led NHTSA to pull back rules in the pipeline out of fear of litigation so as to take substantially more time in conducting additional internal analysis and development.

One possibility, of course, is that even if the 1972 judicial losses did not affect the completion of rules already in the pipeline, these losses perhaps could have affected NHTSA's willingness to initiate new rulemaking proceedings. If one looks just at NHTSA's proposed rules (Figure 3, appendix), they do drop off earlier than the final rules -- but again not for a couple of years after the *Chrysler* decision. After a slight drop in 1973, NHTSA's proposed rules increased in 1974 to a level *higher* than in 1972. The much more precipitous drop-off in proposed rules corresponds not with the court losses in 1972 -- but with the bipartisan congressional decision in late October 1974 to override and revoke NHTSA's rulemaking authority in connection with the controversial ignition interlock rule, a NHTSA standard adopted in 1972 that provided for the installation of continuous buzzers or interlock devices that prevented drivers from starting their cars until the seat belts were fastened.

Another reason to doubt that judicial review led to the kind of debilitating effects that have been generally assumed is that the probability of any NHTSA rulemaking being blocked by

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[36] Mashaw & Harfst, Struggle, supra note 1, at 107. In addition, allegedly "*Chrysler*, combined with other judicial opinions, enormously enhanced the perceived burdens of standard setting." Id. at 92.

[37] Mashaw & Harfst, Struggle, supra note 1, at 121.

[38] Id. at 106 ("NHTSA's rulemaking activity was slowing dramatically in the 1970s").

[39] Id. at 106-107.

the courts appears to be quite low. A search for court decisions resolving challenges to federal auto safety final rules resulted in less than two dozen cases from 1967 to the present (or an average of less than half a case per year).[40] Based on the experience of the past four decades, the risk that an auto safety rule will be subject to a court decision would appear to be about 2%. Moreover, of the twenty-three cases shown in Table 1 (appendix), the agency won completely in more than half of them – a 61% affirmance rate that compares favorably to the rate for other agencies.[41] Even when NHTSA has "lost," this has usually just meant that the court accepted one or two of the petitioners' arguments; the agency still withstood the bulk of the objections leveled against it. And while no doubt a remand requires extra work for the agency, it is hard to see why such an outcome would ever be debilitating or paralyzing to NHTSA or any other agency. On remand NHTSA has an opportunity to revise the rule, or elaborate its justification of it, to address the court's concerns. In most of NHTSA's remands, NHTSA has been able to revise and reissue its rules in a way that preserves the agency's basic initial decision or involves only minor modifications. As even Mashaw and Harfst acknowledge, in response to the *Chrysler* decision, NHTSA was able to reissue its passive restraints standard with new dummy specifications in about nine additional months.[42]

The conclusion that judicial review has not systematically dampened NHTSA's rulemaking is consistent with empirical findings with respect to other agencies. For example, decision makers at the Environmental Protection Agency do not tend to behave as if judicial review is particularly threatening or unfriendly.[43] Even in the wake of judicial remands, the Environmental Protection Agency has usually been able to achieve it rulemaking goals by revising and reissuing its rules.[44]

When it comes to recalls, the courts again do not appear to have been a factor accounting for NHTSA's behavior. Although administrative law scholars argue that NHTSA shifted to recalls due to its rulemaking losses, the rate of agency-initiated defect recalls actually *decreased* immediately following NHTSA's three court losses in 1972 (Figure 4, appendix). Furthermore, even though NHTSA scored key judicial victories in recall cases between 1975 and 1977 –

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[40] Table 1 includes cases in which the courts reached the merits. It does not include an additional challenge to a 2005 NHTSA rulemaking that was dismissed by the D.C. Circuit Court of Appeals on standing grounds. It also does not include petitions for review that were filed but settled before reaching a judicial decision.

[41] EPA has tended to win about half of its adjudicated cases. Cary Coglianese, Assessing Consensus: The Promise and Performance of Negotiated Rulemaking, 46 Duke L. J. 1255 (1997). See also Hearing on the Regulatory Improvement Act of 2007: Hearing Before the Subcomm. on Courts, Commercial, and Administrative Law of the H. Comm. on the Judiciary, 110th Cong. 11 (2007) (statement of Professor Jody Freeman) (reporting data showing that "on average, 58% of all rules are upheld in their entirety").

[42] Mashaw & Harfst, Struggle, supra note 1 at 92.

[43] Cary Coglianese, Litigating Within Relationships: Disputes and Disturbance in the Regulatory Process, 30 Law & Society Review 735 (1997).

[44] William S. Jordan, III, Ossification Revisited: Does Arbitrary and Capricious Review Significantly Interfere with Agency Ability to Achieve Regulatory Goals through Informal Rulemaking?, 94 Nw. U. L. Rev. 393 (2000).

decisions that Mashaw and Harfst have suggested gave NHTSA the "green light" on recalls[45] -- the number of NHTSA-initiated defect recalls only made a brief uptick before again *decreasing* for several years after these recall-case wins (Figure 4, appendix). Even more pronounced decreases in the number of recalled vehicles can be observed after rulemaking losses and recall wins (Figure 5, appendix). These observed patterns are simply not consistent with the literature's expected response to the courts' external stimuli.

