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FORMAL RULEMAKING AND JUDICIAL REVIEW: PROTECTING JOBS AND THE ECONOMY WITH GREATER REGULATORY TRANSPARENCY AND ACCOUNTABILITY

HEARING

BEFORE THE

SUBCOMMITTEE ON COURTS, COMMERCIAL AND ADMINISTRATIVE LAW

OF THE

COMMITTEE ON THE JUDICIARY
HOUSE OF REPRESENTATIVES

ONE HUNDRED TWELFTH CONGRESS

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FORMAL RULEMAKING AND JUDICIAL REVIEW: PROTECTING JOBS AND THE ECONOMY WITH GREATER REGULATORY TRANSPARENCY AND ACCOUNTABILITY

TUESDAY, MAY 31, 2011

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON COURTS,
COMMERCIAL AND ADMINISTRATIVE LAW,
COMMITTEE ON THE JUDICIARY,
Washington, DC.

The Subcommittee met, pursuant to call, at 4:05 p.m., in room 2141, Rayburn House Office Building, the Honorable Trey Gowdy, (Vice-Chairman of the Subcommittee) presiding.

Present: Representatives Gowdy, Franks, and Quigley.

Also Present: Representative Conyers.

Staff Present: (Majority) John Hilton, Counsel; Johnny Mautz, Counsel; Allison Rose, Professional Staff Member; Ashley Lewis, Clerk; (Minority) James Park, Subcommittee Chief Counsel; and Susan Jensen-Lachmann, Counsel.

Mr. GOWDY. The Subcommittee will come to order. This is the Subcommittee on Courts, Commercial and Administrative Law. It is a hearing on formal rulemaking and judicial review, protecting jobs and the economy with greater regulatory transparency and accountability.

I want to welcome our three witnesses. I will recognize myself for an opening statement and then recognize the gentleman from Illinois.

Today the Subcommittee continues to examine whether Washington's regulatory scheme cycles job creation and impedes economic growth, and will look at practical, commonsense alternatives to the status quo which has placed a $1.75 trillion regulatory burden on the back of our economy.

Our specific focus today will be on whether increased use of formal rulemaking and more vigorous judicial review can help to take unnecessary and redundant deleterious regulations out of the equation.

For the first 3 decades after the Administrative Procedure Act was adopted in 1946, agencies routinely made regulations by formal rulemaking. As a former prosecutor I am aware of the value of this process. Like a trial, formal rulemaking allows persons who are affected by a proposed regulation to introduce evidence, call

witnesses to testify under oath, and, most critically, cross-examine other witnesses.

Since the 1970's, however, agencies have avoided formal rulemaking whenever possible, and courts rarely require agencies to engage in it. Instead, agencies make regulations through informal notice and comment procedures. This offers the public and regulated entities less opportunity to challenge agency predispositions in the rulemaking process. It also shields burdensome rules from the most effective way to vet them for mistakes.

Another factor that encourages excessive regulation is the deferential standards of judicial review courts apply when a regulation is challenged. When an agency makes a regulation through informal rulemaking, a court will uphold that regulation unless it is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. A regulation made by formal rulemaking is upheld if it is based on substantial evidence, but courts often treat these standards as identical and lenient, which I am sure our witnesses can and hopefully will address.

The Supreme Court has held that a court should be, quote, at its most deferential when an agency makes a scientific determination in the process of rulemaking. This principle has been called "superdeference," although that term certainly cannot be found anywhere in the text of the Administrative Procedure Act. Courts defer to agencies' legal conclusion according to the well-established Chevron doctrine. If Congress has granted an agency the discretion to make a rule, then the rule will be upheld if it is reasonable. Less clear is how a court should treat an agency's own determination of whether Congress actually granted the agency the discretion to make the rule in the first instance.

Relatedly, courts also defer to an agency's own interpretation of its own sometimes ambiguous regulations. How a court should approach these questions is up for discussion at today's hearing.

Finally, at our hearing on February 28, 2011, we heard testimony that courts should be able to review agency compliance with the Information Quality Act and other statutes that are ancillary to the APA rulemaking process. This Subcommittee will also hopefully be able to explore that suggestion in more depth today.

I look forward to our witnesses' testimony. And again I thank you for your presence.

[The prepared statement of Mr. Gowdy follows:]

Prepared Statement of the Honorable Trey Gowdy, a Representative in Congress from the State of South Carolina, and Vice-Chairman, Subcommittee on Courts, Commercial and Administrative Law

Today the Subcommittee continues to examine why Washington's regulatory system stifles job creation and impedes economic growth, and will look at practical, common-sense alternatives to the over-burdensome status quo that has placed a $1.75 trillion regulatory burden on the back of our economy.

Our specific focus today will be on whether increased use of formal rulemaking and more vigorous judicial review can help to tame out-of-control regulation.

For the first three decades after the Administrative Procedure Act was adopted in 1946, agencies routinely made regulations by formal rulemaking. As a former prosecutor, I am aware of the value of this process. Like a trial, formal rulemaking allows persons who are affected by a proposed regulation to introduce evidence, call witnesses to testify under oath, and—critically—cross-examine other witnesses.

Since the 1970s, however, agencies have avoided formal rulemaking whenever possible, and courts rarely require agencies to engage in it. Instead, agencies make

regulations through informal, notice-and-comment procedures. This offers the public and regulated entities less opportunity to challenge agency predispositions in the rulemaking process. It also shields burdensome rules from the most effective way to vet them for mistakes.

Another factor that encourages excessive and misguided regulation is the deferential standards of judicial review courts apply when a regulation is challenged. When an agency makes a regulation through informal rulemaking, a court will uphold that regulation unless it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." A regulation made by formal rulemaking is upheld if it is based on "substantial evidence." But courts often treat these standards as identical and lenient, which I am sure our witnesses can address.

The Supreme Court has held that a court should be "at its most deferential" when an agency makes a "scientific determination" in the course of rulemaking. This principle has been called "super-deference," although that term certainly is not found anywhere in the text of the Administrative Procedure Act.

Courts defer to agencies' legal conclusions according to the well-established Chevron doctrine: If Congress has granted an agency the discretion to make a rule, then the rule will be upheld if it is reasonable. But less clear is how a court should treat an agency's own determination of whether Congress actually granted the agency the discretion to make the rule. Relatedly, courts also defer to an agency's own interpretation of its own ambiguous regulation. How courts should approach these questions is up for discussion at today's hearing.

Finally, at our hearing on February 28, 2011, we heard testimony that courts should be able to review agency compliance with the Information Quality Act and other statutes that are ancillary to the Administrative Procedure Act rulemaking process. The Subcommittee will be able to explore that suggestion in more depth today.

I look forward to our witnesses' testimony and reserve the balance of my time.

Mr. GOWDY. At this point, I recognize the gentleman from Illinois, Mr. Quigley.

Mr. QUIGLEY. Thank you, Mr. Chairman. As the overarching procedural framework for the Federal administrative agencies, the Administrative Procedure Act, or APA, is largely responsible for creating a regulatory process that is best characterized as balanced. On one hand the APA provides procedural protections sufficient to guarantee all affected parties both due process and decisions based on accurate factual findings. On the other hand, it gives administrative agencies a great deal of rulemaking informality and flexibility. It is this informality and flexibility that allows agencies to confront the myriad of complex problems that American society must face to protect the public from harm.

Congress has generally seen fit to permit this level of flexibility because of the agencies' expertise in specific areas of public policy. This allows the agencies to tailor their response to specific problems in a way that Congress, the courts, and the elected executive branch officials cannot.

In light of the need to maintain this balance developed over decades of practice, agencies have largely abandoned formal rulemaking in favor of the still substantial procedural requirements of informal rulemaking. Likewise, the courts have adopted a stance that is mostly deferential to agency decision making, while still exercising real scrutiny through the, "Hard-Look Doctrine" under which courts will carefully scrutinize an agency's informal rulemaking process while being careful to avoid the taint of "rulemaking from the bench."

Both the expanded use of formal rulemaking and more stringent judicial review of agency rulemaking conflict with the longstanding balance between procedural protections and rulemaking flexibility,

and they would hamper government's ability to respond promptly to pressing societal problems.

Most scholars of administrative law, regardless of ideological persuasion, appear to agree that expanding the use of formal rulemaking is effectively the equivalent of simply stopping rulemaking in its tracks.

Formal rulemaking is an adversarial process in which the agency and affected parties engage in a trial-type process to determine whether a proposed rule should go into effect. Moreover, formal rulemaking places the burden of proving that a proposed rule is supported by substantial evidence on the agency, which is a fairly high burden to meet.

More than two generations of expertise with formal rulemaking has taught us that it adds little to the accuracy or fairness of the rulemaking process, while tremendously increasing costs and delay.

Similar concerns exist with respect to imposing a more stringent judicial review standard. As with the expanded use of formal rulemaking procedures, Congress considered and rejected creating a more stringent judicial review standard for agency rulemaking back in the early 1980's. The concerns expressed then continue to exist today. Heightened judicial review would increase costs and delay in the process by opening the door to unending appeals in which parties opposed to a given rule will ask simply to second-guess the wisdom of that rule.

Finally, we should be careful about extending judicial review requirements to other statutes that touch on administrative procedure, including the Information Quality Act, or IQA.

While the discussion of how much regulation we should have in our society today is one we should embrace, it is also one we must get right. There is indeed a healthy tension between the tug on industry to be free of constraints to fuel innovation, growth in job creation, and the duty of regulators to shape policy that will thrive to the public's health, safety, and welfare.

Effective regulation is a complex balancing act, the result of a vigorous process that weighs costs against benefits.

While I look forward to hearing the testimony of our distinguished panel of witnesses today, I am inclined to think that the rulemaking procedures instituted by the APA and further clarified by the courts have properly struck this balance.

Mr. Chairman, I close with an anecdotal reminder that we should be wary of returning to an APA of old. In the 1960's, of the 16 formal rulemakings under the Food, Drug, and Cosmetic Act, not one was completed in less than 2 years, and the average time that elapsed between first proposal and final order was 4 years. In one proceeding, the question concerned whether the FDA should require that peanut butter contain at least 90 percent peanuts as opposed to 87 percent peanuts. In the peanut butter case, a government witness was cross-examined for an entire day about a survey of cookbook and patented peanut butter formulas, missing recipes, and his personal preferences regarding peanut butter.

I think that you and I can agree that while we may celebrate the fact that the personal peanut butter preferences in this room likely range from extra creamy to extra chunky, America has far too

many challenges in front of it today to dedicate taxpayer resources to investigating such matters. Thank you, and I yield back.

Mr. GOWDY. I thank the gentleman from Illinois.

The Chair at this point would recognize the former Chairman of the full Committee, the gentleman from Michigan Mr. Conyers.

Mr. CONYERS. Thank you, Mr. Trey Gowdy, Vice-Chairman of this Subcommittee, who in your first term has accomplished more than most Members of Congress. Your meteoric rise is sometimes frightening. But I am happy to be here with you and will try to remind you of some of the history that is involved in this notion of having agencies have trials in terms of their rulemaking. And as a former prosecutor, you have gotten into that mode pretty well across the years, and you have done quite brilliantly in that regard.

Mr. GOWDY. Thank you.

Mr. CONYERS. But this is not a trial. The agency rules should not be subjected to a trial. The infamous peanut butter case with the FDA, in which it took 10 years under the process that you now recommend to determine whether 90 percent or 87 percent of the peanut butter should have peanuts in it, that is almost Saturday Night Live material.

But I want to also remind you that even another colleague of ours in the other body, Mark Warner, is sympathetic to some kind of change. But he has restrained himself—even though I might remind you that he too is a freshman in the other body—about this whole idea.

Now, I am going to study your comment that the more formalized rulemaking will help create jobs. This is the most astounding statement that I have heard this week in the House of Representatives. And as one who comes from a place that needs jobs desperately, if there is a scintilla of evidence that would support that premise, you and I are going to be on whatever legislation that you will attach to that theory. It is clearly another way of trying to stop the ObamaCare bill, as I like to call it, the new health care reform measure, by subjecting it to even more delay because there are so many requirements for agency regulations. And I want to give the conservative leadership credit in the House, that even after they lose the vote, they never give up. And I admire that kind of determination to even undermine a popular vote in the House of Representatives.

It reminds me of what the dean of the House of Representatives, John Dingell of Michigan, talked about in 1982. I don't know what you were doing then. I warrant you weren't even practicing law then. But nevertheless, Chairman Dingell talked about that they were opposing comprehensive regulatory reform legislation that follows to a "T" what is being proposed in the notion that is before us today. And Chairman Dingell charged opponents with the accusation that the legislation wouldn't improve Federal rulemaking but rather would harm it by creating further delays and giving a small group of people an unfair advantage in getting heard during the process.

I have some other comments to make, but I think you get my drift. I will turn back my time and thank you for allowing me to speak.

Mr. GOWDY. I thank the gentleman from Michigan.

Without objection, other Members' opening statements will be made part of the record.

[The prepared statement of Mr. Quigley follows:]

Statement of the Honorable Mike Quigley
For the Hearing on "Final Rulemaking and Judicial Review: Protecting Jobs and the Economy with Greater Regulatory Transparency and Accountability"
Before the Subcommittee on Courts, Commercial and Administrative Law

Tuesday, May 31, 2011 at 4:00 p.m.
2141 Rayburn House Office Building

As the overarching procedural framework for federal administrative agencies, the Administrative Procedure Act, or APA, is largely responsible for creating a regulatory process that is best characterized as a balance.

On the one hand, the APA provides procedural protections sufficient to guarantee all affected parties both due process and decisions based on accurate factual findings. On the other hand, it gives administrative agencies a great deal of rulemaking informality and flexibility.

It is this informality and flexibility that allows agencies to confront the myriad complex problems that American society must face and to protect the public from harm.

Congress has generally seen fit to permit this level of flexibility because of agencies' expertise in specific areas of public policy, which allows agencies to tailor their response to specific problems in a way that Congress, the courts, and elected Executive Branch officials cannot.

In light of the need to maintain this balance, developed over decades of practice, agencies have largely abandoned formal rulemaking in favor of the still-substantial procedural requirements of informal rulemaking.

Likewise, the courts have adopted a stance that is mostly deferential to agency decisionmaking while still exercising real scrutiny through the "hard look" doctrine, under which courts will carefully scrutinize an agency's informal rulemaking process while being careful to avoid the taint of "rulemaking from the bench."

Both the expanded use of formal rulemaking and more stringent judicial review of agency rulemaking conflict with the longstanding balance between procedural protections and rulemaking flexibility, and they would hamper government's ability to respond promptly to pressing societal problems.

Most scholars of administrative law – regardless of ideological persuasion – appear to agree that expanding the use of formal rulemaking is effectively the equivalent of simply stopping rulemaking in its tracks.

Formal rulemaking is an adversarial process in which the agency and affected parties engage in a trial-type process to determine whether a proposed rule should go into effect.

It's a process that employs cross-examination of witnesses by interested parties, the presentation of evidence by any interested party, and the presence of an administrative law judge or other presiding officer who can make evidentiary rulings, issue subpoenas, and make other decisions concerning the conduct of the proceeding.

Moreover, formal rulemaking imposes the burden of proving that a proposed rule is supported by substantial evidence on the agency, which is a fairly high burden to meet.

More than two generations of experience with formal rulemaking has taught us that it adds little to the accuracy or fairness of the rulemaking process, while tremendously increasing cost and delay.

Indeed, as far back as 1941, the Attorney General's Committee on Administrative Procedure, in a Final Report that ultimately led to the APA's enactment, described formal rulemaking as "cumbersome and expensive" and further noted that restrictions imposed by the Bituminous Coal Act – which required adversary proceedings – had "nearly induced paralysis."

Similar concern about the use of trial-like procedures in the rulemaking process surfaced 30 years ago, when Congress considered and rejected legislation that would have, among other things, expanded the use of so-called "hybrid" rulemaking for major rules.

In a 1982 report, the Congressional Research Service concluded that this legislation, which would have included the opportunity for parties to cross-examine agency officials, was "ineffective, costly and a source of delay and uncertainty and an increased risk of judicial reversal on procedural grounds."

I ask unanimous consent that copies of Chapter VII of the 1941 Final Report of the Attorney General's Committee on Administrative Procedure and the Congressional Research Service report on "The Future of Public Participation in Informal Agency Rulemaking Under Pending Regulatory Reform Proposals," dated December 7, 1982, be entered into the record.

Similar concerns exist with respect to imposing a more stringent judicial review standard.

As with the expanded use of formal rulemaking procedures, Congress considered and rejected creating a more stringent judicial review standard for agency rulemaking back in the early 1980's. The concerns expressed then continue to exist today.

Heightened judicial review would increase costs and delay in the rulemaking process by opening the door to unending appeals in which parties opposed to a given rule will ask courts simply to second-guess the wisdom of that rule.

I fear that this would do little to maximize the benefits or minimize the costs of regulation, but instead primarily serve as a way for moneyed interests to engage in dilatory tactics to stop vital public health and safety rules from going into effect.

Finally, we should be careful about extending judicial review requirements to other statutes that touch on administrative procedure, including the Information Quality Act, or IQA.

Critics in the scientific community in particular claim that the IQA - which, among other things, allows industry to challenge any scientific data disseminated by a federal agency - is simply a tool that allows corporations to try to discredit any information that is contrary to their business interests, whether they be coal companies challenging the bases for clean air regulations, pharmaceutical companies challenging safety concerns about new medication, or mining companies challenging the need for better mine safety rules.

I question the wisdom of extending judicial review of agency compliance with the IQA when the wisdom of the IQA itself is questionable.

While the discussion of how much regulation we should have in our society today is one we should embrace, it is also one we must get right.

There is indeed a healthy tension between the tug on industry to be free of constraints to fuel innovation, growth, and job creation, and the duty of regulators to shape policy that will provide for the public's health, safety, and welfare.

Effective regulation is a complex balancing act, the result of a rigorous process that weighs costs against benefits.

While I look forward to hearing the testimony of our distinguished panel of witnesses here today, I am inclined to think that the rule-making procedures instituted by the APA and further clarified by the courts have properly struck this balance, and the proposals before us today would serve only to hamper government's ability to respond promptly to great societal problems and challenges of our day.

Mr. Chairman, I close with an anecdotal reminder that we should be wary of returning to an APA of old.

In the 1960's, of 16 formal rulemakings under the Food, Drug and Cosmetic Act, not one was completed in less than two years and the average time elapsed between first proposal and final order was four years. In two of the 16 cases, the formal rulemaking proceedings took more than a decade, including one proceeding to determine whether the Food and Drug Administration (FDA) should require that peanut butter contain at least 90% peanuts (as the FDA proposed) as opposed to 87% peanuts (as proposed by industry.)

In the peanut butter case, a government witness was examined and cross-examined for an entire day about a survey of cookbook and patented peanut butter formulas, missing recipes, and his personal preferences regarding peanut butter.

Mr. Chairman, I think you and I can agree that, while we may celebrate the fact that the personal peanut butter preferences in this room today likely range from extra creamy to extra chunky, Congress simply lacks the resources in this tough fiscal climate to spend its time investigating such matters.

Thank you and I yield back.

[The prepared statement of Mr. Conyers follows:]

Statement of the Honorable John Conyers, Jr.
for the Hearing on "Formal Rulemaking and Judicial Review: Protecting Jobs and the Economy with Greater Regulatory Transparency and Accountability"
Before the Subcommittee on Courts, Commercial and Administrative Law

Tuesday, May 31, 2011, at 4:00 p.m.
2141 Rayburn House Office Building

I have been saying for some time now that this Subcommittee has wasted an inordinate amount of time addressing ways to obstruct the administrative rulemaking process. Today's hearing – the *seventh* such hearing in less than five months – will, unfortunately, be no different.

While we have spent seven hearings to date on how to improve the bottom line of private industry, I note that this Subcommittee has not held a *single* hearing this Congress on the ongoing home foreclosure crisis that is ravaging communities across our Nation.

Nor, has the Subcommittee devoted any time at all examining what could very well be the next subprime mortgage crisis, namely, the tremendous educational loan debt that students are being saddled with in an a recessionary economy.

Just last week, as some of you may know, Ranking Member Steve Cohen and I introduced H.R. 2028, the "Private Student Loan Bankruptcy Fairness Act of 2011," which would provide meaningful relief to students overburdened with private school loan debt.

Rather, this Subcommittee appears to be steadfastly committed to finding ways to promote the interests of big business by hobbling and slowing down the administrative rulemaking process.

And, what would be the impact of slowing down the rulemaking process? It means that rules intended to protect the health and safety of American citizens will take longer to promulgate and become effective.

We are talking about regulations that protect the quality of the air we breathe, the water we drink, and the food we consume.

And, we are also talking about rules that ensure the safety of the cars we drive, the airplanes that convey us, and the places where we work.

Slowing down the promulgation of these rules would only serve to put Americans at greater risk, while allowing polluters, makers of dangerous toys, and manufacturers of tainted drugs more time to avoid regulation.

Indeed, the benefits of regulation far outweigh the costs. The latest draft Office of Management and Budget report to Congress on the cost and benefits of regulations concluded that for fiscal year 2010, federal regulations cost between $6.5 billion and $12.5 billion but resulted in between $23.3 billion and $82.3 billion in benefits.

In other words, even when taking the highest cost estimate and the lowest benefit estimate, the benefits of federal regulation last fiscal year were nearly *double* the costs.

While admittedly the rulemaking process is probably not perfect, the proposals we will be discussing today will make that process much worse, not better.

For example, the proposal to expand the use of the Administrative Procedure Act's formal rulemaking procedures has been soundly rejected by virtually every administrative law scholar of all ideological persuasions as unnecessary and even harmful to the rulemaking process.

More than one commentator, in fact, has said that expanding the use of formal rulemaking is simply another way of telling agencies to stop issuing rules, including the kind of public health and safety rules that I just alluded to.

It is puzzling to me why my friends on the other side of the aisle are promoting this idea when, in fact, more than a generation ago a similar idea was considered and rejected by Congress?

Are we, yet again, being offered old wine in new bottles without any good reason.

Encumbering rulemaking with trial-like requirements such as cross-examination of government witnesses would not meaningfully improve the accuracy or fairness of agency decisionmaking. Rather, it would greatly increase the cost and delay of issuing regulations.

Current informal, notice-and-comment rulemaking already imposes numerous procedural requirements. Formal rulemaking procedures, on the other hand, would severely hamper the ability of agencies to promulgate beneficial rules or to revise or rescind existing regulations.

Formal rulemaking would also favor industry, which has the ability to fund protracted cross-examination and dilatory challenges to agency fact findings, while taxpayers would have to fund the agency's ligation expenses.

And it would allow these regulated entities to effectively shape the agency's rulemaking record to their advantage.

There is also the risk that requiring more formal rulemaking will cause agencies to rely more on adjudications or guidance documents and other non-rulemaking processes as a means of policymaking, something that is not in anyone's interest.

I would also be wary of statutorily creating a more stringent judicial review standard for agency rulemaking.

More stringent judicial review – like formal rulemaking – would make rulemaking even more costly and time-consuming for agencies. This would force agencies to adopt more detailed factual records and explanations, effectively making it a back-door way to impose more procedural requirements on agency rulemaking.

Also, a more stringent, less deferential judicial review standard runs the risk that judges could effectively make public policy from the bench without the specialized expertise that agencies possess. It also could allow a judge to impose his or her personal policy preferences as part of their review of an agency rule.

A more stringent judicial review standard opens the door to abusive litigation by well-funded business entities and others who oppose regulations generally by creating more opportunities to appeal an agency's decisions, which would make rulemaking more costly and expensive without maximizing the benefits or minimizing the costs of regulation.

I find it particular ironic that the Majority – which has long decried "judicial activism" and "abusive litigation by trial lawyers" – would support insinuating both of these elements as part of so-called regulatory reform efforts.

As has been shown time and again, the benefits of regulation far exceed its costs. Measures that ultimately are designed to hobble or prevent regulation altogether therefore put society at risk.

This effort is just another example of how some want to allow the fox to guard the chicken coop, and we all know how well that worked given the events that led to the Great Recession.

Even former Federal Reserve Chairman Alan Greenspan, one of the most ardent proponents of unregulated capitalism in the marketplace, belatedly recognized he was wrong.

Likewise, I believe both measures that we will consider today are wrongheaded. Perhaps it is a sign of desperation that big business – in trying to stop regulation – seeks to push long-discredited ideas that prioritizes profit over consumer protection.

I hope we can stop wasting our time on these types of hearings – which almost fetishize corporate interest above broader societal interest – and get back to focusing on issues that matter to ordinary Americans.

Mr. GOWDY. We have a very distinguished panel of witnesses today. Each of the witnesses' written statements will be entered into the record in its entirety. I ask that each witness summarize his testimony in 5 minutes or less. To help you stay within that time frame, you will notice, hopefully, some lights illuminating red, yellow, and green. And they mean what they traditionally mean.

So without further ado, I will introduce, starting from my left to right, your right to left, Mr. Edward W. Warren who is with the environmental practice group at Kirkland & Ellis, considered one of the first generation of environment attorneys. Mr. Warren has been practicing environmental law almost since the EPA was founded. Despite his youthful appearance, I assume that that is a correct statement. A renowned litigator, Mr. Warren is a leading practitioner in the environmental practice group at Kirkland & Ellis. He received his B.A. Degree from Yale. After graduating from the University of Chicago law school, he clerked for judge Luther Swygert on the U.S. Court of Appeals for the Seventh Circuit. He is an adjunct professor at the University of Chicago and has taught administrative law at Georgetown and appellate litigation at George Mason University. He is a member of the American Law Institute and chairman of the Federalist Society's administrative law practice group. Suffice it to say he is one of the foremost experts in the country.

So at this point, we will recognize Mr. Warren for his 5 Minutes.

TESTIMONY OF EDWARD W. WARREN, P.C., KIRKLAND & ELLIS, LLP

Mr. WARREN. Thank you. Thank you very much. And thank you for the opportunity to testify before this Committee this afternoon.

Mr. CONYERS. Mic, please.

Mr. WARREN. I am sorry. Can you hear me now?

Mr. CONYERS. I can.

Mr. WARREN. I have taught administrative law for a number of years, since 1995. But equally important, as the Chairman suggested, I have been an administrative law practitioner and litigator since 1970.

This afternoon I will share with you my perspective about how administrative law has changed since I began practicing in 1970, and suggest that today's agency practice has moved too far in the direction of exclusively notice and comment rulemaking. Specifically, I recount my experience in various rulemaking cases where limited cross-examination of agency projections were key scientific and technical studies proved extremely helpful in facilitating effective judicial review and improving the agency's work product.

My experience suggests that it would be wise to make carefully tailored amendments to the Administrative Procedure Act, which would permit slightly more formal proceedings in only major rules currently reviewed by the OIRA office. I am not suggesting formal rulemaking in every case, or that the procedures in 556 would apply to all of these rulemakings. I am suggesting something more limited, as you will see from my testimony. And I am suggesting also that this process that I am suggesting would improve not just for judicial review but the OIRA process at OMB whereby the executive branch reviews agency rules before they take effect.

Now, I began by reminding us all that the Administrative Procedure Act was enacted in 1946 in response to perceived excesses by New Deal agencies. In reflecting that understanding, Justice Frankfurter, an administrative law professor at Harvard, concluded in Universal Camera that quote, Courts must now assume more responsibility for the reasonableness and fairness of agencies'

decisions and, quote, that they not abdicate the conventional judicial function.

Now at that time, the normal way that agencies proceeded was by adjudication. Rulemaking was a novel idea contained in the Administrative Procedure Act. But rulemaking became more popular in the 1950's as sort of a summary judgment device whereby issues that were recurring in licensing proceedings or in adjudication could be dealt with once and for all by rulemaking. And then rulemaking blossomed in 1970 with the enactment of various health safety and environmental statutes.

Now at that time, many of the leading jurists and administrative law experts envisioned a limited role for oral hearings and cross-examination, again on the same things I am talking about, the issue of central importance, the key scientific and technical evidence underlying the agency's decision. And that was especially true, as it is today, because of the enormous impact that some of these major rules can have on our economy.

The likelihood of that occurring was sort of snuffed out in the 1970's by two Supreme Court decisions, the Florida East Coast Railroad case and the Vermont Yankee case. And where does that leave us with judicial review; because the process is now gone and the ability to have even the limited kind of suggestion that I am making has gone.

So what do we have? We have a process-oriented judicial review with massive records, records that I can tell you as a litigator, most of which is irrelevant. It always boils down to a few key pieces of evidence. And on those key pieces of evidence, the ability to get at the heart of them and to find out what the assumptions are and how viable those assumptions are, the projections of the agency, these are the heart and soul of judicial review. And yet without cross-examination, it doesn't work very well.

Now I have given you, in my testimony, examples of three cases that are, in my own experience as a litigator—the International Harvester Case, the so-called benzene case, and a case called Corrosion Through Fitting, where for various reasons that are contained in my testimony, some kind of cross-examination was permitted. And I think those cases illustrate how a limited function for cross-examination would facilitate judicial review and improve the work product.

I also suggest—my last sentence—I suggest in the third part of my testimony how this could be done in a limited, carefully tailored way in amending section 553 of the APA. Thank you.

Mr. GOWDY. Thank you Mr. Warren.

[The prepared statement of Mr. Warren follows:]

Prepared Statement of Edward W. Warren
Of Counsel
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Hearing on: "Formal Rulemaking and Judicial Review: Protecting Jobs and the Economy with Greater Regulatory Transparency and Accountability"

Subcommittee on Courts, Commercial and Administrative Law
Committee on the Judiciary
U.S. House of Representatives

May 31, 2011

Thank you for the opportunity to testify before you this afternoon. As reflected in my attached CV, I have taught administrative law as an adjunct professor at various law schools since 1995. But equally important for my testimony today, I have been an administrative law practitioner and litigator since 1970, and it is that latter experience that gives rise to much of my testimony today.

This afternoon, I will share with you my perspective about how administrative law has changed since I began practicing in 1970 and suggest that today's agency practice has moved too far in the direction of exclusively notice-and-comment rulemaking with gigantic, written administrative records subject to process-oriented and deferential judicial review. Specifically, I recount my own experience in various rulemaking cases where limited oral cross-examination of agency projections or key scientific and technical studies proved extremely helpful in facilitating effective judicial review and improving the agency's work-product. My experience suggests that it would be wise to make carefully-tailored amendments to the Administrative Procedure Act ("APA") which would permit slightly more formal procedures for major rules currently reviewed by the Office of Information and Regulatory Affairs ("OIRA") under Executive Orders 12866 and 13563.[1] I also suggest that OIRA's record and final review documents be formally made part of the administrative record so that reviewing courts will have the benefit of OIRA's expert analysis of key evidence and policy recommendations.

I. The History of the APA

As is well-known, the APA was enacted in reaction to the perceived excesses of New Deal agencies. Reflecting this understanding, Justice Frankfurter—in the first APA case to reach the Supreme Court—concluded "that courts must now assume more responsibility for the reasonableness and fairness" of agency decisions and "they are not to abdicate the conventional

[1] *See* Exec. Order No. 12866 (Sept. 30, 1993); Exec. Order No. 13563 (Jan. 18, 2011).

judicial function."[2] The agency decisional norm when the Court decided *Universal Camera* was adjudication in rate-making and licensing proceedings, with rulemaking a new and little-used tool. Rulemaking, however, began to blossom in the 1950s and 1960s, first as a sort of summary judgment device to decide recurring issues in licensing and adjudications.[3] But with the advent of major environmental, health, and safety legislation in 1970, rulemaking quickly became the preferred form of agency decision-making.

Many leading jurists and administrative law experts envisioned a limited role for oral hearings and cross-examination in rulemaking, especially given the enormous significance and economic impact on the private sector of certain major rules being issued by EPA and other agencies.[4] For example, Judge Friendly, himself a leading administrative law scholar, would have adopted a nuanced approach, acknowledging that rulemaking hearings often invoke Section 556 of the APA (setting forth the procedures for formal rulemakings), but also that the entitlement to cross-examination in Section 556(d) is tempered by the limitation that the agency may adopt procedures "'for the submission of all or part of the evidence in written form'" when "'a party will not be prejudiced thereby.'"[5] But Judge Friendly's decision in *Long Island Railroad* was expressly overturned in *United States v. Florida East Coast Railroad*, which held that Section 556 does not apply at all unless the organic statute mentioning a hearing expressly employs the expression "'on the record after opportunity for an agency hearing'" found in Section 553(c).[6]

Significantly, the Court's leading liberal, Justice Douglas, and its leading pragmatist, Justice Stewart, both dissented in *Florida East Coast Railroad*,[7] and soon liberal judges on the D.C Circuit (Judges Bazelon, Wright and McGowan) continued the practice of imposing cross-examination and selected aspects of formal proceedings in rulemaking cases, sometimes on behalf of environmental groups but sometimes also for the benefit of regulated parties.[8] The Supreme Court's decision in *Vermont Yankee Nuclear Power Corp. v. Natural Resources*

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[2] *Universal Camera v. NLRB*, 340 U.S. 474, 590 (1951).

[3] *See, e.g., United States v. Storer Broad. Co.*, 351 U.S. 192 (1956); *FPC v. Texaco*, 377 U.S. 33 (1964).

[4] *See, e.g., Int'l Harvester v. Ruckelshaus*, 478 F.2d 615, 630 (D.C. Cir. 1973) ("In context, the 'public hearing' provision amounts to an assurance by Congress that the issues would not be disposed of merely on written comments, the minimum protection assured by the Administrative Procedure Act for rulemaking, but would also comprehend oral submissions of a legislative nature. These are required even for rule-making when 'controversial regulations governing competitive practices' are involved."); *Walter Holm & Co. v. Hardin*, 449 F.2d 1009, 1016 (D.C. Cir. 1971) ("[T]he oral hearing may be legislative in type, although fairness may require an opportunity for cross-examination on the crucial issues."); *see generally* Glenn O. Robinson, *The Making of Administrative Policy: Another Look at Rulemaking and Adjudication and Administrative Procedure Reform*, 118 U. PA. L. REV. 485, 485 (1969) (arguing that agencies should use rulemaking more often because they are too tethered to "judicial forms of proceeding," but not suggesting that "judicial forms" should be done away with in all contexts).

[5] *Long Island R.R. v. United States*, 318 F. Supp. 490, 498 (E.D.N.Y 1970) (quoting 5 U.S.C. § 556(d)).

[6] 410 U.S. 224, 236-37 (1973) (quoting 5 U.S.C. § 553(c))

[7] *See id.* at 246.

[8] *See, e.g., Automotive Parts & Accessories v. Boyd*, 407 F.2d 330 (D.C. Cir. 1968); *Greater Boston Television v. FCC*, 444 F.2d 841(D.C. Cir. 1970); *Home Box Office v. FCC*, 567 F.2d 9 (D.C. Cir. 1977).

Defense Council ended this practice and effectively limited the procedures applicable in rulemaking to those expressly prescribed in Section 553(c).[9]

So where does that leave judicial review of agency rulemakings? Under the APA, there are three components of judicial review: procedural (Section 706(2)(D)); statutory fidelity (Section 706(2)(C)); and substantive (Section 706(2)(A) & (E)). Except where an agency attempts to proceed without notice-and-comment under Section 553 (for instance, via an interpretative rule or policy statement),[10] procedural review is effectively a nullity after *Vermont Yankee*. Statutory fidelity is governed by the deferential *Chevron* decision[11] and its progeny, and substantive review generally takes place under the deferential "arbitrary and capricious" test. The latter test, according to the Supreme Court, is "at its most deferential" when the agency makes decisions "at the frontiers of science."[12]

To be sure, judicial review of rulemakings is not quite the nullity that this suggests. There still is a current arising from *Citizens to Preserve Overton Park v. Volpe*, that the arbitrary-and-capricious test necessitates "a thorough, probing in-depth review."[13] But what does this mean, especially in the context of the expansive, flat landscape found in the massive written records created today in support of major agency rules? Records often run for millions of pages. Typically, nothing stands out in these mind-numbing pages of comments and studies. But to pass judicial muster, agency counsel and technical staff in practice must spend months and man-years responding in the final Federal Register Notice and supporting "Response to Comments" documents to every comment, no matter how trivial or irrelevant.

With judicial review focused almost entirely on the agency's process rather than the agency's end-product, the "hard look" approach of *Overton Park* has become amorphous and ill-defined. Courts possess wide latitude to affirm an agency decision with only the most cursory explanation, or to reverse whenever the reviewing panel discovers the virtually inevitable flaw in some aspect of the agency's decision-making process. None of this improves the agency's end-product or helps to ensure that private sector resources are expended in a manner that serves the public interest.

Judicial review accordingly has become both unpredictable and largely unrelated to the substance of the agency's end-product. That being the case, the role of curbing substantive excesses in major agency rules has fallen significantly to the OIRA office within the Office of Management and Budget under the various Executive Orders issued by every President since Nixon. In my judgment, the OIRA process has been only moderately successful for a number of reasons. First, OIRA has generally been understaffed and its budget is always under scrutiny, especially when one or both houses of Congress and the Presidency are controlled by different political parties. Second, the OIRA process is informal and closed and suffers from the fact that key evidence on which the agency's decision depends generally is not subjected to adversarial

[9] 435 U.S. 519, 547-48 (1978).

[10] *See, e.g.*, *Hoctor v. United States Dept. of Agric.*, 82 F.3d 165, 169 (7th Cir. 1996).

[11] *Chevron USA Inc. v. Natural Res. Defense Council, Inc.*, 467 U.S. 837, 842-45 (1984).

[12] *Baltimore Gas & Electric Co. v. Natural Res. Defense Council, Inc.*, 462 U.S. 87,103 (1984.)

[13] 401 U.S. 402, 415 (1971).

give-and-take, much less cross-examination. And finally, the OIRA process itself is excluded from judicial review, thus depriving reviewing courts of what is often the most expert and dispassionate consideration of the critical evidence on which the agency's decision is based.

In sum, today's judicial review of major agency rules does not remotely resemble Justice Frankfurter's admonition that courts must not "abdicate the conventional judicial function" and that they instead should "assume more responsibility for the reasonableness and fairness" of agency decisions.[14] Are there modifications in current agency practice and judicial review of agency rulemaking which would bring them closer to Justice Frankfurter's view of the APA's purpose and his understanding of the proper judicial role? How might the APA be amended to achieve this objective while at the same time focusing the rulemaking process on issues of central importance and improving the agency's end-product? The remainder of my testimony is devoted to answering these questions.

II. A Practitioner's View

As my CV reflects, since 1995 I have taught administrative law and related subjects as an adjunct faculty at the University of Chicago, George Mason Law School, and Pepperdine Law School. The balance of my testimony, however, relies much more on my forty years of experience as an administrative law practitioner and litigator than on my experience teaching administrative law. With all due respect to administrative law professors, few have ever handled a major rulemaking or cross-examined key scientific or technical witnesses regarding the central issues on which those rulemakings so often turn. In my experience, nearly all of the "evidence" in the massive records before the courts of appeal is essentially irrelevant. Only a few projections by the agency, or scientific or technical studies relied upon by the agency, or counter-submissions made by regulated parties or public interest groups are really important. And well-informed counsel for all parties know generally which issues are central and which are not (although client interests sometimes cause counsel to obscure those issues).

Justice Frankfurter's views in *Universal Camera* and Judge Friendly's more nuanced approach to rulemakings procedures reflect, I believe, a similar understanding of the role of evidence in administrative proceedings. Regulation of private sector conduct today can be either prospective—namely agency rulemaking—or retrospective, as reflected in toxic tort and similar civil litigation brought against the same regulated parties. As a practical matter, the two forms of regulation are similar in many respects—the same core types of scientific or technical studies are likely to be dispositive in both settings. Cases like *Wyeth v. Levine*,[15] *Geier v. America Honda*,[16] and *Daubert v. Merrell Dow*,[17] and its progeny, reflect the Supreme Court's view that there must be rigorous judicial oversight to assure that decisions in the civil litigation regulatory arena are made based on reliable scientific and technical evidence. Surely the same considerations ought to apply in major agency rulemakings.

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[14] *Universal Camera v. NLRB*, 340 U.S. 474, 490 (1951).

[15] 555 U.S. 555 (2009).

[16] 529 U.S. 861 (2000).

[17] 509 U.S. 579 (1993).

My experience suggests that there should be a role for more formal process and cross-examination in agency rulemakings. These more formal procedures, including cross-examination, proved efficacious in the three cases described below (which are attached). They invariably improved the regulatory end-product, sometimes thwarting unnecessary measures and other times tempering their stringency. To be sure, I am speaking from personal experience, having served as counsel in all three cases. Other administrative practitioners may be able to add or detract from my account. But I believe these cases point the way to narrow use of more formal procedures in major agency rulemakings and, as described in Part III below, the APA could be amended in a manner that would both improve and streamline the rulemaking process.

(a) *International Harvester v. Ruckelshaus*

I begin by paying homage to Judge Leventhal, the author of the D.C. Circuit's opinion in *International Harvester v. Ruckelshaus*.[18] The issue in *International Harvester* was whether to overturn the Environmental Protection Agency's ("EPA") decision denying the auto companies' request for a one-year suspension of the tailpipe emission standards set in the Clean Air Act. Judge Leventhal, perhaps the leading administrative law jurist of his era, was not in favor of procedure for procedure's sake—and hence prominently parted company with his liberal colleagues, Judges Bazelon, Wright and McGowan, whose judicial imposition of more formal processes was rejected by the Supreme Court in *Vermont Yankee*. Instead, Judge Leventhal viewed, as an "inescapable aspect of the judicial condition," the need to probe into "matters of ... technical complexity" as a means of "constructive cooperation with the agency" in "furtherance of the public interest."[19]

Judge Leventhal began by framing the issue before him in terms of risks and costs. What were the environmental risks of granting a one-year suspension of the auto emission standards? What were the potential economic and social costs if a one-year waiver was not granted and one or more auto companies could not meet the standards? He then balanced the risks and costs of granting or denying a one-year suspension as a means of determining which evidence was of central importance to EPA's decision.

With this framework in mind, Judge Leventhal concluded that the burden was on the auto companies to show that compliance with the statutory standards was not technologically feasible for the 1975 model year. The auto companies had made this prima facie showing by presenting data that "no car had actually been driven 50,000 miles" in conformity with the 1975 standards.[20] EPA, however, had developed a model which predicted that the auto companies would be able to make sufficient improvements in coming months to meet the standards. On this point, Judge Leventhal judged that EPA, as the proponent of denying a one-year suspension, must bear the burden of proof.[21] As he put it, the "judicial task" was to require a "reasoned decision" and this

[18] 478 F.2d 615 (D.C. Cir.1973).

[19] *Id.* at 647-48.

[20] *Id.* at 642.

[21] *Id.* at 643.

necessitated that EPA make "a reasoned presentation of the reliability of a prediction and methodology" to overcome the prima facie showing of technological infeasibility.[22]

Judge Leventhal concluded that EPA had not met its burden on the record before him but that EPA might do so on remand in proceedings focused on EPA's predictive methodology. So focused on the central issues, "the remand proceeding[s] will involve some opportunity for cross-examination," although "EPA may properly confine cross examination to the essentials, avoiding discursive or repetitive questioning."[23]

(b) *Industrial Union Department, AFL-CIO v. American Petroleum Institute*

The issue of agency predictions and the methodology (typically technological feasibility assessments, risk assessments, or cost-benefit analyses) are recurring issues in major environmental, health, and safety rules issued by EPA, the Occupational Safety and Health Administration ("OSHA"), the National Highway Traffic Safety Administration, and other agencies. The importance of key underlying scientific studies and the need for reliable predictive methodologies is well-illustrated by the Supreme Court's decision in *Industrial Union Department, AFL-CIO v. American Petroleum Institute*.[24] There, the issue was whether OSHA adequately justified its decision to reduce the occupational exposure limit for benzene from 10 parts per million ("ppm") to 1 ppm. The OSH Act provided a form of hybrid rulemaking that necessitated that OSHA present its key decision maker and the authors of several critical scientific studies to be cross-examined by regulated parties and labor representatives. Evidence from both of these sources proved crucial in the Supreme Court's decision affirming the Fifth Circuit's reversal of OSHA's 1 ppm standard.

Justice Stevens' opinion reviewed the testimony of OSHA's experts and concluded that "the evidence in the administrative record of adverse effects of benzene exposure at 10 ppm is sketchy at best."[25] So how did OSHA support reducing the occupational standard to 1 ppm? Cross-examination of OSHA's key decision maker, Deputy Director Wrenn, quoted in the opinion, demonstrated that OSHA relied only on (1) the conclusion that benzene was a carcinogen at higher levels; and (2) "that no safe level of exposure exists in the absence of clear proof establishing such a level."[26] On this basis, OSHA predicted that there would be "appreciable benefits" from reducing the 10 ppm standard to 1 ppm.[27]

As Justice Stevens observed, this form of prediction was not enough. Construing the statutory test that OSHA standards must be "reasonably necessary or appropriate to provide safe or healthful employment," Justice Stevens ruled that OSHA must demonstrate a "significant risk

[22] *Id.* at 648.

[23] *Id.* at 649.

[24] 448 U.S. 607 (1980).

[25] *Id.* at 631.

[26] *Id.* at 624.

[27] *Id.* at 623-24.

of material health impairment" at 10 ppm before reducing the standard.[28] Citing the same burden of proof provision relied on by Judge Leventhal in *International Harvester*, he found that the burden was on OSHA to show "that it [was] more likely than not that long-term exposure to 10 ppm" benzene met his test.[29] As proof that there was methodology that might address this issue, Justice Stevens cited industry expert testimony "that a dose-response curve can be formulated on the basis of current epidemiological evidence and that, even under the most conservative extrapolation theory, current exposure levels would cause at most two deaths out of a population of about 30,000 workers every six years."[30]

So once again, it was a few key scientific studies and the agency's predictive methodology (or lack thereof)—not the millions of pages of record materials so common in major rulemaking records—which formed the core of the agency's decision-making process. It was only with respect to this central core evidence that cross-examination proved efficacious.

(c) *Corrosion Proof Fittings v. EPA*

The same can be said of my third and last example, the Fifth Circuit's decision in *Corrosion Proof Fittings v. EPA*, overturning EPA's ban of certain asbestos products under the Toxic Substances Control Act ("TSCA").[31]

Like the OSH Act, TSCA provided a form of hybrid rulemaking with the added statutory requirement that EPA present "a reasonable basis to conclude" that the product being regulated "presents or will present an unreasonable risk of injury," coupled with the proviso that EPA impose requirements "to protect adequately against such risk using the least burdensome requirements."[32] Once again, EPA's predictive methodology in attempting to meet this test proved critical.

EPA estimated that its rule would "save either 202 or 148 lives, depending upon whether the benefits are discounted, at a cost of approximately $450-800 million, depending on the price of substitutes."[33] The problem with this calculation, however, was that it depended critically upon so-called "analogous exposure estimates" which EPA developed "during the final weeks of the rulemaking process after the public comment was concluded."[34] The court held that by "depriving the petitioners of their right to cross-examine EPA witnesses on methodology and data used to support as much as eighty percent of the proposed benefits in some areas, the EPA [] violated the dictates of TSCA."[35]

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[28] *Id.* at 639.

[29] *Id.* at 653.

[30] *Id.* at 654.

[31] 947 F.2d 1201 (5th Cir. 1991).

[32] 15 U.S.C. § 2605(a).

[33] *Corrosion Proof Fittings*, 947 F.2d at 1208.

[34] *Id.* at 1229.

[35] *Id.* at 1229-30.

Other key testimony also proved telling in leading to a reversal of EPA's asbestos product ban. For example, petitioners introduced "credible studies and evidence showing the toxicity of workplace substitutes, or the decreased effectiveness of safety alternatives such as non-asbestos brakes."[36] These studies showed, for instance, that non-asbestos brakes, particularly in the brake replacement market, "could increase significantly the number of highway fatalities."[37] Moreover, "many of the EPA's own witnesses conceded on cross-examination that the non-asbestos fibrous substitutes also pose a cancer risk upon inhalation."[38] Yet, EPA failed to account for these risk tradeoffs in its methodology, thereby providing an alternative ground for reversing EPA's standards.

Certainly, these three cases are not typical in all respects of major rules issued by EPA and other agencies. Two of the three cases provided limited cross-examination rights by statute and each had its unique decision-making framework. That said, each case demonstrates that a more formal process and limited cross-examination of the agency's predictive methodology and key scientific and technical studies can be very efficacious in highlighting defects in the agency's reasoning and in improving the agency's final product.

No doubt, the OIRA process mirrors in many respects this focus on the agency's predictive methodology and key underlying studies. But, as noted previously, it is a closed process which addresses these issues in a non-transparent manner without the benefit of adversarial give-and-take or cross-examination by experienced counsel. There is much to be said for combining the best of these processes and making the results of OIRA's analysis judicially reviewable. If this were the case, OIRA's regulatory review would provide the reviewing court with a probing, in-depth analysis of the validity of the agency's methodology and assumptions in advance of judicial review. That analysis would focus the parties and the court's attention on those parts of record which are really important, thereby making judicial review much more confident and effective.

The question, of course, is whether these reforms can be carried out though concise amendments to the APA and whether they would really advance the goal of efficient and effective agency rulemaking. It is to these questions that I now turn.

III. Recommendations.

In terms of the particular issues that I am addressing, there is relatively little need to make significant changes in the overall *structure* of the APA, though there are obviously other things that could be improved after 65 years. Hence, some vital improvements could be made relatively simply. From my standpoint, the most important issues are mostly in the case of major rules, as defined by the Executive Orders and subjected to the most searching OIRA review, that additional procedures are warranted in the interest of improving the agency work product. Major rules, of course, call for the greatest expenditure of private sector resources. It is essential, therefore, that those resources be deployed efficiently and in the least burdensome manner

[36] *Id.* at 1221.

[37] *Id.* at 1224.

[38] *Id.* at 1225.

consistent with achieving the statutory aim intended by Congress. After all, as recognized by both the Clinton and Obama Administrations, "private markets are the best engine for economic growth," and "[f]ederal agencies should promulgate only such regulations as ... are made necessary by compelling public need, such as material failures of private markets ...."[39]

In modifying the APA, I would begin with Section 551 which provides definitions of all the important terms used in the statute. Writing a definition of "major rule" to be added to Section 551 would be easy since that term is already defined in the Congressional Review Act.[40]

Most of the amendments needed to accomplish the changes covered by my testimony could be made by simply adding a new subsection to Section 553. Subsections (a) through (c) would remain because most rulemakings will still be governed by notice-and-comment and because there are still a few rulemakings that satisfy the talismanic test of *Florida East Coast Railroad*. The new subsection suggested here should be drafted to make clear that the procedures provided therein are in addition to, not in lieu of, those provided in subsection (c). I leave the drafting of specific text to congressional experts but would suggest that any new subsection (d) include the following conceptual components:

1. Paralleling the first sentence of Section 556(d), it should be expressly stated that the proponent of a rule, namely the agency, has the burden of proof. The agency should be required to identify each scientific or technical study or other evidence which is of central importance in carrying its burden. This would include any technological feasibility, risk assessment or other projection on which the agency relies to carry its burden.

2. Regulated parties and other interested persons should have the burden of going forward with respect to evidence over which that party has control. This would include, for example, prima facie evidence regarding technological infeasibility as in *International Harvester*, cost data as in *Industrial Union*, or evidence regarding the risks or effectiveness of substitutes as in *Corrosion Proof Fittings*. Regulated parties or other interested persons also would bear the burden of counter-designating any studies, not designated by the agency, which they argue are, or should have been, of central importance to the agency's decision. Such counter-designations may include evidence that arguably would provide a less burdensome means of achieving the agency's specified regulatory objective.

3. Regulated parties or other interested parties would be entitled to request "such cross-examination" of the authors or proponents of studies or projections which are of central importance to the agency's decision "as may be required for a full and true disclosure of the facts." Again, paralleling Section 556(d), the presiding officer may "adopt procedures for the submission of all or part of the evidence in written form" but only "when the party will not be prejudiced thereby."

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[39] Exec. Order No. 12866 (Sept. 30, 1993); *see also* Exec. Order No. 13497 (Jan. 30, 2009) (adopting Exec. Order No. 12866).

[40] *See* 5 U.S.C. § 804(2).

4. The presiding officer may include any of the persons specified in Section 556(a) or any other agency employee designated by the agency (as was the case in *Corrosion Proof Fittings*).

5. The presiding officer should make a written decision with respect to each and every contested question presented by regulated parties or other interested persons with respect to the preceding paragraphs. This would include counter-designations of evidence claimed to be of central importance to the agency's decision and rulings which limit or deny oral cross-examination of testimony regarding studies or projections determined to be of central importance to the agency's decision.

6. The record for judicial review should include any and all oral cross-examination of witnesses and each written decision made by the presiding officer under paragraph 5 above. Judicial review with respect to such evidence and rulings as well as all studies and projections of central importance supporting the agency's decision should be conducted under Section 706(2)(E) (i.e., the "substantial evidence" standard).

7. In addition, the administrative record should include the record before OIRA—including any and all reviews by that agency as well as all the entire record developed under Section 553(c).

I am sure other witnesses may suggest other changes that would further improve the rulemaking process. But speaking only to the changes I have suggested, they, in my judgment, would actually streamline the rulemaking process for major rules by putting the agency's focus and that of all concerned parties on the evidence that truly matters to the agency's decision. Judicial review would be enhanced and made more effective by this more focused approach which would combine non-repetitive cross-examination of key studies and agency projections with the results of the OIRA review process. The result would be improved agency rules which achieve Congress' aims in a less burdensome and more cost effective manner.