Alternative Explanations

In 1976, a House Commerce Committee issued a report on perceived delays at NHTSA and made no mention of the courts as a factor. Instead, the House committee staff, working in consultation with NHTSA, attributed the agency's apparent rulemaking slowdown to the increasing complexity of the regulatory issues, weak public support for new rules, resistance from industry, requests for economic analysis by the administration, and "political interference" from the executive branch.[46] Might these or other alternatives better explain the patterns in NHTSA's rulemaking outputs than can judicial review? I believe other explanations are much more plausible. After all, not only do the conventional claims about NHTSA's shift from rulemaking to recalls fail to withstand close scrutiny, but the APA's arbitrary-and-capricious standard has remained substantively unchanged over the last several decades. NHTSA has remained subject to the supposedly debilitating *Chrysler* decision, as well as its underlying uncertainty-inducing arbitrary-and-capricious test, and yet it has continued to issue substantial new rules, ones that are no doubt much more complex than many rules from the early 1970s and ones that also yield significantly higher estimated benefits and costs.

A full consideration of alternatives remains the subject of ongoing research, but I will briefly mention three quite plausible alternative explanations. These alternatives illustrate why caution is in order before attributing to the courts the relative burst of rulemaking activity in NHTSA's first decade followed by seemingly reduced rulemaking activity in the late 1970s and 1980s. That pattern could quite readily be explained by other factors.

(1) *Regulatory Life Cycle*. The initial passage of any new legislation can be expected to generate a relative flurry of new rules as a previously unregulated sphere of activity comes under governmental oversight for the first time. In NHTSA's case, the agency faced the task of putting in place a regulatory structure for the safety of automobiles and all their attendant parts. To accomplish that task, NHTSA in some cases turned to the work of private standard-setting organizations such as the Society of Automotive Engineers (SAE). Some of the government rules adopted during the perceived heyday of auto safety rulemaking were not really new rules at all, just codifications of existing industry standards. For example, the 1969 *Code of Federal Regulations* stated that "[e]ach passenger car shall have a windshield washing system that meets

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[45] Mashaw & Harfst, Struggle, supra note 1, at 164. See also Mashaw & Harfst, Legal Determinants, supra note 1, at 458 ("The courts responded between 1975 and 1977 [by ruling] that recalls could be ordered on the basis of evidence that would have been laughed out of court if offered as support for a motor vehicle standard.").

[46] Report by the House Subcommittee on Oversight and Investigations (1976).

the requirements of SAE Recommended Practice J942"[47] and that "[t]he performance ability of the fully operational service brake system for passenger cars shall be not less than that described in section D of Society of Automotive Engineers Recommended Practice J937."[48]

Furthermore, when Mashaw and Harfst suggested that by 1974 NHTSA had completed 90 percent of its "total rulemaking output," they were actually referring to the number of safety standards (or *sections* in Part 571 of the CFR) -- not to the number of rulemakings NHTSA engaged in. For NHTSA, a "safety standard" is essentially a section of Part 571 that corresponds to a particular feature of an automobile, such as windshields, brakes, seat belts, or rear view mirrors. Although Mashaw and Harfst were correct that nearly all of the conceptually distinct sections found in Part 571 in the mid-1980s had been in place since the mid-1970s, NHTSA has made many subsequent additional and revised requirements to the regulatory language within these various sections, with each change and addition made via a new rulemaking proceeding subject to judicial review. Furthermore, since the mid-1980s when Mashaw and Harfst conducted their research, additional sections (or safety standards) have been added to Part 571. By 2003, Part 571 included 19 new sections or standards that did not exist in 1974, including those addressing child restraint anchorage systems, internal trunk releases, rear impact protection, school bus rollover protection and body joint strength, compressed natural gas fuel container integrity, and school bus pedestrian safety devices. To be sure, 19 new standards over nearly three decades may look like slow progress compared with the 46 standards found in Part 571 in 1974, only eight years after the passage of the Motor Vehicle Safety Act. But once the agency had established a framework for Part 571 consisting of sections addressing virtually all the relevant parts of a car (e.g., bumpers, brakes, steering wheels, headlights, rearview mirrors, and so forth), it should hardly be surprising that there were not as many additional categories or sections left to add in subsequent years.

(2) *Reduced Public Support.* A couple of years after NHTSA encountered its early losses in court, the agency confronted a notable shift in the political climate surrounding auto safety regulation and suffered a major setback in its relationship with Congress. In 1966, Congress unanimously adopted the Motor Vehicle Safety Act, which authorized the federal government to regulate automobile design and manufacturing to protect the safety of vehicle occupants. But by 1974, due to an outcry by the consuming public, Congress demanded a rollback in NHTSA's authority in response to the infamous ignition interlock standard. As already noted, NHTSA made a sharp decline in new, proposed auto safety rules after 1974.

The 1973-1975 recession may also have contributed to the weakening of public support for government regulation of the automobile industry. Since that time, it is hard to find strong indications of the public demanding much in the way of new or bolder auto safety regulations, at least not to the extent that seemed to exist around the time leading up to the enactment of the 1966 Motor Vehicle Safety Act. A NHTSA survey in the 1990s asked citizens about "the single most important thing that the Federal government could do to reduce fatal traffic accidents," and only 8 percent called for the government to "research/strengthen/enforce safety standards."[49]

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47 49 CFR § 371.21 (Standard 104).

48 49 CFR § 371.21 (Standard 105).