No doubt there are those who will cling to the current process of exclusively written administrative records, notwithstanding the massive effort required of agency counsel and technical staff to assemble final Federal Register preambles and Response to Comment documents capable of withstanding judicial review. But, as Professor Richard Pierce noted ten years after *Vermont Yankee*, "the open-ended requirement of adequate reasoning is having the same effect on agencies as that the open-ended requirement of adequate procedures had before *Vermont Yankee*—it is delaying the policymaking process to the point of near paralysis."[41] The current rulemaking system, especially for major rules which matter most, is broken. Now is the time to fix it with improvements along the lines I have suggested this afternoon.

* * *

Thank you for the opportunity to appear here today. I will be pleased to answer any questions or supply additional information for the record.

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[41] Richard J. Pierce, Jr., *The Role of the Judiciary in Implementing an Agency Theory of Government*, 64 N.Y.U. L. REV. 1239, 1265 (1989).

defense counsel's criminal trial strategy will be crucially affected by a necessarily speculative evaluation of his post-trial chances of dealing with one or another standard of proof. More important, it seems anomalous, to say the least, that this court, which has given such consistent recognition to the need for a carefully administered insanity defense, *see, e. g.*, United States v. Brawner, 153 U.S. App.D.C. 1, 471 F.2d 969 (1972) (*en banc*), should suddenly embrace such a roughhewn and very possibly useless means of restraining its use.

It is doubtless true, as the majority suggests, that the insanity defense as it has been administered in this case, when coupled with the *Bolton* decision, might in theory give rise to a "revolving door" phenomenon whereby persons who have committed dangerous acts may be first acquitted by reason of insanity and next totally freed because of the Government's inability to meet the standards of proof for civil commitment. But this problem of slippage is not eliminated by the disparity in burdens of proof endorsed by the majority. At best it is only reduced, and at the terrible price of incarcerating persons for a mental illness we are not sure they have.[7] *Bolton* sought to place those acquitted by reason of insanity on the same footing as those haled before the court in ordinary civil commitment proceedings. I would continue to follow its teaching. Indeed, given *Baxstrom*, in my judgment we have no choice.

I respectfully dissent.

ment of persons acquitted by reason of insanity. Under the new legislation, those acquitted by reason of insanity shall be committed to a hospital for the mentally ill and provided with a hearing within 50 days to determine whether they shall be released. In that hearing, unlike the hearing utilized in this case, the burden of proof is on the person confined to prove that he has recovered his sanity and will not in the reasonable future be dangerous to himself or others. *See* 24 D.C. Code § 301(d)(1)–(2) & (e) (Supp. V 1972).

7. Because of the ambiguous nature of the very concept of mental illness, *see* Washington v. United States, 129 U.S.App. D.C. 29, 31, 390 F.2d 444, 446 (1967), and its potentially "grab bag" quality, *see* Boutilier v. Immigration & Naturalization Service, 387 U.S. 118, 131, 87 S.Ct. 1563, 18 L.Ed.2d 661 (1967) (Mr. Justice Douglas, dissenting), it has been repeatedly recognized that endorsing a mild standard of proof in commitment cases can result in grave injustice. *See* Murel v. Baltimore City Criminal Court, *supra* note 2, 407 U.S. at 359, 92 S.Ct. 2091, 32 L.Ed.2d 701 (Mr. Justice Douglas, dissenting); Note, *supra* note 2, 79 Harv. L.Rev. at 1291; *cf.* Lessard v. Schmidt, *supra* note 2.

INTERNATIONAL HARVESTER COMPANY, Petitioner,

v.

William D. RUCKELSHAUS, Administrator, Environmental Protection Agency, Respondent.

GENERAL MOTORS CORPORATION, Petitioner,

v.

William D. RUCKELSHAUS, Administrator, Environmental Protection Agency, Respondent.

CHRYSLER CORPORATION, a Delaware Corporation, Petitioner,

v.

William D. RUCKELSHAUS, Administrator, Environmental Protection Agency, Respondent.

FORD MOTOR COMPANY, Petitioner,

v.

William D. RUCKELSHAUS, Administrator, Environmental Protection Agency, Respondent.

Nos. 72-1517, 72-1525, 17-1529, 72-1537.

United States Court of Appeals, District of Columbia Circuit.

Argued Dec. 18, 1972.

Decided Feb. 10, 1973.

As Amended Feb. 12, 1973.

Proceedings on consolidated petitions by truck manufacturer and the three major auto companies seeking re-

view of decision by the Administrator of Environmental Protection Agency denying applications for one-year suspension of 1975 emission standards prescribed by Clean Air Act for light-duty vehicles. The Court of Appeals, Leventhal, Circuit Judge, held that proceedings were required to be remanded for further proceedings where vehicle manufacturers established by preponderance of record evidence that technology was not available within meaning of Clean Air Act, Administrator's reliance on technological methodology to offset actual test results raised serious doubts and failed to meet burden of proof assignable to him when considering that risk of erroneous denial of suspension outweighed risk of erroneous grant of suspension, National Academy of Science had considered that technology was not available to meet standards of 1975 and statutorily required determinations of public interest and good faith had not been made.

Remanded for further proceedings.

Bazelon, Chief Judge, concurred in result and filed opinion.

1. Health and Environment ⇐28

Denial of motor vehicle manufacturers' request for one-year suspension of 1975 emission standards for light-duty vehicles, on ground that technology was "available," within meaning of Clean Air Act, was not required to be based solely on technology in being at time of application; availability requirement did not preclude consideration of what Administrator of Environmental Protection Agency determined to be the probable or likely sequence of technological development during the production lead time period. Clean Air Act, § 202(b)(5)(D) as amended 42 U.S.C.A. § 1857f-1(b)(5)(D).

2. Health and Environment ⇐28

Administrator of Environmental Protection Agency's latitude for projection of technology existing at time of application for one-year suspension of 1975 emission standards for light-duty vehicles was subject to restraints of reasonableness, did not open the door to crystal ball inquiry and was limited by relevant considerations of lead time needed for production; implicit also was requirement of reason in reliability of EPA projection. Clean Air Act, § 202(b)(5)(D) as amended 42 U.S.C.A. § 1857f-1(b)(5)(D).

3. Health and Environment ⇐28

Where Administrator's prediction of available technology was based on known elements of existing catalytic converter systems and admission by vehicle manufacturer's engineers that technology improvements could continue during the two-year period prior to production, Administrator's predictive approach to determination of whether technology would be available to meet statutory 1975 exhaust emission standards for light-duty vehicles, and thus whether one-year suspension was required, was a proper approach, subject to requirement that any technological developments or refinements of existing systems, used as part of Environmental Protection Agency methodology, would have to rest on a reasoned basis. Clean Air Act, § 202(b)(5)(D) as amended 42 U.S.C.A. § 1857f-1(b)(5)(D).

4. Health and Environment ⇐28

Provision of Clean Air Act requiring public hearing on application for one-year suspension of 1975 emission standards prescribed for light-duty vehicles did not contemplate an adjudicatory type of hearing with auto manufacturers having right to engage in cross-examination or to present arguments against methodology used in Administrator's Technical Appendix, which served as basis for his decision. Clear Air Act, § 202(b)(5)(D) as amended 42 U.S.C.A. § 1857f-1(b)(5)(D).

5. Health and Environment ⇐28

Requirement of Clean Air Act that public hearing precede decision granting or refusing request for one-year suspension of 1975 emission standards prescribed for light-duty vehicles amounted to an insurance by Congress that the issues would not be disposed of merely

on written comments, the minimum protection assured by the Administrative Procedure Act for rule making, but would also comprehend oral submissions of a legislative nature. Clean Air Act, § 202(b)(5)(D) as amended 42 U.S.C.A. § 1857f-1(b)(5)(D); 5 U.S.C.A. §§ 553, 556(d).

6. Administrative Law and Procedure ⇐400

Comprehensive oral submissions of a legislative nature are required even for rule making when controversial regulations governing competitive practices are involved; even assuming oral submission, in a situation where general policy is the focal question, a legislative type hearing is appropriate. 5 U.S.C.A. §§ 553, 556(d).

7. Administrative Law and Procedure ⇐398
Health and Environment ⇐28

Within the context of a quasi-legislative hearing and 60-day time limit provided by Clean Air Act for decision on application for one-year suspension of 1975 emission standards prescribed for light-duty vehicles, absence of a general right of cross-examination on part of motor vehicle manufacturers did not constitute a departure from basic considerations of fairness; EPA's technique of prescreening written questions submitted in advance by manufacturers, with hearing officers "following up" on questions, was a reasonable attempt to elicit the facts and at the same time cope with time constraints; procedure employed permitted a meaningful opportunity to be heard. Clear Air Act, § 202(b)(5)(D) as amended 42 U.S.C.A. § 1857f-1(b)(5)(D).

8. Administrative Law and Procedure ⇐398
Constitutional Law ⇐318(1)

Specific nature of a hearing varies with circumstances; whether particular attributes of forensic presentation are not only salutary but also mandatory under due process clause must also depend on circumstances. U.S.C.A.Const. Amends. 5, 14.

9. Administrative Law and Procedure ⇐398

Right of cross-examination, consistent with time limitations, might extend to particular cases of need, on critical points where the general administrative procedure proved inadequate to probe soft and sensitive subjects and witnesses. U.S.C.A.Const. Amends. 5, 14.

10. Administrative Law and Procedure ⇐309

Detailed elucidation of Agency methodology is salutary and of particular aid to a reviewing court.

11. Administrative Law and Procedure ⇐392

Requirement of submission of a proposed rule for comment does not automatically generate a new opportunity for comment merely because the rule promulgated by the Agency differs from the rule it proposed, partly at least in response to submissions. 5 U.S.C.A. § 551.

12. Administrative Law and Procedure ⇐392
Constitutional Law ⇐318(2)
Health and Environment ⇐28

Failure to provide reasonable opportunity for vehicle manufacturers to comment on methodology employed by Environmental Protection Agency in determining whether available technology existed to meet 1975 emission standards prescribed for light-duty vehicles did not violate Clean Air Act or due process, though such opportunity would have been salutary for purpose of judicial review. Clean Air Act, § 202(b)(5)(D) as amended 42 U.S.C.A. § 1857f-1(b)(5)(D).

13. Administrative Law and Procedure ⇐229
Health and Environment ⇐28

Opportunity of vehicle manufacturers, on petition for reconsideration or modification of denial of request for one-year suspension of 1975 emissions standards prescribed for light-duty vehicles, to present to Environmental Protection Agency any comments as to

methodology did not permit invocation of doctrine of failure to exhaust administrative remedies as a bar to appeal from initial denial since such petition could not have affected or deferred the finality of the EPA decision or the time for seeking judicial review. Clean Air Act, § 202(b)(5)(D) as amended 42 U.S.C.A. § 1857f-1(b)(5)(D).

14. Health and Environment ⇐28

While Clean Air Act imposes some unusual time restraints as regards application for one-year suspension of 1975 emission standards prescribed for light-duty vehicles, it does not jettison the flexibility and capacity of reexamination that is rooted in the administrative process; agency consideration was not frozen from moment the suspension decision was rendered and Environmental Protection Agency had latitude to continue further consideration even without requesting a court remand that would suspend judicial consideration. Clean Air Act, § 202(b)(5)(D) as amended 42 U.S.C.A. § 1857f-1(b)(5)(D).

15. Health and Environment ⇐28

Phrase "light duty vehicles" as used in provision of Clean Air Act amendments of 1970 prescribing 1975 emission standards for light-duty vehicles encompasses passenger cars but does not include light-duty trucks; lightweight trucks are to be governed by standards duly promulgated by EPA for trucks and buses and other commercial vehicles. Clean Air Act, § 202(b)(1)(A) as amended 42 U.S.C.A. § 1857f-1(b)(1)(A).

See publication Words and Phrases for other judicial constructions and definitions.

16. Health and Environment ⇐28

Legislative intent, consisting of bountiful references in congressional debate to scope of statutory emission standards prescribed for 1975 light-duty vehicles as encompassing passenger automobile and excluding light-duty trucks, was required to be given priority in interpreting Clean Air Act amendments of 1970, over any presumption of continuous and prior administrative definition of that term or to policy of upholding reasonable interpretations of statute by administrative agencies in absence of other discernible legislative intent. Clean Air Act, § 202(b)(1)(A) as amended 42 U.S.C.A. § 1857f-1(b)(1)(A).

17. Administrative Law and Procedure ⇐663
Health and Environment ⇐28

Court of Appeals, on petition for review of order of Administrator of Environmental Protection Agency denying vehicle manufacturers' request for one-year suspension of 1975 emission standards for light-duty vehicles, had jurisdiction to determine validity of Administrator's regulation defining statutory term "light duty vehicles" to include light weight trucks, notwithstanding that reasonableness of regulation could be challenged in a separate proceeding in district court, where validity of regulation was a premise of refusal to grant truck manufacturer's application for suspension. Clean Air Act, § 202(b)(5)(D) as amended 42 U.S.C.A. § 1857f-1(b)(5)(D).

18. Health and Environment ⇐28

As long as feasible technology permits demand for new passenger automobiles to be generally met, basic requirements of Clean Air Act amendments establishing emission standards for 1975 light-duty vehicles will be satisfied, even though this might occasion fewer models and a more limited choice of engine types; the driving preferences of hotrodders are not to outweigh the goal of a clean environment. Clean Air Act, § 202(b)(1)(A) as amended 42 U.S.C.A. § 1857f-1(b)(1)(A).

19. Health and Environment ⇐28

In passing on automobile manufacturers' application for one-year suspension of 1975 emission standards for light-duty vehicles, Administrator of Environmental Protection Agency was required to make finding on manufacturers' contentions that production and

major retooling capacity did not exist to shift production from large number of previous models and engine types to those capable of complying with the 1975 standards and meeting demand for new cars; Administrator was required to take such demand considerations into account in passing on suspension request and underlying issue of technological feasibility. Clean Air Act, § 202(b)(5)(D) as amended 42 U.S.C.A. § 1857f-1(b)(5)(D).

20. Health and Environment ⇐28

Exhaust emission standards specified by Clean Air Act amendments for 1976 light-duty vehicles cannot be breached by Environmental Protection Agency, since standard represents an absolute judgment of Congress. Clean Air Act, § 202(b)(1)(A) as amended 42 U.S.C.A. § 1857f-1(b)(1)(A).

21. Health and Environment ⇐28

Light-duty vehicle manufacturers' request for one-year suspension of 1975 exhaust emission standards presented a need for a perspective on suspension that was informed by an analysis which balanced the cost of a wrong decision on technological feasibility against the gains of a correct one; costs included risks of grave maladjustments for technological leader from eleventh-hour grant of suspension and impact on jobs and economy from a decision which was only partially accurate, allowing manufacturers to produce cars at significantly reduced level of output, against which environmental savings from denial of suspension was required to be weighed along with possibility that failure to grant suspension would be counterproductive to the environment because of significant decline in performance characteristics. Clean Air Act, § 202(b)(5)(D) as amended 42 U.S.C.A. § 1857f-1(b)(5)(D).

22. Administrative Law and Procedure ⇐390

Considerations of fairness will support comprehensive and firm, even drastic, government regulations, provided a "safety valve" is included—ordinarily provisions for waiver, exception or adjustment or provision for suspension; such limited safety valve permits a more rigorous adherence to an effective regulation; however, to hold the safety valve too rigidly is to interfere with the relief that was contemplated as an integral part of the firmness of an overall, enduring program.

23. Health and Environment ⇐28

Court of Appeals review of denial of one-year suspension of 1975 emission standards prescribed for light-duty vehicles is a judicial review and not a technical or policy redetermination; judicial review was channeled by salutary restraint and deference to Agency's expertise based on reasoned analysis. Clean Air Act, § 202(b)(5)(D) as amended 42 U.S.C.A. § 1857f-1(b)(5)(D).

24. Health and Environment ⇐28

Burden was on light duty vehicle manufacturers, seeking one-year suspension of 1975 emission standards prescribed for light-duty vehicles, to come forward with data which showed that they could not comply with the statutory standards; since manufacturers were in possession of data about emission performance of their vehicles, it was their burden to come forward with such evidence. Clean Air Act, § 202(b)(5)(D) as amended 42 U.S.C.A. § 1857f-1(b)(5)(D).

25. Health and Environment ⇐28

Since light duty vehicle manufacturers, which sought one-year extension of 1975 exhaust emission standards presented for light-duty vehicles, presented actual test data in support of their contention of lack of available technology, burden was on Administrator of Environmental Protection Agency to show reliability of methodology used to predict feasibility of meeting 1975 standards. Clean Air Act, § 202(b)(5)(D) as amended 42 U.S.C.A. § 1857f-1(b)(5)(D).

26. Health and Environment ⇐28

Standard of proof on issue of availability of technology to meet 1975 ex-

haust emission standards for light-duty vehicles was a preponderance of the evidence rather than beyond a reasonable doubt; such standard, which was to be applied by Administrator of Environmental Protection Agency in passing on request for one-year suspension of standards, was required to take into account the nature and consequences of risk of error. Clean Air Act, § 202(b)(5)(D) as amended 42 U.S.C.A. § 1857f-1(b)(5)(D).

27. Evidence ⇐93

When certain material lies particularly within the knowledge of a party he is ordinarily assigned the burden of adducing the pertinent information; this assignment of burden to a party is fully appropriate when the other party is confronted with the often formidable task of establishing a negative averment.

28. Health and Environment ⇐28

Burden on Environmental Protection Agency to support methodology employed in predicting feasibility of technology to meet 1975 emission standards prescribed for light-duty vehicles required more than reliance on the unknown, either by speculation, or merely shifting burden of proof back to vehicle manufacturers, seeking a one-year suspension of the 1975 standards. Clean Air Act, § 202(b)(5)(D) as amended 42 U.S.C.A. § 1857f-1(b)(5)(D).

29. Administrative Law and Procedure ⇐741

A court's role on judicial review embraces that of a constructive cooperation with the Agency involved in furtherance of the public interest.

30. Health and Environment ⇐28

Requirement of a "reasoned decision" by Environmental Protection Agency on application for one-year suspension of 1975 exhaust emission standards prescribed for light-duty vehicles meant a reasoned presentation of the reliability of prediction and methodology relied on to overcome conclusion of lack of available technology, which conclusion was supported prima faciely by the only actual and observed data available, to wit, the vehicle manufacturers' testing. Clean Air Act, § 202(b)(5)(D) as amended 42 U.S.C.A. § 1857f-1(b)(5)(D).

31. Health and Environment ⇐28

Proceedings on application for one-year suspension of 1975 exhaust emission standards for light-duty vehicles were required to be remanded for further proceedings where vehicle manufacturers established by preponderance of record evidence that technology was not available within meaning of Clean Air Act; Administrator's reliance on technological methodology to offset actual test results raised serious doubts and failed to meet burden of proof assignable to him when considering that risk of erroneous denial of suspension outweighed risk of erroneous grant of suspension, National Academy of Science had considered that technology was not available to meet standards by 1975 and statutorily required determinations of public interest and good faith had not been made. Clean Air Act, § 202(b)(5)(D) as amended 42 U.S.C.A. § 1857f-1(b)(5)(D).

32. Health and Environment ⇐28

Provision for one-year suspension of 1975 emission standards for light-duty vehicles was a purposeful cushion, with the twin purpose of providing "escape hatch" relief for 1975, and thus establishing a context supportive of the rigor and firmness of the basic standards slated for no later than 1976; the overall legislative firmness did not necessarily acquire a "hard-nosed" approach to application for suspension. Clean Air Act, § 202(b)(5)(D) as amended 42 U.S.C.A. § 1857f-1(b)(5)(D).

33. Health and Environment ⇐28

Conclusion of National Academy of Sciences as to availability of technology to meet 1975 exhaust emission standards prescribed for light-duty vehicles is a necessary, but not a sufficient consideration, for one-year suspension of standards; while Environmental Protection Agency in consideration of other conditions of suspension, was not necessarily

bound by NAS's approach, particularly as to matters interlaced with policy and legal aspects, EPA could not alter conclusion of NAS as to unavailability of technology by revising NAS assumptions, or injecting new ones, unless it stated its reasons for finding reliability, such as by challenging NAS approach in terms of later acquired research and experience. Clean Air Act, § 202(b)(5)(D) as amended 42 U.S.C.A. § 1857f-1(b)(5)(D).

34. Health and Environment ⇐28

On remand, for further consideration, of proceeding seeking one-year suspension of 1975 exhaust emission standards for light-duty vehicles the interest of justice and mutual regard for congressional objective require that the parties have opportunity to address themselves to matters not previously put before them by Environmental Protection Agency for comment, including material contained in administrator's Technical Appendix filed subsequent to denial. Clean Air Act, § 202(b)(5)(D) as amended 42 U.S.C.A. § 1857f-1(b)(5)(D); 28 U.S.C.A. § 2106.

35. Health and Environment ⇐28

Court of Appeals could not order one-year suspension of 1975 exhaust emission standards for light-duty vehicles where determinations which Congress had made necessary conditions of suspension, to wit, public interest and good faith, had not been made by Administrator of Environmental Protection Agency. Clean Air Act, § 202(b)(5)(D) as amended 42 U.S.C.A. § 1857f-1(b)(5)(D).

36. Health and Environment ⇐28

Initial statutory requirement that Environmental Protection Agency decision on request for one-year suspension of 1975 exhaust emission standards prescribed for light-duty vehicles be made within 60 days of application did not preclude further consideration following remand by Court of Appeals; however, on remand, it would be required that suspension deliberations be complete within 60 days. Clean Air Act, §§ 202(b)(5)(B), 307(b)(1) as amended 42 U.S.C.A. §§ 1857f-1(b)(5)(B), 1857h-5(b)(1).

37. Health and Environment ⇐25.5

Requirements of National Environmental Policy Act are subject to a construction of reasonableness. National Environmental Policy Act of 1969, § 2 et seq., 42 U.S.C.A. § 4321 et seq.

38. Health and Environment ⇐25.10

To require that, in addition to a decision setting forth the same considerations, the Environmental Protection Agency file an environmental impact statement in connection with decision on application for one-year suspension of 1975 exhaust emission standards for light-duty vehicles would be a legalism carried to the extreme. Clean Air Act, § 202(b)(5)(D) as amended 42 U.S.C.A. § 1857f-1(b)(5)(D); National Environmental Policy Act of 1969, § 2 et seq., 42 U.S.C.A. § 4321 et seq.

39. Health and Environment ⇐28

Environmental Protection Agency's determination on applications for one-year suspension of 1975 exhaust emission standards for light-duty vehicles could consist of a conditional suspension that would result in higher standards than an outright grant of application for suspension. Clean Air Act, § 202(b)(5)(D) as amended 42 U.S.C.A. § 1857f-1(b)(5)(D).

Reuben L. Hedlund, of the Bar of the Supreme Court of Illinois, pro hac vice, by special leave of the Court, with whom Lawrence Gunnels, Chicago, Ill., was on the brief for petitioner in No. 72-1517.

Frederick M. Rowe, Washington, D. C., with whom Edward W. Warren, F. F. Hilder, Asst. Gen. Counsel, William L. Weber, Jr., Detroit, Mich., and Hammond E. Chaffetz, Washington, D. C., were on the brief for petitioner in No. 72-1525.

John E. Nolan, Jr., Washington, D. C., with whom Robert E. Jordan, III, William G. Christopher, Michael J. Mal-

ley, Richard H. Porter, Scott R. Schoenfeld, Washington, D. C., and Victor C. Tomlinson were on the brief for petitioner in No. 72-1529.

Howard P. Willens, Washington, D. C., with whom Jay F. Lapin, William P. Hoffman, Jr., Gerald Goldman, Washington, D. C., were on the brief for petitioner in No. 72-1537.

James A. Glasgow, Atty., Department of Justice, with whom Kent Frizzell, Asst. Atty. Gen., Edmund B. Clark and Raymond N. Zagone, Attys., Department of Justice, were on the brief for appellee.

Jerome Maskowski was on the brief for State of Michigan, amicus curiae.

Before BAZELON, Chief Judge, and TAMM and LEVENTHAL, Circuit Judges.

LEVENTHAL, Circuit Judge:

These consolidated petitions of International Harvester and the three major auto companies, Ford, General Motors and Chrysler, seek review[1] of a decision by the Administrator of the Environmental Protection Agency denying petitioners' applications, filed pursuant to Section 202 of the Clean Air Act,[2] for one-year suspensions of the 1975 emission standards prescribed under the statute for light duty vehicles in the absence of suspension.

I. STATEMENT OF THE CASE

The tension of forces presented by the controversy over automobile emission standards may be focused by two central observations:

(1) The automobile is an essential pillar of the American economy. Some 28 per cent of the nonfarm workforce draws its livelihood from the automobile industry and its products.[3]

(2) The automobile has had a devastating impact on the American environment. As of 1970, authoritative voices stated that "[a]utomotive pollution constitutes in excess of 60% of our national air pollution problem" and more than 80 per cent of the air pollutants in concentrated urban areas.[4]

A. *Statutory Framework*

Congressional concern over the problem of automotive emissions dates back to the 1950's,[5] but it was not until the passage of the Clean Air Act in 1965 that Congress established the principle of Federal standards for automobile emissions. Under the 1965 act and its successor, the Air Quality Act of 1967, the Department of Health, Education and Welfare was authorized to promulgate emission limitations commensurate with existing technological feasibility.[6]

The development of emission control technology proceeded haltingly. The Secretary of HEW testified in 1967 that

1. Under Section 307 of the Clean Air Act, 42 U.S.C. § 1857h-5(b)(1), which provides for direct review of the Administrator's decision by the United States Court of Appeals for the District of Columbia Circuit (all citations are to the 1970 edition of the U.S.Code).

2. 42 U.S.C. § 1857f-1(b)(5)(B).

3. Statement of Sen. Robert Griffin, 116 Cong.Rec. 33,081 (1970).

4. For the 60% figure, *see* H.R.Rep.No. 91-1146, 91st Cong., 2d Sess., 6 (1970); for 64% national figure and the 80% urban figure, see statement of Nat'l Assoc. of Professional Engineers in Hearings on S. 3229, S. 3466, and S. 3546, before Subcomm. on Air and Water Pollution, Senate Comm. on Public Works, 91st Cong., 2d Sess., 114 (1970).

5. The Act of July 14, 1955, Ch. 360, §§ 1-7, 69 Stat. 322, authorized the Department of Health, Education and Welfare to provide research and assistance to local and state governments attempting to deal with air pollution. The Act of June 8, 1960, 74 Stat. 162, called for a federal study on the specific problem of automotive emissions.

6. Motor Vehicle Air Pollution Control Act § 202(a), P.L. 89-272, Oct. 20, 1965, 79 Stat. 992 (Amendments to Clean Air Act); National Emission Standards Act § 202(a), P.L. 90-148, Nov. 21, 1967, 81 Stat. 499 (part of Air Quality Act of 1967).

"the state of the art has tended to meander along until some sort of regulation took it by the hand and gave it a good pull. . . . There has been a long period of waiting for it, and it hasn't worked very well."[7]

The legislative background must also take into account the fact that in 1969 the Department of Justice brought suit against the four largest automobile manufacturers on grounds that they had conspired to delay the development of emission control devices.[8]

On December 31, 1970, Congress grasped the nettle and amended the Clean Air Act to set a statutory standard for required reductions in levels of hydrocarbons (HC) and carbon monoxide. (CO) which must be achieved for 1975 models of light duty vehicles. Section 202(b) of the Act added by the Clean Air Amendments of 1970, provides that, beginning with the 1975 model year, exhaust emission of hydrocarbons and carbon monoxide from "light duty vehicles" must be reduced at least 90 per cent from the permissible emission levels in the 1970 model year.[9] In accordance with the Congressional directives, the Administrator on June 23, 1971, promulgated regulations limiting HC and CO emissions from 1975 model light duty vehicles to .41 and 3.4 grams per vehicle mile respectively. 36 Fed.Reg. 12,657 (1971).[10] At the same time, as required by section 202(b)(2) of the Act, he prescribed the test procedures by which compliance with these standards is measured.[11]

Congress was aware that these 1975 standards were "drastic medicine,"[12] designed to "force the state of the art."[13] There was, naturally, concern whether the manufacturers would be able to achieve this goal. Therefore, Congress provided, in Senator Baker's phrase, a "realistic escape hatch": the manufacturers could petition the Administrator of the EPA for a one-year suspension of the 1975 requirements, and Congress took the precaution of directing the National Academy of Sciences to undertake an ongoing study of the feasibility of compliance with the emission standards. The "escape hatch" provision addressed itself to the possibility that the NAS study or other evidence might indicate that the standards would be unachievable despite all good faith efforts at compliance. This provision was limited to a one-year suspension, which would defer compliance with the 90% reduction requirement until 1976. Under section 202(b)(5)(D) of the Act, 42 U.S.C. § 1857f-1(b)(5)(D), the Administrator is authorized to grant a one-year suspension

> only if he determines that (i) such suspension is essential to the public interest or the public health and wel-

7. Hearings on Air Pollution—1967, Hearings before the Subcomm. on Air and Water Pollution, Sen. Comm. On Public Works, 90th Cong., 1st Sess., pt. 3, 1155-1156 (1967).

8. The suit was settled by consent decree. United States v. Automobile Manufacturers Ass'n., 307 F.Supp. 617 (C.D.Cal. 1969), aff'd sub nom. City of New York v. United States, et al., 397 U.S. 248, 90 S.Ct. 1105, 25 L.Ed.2d 280 (1970).

9. 42 U.S.C. § 1857f-1(b)(1)(A) provides that "engines manufactured during or after model year 1975 shall contain standards which require a reduction of at least 90 per centum from emissions of carbon monoxide and hydrocarbons allowable under the standards . . . applicable to light duty vehicles and engines manufactured in model year 1970."

10. Section 1201.21 of this regulation also prescribes an oxides of nitrogen standard of 3.0 grams per vehicle mile for 1975. That standard has apparently not been challenged. In any event, it is not before us in the present case.

11. "Emission standards under paragraph (1), and measurement techniques on which such standards are based (if not promulgated prior to December 31, 1970), shall be prescribed by regulation within 180 days after such date." 42 U.S.C. § 1857f-1(b)(2).

12. Sen. Muskie, 116 Cong.Rec. 32,904 (1970).

13. 116 Cong.Rec. 33,120 (1970) (newspaper report of statement of Senator Eagleton introduced into the record by Senator Muskie).

fare of the United States, (ii) all good faith efforts have been made to meet the standards established by this subsection, (iii) the applicant has established that effective control technology, processes, operating methods, or other alternatives are not available or have not been available for a sufficient period of time to achieve compliance prior to the effective date of such standards, and (iv) the study and investigation of the National Academy of Sciences conducted pursuant to subsection (c) of this section and other information available to him has not indicated that technology, processes, or other alternatives are available to meet such standards.

The statute provides that an application for suspension may be filed any time after January 1, 1972, and that the Administrator must issue a decision thereon within 60 days. On March 13, 1972, Volvo, Inc., filed an application for suspension and thereby triggered the running of the 60 day period for a decision. 37 Fed.Reg. 5766 (March 21, 1972.)[14] Additional suspension requests were filed by International Harvester on March 31, 1972, and by Ford Motor Company, Chrysler Corporation, and General Motors Corporation on April 5, 1972. Public hearings were held from April 10–27, 1972. Representatives of most of the major vehicle manufacturers (in addition to the applicants), a number of suppliers of emission control devices and materials, and spokesmen from various public bodies and groups, testified at the hearings and submitted written data for the public record. The decision to deny suspension to all applicants was issued on May 12, 1972.

The Decision began with the statement of the grounds for denial: ". . . I am unable, on the basis of the information submitted by the applicants or otherwise available to me, to make the determinations required, by section 202 (b)(5)(D)(i), (iii), or (iv) of the Act."[15] The EPA Decision specifically focused on requirement (iii) that:

> the applicant has established that effective control technology, processes, operating methods, or other alternatives are not available or have not been available for a sufficient period of time to achieve compliance prior to the effective date of such standards . . .,

A Technical Appendix, containing the analysis and methodology used by the Administrator in arriving at his decision, was subsequently issued on July 27, 1972.

B. *Initial Decision of the Administrator*

The data available from the concerned parties related to 384 test vehicles run by the five applicants and the eight other vehicle manufacturers subpoenaed by the Administrator. In addition, 116 test vehicles were run by catalyst and reactor manufacturers subpoenaed by the Administrator. These 500 vehicles were used to test five principal types of control systems: noble metal monolithic catalysts, base metal pellet catalysts, noble metal pellet catalysts, reactor systems, and various reactor/catalyst combinations.

At the outset of his Decision, the Administrator determined that the most effective system so far developed was the noble metal oxidizing catalyst.[16] Addi-

14. Evidently the Administrator decided to avoid separate suspension hearings for different applicants and awaited further filings which he anticipated. Volvo's application triggered the time period on the assumption that all applications were to be considered together. For the subsequent filings, *see* 37 Fed.Reg. 7039 (April 7, 1972).

15. In re: Applications For Suspension of 1975 Motor Vehicle Exhaust Emission Standards, Decision of The Administrator, May 12, 1972 [hereinafter Decision], at 1.

16. *Id.* at 14.

tionally, he stated that the "most effective systems typically include: improved carburetion; a fast-release choke; a device for promoting fuel vaporization during warm-up; more consistent and durable ignition systems; exhaust gas recirculation; and a system for injecting air into the engine exhaust manifold to cause further combustion of unburned gases and to create an oxidizing atmosphere for the catalyst." [17] It was this system to which the data base was initially narrowed: only cars using this kind of system were to be considered in making the "available technology" determination.

The problem the Administrator faced in making a determination that technology was available, on the basis of these data, was that actual tests showed only one car with actual emissions which conformed to the standard prescribing a maximum of .41 grams, per mile, of HC and 3.4 grams per mile of CO.[18] No car had actually been driven 50,000 miles, the statutory "useful life" of a vehicle and the time period for which conformity to the emission standards is required.[19] In the view of the EPA Administrator, however, the reasons for the high test readings were uncertain or ambivalent.

Instead, certain data of the auto companies were used as a starting point for making a prediction, but remolded into a more useable form for this purpose. As the Administrator put it:[20]

> Much of the data reports emissions measured by test procedures different from the 1975 Federal test procedure and requires conversion to the 1975 procedure by calculations which cannot be regarded as precise. Emission data was frequently submitted without an adequate description of the vehicle being tested, the emission control systems employed, or the purpose of the test. The fuel and oil used in tests were not always specified. Adjustments made to components of the engine or emission control system were frequently made and seldom fully explained. In most cases, tests were not repeated, even where results departed significantly from established trends, and little or no information was submitted to explain the diagnosis of failure, where test results showed poor results. Most important, only a few test cars were driven to 20,000 miles or more, and no vehicle employing all components of any applicant's proposed 1975 control systems has yet been driven to 50,000 miles. *In the face of these difficulties, analysis and interpretation of the data required assumptions and analytical approaches which will necessarily be controversial to some degree.* (emphasis added)

In light of these difficulties, the Administrator "adjusted" the data of the auto companies by use of several critical assumptions.

First, he made an adjustment to reflect the assumption that fuel used in 1975 model year cars would either contain an average of .03 grams per gallon or .05 grams per gallon of lead.[21] This usually resulted in an increase of emissions predicted, since many companies

17. *Id.*

18. This was Chrysler car #333, but even this car had not been run 50,000 miles; and conformity with the 1975 standard depended on not taking into account certain emissions over the standards, claimed by the Administrator to be due to engine malfunction. *See* Appendix C to the Decision of the Administrator, Analysis of Vehicle Test Data [hereinafter Technical Appendix], at 17.

19. 42 U.S.C. § 1857f-1(d) provides that "The Administrator shall prescribe regulations under which the useful life of vehicles and engines shall be determined . . . . . " for purposes of the 1975 standards. "Such regulations shall provide that useful life shall—(1) in the case of light duty vehicles and light duty vehicle engines, be a period of use of five years or of fifty thousand miles (or the equivalent), whichever first occurs . . . . ."

20. Decision at 16–17.

21. *Id.* at 18.

had tested their vehicles on lead-free gasoline.

Second, the Administrator found that the attempt of some companies to reduce emissions of nitrogen oxides below the 1975 Federal standard of 3.0 grams per vehicle mile [22] resulted in increased emissions of hydrocarbons and carbon monoxide. This adjustment resulted in a downward adjustment of observed HC and CO data, by a specified factor.[23]

Third, the Administrator took into account the effect the "durability" of the preferred systems would have on the emission control obtainable. This required that observed readings at one point of usage be increased by a deterioration factor (DF) to project emissions at a later moment of use. The critical methodological choice was to make this adjustment from a base of emissions observed at 4000 miles. Thus, even if a car had actually been tested over 4000 miles, predicted emissions at 50,000 miles would be determined by multiplying 4000 mile emissions by the DF factor.[24]

Fourth, the Administrator adjusted for "prototype-to-production slippage." This was an upward adjustment made necessary by the possibility that prototype cars might have features which reduced HC and CO emissions, but were not capable of being used in actual production vehicles.[25]

Finally, in accord with a regulation assumed, as to substance, in the text of the Decision, but proposed after the suspension hearing,[26] a downward adjustment in the data readings was made on the basis of the manufacturers' ability, in conformance with certification procedures, to replace the catalytic converter "once during 50,000 miles of vehicle operation," a change they had not used in their testing.[27]

With the data submitted and the above assumptions, the Administrator concluded that no showing had been made that requisite technology was not available. The EPA noted that this did not mean that the variety of vehicles produced in 1975 would be as extensive as before. According to EPA, "Congress clearly intended to require major changes in the kinds of automobiles produced for sale in the United States after 1974" and there "is no basis, therefore, for construing the Act to authorizing suspension of the standards simply because the range of performance of cars with effective emission control may be restricted as compared to present cars." As long as "basic demand" for new light duty motor vehicles was satisfied, the applicants could not establish that technology was not available.[28]

For purposes of judicial review, the initial EPA decision rests on the technology determination. The Administrator did state:[29]

> On the record before me, I do not believe that it is in the *public interest* to grant these applications, where compliance with 1975 standards by application of present technology can probably be achieved, and where ample additional time is available to manufacturers to apply existing technology to 1975 vehicles. (Emphasis added.)

The statute apparently contemplates the possibility of an EPA denial of suspension for failure to meet criterion (i) of § 202(b)(5)(D) ("essential to the public interest") even though criterion (iii) has been satisfied ("applicant has established that effective control technology . . . [is] not available").[30] It suffices here

22. *See* note 10 *supra*.

23. Decision at 18.

24. *Id.* The choice of 4000 mile emissions as a base point corresponds to certification testing procedures. 37 Fed.Reg. 24,250, 24,263 (1972), § 85.073-28.

25. Decision at 20.

26. 37 Fed.Reg. 23,778 (November 8, 1972).

27. Decision at 20.

28. *Id.* at 9.

29. *Id.* at 30.

30. See Part III of the opinion where factors which might properly enter into such a determination are discussed.

to say that the EPA's 1972 "public interest" finding was obviously only a restatement of, and dependent on the validity of, the conclusion of a failure to satisfy standard (iii) by showing that effective control technology is not available.

The Administrator also offered some "comments" on issues pertinent to the required "good faith" determination under standard (ii), as guidance to applications who might seek a one year suspension next year of the 1976 oxides of nitrogen standard. But he explictly disclaimed reaching that question in this proceeding. The thrust of his comment was to call into question the rigid "arms length" relationship structure which vehicle manufacturers imposed on their suppliers, as a source of a halter on progress in developing the required technology.[31]

C. *This Court's December 1972 Remand*

After oral argument to this court on December 18, 1972, in a per curiam order issued December 19, 1972, we remanded the record to the Administrator, directing him to supplement his May 12, 1972 decision by setting forth:

> (a) the consideration given by the Administrator to the January 1, 1972 Semiannual Report on Technological Feasibility of the National Academy of Sciences; and (b) the basis for his disagreement, if any, with the findings and conclusion in that study concerning the availability of effective technology to achieve compliance with the 1975 model year standards set forth in the Act.

Our remand order was not intended to indicate that we had concluded that an EPA conclusion was required as to clause (iv)—concerning the evaluation based on the NAS study and other information (from sources other than applicants)—when the Administrator had determined under (iii) that the auto companies had not shown technology was not available. We were nevertheless troubled by arguments advanced by petitioners that the methodology used by the Administrator in reaching his conclusion, and indeed the conclusion itself, was inconsistent with that of the Academy. It was our view that if and to the extent such differences existed they should be explained by EPA, in order to aid us in determining whether the Administrator's conclusion under (iii) rested on a reasoned basis.

D. *Supplement to the Decision of the Administrator*

Our remand of the record resulted in a "Supplement to Decision of the Administrator" issued December 30, 1972. The Administrator in his Supplement stated that "In general I consider the factual findings and technical conclusions set forth in the NAS report and in the subsequent Interim Standards Report dated April 26, 1972 . . . to be consistent with my decision of May 12, 1972."[32]

The Report made by the NAS, pursuant to its obligation under 202(b)(5)(D) of the Clean Air Act, had concluded: "The Committee finds that the technology necessary to meet the requirements of the Clean Air Act Amendments for 1975 model year light-duty motor vehicles is not available at this time."[33]

The Administrator apparently relied, however, on the NAS Report to bolster his conclusion that the applicants had not established that technology was un-

31. The Administrator noted, however, that the "closest working relationship between a vehicle manufacturer and a catalyst company that has been brought to my attention has been the Ford technical interchange arrangement with Englehard." Decision at 26.

32. In re: Applications For Suspension of 1975 Motor Vehicle Exhaust Emission Standards, Supplement to Decision of the Administrator, December 30, 1972 [hereinafter Supplement to Decision] at 1.

33. Committee on Motor Vehicle Emissions, National Academy of Sciences, Semiannual Report to the Environmental Protection Agency, January 1, 1972 [hereinafter NAS Report] at 49.

available. The same NAS Report had stated:[34]

> . . . the status of development and rate of progress made it possible that the larger manufacturers will be able to produce vehicles that will qualify, provided that provisions are made for catalyst replacement and other maintenance, for averaging emissions of production vehicles, and for the general availability of fuel containing suitably low levels of catalyst poisons.

The Administrator pointed out that two of NAS's provisos—catalytic converter replacement and low lead levels—had been accounted for in his analysis of the auto company data, and provision therefor had been insured through regulation.[35] As to the third, "averaging emissions of production vehicles," [36] the Administrator offered two reasons for declining to make a judgment about this matter: (1) The significance of averaging related to possible assembly-line tests, as distinct from certification test procedure, and such tests had not yet been worked out. (2) If there were an appropriate assembly-line test it would be expected that each car's emissions could be in conformity, without a need for averaging, since the assembly line vehicles "equipped with fresh catalysts can be expected to have substantially lower emissions at zero miles than at 4000 miles." [37]

The Administrator also claimed that he had employed the same methodology as the NAS used in its Interim Standards Report, evidently referring to the use of 4000 mile emissions as a base point, and correction for a deterioration factor and a prototype-production slippage factor.[38] The identity of methodology was also indicated, in his view, by the fact the EPA and NAS both agreed on the component parts of the most effective emission control system.

The Administrator did refer to the "severe driveability problems" underscored by the NAS Report, which in the judgment of NAS "could have significant safety implications," [39] stating that he had not been presented with any evidence of "specific safety hazard" nor knew of any presented to the NAS. He did not address himself to the issue of performance problems falling short of specific safety hazards.

II. REJECTION OF MANUFACTURERS' GENERAL CONTENTIONS

We begin with consideration, and rejection, of the broad objections leveled by petitioners against EPA's over-all approach.

A. *Future Technological Developments*

[1] We cannot accept petitioners' arguments that the Administrator's determination whether technology was "available," within the meaning of section 202(b)(5)(D) of the Act, must be based solely on technology in being as of the time of the application, and that the requirement that this be "available" precludes any consideration by the Administrator of what he determines to be the "probable" or likely sequence of the technology already experienced. Congress recognized that approximately two years' time was required before the start of production for a given model year, for the preparation of tooling and manufacturing processes.[40] But Congress did not decide—and there is no reason

34. *Id.*

35. Supplement to Decision at 2–3.

36. *Id.* at 3–4.

37. *Id.* at 4, quoting from Decision at 11.

38. *See* Committee on Motor Vehicle Emissions, National Academy of Sciences, Interim Standards Report, April 26, 1972 [hereinafter Interim Standards Report].

39. NAS Report at 30.

40. Although various estimates were made during the debate, the consensus seemed to be that two years is the most reasonable estimate. This was apparently the understanding of the Conference Committee. *See* 116 Cong.Rec. 42,522 (1970) (Rep. Staggers, Manager on the part of the House).

for us to do so—that all development had to be completed before the tooling-up period began. The manufacturers' engineers have admitted that technological improvements can continue during the two years prior to production.[41] Thus there was a sound basis for the Administrator's conclusion that the manufacturers could "improve, test, and apply" technology during the lead time period.[42]

The petitioners' references to the legislative history are unconvincing. None of the statements quoted in their briefs specifically states that "available" as used in the statute means "available in 1972." There is even comment that points to a contrary interpretation.[43] In any event, we think the legislative history is consistent with the EPA's basic approach and evidences no ascertainable legislative intent to the contrary.

[2, 3] While we reject the contention as broadly stated, principally by General Motors, we hasten to add that the Administrator's latitude for projection is subject to the restraints of reasonableness, and does not open the door to "'crystal ball' inquiry."[44] The Administrator's latitude for projection is unquestionably limited by relevant considerations of lead time needed for production.[45] Implicit also is a requirement of reason in the reliability of the EPA projection. In the present case, the Administrator's prediction of available technology was based on known elements of existing catalytic converter systems. This was a permissible approach subject, of course, to the requirement that any technological developments or refinements of existing systems, used as part of the EPA methodology, would have to rest on a reasoned basis.

B. *Claimed Right of Cross-Examination*

Chrysler has advanced a due process claim based upon two principal features of the proceeding, the inability to engage in cross-examination and the inability to present arguments against the methodology used in the Technical Appendix of the Administrator, which served as a basis for his decision.

The suspension provision of Section 202(b)(5)(D) does not require a trial type hearing. It provides:

> Within 60 days after receipt of the application for any such suspension, and after public hearing, the Administrator shall issue a decision granting or refusing such suspension.

[4] First, this provision for a "public hearing" contrasts significantly with other provisions that specifically require an adjudicatory hearing.[46] More importantly, the nonadjudicatory nature of the "public hearing" contemplated is underscored by the 60 day limit for a decision to be made. The procedure contemplated by Congress in its 1970 legislation must be appraised in light of its

41. In testimony before the Administrator, Ford's Vice President for Engineering and Manufacturing identified as the "last date for incorporation of proven new technology" November 1, 1973—16 months after the start of the tooling-up period. He testified that the companies could be "developing engineering solutions" until that date. Hearing Tr. at 1916; *cf. id.* at 2033–4. Cf. Statement of Lee A. Iacocca in Hearings on S. 3229, S. 3446, S. 3546, before Subcomm. on Air and Water Pollution, Senate Comm. on Public Works, 91st Cong., 2d Sess., pt. 5, 1620–1621 (1970).

42. Decision at 29.

43. *See* 116 Cong.Rec. 33,086–87 (1970) (Statement of Senator Gurney).

44. National Resources Defense Council, Inc. v. Morton, 148 U.S.App.D.C. 5, 15, 458 F.2d 827, 837 (1972).

45. Remarks of Senator Gurney, 116 Cong. Rec. 33,086 (1970).

46. For instances in the Act where adjudicatory hearings are called for, see § 110(f)(2), 42 U.S.C. § 1857c-5(f)(2) hearing on one-year postponement of a plan requirement on application of State Governor); § 206(b)(2)(B), 42 U.S.C. § 1857f-5(b)(2)(B) (hearing on suspension or revocation of motor vehicle certifications). Both determinations must be made "on the record".

concern with "avoidance of previous cumbersome and time-consuming procedures," *see* Kennecott Copper Corp. v. EPA, 149 U.S.App.D.C. 231, 234, 462 F.2d 846, 849 (1972).

As to legislative history of this provision, the starting point is the provision in Senate Bill 4358:[47]

> Upon receipt of such application, the Secretary shall promptly hold a public hearing to enable such manufacturer or manufacturers to present information relevant to the implementation of such standard. The Secretary, in his discretion, may permit any interested person to intervene to present information relevant to the implementation of such standard.

This was dropped in conference, along with a provision permitting six months for a suspension decision. The resulting legislation both expedited the decision-making, and contemplated EPA solicitation of a wide range of views, from sources other than the auto companies, though the companies' applications and presentation would surely be the focus of consideration. Underlying this approach of both shortening time for decision and enlarging input lies, we think, an assumption of an informative but efficient procedure without mandate for oral cross examination.

[5, 6] In context, the "public hearing" provision amounts to an assurance by Congress that the issues would not be disposed of merely on written comments, the minimum protection assured by the Administrative Procedure Act for rule-making, but would also comprehend oral submissions of a legislative nature. These are required even for rule-making when "controversial regulations governing competitive practices" are involved. American Airlines, Inc. v. CAB, 123 U.S. App.D.C. 310, 317, 359 F.2d 624, 631 (en banc 1966), cert. denied, 385 U.S. 843, 87 S.Ct. 73, 17 L.Ed.2d 75 (1966); Walter Holm & Co. v. Hardin, 145 U.S.App. D.C. 347, 449 F.2d 1009 (1971). Even assuming oral submission, in a situation where "general policy" is the focal question, a legislative-type hearing is appropriate.[48]

[7-9] A complication is presented by the case before us in that the general policy questions became interfused with relatively specific technical issues. Yet within the context of a quasi-legislative hearing and the time constraints of the statute, we do not think the absence of a general right of cross-examination on the part of the companies was a departure from "basic considerations of fairness." Walter Holm & Co. v. Hardin, *supra*, 145 U.S.App.D.C. at 354, 449 F. 2d at 1016. Hearings ran for two weeks and a wide range of participants was included within the proceeding: manufacturers, vendors of the control devices and public interest groups. The auto companies were allowed to submit written questions to the Hearing Panel to be asked to various witnesses. Opportunity to prepare written questions is not as satisfactory to counsel as the opportunity to proceed on oral cross-examination, with questions that develop from previous answers. But examination on interrogatories has long been used in the law when necessary, albeit second best. And

47. *See* S. 4358, 91st Cong., 2d Sess., printed in S.Rep. No. 91-1196, 91st Cong., 2d Sess. 103 (1970).

48. *See* United States v. Florida East Coast R. Co., 410 U.S. 224, 93 S.Ct. 810, 35 L.Ed.2d 223 (1973) where the Court held that rule-making hearings, under 5 U.S.C. § 553, are sufficient where the agency's statute provides for a "hearing." The provision of 5 U.S.C. § 556(d) which gives the opportunity for cross-examination as a matter of right, would only be automatically applicable if "rules are required by statute to be made *on the record* after opportunity for an agency hearing . . . ." (emphasis added). Without the precise words "on the record," § 556 does not automatically apply. At 241, 93 S.Ct. 810.

The words "on the record" are not incorporated into Section 202(b)(5)(D). Only a "public hearing" is required. Moreover, subsection (iv) of that provision allows consideration by the Administrator of "other information available to him" in reaching a conclusion on "available technology."

interrogatories to a live witness—often arranged in private lawsuits by use of a commission—avoid the peril of "canned" affidavits and counsel-assisted, or even counsel-drafted, responses to interrogatories. Their availability was a reasonable attempt by EPA to elicit the facts and at the same time cope with the time constraints. We do not think more was required. There was a meaningful opportunity to be heard. The specific nature of a "hearing" varies with circumstances. Cafeteria & Restaurant Workers Union v. McElroy, 367 U.S. 886, 895, 81 S.Ct. 1743, 6 L.Ed.2d 1230 (1961), cited with approval in Goldberg v. Kelly, 397 U.S. 254, 268, 90 S.Ct. 1011, 25 L.Ed.2d 287 (1970). Whether particular attributes of forensic presentation are not only salutary but also mandatory must also depend on circumstances. The heft of the hearing problem, including the time constraints on decisions, convinces us that the assertion of a broad right of cross-examination cannot be successfully maintained.

We distinguish between the assertion of a broad right of cross-examination, such as that argued to this court, and a claim of a need for cross-examination of live witnesses on a subject of critical importance which could not be adequately ventilated under the general procedures. This is the kind of distinction that this court made in its en banc opinion in American Airlines v. CAB, *supra*, 123 U.S.App.D.C. at 318–319, 359 F.2d at 632–633. We see no principled manner in which firm time limits can be scheduled for cross-examination consistent with its unique potential as an "engine of truth"—the capacity given a diligent and resourceful counsel to expose subdued premises, to pursue evasive witnesses, to "explore" the whole witness, often traveling unexpected avenues.

Given the variances in counsel, the reality that seasoning and experience are required even for trial judges who seek to avoid repetitive and undue cross-examination, the enhancement of difficulties encountered with the breadth of issues involved in a "public interest" proceeding, the fairly-anticipated problem of provision for redirect (and recross) and the interplay of different cross-examinations, there is not insignificant potential for havoc. What is most significant is that these complications are likely to be disproportionate to the values achieved, in a proceeding focusing on technical matters where other techniques generally are sufficient to adduce the pertinent information as to both what is known and unknown.