49 NHTSA Customer Satisfaction Survey 1.60 (1997).

(3) *Budgetary Shifts*. Any agency's production of rules will surely be influenced by the availability of resources. As an agency moves through its life cycle or as it encounters a decrease in public support, it may find corresponding declines in available resources. Mashaw and Harfst aptly note that "[c]ongressional ... appropriations after 1975 hardly revealed a Congress eager to support bold new regulatory initiatives....[C]rucial funding ... declined steadily in real terms from 1972 on. A budget that had never been healthy was by 1980 truly anemic."[50] Whether anemic or just substantially reduced, NHTSA's operations and research budget did decline from 1972 forward, as shown in Figure 6 (appendix). It is important to notice that the trend in NHTSA's budget seems to correspond, with a lag, quite closely to the trends in the agency's development of new rules as shown in Figures 2 and 3 (appendix). For both its rules and budgets, NHTSA's first ten years were above the norm; then the pattern stabilized at a reduced level throughout the administration of President Reagan; and then things fluctuated somewhat in the years to follow.

That there should be a correlation between NHTSA's budget and its rulemaking output certainly makes sense. Whether NHTSA's budget reflects diminished support for regulation during the recession of 1973-1975, or a diminished sense of a need for as many rules once a stock of existing standards had been codified, or something else altogether, one thing is certain: the courts did not set NHTSA's budget.

Conclusion

Despite widespread acceptance by virtually every major scholar of administrative law, the claim that NHTSA has retreated from rulemaking and shifted instead to recalls does not bear the weight of scrutiny. NHTSA has continued to issue a substantial body of new regulations even in wake of judicial losses that have been thought to have been paralyzing to the agency. Its recalls did not increase in the aftermath of either the agency's losses in rulemaking challenges or its wins in recall litigation. When a broad sweep of NHTSA's litigated cases is considered, it is clear that NHTSA has not been beleaguered by high levels of judicial invalidations. The way that NHTSA rules declined after an initial flurry of regulatory activity appears more likely explained by the life cycle of implementing a new statute, diminished public support for auto safety regulation, or changing patterns in the agency's operations and research budget.

My testimony has offered findings from my ongoing research on NHTSA rulemaking. My focus has been on auto safety regulations across the board rather than on any individual rulemaking in particular, even a rulemaking that might be viewed as taking an excessive amount of time to complete. This is because, given the institutional environment within which rulemaking takes place, single cases do not make it possible to assess the impacts of other possible explanatory factors that could affect a regulatory agency's regulatory productivity. Taking the broader view, and seeking to triangulate using multiple sources of data, offers a stronger basis for drawing the kind of empirical generalizations that can support public policy decisions that are themselves a kind of generalization. Important policy decisions, including about the availability of judicial review of administrative action, should be informed by the best available evidence.

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[50] Mashaw & Harfst, Struggle, supra note 1, at 147.