In context, we consider that the technique, adopted by EPA, of pre-screening written questions submitted in advance is reasonable and comports with basic fairness as the general procedure. This approach permits screening by the hearing officer so as to avoid irrelevance and repetition, permits a reasonable estimate of the time required for the questioning, and aids scheduling and allocation of available time among various participants and interests.[49] The record reveals that the hearing officers did not propound the pre-submitted questions like robots; they were charged with conducting a hearing for the purpose of focusing information needed for decision, and they quite appropriately "followed up" on questions.

We revert to our observation that a right of cross-examination, consistent with time limitations, might well extend to particular cases of need, on critical points where the general procedure proved inadequate to probe "soft" and sensitive subjects and witnesses. No such circumscribed and justified requests were made in this proceeding.

C. *Right To Comment on EPA Methodology*

[10–12] A more serious problem, at least from the point of an informed decision-making process, is posed by the

49. The procedure adopted may be justified, in part, on grounds like those supporting voir dire by the trial judge, using questions submitted by counsel. *See* United States v. Bryant, 153 U.S.App.D.C. 72, 471 F.2d 1040 (1972).

inability of petitioners to challenge the methodology of EPA at the hearing. In other contexts, it is commonplace for administrative proceedings to focus in detail on agency methodology,[50] and such elucidation is salutary, of particular aid to a reviewing court. Again, however, we cannot ignore the problem of time. In part, EPA developed its methodology on the basis of submissions made by the companies at the hearings, as to the parameters of its various data. The requirement of submission of a proposed rule for comment does not automatically generate a new opportunity for comment merely because the rule promulgated by the agency differs from the rule it proposed, partly at least in response to submissions.[51] Given the circumstances, we cannot hold the absence of the right to comment on the methodology a violation of the statute or due process, though such opportunity would certainly have been salutary.

[13, 14] While the statute makes no express provision therefor, we assume that Congress contemplated a flexibility in the administrative process permitting the manufacturers to present to EPA any comments as to its methodology, in a petition for reconsideration or modification. However, this opportunity does not permit invocation of the doctrine of failure to exhaust administrative remedies as a bar to these appeals, for those petitions could not have affected or deferred the finality of the EPA decision or the time for seeking judicial review. The opportunity is noted to obviate any possibility that the law, or our comments, may be misunderstood to require a rigid procedure of prompt and unshakeable decision-making. Our own December remand requesting clarification of the Decision illustrates that while this statute imposes some unusual time restraints it does not jettison the flexibility and capacity of reexamination that is rooted in the administrative process. American Airlines v. CAB, *supra*, 123 U.S. App.D.C. at 319; 359 F.2d at 633.

As matters have shaped up, the central technical issue on this appeal concerns the reliability of EPA's methodology. While we do not say that the failure to provide reasonable opportunity to comment on EPA methodology invalidates the EPA Decision for lack of procedural due process, or similar contention, we must in all candor accompany that ruling with the comment that the lack of such opportunity has had serious implications for the court given the role of judicial review.

We shall subsequently develop the legal questions, primarily questions of EPA's burden of proof, that arise with respect to EPA methodology. We preface these with admission of our doubts and diffidence. We are beset with contentions of petitioners that bear indicia of substantiality. Yet we have no EPA comment on the specific questions raised, apart from some discussion by counsel which is not an adequate or appropriate substitute.[52] Our December 1972 re-

50. *E. g.*, Permian Basin Area Rate Cases, 390 U.S. 747, 88 S.Ct. 1344, 20 L.Ed.2d 312 (1968).

51. A contrary rule would lead to the absurdity that in rule-making under the APA the agency can learn from the comments on its proposals only at the peril of starting a new procedural round of commentary.

As we have stated in an analogous context of rule-making proceedings before the Federal Communications Commission, where petitioners have argued that the Commission was "changing the rules in the middle of the game" when it took into consideration factors not specifically indicated in its Section 4(a) notice under the Administrative Procedure Act, 5 U.S.C. § 1001(a), "[s]urely every time the Commission decided to take account of some additional factor it was not required to start the proceedings all over again. If such were the rule the proceedings might never be terminated." Owensboro On the Air v. United States, 104 U.S.App.D.C. 391, 397, 262 F.2d 702, 708 (1958); Logansport Broadcasting Corp. v. United States, 93 U.S.App.D.C. 342, 346, 210 F.2d 24, 28 (1954).

52. Burlington Truck Lines v. United States, 371 U.S. 156, 168-9, 9 L.Ed.2d 207 (1962); Braniff Airways, Inc. v. CAB, 126 U.S.App.D.C. 399, 411, 379 F.2d 453, 465 (1967).

mand opened the door to a candid discussion of these matters, but EPA fashioned a carefully limited response.

The EPA might have indicated that it desired to take a fresh look at its methodology on the basis of petitioners' criticisms, in which case, on an adaptation of the Smith v. Pollin,[53] procedure, this court might have remanded the case to the agency. This remand would come during the course of our judicial review and would not conflict with the 60-day statutory time limit for the hearing and decision on the applications for suspension.

Indeed, the fact that the Administrator issued the Technical Appendix almost three months after his Decision, at a time when judicial review had already begun to run its course, indicates that the agency did not believe that agency consideration was frozen from the moment that the suspension decision was rendered, a view we approve. The EPA had latitude to continue further consideration even without requesting a court remand (under Smith v. Pollin) that would suspend judicial consideration.

III. OVERALL PERSPECTIVE OF SUSPENSION ISSUE

This case ultimately involves difficult issues of statutory interpretation, as to the showing required for applicants to sustain their burden that technology is not available. It also taxes our ability to understand and evaluate technical issues upon which that showing, however it is to be defined, must rest. At the same time, however, larger questions are at stake. As Senator Baker put it, "This may be the biggest industrial judgment that has been made in the United States in this century." 116 Cong.Rec. 33,085 (1970). This task of reviewing the suspension decision was not assigned to us lightly. It was the judgment of Congress that this court, isolated as it is from political pressures, and able to partake of calm and judicious reflection would be a more suitable forum for review than even the Congress.[54]

Two principal considerations compete for our attention. On the one hand, if suspension is not granted, and the prediction of the EPA Administrator that effective technology will be available is proven incorrect, grave economic consequences could ensue. This is the problem Senator Griffin described as the "dangerous game of economic roulette." 116 Cong.Rec. 33,081 (1970). On the other hand, if suspension is granted, and it later be shown that the Administrator's prediction of feasibility was achievable in 1975 there may be irretrievable ecological costs. It is to this second possibility we first turn.

A. *Potential Environmental Costs*

The most authoritative estimate in the record of the ecological costs of a one-year suspension is that of the NAS Report. Taking into account such "factors as the vehicle-age distribution among all automobiles, the decrease in vehicle miles driven per year, per car as vehicle age increases, the predicted nationwide growth in vehicle miles driven each year" and the effect of emission standards on exhaust control, NAS concluded that:[55]

> . . . the effect on total emissions of a one-year suspension with no additional interim standards appears to be small. The effect is not more significant because the emission reduction now required of model year 1974 vehicles, as compared with uncontrolled vehicles (80 percent for HC and 69 percent for CO), is already so substantial.

53. 90 U.S.App.D.C. 178, 194 F.2d 349 (1952). *See also* Greater Boston Television Corp. v. FCC, 149 U.S.App.D.C. 322, 463 F.2d 268 (1971).

54. An amendment to Senate Bill 4358 proposed by Senator Dole of Kansas, which would have made the suspension decision reviewable by Congress instead of the court, as proposed by the Committee, 116 Cong.Rec. 33,078 (1970), was rejected by the Senate, 116 Cong.Rec. 33,089 (1970).

55. NAS Report at 45–48.

Other considerations may diminish the costs even further. There seems to be agreement that there are performance costs for automobiles in employing pollution control devices, even if the effects on performance cannot fairly be characterized as constituting safety hazards. The NAS Report summarized the problem, as follows: [56]

> Three areas of vehicle performance are likely to be adversely affected by the 1975 emission control systems. These are fuel economy, vehicle-acceleration capability, and vehicle driveability (or ability to perform adequately in all normal operating modes and ambient conditions).

The question in this context is not whether these are costs the consumer should rightly bear if ecological damage is to be minimized, but rather the general effect on consumer purchasing of 1975 model year cars in anticipation of lower performance. A drop-off in purchase of 1975 cars will result in a prolonged usage of older cars with *less* efficient pollution control devices. If the adverse performance effect deterred purchasing significantly enough, resulting in greater retention of "older" cars in the "mix" of cars in use, it might even come to pass that total actual emissions (of all cars in use) would be greater under the 1975 than the 1974 standards.

Many of the anticipated performance problems are traceable to the systems introduced to conform cars to control of nitrogen oxides to achieve prescribed 1975 standards, by use of exhaust-gas recycle (EGR). Such systems affect vehicle-acceleration capability because the power output for a given engine displacement, engine speed, and throttle setting is reduced.[57] The NAS Report indicates that such systems could result in direct fuel-economy penalties of up to 12 percent compared with 1973 prototype vehicles.[58]

The NAS Report states that the effects of emission controls on vehicle driveability are difficult to quantify, but nevertheless makes the following qualitative evaluation: [59]

> Driveability after a cold-engine start, and especially with cold ambient conditions, is likely to be impaired. To reduce HC and CO emissions during engine warmup, the choke is set to release quickly, and the fuel-air mixture is leaned out as early as possible after engine startup. Under these conditions, problems of engine stall, and vehicle stumble and hesitation on rapid acceleration, have been prevalent.

The willingness of the consumer to buy 1975 model year cars may also be affected, to some degree, by the anticipated significant costs of pollution control devices. The problem is further bedeviled by the possibility that consumers albeit rightly assigned the cost burden of pollution devices, may seek to avoid that burden, however modest,[60] and to exercise, at least in some measure, an option to use older cars. Again, this would have the thrust of increasing actual total emissions of cars in use.

We may also note that it is the belief of many experts—both in and out of the automobile industry—that air pollution cannot be effectively checked until the industry finds a substitute for the conventional automotive power plant—the reciprocating internal combustion (*i. e.*,

56. *Id.* at 29.

57. *Id.*

58. *Id.*

59. *Id.* at 30.

60. The NAS estimated an increase in initial cost of about $214, *Id.* at 42, over the 1973–74 model year system, and $288 over the 1970 system. To this must be added the EPA assumption of at least one catalytic converter replacement during 50,000 miles of vehicle operation, *see* text at note 35, *supra*, and the possibility that considerable maintenance may be needed to keep converters at required level of efficient operation.

"piston") engine.[61] According to this view, the conventional unit is a "dirty" engine. While emissions from such a motor can be "cleaned" by various thermal and catalytic converter devices, these devices do nothing to decrease the production of emissions in the engine's combustion chambers. The automobile industry has a multi-billion-dollar investment in the conventional engine, and it has been reluctant to introduce new power plants or undertake major modifications of the conventional one.[62] Thus the bulk of the industry's work on emission control has focussed narrowly on converter devices. It is clear from the legislative history that Congress expected the Clean Air Amendments to force the industry to broaden the scope of its research—to study new types of engines and new control systems.[63] Perhaps even a one-year suspension does not give the industry sufficient time to develop a new approach to emission control and still meet the absolute deadline of 1976. If so, there will be ample time for the EPA and Congress, between now and 1976 to reflect on changing the statutory approach. This kind of cooperation, a unique three-way partnership between the legislature, executive and judiciary, was contemplated by the Congress[64] and is apparent in the provisions of the Act.[65]

The NAS estimated that there would be a small environmental cost to suspension of 1975 standards even if 1974 standards were retained, but further recommended intermediate standards that would dilute even such modest environmental cost.[66] The following table shows the various standards, and one put forward by Ford for 1975:

	Maximum emissions (grams per mile)	
	HC	CO
1974 standards	3.4	39.0
Ford proposal	1.6	19.0
NAS recommendation for Intermediate standards:		
No catalyst change	1.1	8.2
One catalyst change	0.8	6.3
1975 Standards	.41	3.4

Our concern that the 1975 standards may possibly be counter-productive, due to decreased driveability and increased cost, is not to be extrapolated into a caution against any improvement, and concomitant reduction in permitted emissions. In such matters, as the NAS recommendation for interim standards implicitly suggests, a difference in degree may be critical, and the insistence on absolute 1975 standards, without suspension or intermediate level, may stretch for the increment that is essentially counter-productive.

61. *See, e. g.*, U.S. General Accounting Office, Report to the Congress: Cleaner Engines for Cleaner Air, at 45–47 (May 15, 1972) (hereinafter "G.A.O. Report"); statement of Fred C. Hart, New York City Environmental Protection Agency, in Implementation of the Clean Air Act Amendments of 1970, Hearings before the Subcomm. on Air and Water Pollution, Senate Comm. on Public Works, 92nd Cong., 2d Sess., pt. 3, 1597 (1972).

62. The General Accounting Office reported in 1972 that the industry was "entrenched" in efforts to retain the conventional engine. G.A.O. Report at 45.

63. 116 Cong.Rec. 32,906 (1970) (Sen. Muskie); H.R.Rep. No. 91–1146, 91st Cong., 2d Sess. 6 (1970).

64. Congress made clear that it would be ready to exercise its right to intervene if it did not agree with the results its statutory "shock treatment" produced. *See* 116 Cong.Rec. 32,905 (1970) (Senator Muskie). Congress, through Oversight Hearings conducted by the Subcommittee on Air and Water Pollution of the United States Senate, continues to keep a watchful eye on the implementation of the Act. *See* Implementation of the Clean Air Act Amendments of 1970, Hearings before the Subcomm. on Air and Water Pollution, Senate Comm. on Public Works, 92d Cong., 2d Sess., pts. 1–3 (1972).

65. The Act provides for various progress reports to be made by the Administrator to the Congress, 42 U.S.C. § 1857j–1 and 2. Additional information is supplied by the Semiannual Reports of the National Academy of Sciences. 42 U.S.C. § 1857f–1(c). More particularly, the Act provides, 42 U.S.C. § 1857f–1(b)(4), for the EPA to make "recommendations for additional congressional action" which he deems advisable.

66. Interim Standards Report at 8.

We also observe that Ford Motor Company is on record as to capability of greater emission controls, *i. e.*, lower level of emissions, than those permitted for 1974 model year cars,[67] and Ford proposed that, given certain regulatory assumptions,[68] the Administrator adopt an interim standard of 1.6 gm/mi HC and 19.0 gm/mi CO levels, about one half those permitted for the 1974 model year cars.

On balance the record indicates the environmental costs of a one-year suspension are likely to be relatively modest. This must be balanced against the potential economic costs—and ecological costs—if the Administrator's prediction on the availability of effective technology is incorrect.

B. *Potential Economic Costs*

Theoretical possibility of industry shutdown

If in 1974, when model year 1975 cars start to come off the production line, the automobiles of Ford, General Motors and Chrysler cannot meet the 1975 standards and do not qualify for certification, the Administrator of EPA has the theoretical authority, under the Clean Air Act, to shut down the auto industry, as was clearly recognized in Congressional debate.[69] We cannot put blinders on the facts before us so as to omit awareness of the reality that this authority would undoubtedly never he exercised, in light of the fact that approximately 1 out of every 7 jobs in this country is dependent on the production of the automobile.[70] Senator Muskie, the principal sponsor of the bill, stated quite clearly in the debate on the Act that he envisioned the Congress acting if an auto industry shutdown were in sight.[71]

The economic consequence of an approach geared to stringency, relying on relaxation as a safety valve

A more likely forecast, and one which enlightens what influenced the EPA decision to deny the suspension, was articulated by George Allen, Deputy Assistant Administrator for General Enforcement and a member of EPA's Hearing Panel:[72]

> The problem really comes down to this: A decision has to be made next month, early next month. If the decision is to suspend the standards and adopt an interim standard . . . and in 1975 it turns out that technology exists to meet the statutory standard, today's decision turns out to be wrong.
>
> * * * * * *
>
> If, on the other hand, a decision is made today that the standards cannot lawfully be suspended, and we go down to 1975 and nobody can meet the standard, today's decision was wrong.
>
> In [the first] case, there is not much to do about the wrong decision; it was made, many people relied on it; it turns out the standard could have been met, but I doubt if we could change it.
>
> In the second case, if a wrong decision is made, there is probably a remedy, a re-application and a recognition by the agency that it is not technically feasible to meet the standards. You can correct the one; you probably can't correct the other.

67. JA at 954–59; Doc. No. 135, Vol. II at 5–18 to 5–23.

68. Ford's proposals were qualified by the following regulatory assumptions: (1) maximum lead grams per gallon of gasoline .03; (2) averaging of emissions for certification test procedures; (3) a methane allowance in interpreting hydrocarbon data; and (4) reasonable maintenance on durability test cars used in determining certification. Only the reasonable maintenance assumption corresponds to actual EPA regulations now in effect or proposed. Doc. No. 135, Vol. II, at 5–28 to 5–33.

69. 116 Cong.Rec. 32,905 (1970).

70. Estimate provided by Senator Griffin, 116 Cong.Rec. 32,906 (1970).

71. 116 Cong.Rec. 32,905 (1970).

72. Transcript at 2034–2035.

Grave problems are presented by the assumption that if technical feasibility proves to be a "wrong decision" it can be remedied by a relaxation.

Certain techniques available to the Administrator, through changes in the certification procedure, can be used in an even handed manner for all three auto companies to facilitate compliance with the 1975 standards. Already lower lead levels in fuel available for 1975 model year cars have been prescribed to increase the efficiency of the catalytic converter. Similarly certain changes in the regulatory system, through allowable maintenance and permitted change in the catalytic converter, have been made by EPA. These techniques work with reasonable impartiality as to the various auto companies.

However, a relaxation of standards, and promulgation of an interim standard, at a later hour—after the base hour for "lead time" has been passed, and the production sequence set in motion—forebodes quite different consequences. The record before us suggests that there already exists a technological gap between Ford and General Motors,[73] in Ford's favor. General Motors did not make the decision to concentrate on what EPA found to be the most effective system at the time of its decision—the noble metal monolithic catalyst. Instead it relied principally on testing the base metal catalyst as its first choice system.[74] In predicting that General Motors could meet the 1975 standards, EPA employed a unique methodological approach. Instead of taking emissions at 4000 miles of cars with preferred systems—with which none of the General Motors cars was equipped—and applying against this, adjustments for lead levels and deterioration, as had been done in the case of Ford and Chrysler, EPA took emissions at 4000 miles of GM cars which had no converters of any kind, and predicted how they would function with an Engelhard monolithic catalytic converter, based on auto manufacturers' use of this device in a number of cars—principally Ford's—when testing it for durability.[75] In his Supplemental Decision the Administrator recognized that this was a departure from NAS methodology, stating:[76]

> In its Interim Standards Report the National Academy recommended a methodology for predicting the emission levels achievable by manufacturers. This recommended methodology is the same methodology that was employed in the technical appendix to my decision in evaluating the test results of all manufacturers *except General Motors*. (Emphasis added.)

The case is haunted by the irony that what seems to be Ford's technological lead[77] may operate to its grievous detriment, assuming the relaxation-if-necessary approach voiced by Mr. Allen,[78] If

73. For purposes of a comparison, Chrysler is omitted from this comparison, although on the basis of the performance of car #333 and its testing of noble metal catalysts, Chrysler seems closer in technological advancement to Ford than to General Motors. *See* Technical Appendix at 17.

74. *Id.* at 44.

75. The data on the efficiency of the Engelhard converter was from converters tested principally on Ford vehicles. *Id.* at 53.

76. Supplement to Decision at 1.

77. See also discussion of good faith in Administrator's Initial Decision at 26, where Ford was singled out as the only auto company which has developed a close relationship with a vendor of emission control devices, in its case Engelhard.

78. We are not unaware of 42 U.S.C. § 1857b-6 which provides under certain specified procedures for the mandatory licensing of patents on pollution control devices to obviate competitive advantages. It provides:

> Whenever the Attorney General determines, upon application of the Administrator—
>
> (1) that—
>
> (A) in the implementation of the requirements of section 1857c-6, 1857c-7, or 1857f-1 of this title, a right under any United States letters patent, which is being used or intended for public or commercial use and not otherwise reasonably available, is necessary to enable any person required to comply with such limitation to so comply, and

in 1974, when certification of production vehicles begins, any one of the three major companies cannot meet the 1975 standards, it is a likelihood that standards will be set to permit the higher level of emission control achievable by the laggard. This will be the case whether or not the leader has or has not achieved compliance with the 1975 standards. Even if the relaxation is later made industry-wide, the Government's action, in first imposing a standard not generally achievable and then relaxing it, is likely to be detrimental to the leader who has tooled up to meet a higher standard than will ultimately be required.

In some contexts high achievement bestows the advantage that rightly belongs to the leader, of high quality. In this context before us, however, the high achievement in emission control results, under systems presently available, in lessened car performance—an inverse correlation. The competitive disadvantage to the ecological leader presents a forbidding outcome—if the initial assumption of feasibility is not validated, and there is subsequent relaxation—for which we see no remedy.[79]

C. *Light Weight Trucks*

We now take up the serious contention of International Harvester (IH) that the EPA decision effectively rules out the production of 1975 model year IH light weight trucks and multi-purpose passenger vehicles (MPVs). This requires us to focus on the Administrator's conception that the 1970 Clean Air Act envisioned restricting production of vehicles to that necessary to fill "basic demand." [80]

The Administrator does not dispute International Harvester's claim that it will not be able to produce the vehicles in question, and indeed the limited testing of one of its MPVs showed, even as evaluated by EPA methodology, that such standards could not be achieved.[81] Yet a suspension was not granted, presumably for the reasons advanced by EPA to this court, that International Harvester was "required to alter the performance characteristics of its vehicles in the interest of meeting the 1975 emission standards." [82] The inability of IH vehicles to meet the standards seems accountable by the uses to which they are

(B) there are no reasonable alternative methods to accomplish such purpose, and

(2) that the unavailability of such right may result in a substantial lessening of competition or tendency to create a monopoly in any line of commerce in any section of the country,

the Attorney General may so certify to a district court of the United States, which may issue an order requiring the person who owns such patent to license it on such reasonable terms and conditions as the court, after hearing, may determine. Such certification may be made to the district court for the district in which the person owning the patent resides, does business, or is found.

No application has, however, been made by the Administrator, presumably because his methodology predicts all three manufacturers can meet the 1975 standards. Moreover, there is no evidence on the record to show that converters will perform equally well on different vehicles. This option may be effectively foreclosed as the lead time for production is approached, at which point the companies will be committed to their own individually developed systems.

79. One could imagine some form of regulation through interim standards, whereby the laggard could be deprived of an expected windfall, through requiring some percentage of his vehicles to meet a standard which can only be met by the leader; but this form of economic regulation does not seem contemplated by Congress and would be subject to innumerable regulatory problems. Congressional indemnities might present a possibility. Obviously neither possibility could reasonably be taken into account as a basis for decision.

80. Decision at 9–10.

81. *See* Technical Appendix at 58–60.

82. (1) Brief of Respondent at 37. (Respondents submitted two briefs to this court, one responsive only to the petition of International Harvester in case No. 72-1517, the other responsive to all four petitioners. For reference the former is denoted as (1), the latter as (2).)

put, hauling large loads or towing heavy trailers. To serve this purpose vehicles must be designed with higher than normal axle ratios, thus requiring greater power from the engine and producing higher exhaust gas temperatures in order to attain any given speed.[83] Therefore, for all practical purposes a redesign of performance characteristics will preclude the present uses to which IH vehicles are put.

The Administrator, nonetheless, takes the position that International Harvester can be denied a suspension because he has found that "new car demand" will be satisfied by the production of the major auto companies, and thus apparently posits that the absence from the 1975 market of all light weight trucks and MPVs is fully consistent with the Act. We cannot agree.

[15, 16] Section 202(b)(1) of the Act applies its drastic standards to 1975 models of "light duty vehicles." It is our view that the legislative history reveals this term to mean "passenger cars." In the Report of the Senate Committee on Public Works on S.4358,[84] the Committee clearly distinguished between the automobile, which must "meet a rigid timetable and a high degree of emission control compliance," and other vehicles, such as "trucks and buses and other commercial vehicles," which are governed by a different authority to promulgate standards. At another point of the Senate Report, the legislative use of the term light duty vehicles, as interchangeable with passenger cars, is made even more clear:[85]

> The authority provided in section 202 (a) would continue to be available to the [Administrator] to establish standards for light duty motor vehicles (passenger cars) during the period prior to and following the effective date of the standards established by subsection (b).

References abound in Congressional debate to the same effect.[86] This kind of legislative intent must be given priority, in interpreting this law, over any presumption of continuance of prior administrative definitions of this term[87] or to the policy of upholding reasonable interpretations of statutes by administrative agencies[88] in the absence of other discernible legislative intent. Volkswagenwerk v. FMC, 390 U.S. 261, 272, 88 S.Ct. 929, 19 L.Ed.2d 1090 (1967); Greater Boston Television Corp. v. FCC (I), 143 U.S.App.D.C. 383, 392, 444 F.2d 841, 850, cert. denied, 403 U.S. 923, 91 S.Ct. 2229, 29 L.Ed.2d 701 (1971).

For the above reasons we cannot sustain the definition of "Light duty vehicle" as:[89]

> any motor vehicle either designed primarily for transportation of property and rated at 6,000 pounds GVW or less or designed primarily for transportation of persons and having a capacity of 12 persons or less

to the extent that it includes light weight trucks in the category that must meet the drastic emission reduction standards

83. Brief of IH at 24–25. *Also see* Transcript at 1167 et seq.

84. S.Rep. No. 91–1196, 91st Cong., 2d Sess. 23 (1970).

85. *Id.* at 24.

86. *See, e. g.*, 116 Cong.Rec. 42,383 (Senator Muskie); 116 Cong.Rec. 32,921–22 (Senator Baker) (standards envisioned to be for automobiles).

87. EPA points out that prior regulation under the Clean Air Act in June 1968 had defined light duty vehicles as motor vehicles "designed for transportation of persons or property on a street or highway and weighing 6,000 pounds GVW or less" 33 Fed.Reg. 8305 (1968), but this cannot be conclusive, given the legislative intent to the contrary. Moreover, the prior regulation did not have the effect of eliminating IH vehicles from the market because the emission standards were within the reach of heavier vehicles at that time.

88. The policies behind the decision in Udall v. Tallman, 380 U.S. 1, 85 S.Ct. 792, 13 L.Ed.2d 616 (1965) are thus inapplicable.

89. 36 Fed.Reg. 22,448 (1971).

set for 1975 models. These light weight trucks will be governed by the standards duly promulgated by EPA for "trucks and buses and other commercial vehicles."

[17] This is not to say that the modification of the "light duty vehicles" definition must exclude MPVs, which largely overlap in their usage with passenger cars. We merely hold the present regulation contrary to legislative intent. We have jurisdiction to decide this issue, even though the reasonableness of the regulation could be challenged in a separate proceeding in the District Court,[90] because the validity of the regulation is a premise of the refusal to grant suspension. "It would be an empty and useless thing to review an order . . . based on a regulation the validity of which might be subsequently nullified." Doe v. Civil Aeronautics Board, 356 F.2d 699, 701 (10th Cir. 1966).

We decline the proposal of International Harvester, therefore, that only its vehicles be granted a suspension. Light weight trucks of other manufacturers, such as Ford, equally demonstrated an inability to comply with the 1975 standards.[91] Under the view taken here, the light weight trucks of all manufacturers are properly exempted from the scope of "light duty vehicles." This comports with competitive as well as statutory considerations, as the Administrator's own brief delineates:[92]

> If International Harvester is granted a suspension, it should be able to sell its vehicles at a lower cost than competitors who met the standards. This is so because International Harvester's 1975 models would not include expensive catalytic devices to control emissions. Also the Company's vehicles would probably perform better for the same reason. Thus, if suspension is granted, it is likely that International Harvester will gain a substantial competitive advantage over manufacturers who sacrificed the performance of their vehicles, and perhaps profits, in order to comply with the 1975 standards.

Assuming light duty vehicles are defined by EPA to include MPVs a question may arise whether they are entitled to a one-year suspension, for lack of feasibility, even though passenger vehicles generally should be denied a suspension. We shall not consider this question unless and until EPA has had an opportunity to address itself to the problems in the light of our opinion herein.

D. *The Issue of Feasibility Sufficient for Basic Auto Demand*

[18] The foregoing conclusion is not to be misunderstood as amounting to an acceptance of another "basic demand" contention raised by the auto manufacturers. We are inclined to agree with the Administrator that as long as feasible technology permits the demand for new passenger automobiles to be generally met, the basic requirements of the Act would be satisfied, even though this might occasion fewer models and a more limited choice of engine types. The driving preferences of hot rodders are not to outweigh the goal of a clean environment.

[19, 20] A difficult problem is posed by the companies' contention that the production and major retooling capacity does not exist to shift production from a large number of previous models and engine types to those capable of complying with the 1975 standards and meeting the demand for new cars. The Administrator made no finding as to this problem. We believe the statute requires such a finding, explaining how the Administrator estimates "basic demand" and how his definition conforms to the statutory objective. The emission standards set for 1976 cannot be breached, since they

90. *See* 42 U.S.C. § 1857h-5(b)(1).

91. *See e. g.*, Technical Appendix at 33-43 where no predictions as to conformity were made for any Ford trucks.

92. (1) Brief of Respondent at 44.

represent an absolute judgment of Congress. But as to the decision on a one-year suspension, and the underlying issue of technological feasibility, Congress intended, we think, that the Administrator should take into account such "demand" considerations.

A significant decrease in auto production will have a major economic impact on labor and suppliers to the companies. We have no reason to believe that "effective technology" did not comport within its meaning sufficient technology to meet a basic level of consumer demand.

E. *Balancing of Risks*

[21] This case inevitably presents, to the court as to the Administrator, the need for a perspective on the suspension that is informed by an analysis which balances the costs of a "wrong decision" on feasibility against the gains of a correct one. These costs include the risks of grave maladjustments for the technological leader from the eleventh-hour grant of a suspension, and the impact on jobs and the economy from a decision which is only partially accurate, allowing companies to produce cars but at a significantly reduced level of output. Against this must be weighed the environmental savings from denial of suspension. The record indicates that these will be relatively modest. There is also the possibility that failure to grant a suspension may be counter-productive to the environment, if there is significant decline in performance characteristics.

[22] Another consideration is present, that the real cost to granting a suspension arises from the symbolic compromise with the goal of a clean environment. We emphasize that our view of a one year suspension, and the intent of Congress as to a one year suspension, is in no sense to be taken as any support for further suspensions. This would plainly be contrary to the intent of Congress to set an absolute standard in 1976. On the contrary, we view the imperative of the Congressional requirement as to the significant improvement that must be wrought no later than 1976, as interrelated with the provision for one-year suspension. The flexibility in the statute provided by the availability of a one-year suspension only strengthens the impact of the absolute standard. Considerations of fairness will support comprehensive and firm, even drastic, regulations, provided a "safety valve" is also provided—ordinarily a provision for waiver, exception or adjustment, in this case a provision for suspension.[93] "The limited safety valve permits a more rigorous adherence to an effective regulation." WAIT Radio v. FCC, *supra*, 135 U.S.App.D.C. at 323, 418 F.2d at 1159. To hold the safety valve too rigidly is to interfere with the relief that was contemplated as an integral part of the firmness of the overall, enduring program.

We approach the question of the burden of proof on the auto companies with the previous considerations before us.

IV. THE REQUIRED SHOWING ON "AVAILABLE TECHNOLOGY"

[23] It is with utmost diffidence that we approach our assignment to review the Administrator's decision on "available technology." The legal issues are intermeshed with technical matters, and as yet judges have no scientific aides. Our diffidence is rooted in the underlying technical complexities, and remains even when we take into account that ours is a judicial review, and not a technical or policy redetermination, our review is channeled by a salutary restraint, and deference to the expertise of an agency that provides reasoned analysis. Nevertheless we must proceed to the task of judicial review assigned by Congress.

93. Permian Basin Area Rate Cases, 390 U.S. 747, 781, 88 S.Ct. 1844, 20 L.Ed.2d 312 (1968); WAIT Radio v. FCC, 135 U.S.App.D.C. 317, 321, 418 F.2d 1153, 1157 (1969) and cases cited.

The Act makes suspension dependent on the Administrator's determination that:

> the applicant has established that effective control technology, processes, operating methods, or other alternatives are not available or have not been available for a sufficient period of time to achieve compliance prior to the effective data of such standards . . . .

A. *Requirement of Observed Data From Manufacturers*

[24] Clearly this requires that the applicants come forward with data which showed that they could not comply with the contemplated standards. The normal rules place such a burden on the party in control of the relevant information.[94] It was the auto companies who were in possession of the data about emission performance of their cars.

The submission of the auto companies unquestionably showed that no car had actually been driven 50,000 miles and achieved conformity of emissions to the 1975 standards. The Administrator's position is that on the basis of the methodology outlined, he can predict that the auto companies can meet the standards, and that the ability to make a prediction saying the companies can comply means that the petitioners have failed to sustain their burden of proof that they cannot comply.

B. *Requisite Reliability of Methodology Relied on by EPA To Predict Feasibility Notwithstanding Lack of Actual Experience*

[25] We agree with the Administrator's proposition in general. Its validity as applied to this case rests on the reliability of his prediction, and the nature of his assumptions. One must distinguish between prediction and prophecy. *See* EDF v. Ruckelshaus, 142 U.S. App.D.C. 74, 89, 439 F.2d 584, 597 (1971). In a matter of this importance, the predictor must make a showing of reliability of the methodology of prediction, when that is being relied on to overcome this "adverse" actual test data of the auto companies. The statute does not contemplate use of a "crystal ball." *See* National Resources Defense Council, Inc. v. Morton, 148 U.S.App.D.C. 5, 15, 458 F.2d 827, 837 (1972).

[26] The Administrator, however, raises a different issue by contending that the companies, wholly aside from his methodology, did not submit sufficient evidence to enable him to make the required determination as to "available technology." This goes to the standard rather than the burden of proof, and comes close to adoption of "beyond a reasonable doubt" as the required showing. Aside from a possible finding of bad faith, which the Administrator specifically eschews making, this position cannot stand. The companies came forward with all the data that there was to be had, and the Administrator did not specifically ask for more. Additionally, our perspective on the interests furthered by a sound EPA decision, and jeopardized by a "wrong decision," are material to the issue of standard of proof. This is a situation where, as we have stated, the risks of an erroneous denial of suspension outweigh the risks of an erroneous grant. On the issue of burden of proof, the standard adopted must take into account the nature and consequences of risk of error. *See* In re Winship, 397 U.S. 358, 371–372, 90 S.Ct. 1068, 25 L.Ed.2d 368 (1970) (Mr. Justice Harlan, concurring); U. S. v. Brown, 155 U.S.App.D.C. —, 478 F.2d 606 (1973). This view of the standard of proof dictates the standard normally adopted in civil matters, a preponderance of the evidence.[95]

94. IX Wigmore, On Evidence § 2486 (3d ed. 1940).

95. The fact that a preponderance of evidence standard was originally in Senate Bill 4358, but deleted in Conference, offers no basis for an opposite conclusion. No affirmative indication exists that Congress wanted a higher standard and the Conference delegation may simply

Our approach relates considerations of ecological and economic costs, dealt with above, to the legal issue of burden and standard of proof. Nominally the statute, in § 202(b)(5)(D), sets forth separate criteria as to "public interest," in clause (i), and "available technology," in clause (iii). But the assignment of the burden and standard of proof on "available technology" inescapably involves many of the same considerations as those involved in a "public interest" determination, and it would have been helpful to this court if the Administrator had expressly commented on the public interest in this connection.

[27] The underlying issue is the reasonableness and reliability of the Administrator's methodology, for it alone offsets the data adduced by petitioners in support of suspension. It is the Administrator who must bear the burden on this matter, because the development and use of the methodology are attributable to his knowledge and expertise. When certain material "lies particularly within the knowledge" of a party he is ordinarily assigned the burden of adducing the pertinent information.[96] This assignment of burden to a party is fully appropriate when the other party is confronted with the often-formidable task of establishing a "negative averment." United States v. Denver & R.G.R. Co., 191 U.S. 84, 92, 24 S.Ct. 33, 48 L.Ed. 106 (1903). In the context of this proceeding, this requires that EPA bear a burden of adducing a reasoned presentation supporting the reliability of its methodology.

have been intended to eliminate a requirement which is mere surplusage in the civil litigation context. *See* S. 4358, 91st Cong., 2d Sess., printed in S.Rep. No. 91-1196, 91st Cong., 2d Sess. 103 (1970), § 202(b)(4)(C)(iii). *See also* Conference Report, H.R.Rep. No. 91-1783, 91st Cong., 2d Sess. 48-49 (1970), U.S. Code Cong. & Admin.News, 1970, p. 5374.

C. *Analysis of EPA Assumptions*

The multiple assumptions used by the Administrator in making his prediction are subject to serious doubts.

The basic formula used to make the prediction that each of the manufacturers could meet the 1975 standards was based on 1975 certification requirements, so that in part it paralleled testing procedures which would be used in 1975 to certify automobiles for sale. The formula is:[97]

$$\text{50,000 mile emissions} = \text{4000 mile emissions} \times \text{deterioration factor}$$

Four kinds of assumptions were used in making the 50,000 mile emission prediction: (1) regulatory, (2) engineering or scientific, (3) techniques of application of basic formula to particular companies, and (4) statistical reliability of the final prediction.

1. *Regulatory assumptions*

First, EPA assumed that certain types of maintenance would have to be performed on 1975 model year cars, if its 50,000 miles emission predictions were to be meaningful. Subsequent to the issue of its Technical Appendix, a Proposed Rule Making formulated these requirements as part of 1975 certification procedure.[98] This assumption was necessary because much of the data supplied by the companies was obtained from cars that were under rigid controls during testing.[99] The problem with such maintenance assumptions is whether the ordinary driver will actually pay for this kind of maintenance just to reduce the

96. Compare Commonwealth of Puerto Rico v. FMC, 152 U.S.App.D.C. 28, 468 F.2d 872 (1972).

97. Technical Appendix at 3.

98. *See* note 26 *supra*.

99. Car # 333, used as the basis for the Chrysler prediction, is the outstanding example. *See* Transcript at 2095-2107; JA 1331, Doc. 143.

emission levels of his automobile. It is one thing to build maintenance into the 1975 certification procedure, when fleet samples are durability tested. It is another to posit that such standards will be maintained, or are reasonably likely to be maintained, by consumers. A hard question is raised by the use of a methodological assumption without evidence that it will correspond to reality, or a reasonable and forthright prediction based on expertise.

Secondly, the predicted emission level assumes that there will be one total replacement of the catalytic converter at some time after 25,000 miles. This entered into the formula as an adjustment to the predicted deterioration factor.[100] The critical question is how much will the one replacement reduce emissions otherwise obtainable by use of a single catalyst. This relationship had to be assumed because manufacturers had not used catalytic converter replacements in their testing. The Administrator admitted that this factor was imprecise.[101] Yet, in the case of General Motors, the use of the assumed value of this factor was critical in allowing the Administrator to make a 50,000 mile emission prediction under the 1975 standards.[102]

The third regulatory assumption relates to the average lead level which will exist in gasoline available for 1975 model year cars. Lead levels in gasoline contribute to the levels of HC and CO both in terms of normal emission control achievable (the 4000 mile emission) and to the deterioration in emissions over time (deterioration factor). Thus, in the case of the Chrysler car used to predict conformity with the 1975 standards, a .03 lead in gasoline produced 4000 mile emissions of .27 grams HC and 1.51 CO, whereas a .05 level of lead resulted in .29 and 1.66 grams respectively. Similarly .03 lead produced a corrected deterioration factor of .67 HC and 1.5 CO, whereas a .05 level produced .73 HC and 1.65 CO.[103]

On December 27, 1972, a regulation was promulgated "designed to assure general availability by July 1, 1974, of suitable gasolines containing no more than .05 grams per gallon of lead. . . ."[104] It was the assumption of the Administrator that the .05 maximum would result in gas containing on the average .03 grams per gallon of lead. The discrepancy between the maximum and average is accounted for by the contamination of lead free gasoline from its point of production to its marketing outlet. Thus EPA will allow a maximum of .05 but anticipates that on the average fuel will be at .03. This assumption is, however, subject to testimony in the record indicating a difference between companies in their ability to achieve gasoline with a low lead level complying with the proposed regulation. Amoco said that its proposal for a .07 maximum "should result in effective lead levels of .02 to .03 grams of lead per gallon."[105] Texaco did not think it could deliver gas to service stations at a lead level below .07.[106] We cannot resolve whether a differential ability really exists, but we also have no refinement and resolution by the EPA (as distinguished from the briefs of its counsel). We do not say this matter is a critical defect; still it leaves a residue of uncertainty that beclouds the EPA assumption of a .03 average, needed in its methodology to predict conformity with the 1975 standards.

100. Technical Appendix at 10.

101. This statement was made in the context of the application of this assumption to predicting the conformity of General Motors with prescribed standards. Technical Appendix at 47.

102. *Id.* at 51.

103. *Id.* at 22.

104. Supplement to Decision at 2.

105. Letter, B. J. Yarrington, Amoco, to EPA, May 9, 1972, at 2, JA at 1539.

106. JA at 1704–1705.

2. *Engineering and scientific assumptions*

Engineering or scientific assumptions are made in predicting 4000 mile emissions and deterioration factors, and we shall give separate consideration to each independent variable.

a. *The 4000 mile emission factor*

The use of 4000 mile emissions as a starting point is based on certification procedures.[107] No challenge has been made to this mileage as a base point, largely because it appears that at this mileage the engine is broken in and emission levels are relatively stabilized.[108] EPA decided to adjust raw data supplied, at least in the case of Ford and Chrysler, of emissions at 4000 miles to take account of a "Lead Adjustment Factor." [109] This was done because in most cases emissions data reflected fuels with a close to zero lead level which had been used by the manufacturers in their testing programs.

Lead adjustment factor

This Lead Adjustment Factor was calculated using only Ford cars, but the value of the factor was assumed to be the same in adjusting Chrysler 4000 mile emissions with this factor.[110] The cars had been tested with a dynamometer, a type of test equipment used for laboratory testing of an engine. A measurement of the efficiency of the catalytic converter at the 4000 mile mark was the critical value which had to be obtained from the dynamometer since this would indicate what the proper lead adjustment factor would be.[111]

EPA assumed that 200 hours on the dynamometer corresponded to 4000 miles usage, based on a critical and contested EPA assumption that the tests were conducted at 1000 RPM. Petitioners claim that the high temperature readings on the dynamometer reflect a higher RPM, and hence that a testing below 200 hours corresponded to 4000 miles of use. EPA disputes the steps in that chain of reasoning, and argues that a higher temperature may be attributable not to a RPM in excess of 1000, but to a heavy load on the vehicle, and in the alternative contends that even if there was a RPM greater than 1000, the speed may not have increased, due to a shift in gear.

[28] The cause of higher than expected temperature readings cannot be ascertained from the record, and we are left with the alternative contentions of the parties. It is up to EPA, however, to support its methodology as reliable, and this requires more than reliance on the unknown, either by speculation, or mere shifting back of the burden of proof.[112]

107. See note 24 *supra*.

108. Joint Supplement to Briefs of Petitioners General Motors Corporation, Chrysler Corporation and Ford Motor Company at 8.

109. Technical Appendix at 22 (Chrysler); at 36 (Ford).

110. *Id.* at 6.

111. The parties are apparently agreed that it would be to the advantage of the companies to take fewer hours than 200 on the dynamometer to represent 4000 mile emissions, presumably on the assumption that this will mean that emissions would be higher. This is not readily apparent to the court, given its limited understanding, from the graphs or equations provided in the Technical Appendix, at 5–6, 11–12, 18, 34. If this were a critical issue it might be necessary to arrange further submission on this point, but since it relates to one of many problems with EPA methodology we do not deem it necessary. A lacuna in judicial understanding is to some extent inescapable in matters of such technical difficulty, and here it does not seem critical for the court to refine this particular problem.

112. A scientific paper was cited by petitioners to establish that RPM was in fact 1750, JA 1616. Apparently this was not in the record made before EPA. In any event, we do not discern how this paper supports the claim made, though we are aware that this statement may merely reflect the court's lack of scientific understanding.

b. *Deterioration factor*

Methodological problems also existed with the calculation of the deterioration factor, which took account of possible deterioration in emission quality from 4000 miles to 50,000 miles. Different questions arose as to the calculation of this factor for Ford and Chrysler.

In the case of Ford, the Administrator predicted that emissions would *improve* from 4000 to 50,000 miles, and arrived at a deterioration factor of less than 1.[113] He calculated average deterioration factors for Ford vehicles of .80 HC and .83 CO. This is to be compared with a deterioration factor of 2.5 used by NAS.[114] The Administrator never explained why there should be no deterioration. Nor does EPA explain how this result can be squared with other data on Ford catalyst efficiencies, which was used in the case of the General Motors prediction, showing 50,000 mile catalyst efficiencies ranging from 21% to 53% for HC and 47% to 72% for CO.[115]

In the case of Chrysler, the deterioration factor was also calculated to be less than 1, but this figure was only arrived at after eliminating some data points from the emission measurement on the tested car #333, due to what EPA claimed were unrepresentative points resulting from non-catalyst malfunctions.[116] Although it may be, as EPA argues here, that including the data points would still produce predicted 50,000 emission levels in conformity with the 1975 standard, the fact remains that these data points were removed. Moreover, it is not apparent why one should ignore malfunctions of a car which contribute to high emissions, even if they are not malfunctions of the converter. Malfunctions of cars occur to some degree, and cars operating in 1975 will undoubtedly be subject to them.

Lead adjustment factor

A lead adjustment factor is applied to the deterioration factor, as well as to 4000 mile emissions. EPA estimated on the basis of the questionable Ford dynamometer data, that lead levels had no observable effect, which was contrary to industry testimony on the subject.[117] The Administrator evidently had doubts as to the dependability of these results as well, and therefore assumed a 10% factor for lead adjustment.[118] No explanation is given of the origins of this 10% figure. If the willingness to take some factor evidences distrust in the data, the question then becomes whether 10% is enough.

3. *EPA methodology for General Motors*

In the case of General Motors an entirely different methodology from that used for Ford and Chrysler was employed. This was adopted due to limited testing by GM of noble metal catalysts.

The methodology was to take the raw emission values produced by a GM car prior to catalyst treatment of any kind multiplied by a factor representing the efficiency of the catalyst, *i. e.*, the percentage of a given pollutant that the catalyst converts to harmless vapor, in order to obtain the projected overall emission performance at 50,000 miles.[119] These methods of calculation were developed by the Administrator and were not used by NAS in their evaluation.[120]

113. Technical Appendix at 34.

114. Interim Standards Report at 8.

115. JA at 957, Doc. 135.

116. Technical Appendix at 17.

117. EPA merely responds to the testimony by stating that it was unaccompanied by data, but offers no expert opinion which indicates that such a relationship does not exist. (2) Brief of Respondent, App. A and B at 24, n. 35.

118. Technical Appendix at 7.

119. *Id.* at 3, 44–55.

120. No mention of this possible methodology is mentioned in the NAS Interim Report, and the Administrator admits this in Supplement to Decision at 1. *See* text at note 76.

The catalyst efficiency data were taken from Engelhard converters used principally on Ford cars and applied against the raw emissions of a General Motors engine. This assumed, with no explanation of the validity of such an assumption, that Engelhard catalysts will function as efficiently in General Motors cars as in those of Ford. A prediction was made on the basis of a hypothetical case. One cannot help be troubled by the adoption of this technique for General Motors. It was apparently recognized as at best a second best approach, in terms of the reliability of the prediction, or the same catalyst efficiency procedure would also have been used for Ford and Chrysler.

4. *Statistical reliability of assumptions*

In this case the Administrator is necessarily making a prediction. No tests exist on whether this prediction is or is not reliable. It would, therefore, seem incumbent on the Administrator to estimate the possible degree of error in his prediction. The NAS, for example, said that the data of the manufacturers were subject to ± 20–30% margin of error,[121] and this is separate from any margin of error that may be due to the various assumptions made by the Administrator. It is not decisive to say, as EPA argues in its brief, that this is just a matter of quality control in production. The first issue is whether the automobile built with rigid adherence to specifications will perform as predicted. The issue of quality control, whether cars will indeed be built in accordance with specifications, raises a separate and additional problem.

The possibility of error must take into account that only 1 Ford car, 1 Chrysler car, and 1 hypothetical General Motors car form the foundation for predicted conformity with the 1975 standard.[122] The Administrator would say that it is enough to validate the principle of the electric light bulb if only one is seen at work. But we do not yet have one that has worked; instead we have four predictions. Questions like these arise: (1) For how many different types of engines will these predictions be valid? (2) Does it make a difference that the tested cars were experimental and driven under the most controlled conditions? The best car analysis of EPA raises even further doubts when considered alongside the NAS Report which used 55 vehicles in arriving at its recommended interim standard.[123]

V. CONCLUSION AND DISPOSITION

[29] We may sensibly begin our conclusion with a statement of diffidence.[124] It is not without diffidence that a court undertakes to probe even partly into technical matters of the complexity of those covered in this opinion. It is with even more diffidence that a court concludes that the law, as judicially construed, requires a different approach from that taken by an official or agency with technical expertise. Yet this is an inescapable aspect of the judicial condition, though we stay mindful of the overarching consideration that a court's role on judicial review embraces that of a constructive cooperation with the agency involved in furtherance of the public interest.[125]

121. Interim Standards Report at 7.

122. Technical Appendix at 41 (Ford 351 C); at 22 (Chrysler car 333); at 51 (General Motors engine 455/full size).

123. Interim Standards Report at 8. EPA, moreover, offers no explanation as to whether there were "best system" cars besides those included in the Appendix which did not meet the standards, and why one should not be concerned about the fact that the "best system" cars which are in the Technical Appendix, other than those cited in note 103, *supra*, do not meet the standard.

124. Compare Blair v. Freeman, 125 U.S. App.D.C. 207, 210, 370 F.2d 229, 232 (1966).

125. Morgan v. United States, 304 U.S. 1, 58 S.Ct. 999, 82 L.Ed. 1129 (1938); Greater Boston TV v. FCC (I), *supra*.

A court does not depart from its proper function when it undertakes a study of the record, hopefully perceptive, even as to the evidence on technical and specialized matters, for this enables the court to penetrate to the underlying decisions of the agency, to satisfy itself that the agency has exercised a reasoned discretion, with reasons that do not deviate from or ignore the ascertainable legislative intent.[126]

[30] In this case technical issues permeate the "available technology" determination which the Administrator made the focal point of his decision. In approaching our judicial task we conclude that the requirement of a "reasoned decision" by the Environmental Protection Agency means, in present context, a reasoned presentation of the reliability of a prediction and methodology that is relied upon to overcome a conclusion, of lack of available technology, supported prima faciely by the only actual and observed data available, the manufacturers' testing.

[31] The number of unexplained assumptions used by the Administrator, the variance in methodology from that of the Report of the National Academy of Sciences, and the absence of an indication of the statistical reliability of the prediction, combine to generate grave doubts as to whether technology is available to meet the 1975 statutory standards. We say this, incidentally, without implying or intending any acceptance of petitioners' substitute assumptions. These grave doubts have a legal consequence. This is customarily couched, by legal convention, in terms of "burden of proof." We visualize the problem in less structured terms although the underlying considerations, relating to risk of error, are related. As we see it the issue must be viewed as one of legislative intent. And since there is neither express wording or legislative history on the precise issue, the intent must be imputed. The court must seek to discern and reconstruct what the legislature that enacted the statute would have contemplated for the court's action if it could have been able to foresee the precise situation.[127] It is in this perspective that we have not flinched from our discussion of the economic and ecological risks inherent in a "wrong decision" by the Administrator. We think the vehicle manufacturers established by a preponderance of the evidence, in the record before us, that technology was not available, within the meaning of the Act, when they adduced the tests on actual vehicles; that the Administrator's reliance on technological methodology to offset the actual tests raised serious doubts and failed to meet the burden of proof which in our view was properly assignable to him, in the light of accepted legal doctrine and the intent of Congress discerned, in part, by taking into account that the risk of an "erroneous" denial of suspension outweighed the risk of an "erroneous" grant of suspension. We do not use the burden of proof in the conventional sense of civil trials, but the Administrator must sustain the burden of adducing a reasoned presentation supporting the reliability of EPA's methodology.

[32] EPA's diligence in this proceeding, fraught with questions of statutory interpretation, technical difficulties and burdensome time constraints placed on the decision-making process, has been commendable. The agency was presented with a prickly task, but has acted expeditiously to carry out what it perceived to be a drastic mandate from Congress. This statute was, indeed, deliberately designed as "shock treatment" to the industry. Our central difference with the Administrator, simply put, stems from our view concerning the Congressional intent underlying the one year suspension pro-

126. Greater Boston TV v. FCC, *supra*, 143 U.S.App.D.C. at 392; 444 F.2d at 850.

127. Montana Power Co. v. FPC, 144 U.S. App.D.C. 263, 270, 445 F.2d 739, 746 (en banc, 1970), cert. denied 400 U.S. 1013, 91 S.Ct. 566, 27 L.Ed.2d 627 (1971).

vision. That was a purposeful cushion —with the twin purpose of providing "escape hatch" relief for 1975, and thus establishing a context supportive of the rigor and firmness of the basic standards slated for no later than 1976. In our view the overall legislative firmness does not necessarily require a "hard-nosed" approach to the application for suspension, as the Administrator apparently supposed, and may indeed be furthered by our more moderate view of the suspension issue, particularly in assigning to the Administrator the burden of producing a reasoned presentation of the reliability of his methodology. This is not a matter of clemency, but rather a benign approach that moderates the "shock treatment" so as to obviate excessive and unnecessary risk of harm.