Appendix: Tables and Figures

Figure 1:
Number of Vehicles Recalled, 1966-1980

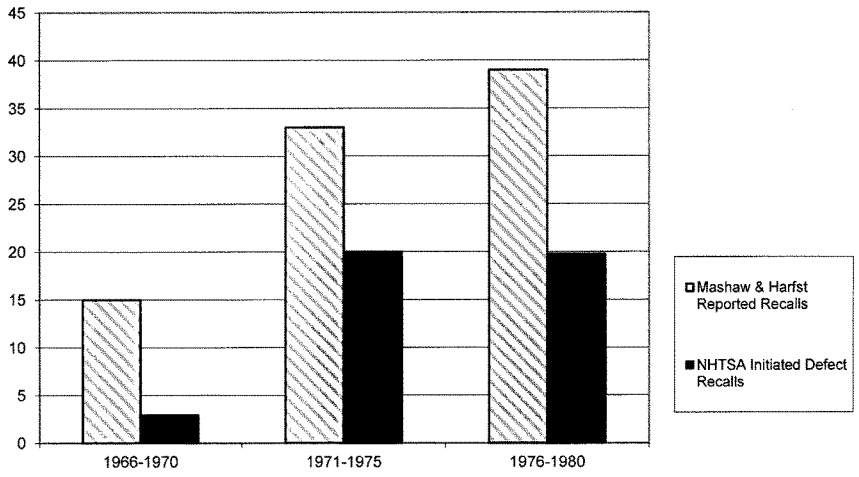


Figure 2:
Auto Safety Rules, 1967-2003

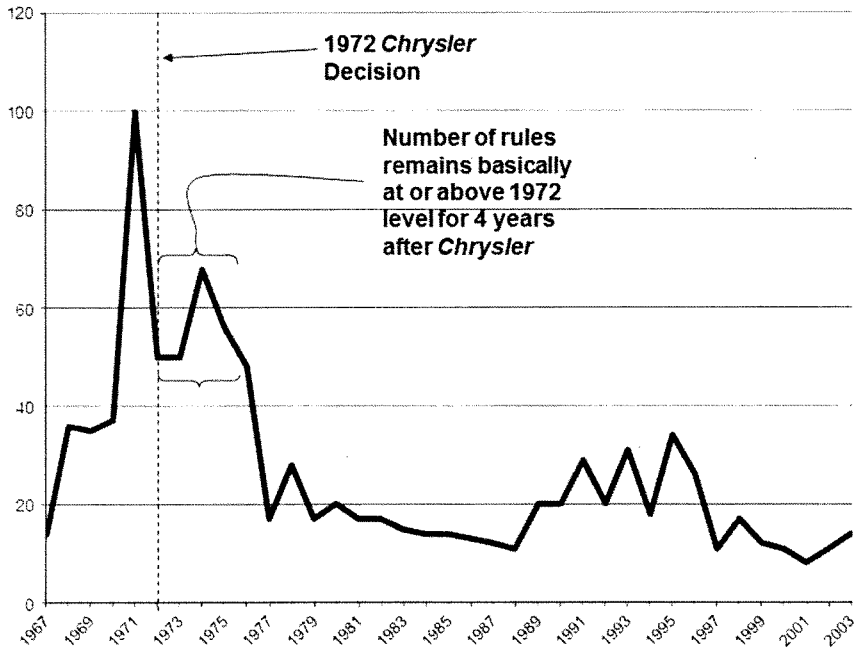


Figure 3:
Proposed Auto Safety Rules, 1967-2003

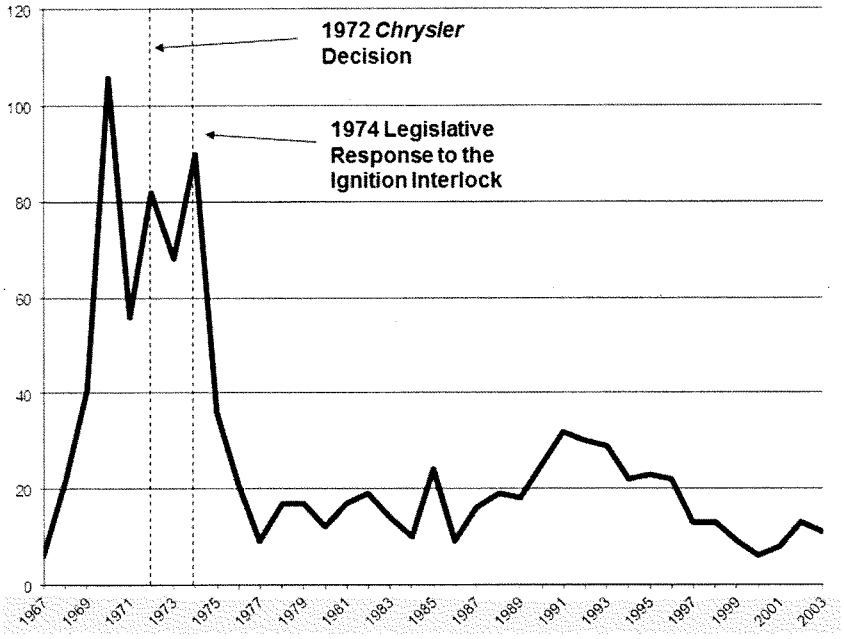


Table 1:
NHTSA's Rulemaking Record in Court

Year	Case Name	Citation	Outcome
1968	Automotive Parts & Accessories Ass'n v. Boyd	407 F.2d 330 (D.C. Cir.).	**Rule Upheld**
1969	Boating Industry Ass'n v. Boyd	409 F.2d 408 (7th Cir.).	**Rule Upheld**
1972	Wagner Elec. Corp. v. Volpe	466 F.2d 1013 (3rd Cir.).	Remanded
1972	H & H Tire Co. v. U. S. Dept. of Transportation	471 F.2d 350 (7th Cir.).	Remanded
1972	Chrysler Corp. v. Department of Transportation	472 F.2d 659 (6th Cir.).	Remanded
1973	Ford Motor Co. v. NHTSA	473 F.2d 1241 (6th Cir.).	**Rule Upheld**
1974	National Tire Dealers & Retreaders Ass'n, Inc. v. Brinegar	491 F.2d 31 (D.C. Cir.).	Remanded
1975	Chrysler Corp. v. Department of Transportation	515 F.2d 1053 (6th Cir.).	**Rule Upheld**
1976	Goodrich v. Department of Transportation	541 F.2d 1178 (6th Cir.)	Remanded
1978	Paccar, Inc. v. NHTSA	573 F.2d 632 (9th Cir.).	Remanded
1979	B.F. Goodrich Co. v. Department of Transportation	592 F.2d 322 (6th Cir.)	**Rule Upheld**
1979	Pacific Legal Foundation v. Department of Transportation	593 F.2d 1338 (D.C. Cir.).	**Rule Upheld**
1979	Vehicle Equipment Safety Commission v. NHTSA	611 F.2d 53 (4th Cir.).	**Rule Upheld**
1983	Motor Vehicle Mfrs. Ass'n v. State Farm Insur.	463 U.S. 29.	Remanded
1985	Center for Auto Safety v. Peck	751 F.2d 1336 (D.C. Cir.).	**Rule Upheld**
1986	State Farm Mut. Auto. Ins. Co. v. Dole	802 F.2d 474 (D.C. Cir.).	**Rule Upheld**
1988	Public Citizen v. Steed	851 F.2d 444 (D.C. Cir.).	**Rule Upheld**
1990	National Truck Equipment Association v. NHTSA	919 F.2d 1148 (6th Cir.).	Remanded
1995	Simms v. NHTSA	45 F.3d 999 (6th Cir.).	**Rule Upheld**
1996	Washington v. Department of Transportation	84 F.3d 1222 (10th Cir.)	**Rule Upheld**
2003	Public Citizen v. Mineta	340 F.3d 39 (2nd Cir.).	Remanded
2004	Public Citizen v. NHTSA	374 F.3d 1251 (D.C. Cir.)	**Rule Upheld**
2013	National Truck Equipment Ass'n v. NHTSA	711 F.3d 662 (6th Cir.)	**Rule Upheld**