[33] Our decision is also responsive to the differences between the EPA decision and the NAS Report. Although in some instances "the factual findings and technical conclusions" [128] are consistent with those of the Administrator, the NAS conclusion was that technology was not available to meet the standards in 1975. Congress called on NAS, with presumed reliance on the knowledge and objectivity of that prestigious body, to make an independent judgment. The statute makes the NAS conclusion a necessary but not sufficient condition of suspension. While in consideration of the other conditions of suspension, EPA was not necessarily bound by NAS's approach, particularly as to matters interlaced with policy and legal aspects, we do not think that it was contemplated that EPA could alter the conclusion of NAS by revising the NAS assumptions, or injecting new ones, unless it states its reasons for finding reliability—possibly by challenging the NAS approach in terms of later-acquired research and experience.

These factors combine to convince us that, under our view of Congressional intent, we cannot affirm the EPA's denial of suspension as stated. That is not necessarily to assume, as at least some petitioners do, that the EPA's process must be brought to nullity.

[34] The procedures followed in this case, whether or not based on rulings that were "mistaken" when made, have resulted in a record that leaves this court uncertain, at a minimum, whether the essentials of the intention of Congress were achieved. This requires a remand whereby the record as made will be supplemented by further proceedings. In the interest of justice, see 28 U.S.C. § 2106, and mutual regard for Congressional objective, the parties should have opportunity on remand to address themselves to matters not previously put before them by EPA for comment, including material contained in the Technical Appendix filed by EPA in 1972 subsequent to its Decision.

It is contemplated that, in the interest of providing a reasoned decision, the remand proceeding will involve some opportunity for cross-examination. In the remand proceeding—not governed by the same time congestion as the initial Decision process—we require reasonable cross-examination as to new lines of testimony, and as to submissions previously made to EPA in the hearing on a proffer that critical questions could not be satisfactorily pursued by procedures previously in effect. There is, however, still need for expedition, both by virtue of our order and the "lead time" problem, and the EPA may properly confine cross-examination to the essentials, avoiding discursive or repetitive questioning.

Following our suggestion in Environmental Defense Fund, Inc. v. EPA, 150 U.S.App.D.C. 348, 465 F.2d 528 (1972), the Administrator may consider possible use of interim standards short of complete suspension. The statute permits conditioning of suspension on the adoption, by virtue of the information adduced in the suspension proceeding, of

128. Supplement to Decision at 1.

interim standards, higher than those set for 1974.[129]

[35, 36] We cannot grant petitioners' request that this court order a suspension since determinations which Congress made necessary conditions of suspension, as to the public interest and good faith, have not been made by the Administrator. The Administrator's decision did not reach these questions and accordingly we must remand for further consideration. The initial requirement that an EPA decision on the suspension, aye or nay, be made within 60 days of the application, obviously does not preclude further consideration following remand by the court. In the interest of justice, 28 U.S.C. § 2106, and the Congressional intention that decisions be made timely in the light of considerations of "lead time" for 1975 model year production, we require the suspension deliberations by EPA to be completed within 60 days. The Administrator's decision on remand must, of course, be consistent with our legal rulings herein—including the need for redefinition of light duty vehicles, and promulgation of an appropriate regulation.

[37-39] In conformance to the Congressional contemplation of expedition, and our responsibilities as an appellate court, we further require that the Administrator render a decision, on the basis of the best information available, which extends to all the determinations which the statute requires as a condition of suspension.[130] We do not preclude further consideration of the question of "available technology," especially if developments in the art provide enlightenment. Last but not least, especially in view of Ford's submission and the NAS Report concerning interim standards, we reiterate that the EPA's determination may consist of a conditional suspension that results in higher standards than an outright grant of applications for suspension.

The case is remanded for further proceedings not inconsistent with this opinion.

BAZELON, Chief Judge (concurring in result):

Socrates said that wisdom is the recognition of how much one does not know.[1] I may be wise if that is wisdom, because

129. Thus, Section 202(b)(5)(A), 42 U.S.C. § 1857f-1(b)(5)(A), provides, in part:

> If he determines, in accordance with the provisions of this subsection, that such suspension should be granted, he shall *simultaneously* with such determination prescribe by regulation interim emission standards. . . . (Emphasis added.)

130. This obviates the possibility of delay if, for example, on remand the Administrator denied the suspension on the basis of only one of the four statutory findings, and this court subsequently reversed.

Since our disposition on remand requires a public interest determination, it disposes of the claim of petitioner Chrysler that the National Environmental Policy Act, 42 U.S.C. § 4321 et seq., requires that an impact statement be filed by the Administrator pursuant to a suspension decision.

The purpose of NEPA is to assure presentation to Congress and the public of the environmental impact of executive action. Here Congress has already decided that the environmental dangers require the statutory standards. The only executive decision is of a one year deferral, and the very stuff of such a decision, at least with a public interest determination, is to assess, *inter alia*, the environmental consequences of action and inaction. NEPA's objective will be fully served. As we stated in National Resources Defense Council, Inc. v. Morton, 148 U.S.App.D.C. 5, 15, 458 F.2d 827, 837 (1972), the requirements of NEPA should be subject to a "construction of reasonableness." Although we do not reach the question whether EPA is automatically and completely exempt from NEPA, we see little need in requiring a NEPA statement from an agency whose raison d'être is the protection of the environment and whose decision on suspension is necessarily infused with the environmental considerations so pertinent to Congress in designing the statutory framework. To require a "statement," in addition to a decision setting forth the same considerations, would be a legalism carried to the extreme.

1. Plato, Apology of Socrates, § 57B.

I recognize that I do not know enough about dynamometer extrapolations, deterioration factor adjustments, and the like to decide whether or not the government's approach to these matters was statistically valid. Therein lies my disagreement with the majority.

The court's opinion today centers on a substantive evaluation of the Administrator's assumptions and methodology. I do not have the technical know-how to agree or disagree with that evaluation—at least on the basis of the present record. My grounds for remanding the case rest upon the Administrator's failure to employ a reasonable decision-making process for so critical and complex a matter. At this time I cannot say to what extent I could undertake an evaluation of the Administrator's findings if they were based on an adequate decisional process.

I cannot believe that Congress intended this court to delve into the substance of the mechanical, statistical, and technological disputes in this case. Senator Cooper, the author of the judicial review provision, stated repeatedly that this court's role would be to "determine the question of due process."[2] Thus the court's proper role is to see to it that the agency provides "a framework for principled decision-making."[3] Such a framework necessarily includes the right of interested parties to confront the agency's decision and the requirement that the agency set forth with clarity the grounds for its rejection of opposing views.

The majority's interpretation of the present statute and the administrative precedents would give us no right to establish these procedural guidelines. Their opinion maintains that the strict deadlines in the Clean Air Act preclude any right to challenge the Administrator until after the decision has been made. It indicates that, since this hearing was "rule-making" rather than "adjudicatory", cross-examination and confrontation are not required under traditional rules of administrative law.

I understand this viewpoint, but I do not share it. I do not think the authors of the Clean Air Act intended to put such strict limits on our review of the Administrator's decision-making process. Further, the interests at stake in this case are too important to be resolved on the basis of traditional administrative labels. We recognized two years ago that environmental litigation represents a "new era" in administrative law.[4] We are dealing here not with an airline's fares or a broadcaster's wattage, but with all humanity's interest in life, health, and a harmonious relationship with the elements of nature.

This "new era" does not mean that courts will dig deeper into the technical intricacies of an agency's decision. It means instead that courts will go further in requiring the agency to establish a decision-making process adequate to protect the interests of all "consumers" of the natural environment.[5] In some situations, traditional rules of "fairness"—designed only to guard the interests of the specific parties to an agency proceeding—will be inadequate to protect these broader interests. This is such a case. Whether or not traditional administrative rules require it, the critical character of this decision requires at the

2. 116 Cong.Rec. 33,086 (1970); *cf.* 116 Cong.Rec. 33,080, 33,084 (1970). One Senator referred to the court's "fact-finding function"; his remarks make it clear that he could not have been referring to the review function of courts of appeal. 116 Cong.Rec. 33,085 (1970) (Senator Baker).

3. Environmental Defense Fund, Inc. v. Ruckelshaus, 142 U.S.App.D.C. 74, 88, 439 F.2d 584, 598 (1971).

4. *Id.* 142 U.S.App.D.C. at 87, 439 F.2d at 597. To the same effect is Mr. Justice Blackmun's opinion in Sierra Club v. Morton, 405 U.S. 727, 755, 92 S.Ct. 1361, 31 L.Ed.2d 636 (1972) (dissenting opinion).

5. Environmental Defense Fund, Inc. v. Hardin, 138 U.S.App.D.C. 391, 395, 428 F.2d 1093, 1097 (1970).

least a carefully limited right of cross-examination at the hearing and an opportunity to challenge the assumptions and methodology underlying the decision.

The majority's approach permits the parties to challenge the Administrator's methodology only through the vehicle of judicial review. I do not think this is an adequate substitute for confrontation prior to the decision. I reach this position not only out of concern for fairness to the parties (" . . . for if a party first learns of noticed facts through the final report . . . the burden of upsetting a decision announced as final is a heavy one."[6]) but also out of awareness of the limits of our own competence for the task. The petitioners' challenges to the decision force the court to deal with technical intricacies that are beyond our ken.[7] These complex questions should be resolved in the crucible of debate through the clash of informed but opposing scientific and technological viewpoints.

It is true that courts occasionally find themselves in the thick of technological controversies—e. g., in patent cases. But those are different circumstances. We do not review patent disputes until they have been through a full panoply of procedures involving full rights of confrontation. Further, unlike our decision in a patent case, our decision on the Administrator's action here is sure to be tested by analysis and challenge in Congress, in the scientific community, and among the public.

My brethren and I are reaching for the same end—a "reasoned decision"—through different means. They would have us examine the substance of the decision before us. There are some areas of administrative law—involving issues of liberty and individual rights—where judges are on firm ground in undertaking a substantive review of agency action. But in cases of great technological complexity, the best way for courts to guard against unreasonable or erroneous administrative decisions is not for the judges themselves to scrutinize the technical merits of each decision. Rather, it is to establish a decision-making process which assures a reasoned decision that can be held up to the scrutiny of the scientific community and the public.[8] "[T]he best test of truth is the power of the thought to get itself accepted in the competition of the market."[9] If we were to require procedures in this case that open the Administrator's decision to challenge and force him to respond, we could rely on an informed "market" rather than on our own groping in the dark to test the validity of that decision.

Candor requires the admission that the process of confrontation and challenge might not be possible within the statutory decision period of 60 days. My response would be to permit an extension of the time limit—perhaps 30 days more. This would put less strain on the overall statutory scheme—and on the manufacturers' lead time—than the months that have been expended in litigation, and now a remand, over the decision. Congress did not intend for us to enforce this relatively minor time restriction so strictly as to do major damage to the statute as a whole.

My brethren argue that the 60-day time limit in the statute precluded any opportunity for cross-examination or confrontation at the time of the original decision. But their opinion would apparently permit these procedural rights on the remand. This bit of judicial legerdemain confounds me. I can find nothing in the statute or common sense

6. 2 Davis, Administrative Law Treatise, § 15.14 (1958).

7. *Cf.* this court's dictum, in Constructores Civiles de Centro-Americana v. Hannah, that "These forebodingly fecund matters were wisely placed beyond the ken of the judiciary." 148 U.S.App.D.C. 159, 168, 459 F.2d 1183, 1192 (1972).

8. *Cf.* Citizens' Association of Georgetown v. Zoning Commission, 155 U.S.App.D.C. ——, 477 F.2d 402 (1973).

9. Abrams v. United States, 250 U.S. 616, 630, 40 S.Ct. 17, 63 L.Ed. 1173 (1919) (Holmes, J., dissenting).

to support this distinction. If anything, the statute, with its obvious emphasis on reaching a final decision quickly, would dictate procedures at the original decision which were sufficient to produce a reasoned decision without the need for a remand.

Outside of the foregoing differences, I agree with much of the majority opinion. I would have preferred to make the "public interest" factor—the considerations set forth in Part III of that opinion—an independent ground for suspension. The court today deals with the public interest indirectly, through the device of burden of proof. I do not fully understand this approach, but I suspect it leads to essentially the same result I favor.

William S. COOPER, Appellant,
v.
William R. GOODWIN et al.
No. 71-1100.

United States Court of Appeals, District of Columbia Circuit.

Argued April 21, 1972.

Decided Feb. 12, 1973.

Action for injuries to guest allegedly resulting from hosts' negligent maintenance of their basement stairs. The United States District Court for the District of Columbia, Joseph Charles McGarraghy, J., directed a verdict for defendants, and the plaintiff appealed. The Court of Appeals, Bazelon, Chief Judge, held, inter alia, that where guest alleged that hosts had been negligent in failing to have a handrail on the stairs, in failing to have stair treads, in maintaining highly slippery coat of wax on the stairs and in failing to warn of such conditions, it was for jury to consider and weigh all the circumstances of the fall, including those which affected foreseeability of injury, the burden of avoiding the injury, and care which guest as a reasonable man could be expected to take for his own safety.

Reversed and remanded.

Leventhal, Circuit Judge, concurred and filed opinion, and Sobeloff, Senior Circuit Judge for the Fourth Circuit, sitting by designation, concurred and filed opinion.

1. Negligence ⚷124(2)

In action for injuries to guest resulting from alleged negligent maintenance of hosts' basement stairs, portion of Housing Code of District of Columbia providing that interior stairs more than two risers high shall have an enclosing wall, balustrade, or other guard on each side and shall have a hand rail on at least one side was properly admitted solely for purpose of permitting jury to consider it in determining whether there was exercise of due care on part of hosts and not as negligence per se.

2. Negligence ⚷32(1)

The legal rule that a social guest may recover for active negligence only is no longer in effect.

3. Negligence ⚷28

The standard that a landowner must act as a reasonable man in maintaining his property in a reasonably safe condition in view of all the circumstances seeks to eliminate the harshness of and confusion over the common-law classifications.

4. Negligence ⚷136(16, 24, 26)

In action for injuries to guest who slipped on basement stairs, wherein guest alleged that hosts had been negligent in failing to have a handrail on the stairs, in failing to have stair treads, in maintaining highly slippery coat of wax on the stairs and in failing to warn of such conditions, it was for jury to consider and weigh all the circumstances of the fall, including those which affected foreseeability of injury, the burden of

448 U.S. 607, 65 L.Ed.2d 1010

INDUSTRIAL UNION DEPARTMENT, AFL-CIO, Petitioner,
v.
AMERICAN PETROLEUM INSTITUTE et al.

Ray MARSHALL, Secretary of Labor, Petitioner,
v.
AMERICAN PETROLEUM INSTITUTE et al.

Nos. 78-911, 78-1036.

Argued Oct. 10, 1979.

Decided July 2, 1980.

Producers of benzene filed petition for review of a new health standard promulgated by the Occupational Safety and Health Administration limiting occupational exposure to benzene. The Court of Appeals, Fifth Circuit, 581 F.2d 493, held that standard invalid, and certiorari was granted. The Supreme Court, per Mr. Justice Stevens with three Justices joining and one Justice concurring in the judgment, held that the subject standard, reducing the permissible exposure limit on airborne concentrations of benzene from the consensus standard of ten parts benzene per million parts of air to one part per million, was unenforceable since the standard was not supported by appropriate findings; OSHA's rationale for lowering the permissible exposure limit from 10 ppm to 1 ppm was based not on any finding that leukemia has ever been caused by exposure to 10 ppm of benzene and that it will not be caused by exposure to 1 ppm, but rather on a series of assumptions indicating that some leukemia might result from exposure to 10 ppm and that the number of cases might be reduced by lowering the exposure level to 1 ppm.

Judgment affirmed.

Mr. Chief Justice Burger filed a concurring opinion.

Mr. Justice Powell filed an opinion concurring in part and in the judgment.

Mr. Justice Rehnquist filed an opinion concurring in the judgment.

Mr. Justice Marshall, joined by Mr. Justice Brennan, Mr. Justice White and Mr. Justice Blackmun, filed a dissenting opinion.

1. Labor Relations ⇐27

Provision of the Occupational Safety and Health Act defining an "occupational safety and health standard" requires the Secretary of Labor to find, as a threshold matter to the promulgation of a standard concerning a toxic substance, that the substance in question poses a significant health risk in the workplace, and that a new, lower standard is therefore "reasonably necessary or appropriate to provide safe or healthful employment and places of employment." (Per Mr. Justice Stevens, with three Justices joining and one Justice concurring in the judgment.) Occupational Safety and Health Act of 1970, § 3(8), 29 U.S.C.A. § 652(8).

2. Labor Relations ⇐9.5

Occupational safety and health standard promulgated by the Secretary of Labor pursuant to the Occupational Safety and Health Act, reducing the permissible exposure limit on airborne concentrations of benzene from the consensus standard of ten parts benzene per million parts of air to one part per million, was unenforceable since the standard was not supported by appropriate findings; the Occupational Safety and Health Administration's rationale for lowering the permissible exposure limit from 10 ppm to 1 ppm was based not on any finding that leukemia has ever been caused by exposure to 10 ppm of benzene and that it will not be caused by exposure to 1 ppm, but rather on a series of assumptions indicating that some leukemia might result from exposure to 10 ppm and that the number of cases must be reduced by lowering the exposure level to 1 ppm. (Per Mr. Justice Stevens, with three Justices joining and one Justice concurring in the judgment.) Occupational Safety and Health Act of 1970, §§ 3(8), 6(b)(5), 29 U.S.C.A. §§ 652(8), 655(b)(5).

3. Administrative Law and Procedure ⇐753

Validity of an agency's determination must be judged on the basis of the agency's stated reasons for making that determina-

tion. (Per Mr. Justice Stevens, with three Justices joining and one Justice concurring in the judgment.)

4. Labor Relations ⇐27

Provision of the Occupational Safety and Health Act defining an occupational safety and health standard as a standard "reasonably necessary and appropriate to provide safe and healthful employment" does not apply to all permanent standards promulgated under the Act, and requires the Secretary of Labor, before issuing any standard, to determine that it is reasonably necessary and appropriate to remedy a significant risk of material health impairment; only after the Secretary has made the threshold determination that such risk exists with respect to a toxic substance would it be necessary to decide whether the Act requires him to select the most protective standard he can consistent with economic and technological feasibility, or whether the benefits of the regulation must be commensurate with the costs of its implementation. (Per Mr. Justice Stevens, with three Justices joining and one Justice concurring in the judgment.) Occupational Safety and Health Act of 1970, §§ 3(8), 6(b)(5), 29 U.S.C.A. §§ 652(8), 655(b)(5).

5. Labor Relations ⇐9.5

Occupational Safety and Health Act was not designed to require employers to provide absolutely risk-free workplaces whenever it is technologically feasible to do so, so long as the cost is not great enough to destroy the entire industry; rather, both the language and structure of the Act, as well as its legislative history, indicate that it was intended to require the elimination, as far as feasible, of significant risks of harm. (Per Mr. Justice Stevens, with three Justices joining and one Justice concurring in the judgment.) Occupational Safety and Health Act of 1970, § 2 et seq., 29 U.S.C.A. § 651 et seq.

6. Labor Relations ⇐9.5

By empowering the Secretary of Labor to promulgate standards that are "reasonably necessary or appropriate to provide safe or healthful employment and places of employment," the Occupational Safety and Health Act implies that, before promulgating any standard, the Secretary must make a finding that the workplaces in question are not safe; but "safe" is not the equivalent of "risk-free," and a workplace can hardly be considered "unsafe" unless it threatens the workers with a significant risk of harm. (Per Mr. Justice Stevens, with three Justices joining and one Justice concurring in the judgment.) Occupational Safety and Health Act of 1970, §§ 2 et seq., 3(8), 6(b)(5), 29 U.S.C.A. §§ 651 et seq., 652(8), 655(b)(5).

7. Labor Relations ⇐27

Before the Secretary of Labor can promulgate any permanent health or safety standard under the Occupational Safety and Health Act, he must make a threshold finding that the place of employment is unsafe in the sense that significant risks are present and can be eliminated or lessened by a change in practices; this requirement applies to permanent standards promulgated pursuant to the Act, as well as to other types of permanent standards, there being no reason why the Act's definition of a standard should not be deemed incorporated by reference into the provision directing the Secretary to "set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity." (Per Mr. Justice Stevens, with three Justices joining and one Justice concurring in the judgment.) Occupational Safety and Health Act of 1970, §§ 3(8), 6(b)(5), 29 U.S.C.A. §§ 652(8), 655(b)(5).

8. Labor Relations ⇐27

Requiring the Secretary of Labor, before promulgating any permanent health or safety standard under the Occupational Safety and Health Act, to make a threshold finding of significant risk is consistent with the scope of his regulatory power under the Act to promulgate standards for "toxic materials" and "harmful physical agents"; furthermore, this interpretation is supported by other provisions of the Act, such as that which requires the Secretary, in determining the priority for establishing standards, to give due regard to the urgen-

cy of the need for mandatory safety and health standards for particular industries or workplaces, and that which requires the Secretary, when he substantially alters an existing consensus standard, to explain how the new rules will "better effectuate" the Act's purposes. (Per Mr. Justice Stevens, with three Justices joining and one Justice concurring in the judgment.) Occupational Safety and Health Act of 1970, §§ 3(8), 6, (b)(5, 8), (g), 29 U.S.C.A. §§ 652(8), 655, (b)(5, 8), (g).

9. Labor Relations ⇐9.5

Legislative history of the Occupational Safety and Health Act supports the conclusion that Congress was concerned not with absolute safety, but with the elimination of significant harm. (Per Mr. Justice Stevens, with three Justices joining and one Justice concurring in the judgment.) Occupational Safety and Health Act of 1970, § 2 et seq., 29 U.S.C.A. § 651 et seq.

10. Labor Relations ⇐9.5

Secretary of Labor, in promulgating a standard placing the most stringent limitation on exposure to benzene that is technologically and economically possible, relied on a special policy for carcinogens that imposed the burden on industry of proving the existence of a safe level of exposure to benzene; he thereby exceeded his threshold responsibility of establishing the need for more stringent standards and exceeded his power under the Occupational Safety and Health Act. (Per Mr. Justice Stevens, with three Justices joining and one Justice concurring in the judgment.) Occupational Safety and Health Act of 1970, §§ 2 et seq., 3(8), 6(b)(5), 29 U.S.C.A. §§ 651 et seq., 652(8), 655(b)(5).

Syllabus *

The Occupational Safety and Health Act of 1970 (Act) delegates broad authority to the Secretary of Labor (Secretary) to promulgate standards to ensure safe and healthful working conditions for the Nation's workers (the Occupational Safety and Health Administration (OSHA) being the agency responsible for carrying out this authority). Section 3(8) of the Act defines an "occupational safety and health standard" as a standard that is "reasonably necessary or appropriate to provide safe or healthful employment." Where toxic materials or harmful physical agents are concerned, a standard must also comply with § 6(b)(5), which directs the Secretary to "set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity." When the toxic material or harmful physical agent to be regulated is a carcinogen, the Secretary has taken the position that no safe exposure level can be determined and that § 6(b)(5) requires him to set an exposure limit at the lowest technologically feasible level that will not impair the viability of the industries regulated. In this case, after having determined that there is a causal connection between benzene (a toxic substance used in manufacturing such products as motor fuels, solvents, detergents, and pesticides) and leukemia (a cancer of the white blood cells), the Secretary promulgated a standard reducing the permissible exposure limit on airborne concentrations of benzene from the consensus standard of 10 parts benzene per million parts of air (10 ppm) to 1 ppm, and prohibiting dermal contact with solutions containing benzene. On pre-enforcement review, the Court of Appeals held the standard invalid because it was based on findings unsupported by the administrative record. The court concluded that OSHA had exceeded its standard-setting authority because it had not been shown that the 1 ppm exposure limit was "reasonably necessary or appropriate to provide safe and healthful employment" as required by § 3(8), and that [1]§ 6(b)(5) did not give [1608] OSHA the unbridled discretion to adopt standards designed to create absolutely risk-free workplaces regardless of cost.

* The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States v. Detroit Lumber Co.*, 200 U.S. 321, 337, 26 S.Ct. 282, 287, 50 L.Ed. 499.

Held: The judgment is affirmed. Pp. 2858–2874; 2877–2878; 2879–2887.

581 F.2d 493, 5th Cir., affirmed.

Mr. Justice STEVENS, joined by Mr. Chief Justice BURGER, Mr. Justice STEWART, and Mr. Justice POWELL, concluded that the standard in question is invalid. Pp. 2858–2869, 2872–2873.

(a) The Court of Appeals was correct in refusing to enforce the 1 ppm exposure limit on the ground that it was not supported by appropriate findings. OSHA's rationale for lowering the permissible exposure limit from 10 ppm to 1 ppm was based, not on any finding that leukemia has ever been caused by exposure to 10 ppm of benzene and that it will *not* be caused by exposure to 1 ppm, but rather on a series of assumptions indicating that some leukemia might result from exposure to 10 ppm and that the number of cases might be reduced by lowering the exposure level to 1 ppm. Pp. 2858–2862.

(b) By empowering the Secretary to promulgate standards that are "reasonably necessary or appropriate to provide safe or healthful employment and places of employment" as required by § 3(8), the Act implies that, before promulgating any standard, the Secretary must make a finding that the workplaces in question are not safe. But "safe" is not the equivalent of "risk-free." A workplace can hardly be considered "unsafe" unless it threatens the workers with a significant risk of harm. Therefore, before the Secretary can promulgate *any* permanent health or safety standard, he must make a threshold finding that the place of employment is unsafe in the sense that significant risks are present and can be eliminated or lessened by a change in practices. This requirement applies to permanent standards promulgated pursuant to § 6(b)(5), as well as to other types of permanent standards, there being no reason why § 3(8)'s definition of a standard should not be deemed incorporated by reference into § 6(b)(5). Moreover, requiring the Secretary to make a threshold finding of significant risk is consistent with the scope of his regulatory power under § 6(b)(5) to promulgate standards for "*toxic* materials" and "*harmful* physical agents." This interpretation is supported by other provisions of the Act, such as § 6(g), which requires the Secretary, in determining the priority for establishing standards, to give due regard to the urgency of the need for mandatory safety and health standards for particular industries or workplaces, and § 6(b)(8), which requires the Secretary, when he substantially alters an existing consensus standard, to explain how the new rule will "better effectuate" the Act's purposes. Pp. 2862–2866.

(c) The Act's legislative history also supports the conclusion that Congress was concerned not with absolute safety, but with the elimination of significant harm. Pp. 2866–2869.