Figure 4:
NHTSA-Initiated Defect Recall Campaigns, 1967-2003

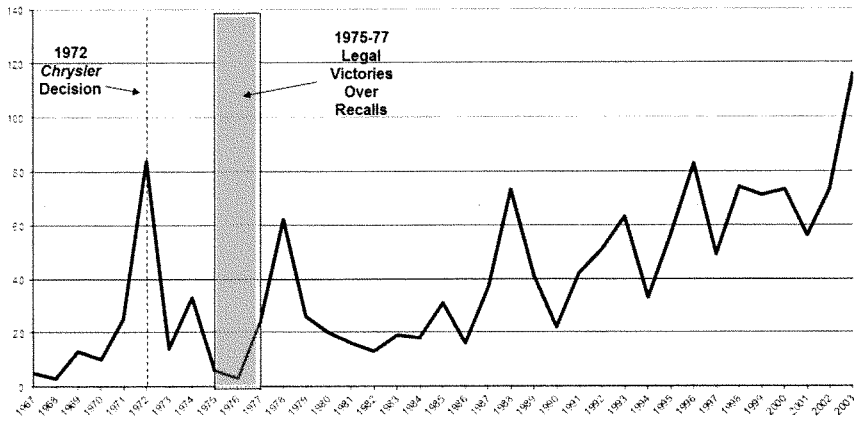


Figure 5:
Vehicles Subject to NHTSA-Initiated Defect Recalls (millions), 1967-2003

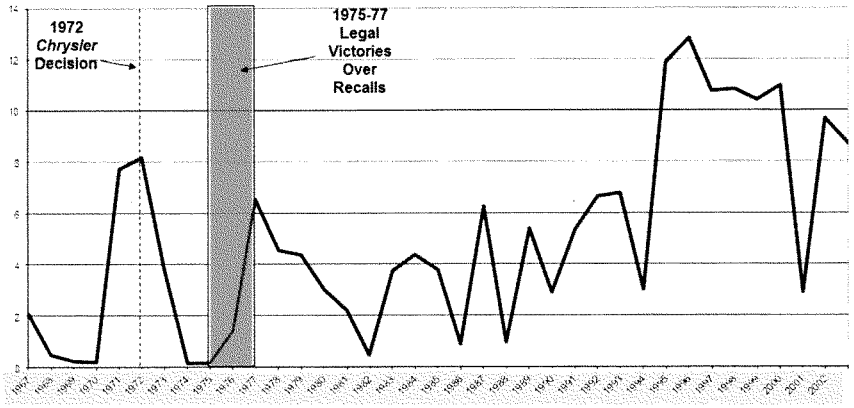
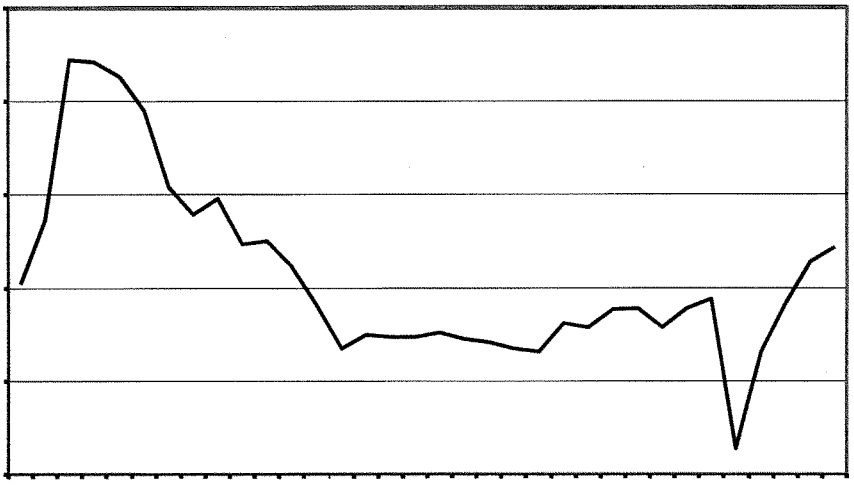


Figure 6:
NHTSA Operations and Research Budget, 1970-2003
(millions 2000 dollars)



QUESTIONS SUBMITTED BY SENATOR WHITEHOUSE FOR THOMAS O. MCGARITY

"Justice Denied: Rules Delayed on Auto Safety and Mental Health."
Subcommittee on Oversight, Federal Rights, and Agency Action
November 7, 2013

Written Questions for the Record for Professor Thomas O. McGarity
Submitted by Senator Sheldon Whitehouse

Regulated industries often seek to "capture" the regulatory agencies that enforce our laws in order to frustrate the laws' intended effects and protect their own private interests. Regulatory capture corrodes the American system of government, and, as we have seen in the cases of the Gulf oil spill, the global financial crisis, and the Sago mine tragedy, can lead to disaster.

According to anonymous senior administration officials, the Office of Information and Regulatory Affairs (OIRA) is highly responsive to political concerns, routinely conducts "off the clock" informal reviews of proposed rules, and demands that agencies ask permission before submitting rules for review.

• How does threat of capture arise in the context of OIRA review of proposed regulations?

• How would you recommend addressing the threat of regulatory capture in the context of the OIRA review process?

RESPONSES OF THOMAS O. MCGARITY TO QUESTIONS SUBMITTED BY SENATOR WHITEHOUSE

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According to anonymous senior administration officials, the Office of Information and Regulatory Affairs (OIRA) is highly responsive to political concerns, routinely conducts "off the clock" informal reviews of proposed rules, and demands that agencies ask permission before submitting rules for review.

• How does threat of capture arise in the context of OIRA review of proposed regulations?

For many years observers of federal regulation, ranging from Chicago School founder George Stigler to consumer activist Ralph Nader, have worried about the possibility that regulatory agencies over time become "captured" by the very entities that they are supposed to regulating.[1] In the less conspiratorial versions of the capture theory, agencies succumb to the sustained influence of one-sided information, blandishments and threats from the regulated entities that are ever-present in agency hallways, that meet with officials in the Office of Information and Regulatory Affairs, and that make their cases for their clients on Capitol Hill and in the media. An agency faced with limited resources and overwhelming responsibilities usually finds it very difficult to maintain a constantly vigilant posture with respect to all of the activities under its jurisdiction. The simple rule of bureaucratic life that "you can't go to the mat every time" limits the extent to which an agency can force a recalcitrant industry to conform to an ideal statutory conception of the public interest. The regulated industries know that, in the words of a former gun industry lobbyist, "[t]he closer relationship you have toward the regulator, the better off you are," and they are prepared to spend significant resources to obtain and maintain access to regulatory decisionmakers.[2] The interests of the beneficiaries of the regulatory programs, on the other hand, are diffuse because the impact of regulatory decision on the daily lives of individual beneficiaries are ordinarily imperceptible. Even when individual beneficiaries are sufficiently affected by a regulatory decision to take notice, they generally "lack preexisting organizations through which their concerns can easily be channeled." The result is an "asymmetry between public and industry attentiveness" on the part of federal agencies.[3]

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[1] Charles McCarry, Citizen Nader 217 (1972); George Stigler, The Theory of Economic Regulation, 2 Bell J. Econ. & Mgmt. Sci. 335 (1971). See also Paul J. Quirk, Industry Influence in Federal Regulatory Agencies 4-21 (1981).

[2] Laura Sullivan, Success of Shift in Guns Policy Is Debatable, Baltimore Sun, October 27, 2004, at A1 (lobbyist quote). See also Paul Quirk, Industry Influence in Federal Regulatory Agencies 13 (1981); Clayton P. Gillette & James E. Krier, Risk, Courts, and Agencies, 138 U. Pa. L. Rev. 1027, 1065-69 (1990); Howard Latin, Ideal versus Real Regulatory Efficiency: Implementation Of Uniform Standards And 'Fine-Tuning' Regulatory Reforms, 37 Stan. L. Rev. 1267, 1331 (1985); Richard B. Stewart, The Reformation of American Administrative Law, 88 Harv. L. Rev. 1669, 1685-87 (1975).

[3] Paul Quirk, Industry Influence in Federal Regulatory Agencies 13 (1981) (quotes); Clayton P. Gillette & James E. Krier, Risk, Courts, and Agencies, 138 U. Pa. L. Rev. 1027, 1067-69 (1990).

This asymmetry is particularly acute in the case of the Office of Information and Regulatory Affairs.[4] A recent study undertaken by the Center for Progressive Reform of OIRA meetings with outside groups concerning pending regulatory initiatives between October 16, 2001 and June 1, 2011 found that OIRA staff had meet with outside groups 1,080 times and those meetings involved 5,759 appearances by outside participants. Fully 65 percent of those participants represented regulated interests, and this was about five times the number of participants that represented public interest groups. 73 percent of the meetings were exclusively with industry groups, while only 7 percent were exclusively with public interest groups. 43 percent of the meetings took place before the agency's proposal was released to the public.[5] Not surprisingly, studies have shown that the vast majority of changes that OIRA demands to agency rulemaking documents favor the regulated industries.[6]

• How would you recommend addressing the threat of regulatory capture in the context of the OIRA review process?

Perhaps the best way to ensure against regulatory capture in the context of OIRA is to increase the transparency of the OIRA review process. OIRA review is not governed by the Administrative Procedure Act, and the transparency of that review process has waxed and waned over the years.[7] Strong congressional reaction to attempts by regulated interests to influence rulemaking outcomes through sympathetic officials in OIRA during the 1980s resulted in somewhat more transparency with respect to communications between outsiders and OIRA and between OIRA and the agencies while rules are pending. For example, the current executive order governing OIRA review of agency rulemaking provides that a "redlined" version of the draft proposed or final rule that the agency submitted to OIRA be made available to the public after the final version is published in the Federal Register, or otherwise issued to the public, or after the agency has announced its decision not to publish or issue the regulatory action.[8] This redlined version is necessary for the public to be able to identify all of the changes that were made to the draft rule while it was undergoing review at OIRA. However, OIRA does not typically make such redlined drafts available on its website or in the online rulemaking docket, and it is sometimes quite difficult for interested citizens to pry those documents loose from OIRA. Although OIRA typically provides on its website notices of meetings that it has had with

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[4] Jonathan Lash, Katherine Gillman & David Sheridan, A Season of Spoils (1984), at 18-29; Susan J. Tolchin & Martin Tolchin, Dismantling America ch. 2 (1983); Teresa M. Schwartz, Regulatory Standards and Products Liability: Striking the Right Balance Between the Two, 30 Mich. J. L. Reform 431, t 447-48 (1997); Mark Seidenfeld, The Psychology of Accountability and Political Review of Agency Rules, 51 Duke L. J. 1059, 1073 (2001) (concluding that industry has better access to OIRA and the White House than public interest groups); David C. Vladeck, Defending Courts: A Brief Rejoinder to Professors Fried and Rosenberg, 31 Seton Hall L. Rev. 631, 639 (2001).

[5] Rena Steinzor, Michael Patoka & James Goodwin, Behind Closed Doors at the White House (Center for Progressive Reform, November, 2011), at 10.

[6] See, e.g., Lisa Schultz Bressman & Michael P. Vandenbergh, Inside the Administrative State: A Critical Look at the Practice of Presidential Control, 105 Mich. L. Rev. 47, 72-73 (2006) (a survey of top political appointees at EPA under Bush I and Clinton, in which 89 percent of respondents agreed that OIRA never or rarely made changes that would enhance protection of human health or the environment, and often or always made regulations less burdensome for regulated entities); David M. Driesen, Is Cost-Benefit Analysis Neutral?, 77 U. Colorado L. Rev. 335, 365 (2006) (examining 25 rules identified by the GAO as "significantly changed" by OIRA between June 2001 and July 2002, and concluding that for 24 of the 25 rules, OIRA's suggested changes "would weaken environmental, health, or safety protection").

[7] Nicholas Bagley & Richard L. Revesz, Centralized Oversight of the Regulatory State, 106 Colum. L. Rev. 1260, 1309-10 (2006).

[8] Executive Order 12866 §6(b)(4)(D), 3 C.F.R. 638 (1993) (requiring OIRA to "make available all documents exchanged between OIRA and the agency during the review by OIRA").

interested parties concerning particular rules, the content of the conversations that took place in those meetings is not available to the public. Without knowing what went on during such meetings, it is impossible to know the extent to which OIRA has been captured by the regulated industries. Similarly, since the content of conversations between OIRA personnel and agency staff need not be memorialized, it is hard to know how much indirect industry pressure on agencies through OIRA is influencing the outcomes of agency rulemakings.

Congress should consider amending the Administrative Procedure Act (APA) to increase the transparency of interactions between private sector actors and OIRA and between OIRA and the agencies, such that this step of the rulemaking process is as transparent as every other step of the rulemaking process that the APA governs. (In drafting this provision, however, Congress should make it explicit that it is not endorsing the institution of centralized regulatory review within the White House.) Transparency enhances the legitimacy of the rulemaking process, ensures that the decisionmaking process is not contaminated by extraneous and irrelevant political considerations unrelated to the agency's statute, and generally enhances the quality of the policy decisions that underlie the resulting rules. Congress could require that the content of such communications be memorialized and placed in the public rulemaking record. Disclosure could go a long way toward holding the initiators and recipients of such contacts accountable for their behind-the-scenes attempts to influence the outcomes of high-stakes rulemakings. That in turn may make entities with an interest in the outcome of rulemaking more reluctant to initiate the contacts in the first place. And that should reduce the threat of industry capture of OIRA.

MISCELLANEOUS SUBMISSIONS FOR THE RECORD

HONDA

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Washington, DC 20001
Phone (202) 661-4400

November 8, 2013

Honorable Richard Blumenthal, Chairman
Subcommittee on Oversight, Federal Rights and Agency Action
Committee on the Judiciary
United States Senate
SD-224 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Mr. Chairman:

In his testimony on Thursday, November 7, 2013 before the Subcommittee's hearing on "Justice Denied: Rules Delayed on Auto Safety and Mental Health," Clarence Ditlow of the Center for Auto Safety suggested there was something untoward with the use of the Transportation Research Center (TRC), which is owned by Honda of America Manufacturing, Inc . (HAM,) by the National Highway Traffic Safety Administration (NHTSA). I would like to clarify for the record the relationship among TRC, HAM and NHTSA.

TRC is owned by HAM and is operated, pursuant to a management agreement, by the Transportation Research Center, Inc. (TRC, Inc.,) a not-for-profit corporation established by The Ohio State University with day-to-day management provided by the College of Engineering. TRC Inc. is responsible for all contractual relationships with all users of the facility. HAM has no direct dealings with NHTSA or any other client of TRC. HAM's involvement in TRC is limited to those associated with its ownership responsibilities such as land management and capital improvements.

TRC is used by Honda's research subsidiary, other companies in the automotive industry, NHTSA, and other federal agencies. NHTSA accounts for less than a quarter of TRC Inc.'s workload. NHTSA occupies a dedicated standalone building at TRC which is protected by its own security systems. It maintains 30 federal employees at the facility. Their work is supplemented by 70 additional TRC Inc. full time employees who work exclusively on NHTSA task orders. They work for no other TRC Inc. clients. No Honda associates work at or have access to the NHTSA facilities, and Honda associates have no contact with NHTSA employees other than that may occur as Honda's status as a regulated company.

The operating surplus of TRC Inc. is paid annually to multiple endowment funds at The Ohio State University, which support transportation-related research. To date, more than $50 million has been contributed to these funds, and the interest generated by the funds provides for the transportation-focused research and educational projects conducted primarily in the College of Engineering.

The cost to replicate the resources of TRC is estimated to be at least $150 million. Given the management structure, physical security and HAM's lack of economic interest in the operation of TRC, it is difficult to understand Mr. Ditlow's objections to NHTSA's use of the TRC.

Sincerely,

Edward B. Cohen
Vice President
Government & Industry Relations

October 31, 2013, 02:00 pm

Regulatory rush job deprives many of health insurance plans they liked

By Jerry Ellig

The media-verse is all a-Twitter with the revelation that the Department of Health and Human Services (HHS) admitted in 2010 that between 40-67 percent of individuals would lose their then-current health insurance plans under the Affordable Care Act (ACA). News coverage focuses on the termination letters sent to hundreds of thousands of holders of individual health insurance policies, along with the substantial premium increases for individuals in the new insurance exchanges. And of course, pundits are pouncing on the stark contrast to the president's promise that if you like your current health insurance plan, you can keep it—but there's more to this controversy than what this media coverage conveys.

The root cause of this controversy is a regulation on the "grandfathering" of existing health plans, rushed into place just three months after the ACA's passage in March 2010. The regulatory rush job also prompted cursory analysis by HHS that requires a careful reading to discern any negative impacts from the ACA. A close inspection of the grandfathering regulation leads to even more shocking revelations: HHS expected the termination of many employer-sponsored plans because they run afoul of the strict requirements, and regulators actually knew that the ACA would increase health insurance premiums.

To prevent this kind of debacle in the future, Congress should require agencies to publish and seek public comment on a thorough analysis of their regulatory options before they make regulatory decisions.

In June 2010, HHS issued the regulation specifying conditions under which existing health plans could be "grandfathered" and hence not subject to all of the new mandates in the ACA. Grandfathered plans would not have to offer the extensive additional coverage the ACA requires new plans to provide, such as childbirth, substance abuse, pediatric vision care, and psychological services.

Previously, individuals who had no need for such coverage, or deemed it too expensive, could opt for cheaper insurance without such coverage. Indeed, HHS analysis admits that "grandfathering could potentially slow the rate of premium growth, depending on the extent to which their current plan does not include the benefits and protections of the new law."

HHS didn't calculate how much the participants in grandfathered plans would save, but such a figure would have highlighted the premium increases expected to flow from the ACA's new mandated coverages. Last year, Duke University health care economist Chris Conover estimated that even if the new mandates cost only $100 per policyholder, grandfathering would save consumers $5.6 billion annually by allowing them to avoid this cost.

But the HHS analysis contains an even more telling admission. Prior to the now oft-quoted discussion of individual policies, the analysis estimated that 39-69 percent of employer plans would no longer be grandfathered by 2013. In other words, between one-third and two-thirds of employers would no longer offer health insurance without costly ACA mandates.

These employer-provided plans would lose grandfathered status because they were expected to make changes in copayments, percentage cost-sharing, or the percentage of premiums covered by the employer that exceed the limits specified by the grandfathering rules. Many of the rules are either extremely narrow or arbitrary. Modest changes policyholders regard as routine could disqualify a plan from being grandfathered.

For example, any change in percentage cost-sharing between the patient and the health plan ("coinsurance") automatically disqualifies the plan from grandfathered status, even if all other terms of the plan remain the same. HHS declined to adopt a more flexible "actuarial equivalence" standard, which could allow an employer to adjust its health plan as long as it delivered the same dollar value of benefits to participants.

Actuarial equivalence is the concept used in the health care exchanges to determine whether a health plan is labeled "bronze," "silver," "gold," or "platinum." Yet HHS rejected an actuarial equivalence standard for grandfathered health plans as too complicated, while simultaneously preparing to use actuarial equivalence to regulate insurance plans offered on the exchanges.

Perhaps it's inevitable that a regulation rushed into place just three months after the ACA's passage would have substantial problems. Unfortunately, one of the biggest casualties was a transparent accounting of the ACA's likely effects. Congress could avoid this transparency problem in the future by requiring agencies to publish a thorough analysis of their regulatory options before writing regulations.

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November 6, 2013

The Honorable Richard Blumenthal
Chair, Senate Judiciary Committee Subcommittee on Oversight,
Federal Rights and Agency Action
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman,

We are writing to commend you for holding the hearing, "Justice Denied: Rules Delayed on Auto Safety and Mental Health," and for your continued efforts to highlight the unacceptable delay in the issuance of a final rule to establish a rear visibility standard for motor vehicles. One of the most important and well-documented motor vehicle safety problems is the blindzone immediately behind passenger vehicles that prevents drivers from seeing pedestrians when backing up. As you are aware, the inability of drivers to be able to see what is in the blindzone results in over 200 fatalities and more than17,000 injuries annually in backover crashes. Forty-four percent of those killed in backover incidents are children under five years old and, tragically, in over seventy percent of these incidents the person behind the wheel of the car is a parent or close relative.

The bipartisan 2008 *Cameron Gulbransen Kids Transportation Safety Act*, Pub. L. 110-189, required that the rear visibility standard be issued by February 28, 2011. The last of four postponements by the U.S. Department of Transportation (DOT) has delayed the final rule until at least January 2015. With each delay, the public is deprived of a proven, life-saving technology and millions of children, pedestrians and others are put at risk of death or serious injury. Repeated postponement of the final rule has resulted in at least 1,100 unnecessary deaths and at least 85,000 injuries of children and other pedestrians in preventable backover crashes.

In response to the inordinate delays, on September 25, 2013, Advocates for Highway and Auto Safety, Consumers Union, and KidsAndCars.org, along with two parents who unintentionally hit their children while backing up, filed a federal lawsuit, in which the advocacy groups and parents are represented by Public Citizen. The lawsuit seeks a court order directing the DOT to promptly issue the final rule as mandated in the 2008 law. This action is necessary because the DOT has unreasonably delayed the action mandated by Congress. The current projected completion date of January 2015 is nearly four years after the deadline originally set by law and seven years after the bill was passed with strong bi-partisan support in the House and Senate and signed into law by President George W. Bush.

Rearview cameras are currently the only technology that is effective in reducing the occurrence of backover crashes with pedestrians located immediately behind the vehicle. Despite industry claims that other technologies such as sensors and mirrors could provide a cheaper option, extensive research has shown that rearview video cameras provide the most comprehensive and realistic view of people and objects in the vehicle blindzone. It is imperative that this critical safety feature be available to consumers as standard equipment to ensure that backover crashes are prevented and lives are saved.

We greatly appreciate your leadership on this important issue and for continuing to exercise oversight on excessive delays on critical public health and safety rules in the federal regulatory process.

Sincerely,

Jacqueline Gillan
President
Advocates for Highway and Auto Safety

Joan Claybrook
Former Administrator
National Highway Traffic Safety Administration

Janette Fennell
Founder and President
KidsAndCars.org

Andrew McGuire
Executive Director
Trauma Foundation

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