(d) Where the Secretary relied on a special policy for carcinogens that imposed the burden on industry of proving the existence of a safe level of exposure, thereby avoiding his threshold responsibility of establishing the need for more stringent standards, he exceeded his power. Pp. 2872–2873.

Mr. Justice STEVENS, joined by Mr. Chief Justice BURGER and Mr. Justice STEWART, also concluded that:

1. The burden was on OSHA to show, on the basis of substantial evidence, that it is at least more likely than not that long-term exposure to 10 ppm of benzene presents a significant risk of material health impairment. Here, OSHA did not even attempt to carry such burden of proof. Imposing such a burden on OSHA will not strip it of its ability to regulate carcinogens, nor will it require it to wait for deaths to occur before taking any action. The requirement that a "significant" risk be identified is not a mathematical straitjacket; OSHA is not required to support its finding that a significant risk exists with anything approaching scientific certainty; and the record in this case and OSHA's own rulings on other carcinogens indicate that there are a number of ways in which OSHA can make a rational judgment about the relative significance of the risks associated with

exposure to a particular carcinogen. Pp. 2869–2872.

2. OSHA did not make the required finding with respect to the dermal contact ban that the ban was "reasonably necessary and appropriate" to remove a significant risk of harm from such contact, but rather acted on the basis of the absolute, no-risk policy that it applies to carcinogens under the assumptions not only benzene in small doses is a carcinogen but also that it can be absorbed through the skin in sufficient amounts to present a carcinogenic risk. These assumptions are not a proper substitute for the findings of significant risk of harm required by the Act. Pp. 2873–2874.

Mr. Justice POWELL, agreeing that neither the airborne concentration standard nor the dermal contact standard satisfied the Act's requirements, would not hold that OSHA did not even attempt to carry its burden of proof on the threshold question whether exposure to benzene at 10 ppm presents a significant risk to human health. He concluded that, even assuming OSHA had met such burden, the Act also requires OSHA to determine that the economic ef- ⌊610 fects of its standard bear a ⌊reasonable relationship to the expected benefits. A standard is neither "reasonably necessary" nor "feasible," as required by the Act, if it calls for expenditures wholly disproportionate to the expected health and safety benefits. Here, although OSHA did find that the "substantial costs" of the benzene regulations were justified, the record contains neither adequate documentation of this conclusion nor any evidence that OSHA weighed the relevant considerations. The agency simply announced its finding of cost-justification without explaining the method by which it determined that the benefits justified the costs and their economic effects. Pp. 2877–2878.

Mr. Justice REHNQUIST would invalidate, as constituting an invalid delegation of legislative authority to the Secretary, the relevant portion of § 6(b)(5) of the Act as it applies to any toxic substance or harmful physical agent for which a safe level is, according to the Secretary, unknown or otherwise "infeasible." In the case of such substances, the language of § 6(b)(5) gives the Secretary absolutely no indication where on the continuum of relative safety he should set the standard. Nor is there anything in the legislative history, the statutory context, or any other source traditionally examined by this Court that provides specificity to the feasibility criterion in § 6(b)(5). Pp. 2879–2887.

William H. Alsup, Washington, D. C., for petitioner in No. 78–1036.

George H. Cohen, Washington, D. C., for petitioner in No. 78–911.

Edward W. Warren and Charles F. Lettow, Washington, D. C., for respondents.

⌊Mr. Justice STEVENS announced the ⌊611 judgment of the Court and delivered an opinion, in which THE CHIEF JUSTICE and Mr. Justice STEWART joined and in Parts I, II, III–A, III–B, III–C and III–E of which Mr. Justice POWELL joined.

The Occupational Safety and Health Act of 1970 (Act), 84 Stat. 1590, 29 U.S.C. § 651 *et seq.*, was enacted for the purpose of ensuring safe and healthful working conditions for every working man and woman in the Nation. This litigation concerns a standard promulgated by the Secretary of Labor to regulate occupational exposure to benzene, a substance which has been shown to cause cancer at high exposure levels. The principal question is whether such a showing is a sufficient basis for a standard that places the most stringent limitation on exposure to benzene that is technologically and economically possible.

The Act delegates broad authority to the Secretary to promulgate different kinds of standards. The basic definition ⌊of an "occupational safety and health standard" is ⌊612 found in § 3(8), which provides:

> "The term 'occupational safety and health standard' means a standard which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or

healthful employment and places of employment." 84 Stat. 1591, 29 U.S.C. § 652(8).

Where toxic materials or harmful physical agents are concerned, a standard must also comply with § 6(b)(5), which provides:

"The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, 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. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws." 84 Stat. 1594, 29 U.S.C. § 655(b)(5).[1]

⊥613 ⊥Wherever the toxic material to be regulated is a carcinogen, the Secretary has taken the position that no safe exposure level can be determined and that § 6(b)(5) requires him to set an exposure limit at the lowest technologically feasible level that will not impair the viability of the industries regulated. In this case, after having determined that there is a causal connection between benzene and leukemia (a cancer of the white blood cells), the Secretary set an exposure limit on airborne concentrations of benzene of one part benzene per million parts of air (1 ppm), regulated dermal and eye contact with solutions containing benzene, and imposed complex monitoring and medical testing requirements on employers whose workplaces contain 0.5 ppm or more of benzene. 29 CFR §§ 1910.1028(c), (e) (1979).

On pre-enforcement review pursuant to 29 U.S.C. § 655(f), the United States Court of Appeals for the Fifth Circuit held the regulation invalid. *American Petroleum Institute v. OSHA*, 581 F.2d 493 (1978). The court concluded that the Occupational Safety and Health Administration (OSHA)[2] had exceeded its standard-setting authority because it had not shown that the new benzene exposure limit was "reasonably necessary or appropriate to provide safe or healthful employment" as required by § 3(8),[3] and because § 6(b)(5) ⊥does "not give ⊥614 OSHA the unbridled discretion to adopt standards designed to create absolutely risk-free workplaces regardless of costs."[4]

1. The second and third sentences of this section, which impose feasibility limits on the Secretary and allow him to take into account the best available evidence in developing standards, may apply to all health and safety standards. This conclusion follows if the term "subsection" used in the second sentence refers to the entire subsection 6(b) (which sets out procedures for the adoption of all types of health and safety standards), rather than simply to the toxic materials subsection, § 6(b)(5). While Mr. Justice MARSHALL, *post*, at 2890, and respondents agree with this position, see Brief for Respondents American Petroleum Institute et al. 39; see also Currie, OSHA, 1976 Am.Bar Found. Research J. 1107, 1137, n. 151, the Government does not, see Brief for Federal Parties 58; see also Berger & Riskin, Economic and Technological Feasibility in Regulating Toxic Substances Under the Occupational Safety and Health Act, 7 Ecology L.Q. 285, 294 (1978). There is no need for us to decide this issue in these cases.

2. The OSHA is the administrative agency within the Department of Labor that is responsible for promulgating and enforcing standards under the Act. In this opinion, we refer to the "Secretary," "OSHA" and the "Agency" interchangeably.

3. "The Act imposes on OSHA the obligation to enact only standards that are reasonably necessary or appropriate to provide safe or healthful workplaces. If a standard does not fit in this definition, it is not one that OSHA is authorized to enact." 581 F.2d, at 502.

4. "Although 29 U.S.C.A. § 655(b)(5) requires the goal of attaining the highest degree of health and safety protection for the employee, it does not give OSHA the unbridled discretion

Reaching the two provisions together, the Fifth Circuit held that the Secretary was under a duty to determine whether the benefits expected from the new standard bore a reasonable relationship to the costs that it imposed. *Id.*, at 503. The court noted that OSHA had made an estimate of the costs of compliance, but that the record lacked substantial evidence of any discernible benefits.[5]

[1] We agree with the Fifth Circuit's holding that § 3(8) requires the Secretary to find, as a threshold matter, that the]615 toxic substance in question poses a significant health risk in the workplace and that a new, lower standard is therefore "reasonably necessary or appropriate to provide safe or healthful employment and places of employment." Unless and until such a finding is made, it is not necessary to address the further question whether the Court of Appeals correctly held that there must be a reasonable correlation between costs and benefits, or whether, as the federal parties argue, the Secretary is then required by § 6(b)(5) to promulgate a standard that goes as far as technologically and economically possible to eliminate the risk.

Because these are unusually important cases of first impression, we have reviewed the record with special care. In this opinion, we (1) describe the benzene standard, (2) analyze the Agency's rationale for imposing a 1 ppm exposure limit, (3) discuss the controlling legal issues, and (4) comment briefly on the dermal contact limitation.

I

Benzene is a familiar and important commodity. It is a colorless, aromatic liquid that evaporates rapidly under ordinary atmospheric conditions. Approximately 11 billion pounds of benzene were produced in the United States in 1976. Ninety-four percent of that total was produced by the petroleum and petrochemical industries, with the remainder produced by the steel industry as a byproduct of coking operations. Benzene is used in manufacturing a variety of products including motor fuels (which may contain as much as 2% benzene), solvents, detergents, pesticides, and other organic chemicals. 43 Fed.Reg. 5918 (1978).

The entire population of the United States is exposed to small quantities of benzene, ranging from a few parts per billion to 0.5 ppm, in the ambient air. Tr. 1029–1032. Over one million workers are subject to additional low-level exposures as a consequence of their employment. The majority of these employees work in gasoline service stations, benzene]616 production (petroleum refineries and coking operations), chemical

to adopt standards designed to create absolutely risk-free workplaces regardless of cost. To the contrary, that section requires standards to be feasible, and it contains a number of pragmatic limitations in the form of specific kinds of information OSHA must consider in enacting standards dealing with toxic materials. Those include 'the best available evidence,' 'research, demonstrations, experiments, and such other information as may be appropriate,' 'the latest available scientific data in the field,' and 'experience gained under this and other health and safety laws.' Moreover, in standards dealing with toxic materials, just as with all other occupational safety and health standards, the conditions and other requirements imposed by the standard must be 'reasonably necessary or appropriate to provide safe or healthful employment and places of employment.' 29 U.S.C.A. § 652(8)." *Ibid.*

5. "The lack of substantial evidence of discernable benefits is highlighted when one considers that OSHA is unable to point to any empirical evidence documenting a leukemia risk at 10 ppm even though that has been the permissible exposure limit since 1971. OSHA's assertion that benefits from reducing the permissible exposure limit from 10 ppm to 1 ppm are likely to be appreciable, an assumption based only on inferences drawn from studies involving much higher exposure levels rather than on studies involving these levels or sound statistical projections from the high-level studies, does not satisfy the reasonably necessary requirement limiting OSHA's action. *Aqua Slide* requires OSHA to estimate the extent of expected benefits in order to determine whether those benefits bear a reasonable relationship to the standard's demonstrably high costs." *Id.*, at 503–504.

processing, benzene transportation, rubber manufacturing, and laboratory operations.[6]

Benzene is a toxic substance. Although it could conceivably cause harm to a person who swallowed or touched it, the principal risk of harm comes from inhalation of benzene vapors. When these vapors are inhaled, the benzene diffuses through the lungs and is quickly absorbed into the blood. ⟨617⟩ Exposure to high concentrations produces an almost immediate effect on the central nervous system. Inhalation of concentrations of 20,000 ppm can be fatal within minutes; exposures in the range of 250 to 500 ppm can cause vertigo, nausea, and other symptoms of mild poisoning. 43 Fed. Reg. 5921 (1978). Persistent exposures at levels above 25–40 ppm may lead to blood deficiencies and diseases of the blood-forming organs, including aplastic anemia, which is generally fatal.

Industrial health experts have long been aware that exposure to benzene may lead to various types of nonmalignant diseases. By 1948 the evidence connecting high levels of benzene to serious blood disorders had become so strong that the Commonwealth of Massachusetts imposed a 35 ppm limitation on workplaces within its jurisdiction. In 1969 the American National Standards Institute (ANSI) adopted a national consensus standard of 10 ppm averaged over an 8-hour period with a ceiling concentration of 25 ppm for 10-minute periods or a maximum peak concentration of 50 ppm. *Id.*, at 5919. In 1971, after the Occupational Safety and Health Act was passed, the Secretary adopted this consensus standard as the federal standard, pursuant to 29 U.S.C. § 655(a).[7]

6. OSHA's figures indicate that 795,000 service station employees have some heightened exposure to benzene as a result of their employment. See 2 U.S. Dept. of Labor, OSHA, Technology Assessment and Economic Impact Study of an OSHA Regulation for Benzene, p. D–7 (May 1977) (hereinafter Economic Impact Statement), 11 Record, Ex. 5B, p. D–7. These employees are specifically excluded from the regulation at issue in this case. See *infra*, at 2857. OSHA states that another 629,000 employees, who are covered by the regulation, work in the other industries described. 43 Fed. Reg. 5935 (1978).

It is not clear from the record or its explanation of the permanent standard how OSHA arrived at the estimate of 629,000 exposed employees. OSHA's consultant, Arthur D. Little, Inc., estimated that there were 191,000 exposed employees, 30,000 of whom were exposed to 1 ppm or more of benzene. 1 Economic Impact Statement, p. 3–5, 11 Record, Ex. 5A, p. 3–5. In its explanation of the permanent standard OSHA stated that there were 1,440 exposed employees who worked in benzene plants, 98,000 in other petroleum refineries, 24,000 in coke ovens, 4,000 in light oil plants, 2,760 in the petrochemical industry, 52,345 who worked in bulk terminals, 23,471 drivers who loaded benzene from those terminals, 74,000 in oil and gas production, 17,000 in pipeline work, 100 at tank-car facilities, 200 at tank-truck facilities, 480 on barges, 11,400 in tire-manufacturing plants, and 13,050 in other types of rubber production. 43 Fed.Reg. 5936–5938 (1978). Although OSHA gave no estimate for laboratory workers, the A. D. Little study indicated that there were 25,000 exposed workers in that industry. These figures add up to 347,246 exposed employees—approximately 282,000 less than the overall estimate of 629,000. It is possible that some of all of these employees work in the "other industries" briefly described in OSHA's explanation; these are primarily small firms that manufacture adhesives, paint and ink or that use benzene solvents. *Id.*, at 5939. No estimate of the number of exposed employees in those industries or the aggregate cost of compliance by those industries is given either by OSHA or by A. D. Little in its consulting report.

7. Section 6(a) of the Act, as set forth in 29 U.S.C. § 655(a), provides:

"Without regard to chapter 5 of Title 5 or to the other subsections of this section, the Secretary shall, as soon as practicable during the period beginning with the effective date of this chapter and ending two years after such date, by rule promulgate as an occupational safety or health standard any national consensus standard, and any established Federal standard, unless he determines that the promulgation of such a standard would not result in improved safety or health for specifically designated employees. In the event of conflict among any such standards, the Secretary shall promulgate the standard which assures the greatest protection of the safety or health of the affected employees."

In this case the Secretary complied with the directive to choose the most protective standard by selecting the ANSI standard of 10 ppm, rather than the 25 ppm standard adopted by the American Conference of Government Industrial Hygienists. 43 Fed.Reg. 5919 (1978).

[618] As early as 1928, some health experts theorized that there might also be a connection between benzene in the workplace and leukemia.[8] In the late 1960's and early 1970's a number of epidemiological studies were published indicating that workers exposed to high concentrations of benzene were subject to significantly increased risk of leukemia.[9] In a 1974 report recommending a permanent standard for benzene, the National Institute for Occupational Safety [619] and Health (NIOSH), OSHA's research arm,[10] noted that these studies raised the "distinct possibility" that benzene caused leukemia. But, in light of the fact that all known cases had occurred at very high exposure levels, NIOSH declined to recommend a change in the 10 ppm standard, which it considered sufficient to protect against nonmalignant diseases. NIOSH suggested that further studies were necessary to determine conclusively whether there was a link between benzene and leukemia and, if so, what exposure levels were dangerous.[11]

Between 1974 and 1976 additional studies were published which tended to confirm the view that benzene can cause leukemia, at least when exposure levels are high.[12] In

8. See Delore & Borgomano, Leucémie aiguë au cours de l'intoxication benzenique. Sur l'origine toxique de certaines leucémies aiguës et leurs relations avec les anémies graves, 9 Journal de Medécine de Lyon 227 (1928). A translation of that document appears in the benzene administrative record. 2 Record, Ex. 2–60. See also Hunter, Chronic Exposure to Benzene (Benzol). II. The Clinical Effects, 21 J.Ind.Hyg. & Toxicol. 331 (1939), 3 Record, Ex. 2–74, which refers to "leucemia" as a side effect of chronic exposure to benzene.

9. Dr. Muzaffer Aksoy, a Turkish physician who testified at the hearing on the proposed benzene standard, did a number of studies concerning the effects of benzene exposure on Turkish shoemakers. The workers in Dr. Aksoy's studies used solvents containing large percentages of benzene and were constantly exposed to high concentrations of benzene vapors (between 150 and 650 ppm) under poorly ventilated and generally unhygienic conditions. See Aksoy, Acute Leukemia Due to Chronic Exposure to Benzene, 52 Am.J. of Medicine 160 (1972), 1 Record, Ex. 2–29; Aksoy, Benzene (Benzol): Its Toxicity and Effects on the Hematopoietic System, Istanbul Faculty of Medicine Monograph Series No. 51 (1970), 2 Record, Ex. 2–55; Aksoy, Erdem, & DinCol, Leukemia in Shoe-Workers Exposed Chronically to Benzene, 44 Blood 837 (1974), 2 Record, Ex. 2–53 (reporting on 26 shoeworkers who had contracted leukemia from 1967 to 1973; this represented an incidence of 13 per 100,000 rather than the 6 cases per 100,000 that would normally be expected).

Dr. Enrico Vigliani also reported an excess number of leukemia cases among Italian shoemakers exposed to glues containing a high percentage of benzene and workers in rotogravure plants who had been exposed over long periods of time to inks and solvents containing as much as 60% benzene. See Vigliani & Saita, Benzene & Leukemia, 271 New Eng.J. of Medicine 872–876 (1964), 1 Record, Ex. 2–27; Forni & Vigliani, Chemical Leukemogenesis in Man, 7 Ser.Haemat. 211 (1974), 2 Record, Ex. 2–50.

10. Title 29 U.S.C. § 669(a)(3) requires the Department of Health, Education, and Welfare (HEW) (now in part the Department of Health and Human Services) to develop "criteria" dealing with toxic materials and harmful physical agents that describe "exposure levels that are safe for various periods of employment." HEW's obligations under this section have been delegated to NIOSH, 29 U.S.C. § 671.

11. See Dept. of HEW, NIOSH, Criteria for a Recommended Standard—Occupational Exposure to Benzene 74–75 (Pub.No. 74–137, 1974), 1 Record, Ex. 2–3. In response to a letter from the Director of the Office of Standards Division, NIOSH stated that its 10 ppm standard was designed to protect against leukemia, as well as other health risks, NIOSH noted, however, that further research was necessary in order to establish adequate dose-response data for benzene and leukemia. 12 Record, Ex. 32A, 32B.

12. Aksoy published another study in 1976 reporting on an additional eight leukemia cases uncovered after 1973. In that article, he also noted that a 1969 ban on the use of benzene as a solvent had led to a decline in the number of reported leukemia cases beginning in 1974. Aksoy, Types of Leukemia in Chronic Benzene Poisoning, 55 Acta Haematologica 65 (1976), 1 Record, Ex. 2–30. Vigliani also noted a decline in leukemia cases in Italy after benzene was no longer used in glues and inks. See Vigliani & Forni, Benzene and Leukemia, 11 Environmental Res. 122 (1976), 1 Record, Ex. 2–15; Vigliani, Leukemia Associated with Benzene Exposure, 271 Annals N. Y. Acad. of Sciences 143 (1976), 2 Record, Ex. 2–49. In the latter study Vigliani noted that in the past 100% pure ben-

[620] an [1]August 1976 revision of its earlier recommendation, NIOSH stated that these studies provided "conclusive" proof of a causal connection between benzene and leukemia. 1 Record, Ex. 2–5, p. 10. Although it acknowledged that none of the intervening studies had provided the dose-response data it had found lacking two years earlier, *id.*, at 9, NIOSH nevertheless recommended that the exposure limit be set low as possible. As a result of this recommendation, OSHA contracted with a consulting firm to do a study on the costs to industry of complying with the 10 ppm standard then in effect or, alternatively, with whatever standard would be the lowest feasible. Tr. 505–506.

In October 1976, NIOSH sent another memorandum to OSHA, seeking acceleration of the rulemaking process and "strongly" recommending the issuance of an emergency temporary standard pursuant to § 6(c) of the Act, 29 U.S.C. § 655(c),[13] for benzene and two other chemicals believed to [1]be carcinogens. NIOSH recommended [621] that a 1 ppm exposure limit be imposed for benzene.[14] 1 Record, Ex. 2–6. Apparently because of the NIOSH recommendation, OSHA asked its consultant to determine the cost of complying with a 1 ppm standard instead of with the "minimum feasible" standard. Tr. 506–507. It also issued voluntary guidelines for benzene, recommending that exposure levels be limited to 1 ppm on an 8-hour time-weighted average basis wherever possible. 2 Record, Ex. 2–44.

In the spring of 1976, NIOSH had selected two Pliofilm plants in St. Marys and Akron, Ohio, for an epidemiological study of the link between leukemia and benzene exposure. In April 1977, NIOSH forwarded an interim report to OSHA indicating at least a fivefold increase in the expected incidence of leukemia for workers who had been exposed to benzene at the two plants [622] from 1940 to 1949.[15] The report submitted

zene solvents had been used and workers had been exposed on a prolonged basis to concentrations of 200–500 ppm, with peaks of up to 1500 ppm.

A number of epidemiological studies were also done among American rubber workers during this period. Dr. A. J. McMichael's studies indicated a ninefold increase in the risk of contracting leukemia among workers who were heavily exposed in the 1940's and 1950's to pure benzene used as a solvent. McMichael, Spirtas, Kupper, & Gamble, Solvent Exposure and Leukemia Among Rubber Workers: An Epidemiologic Study, 17 J. of Occup.Med. 234, 238 (1975), 2 Record, Ex. 2–37. See also Andjelkovic, Taulbee, & Symons, Mortality Experience of a Cohort of Rubber Workers, 1964–1973, 18 J. of Occup.Med. 387 (1976), 2 Record, Ex. 2–54 (also indicating an excess mortality rate from leukemia among rubber workers).

13. Section 655(c) provides:

"(1) The Secretary shall provide, without regard to the requirements of chapter 5 of title 5, for an emergency temporary standard to take immediate effect upon publication in the Federal Register if he determines (A) that employees are exposed to grave danger from exposure to substances or agents determined to be toxic or physically harmful or from new hazards, and (B) that such emergency standard is necessary to protect employees from such danger.

"(2) Such standard shall be effective until superseded by a standard promulgated in accordance with the procedures prescribed in paragraph (3) of this subsection.

"(3) Upon publication of such standard in the Federal Register the Secretary shall commence a proceeding in accordance with subsection (b) of this section, and the standard as published shall also serve as a proposed rule for the proceeding. The Secretary shall promulgate a standard under this paragraph no later than six months after publication of the emergency standard as provided in paragraph (2) of this subsection."

14. At the hearing on the permanent standard NIOSH representatives testified that they had selected 1 ppm initially in connection with the issuance of a proposed standard for vinyl chloride. In that proceeding they had discovered that 1 ppm was approximately the lowest level detectable through the use of relatively unsophisticated monitoring instruments. With respect to benzene, they also thought that 1 ppm was an appropriate standard because any lower standard might require the elimination of the small amounts of benzene (in some places up to 0.5 ppm) that are normally present in the atmosphere. Tr. 1142–1143. NIOSH's recommendation was *not* based on any evaluation of the feasibility, either technological or economic, of eliminating all exposures above 1 ppm. *Id.*, at 1156.

15. Seven fatalities from leukemia were discovered out of the 748 workers surveyed. How-

to OSHA erroneously suggested that exposures in the two plants had generally been between zero and 15 ppm during the period in question.[16] As a result of this new evi- 1623 dence 18 and the continued prodding of NIOSH, 1 Record, Ex. 2–7, OSHA did issue an emergency standard effective May 21, 1977, reducing the benzene exposure limit from 10 ppm to 1 ppm, the ceiling for exposures of up to 10 minutes from 25 ppm to 5 ppm, and eliminating the authority for peak concentrations of 50 ppm. 42 Fed. Reg. 22516 (1977). In its explanation accompanying the emergency standard, OSHA stated that benzene had been shown to cause leukemia at exposures below 25 ppm and that, in light of its consultant's report, it was feasible to reduce the exposure limit to 1 ppm. *Id.*, at 22517, 22521.

On May 19, 1977, the Court of Appeals for the Fifth Circuit entered a temporary restraining order preventing the emergency standard from taking effect. Thereafter, OSHA abandoned its efforts to make the emergency standard effective and instead issued a proposal for a permanent standard patterned almost entirely after the aborted emergency standard. *Id.*, at 27452.

In its published statement giving notice of the proposed permanent standard, OSHA did not ask for comments as to whether or not benzene presented a significant health risk at exposures of 10 ppm or less. Rather, it asked for comments as to whether 1 ppm was the minimum feasible exposure limit.[17] *Ibid.*. As OSHA's Deputy Director of Health Standards, Grover Wrenn, testified at the hearing, this formulation 19 of the issue 1624 to be considered by the Agency was consistent with OSHA's general policy with respect to carcinogens.[18] Whenever a carci-

ever, Dr. Infante, who conducted the study, stated that his statistical techniques had probably underestimated the number of leukemia cases that had actually occurred. *Id.*, at 747. The normal expected incidence of leukemia in such a population would be 1.4. 2 Record, Ex. 2–51, p. 6.

16. The authors' statement with respect to exposure levels was based on a 1946 report by the Ohio Industrial Commission indicating that, after some new ventilation equipment had been installed, exposures at the St. Marys plant had been brought within "safe" limits, in most instances ranging from zero to 10 to 15 ppm. *Id.*, at 3. As the authors later admitted, the level considered "safe" in 1946 was 100 ppm. Tr. 814–815. Moreover, only one of the seven workers who died of leukemia had begun working at St. Marys after 1946. Five of the others had worked at the Akron plant, which employed 310 of the 748 workers surveyed. *Id.*, at 2537–2538. A 1948 report by the Ohio Department of Health indicated exposure levels at the Akron plant of well over 100 ppm, with excursions in some areas up to 1,000 ppm. 17 Record, Ex. 84A, App. A, pp. 61–62. Surveys taken in the intervening years, as well as testimony by St. Marys employees at the hearing on the proposed standard, Tr. 3432–3437, indicated that both of the plants may have had relatively high exposures through the 1970's.

Industry representatives argued at the hearing that this evidence indicated that the exposure levels had been very high, as they had been in the other epidemiological studies conducted in the past. See Post-Hearing Brief for American Petroleum Institute in No. H–059 (OSHRC), pp. 23–37, 31 Record, Ex. 217–33, pp. 23–37. NIOSH witnesses, however, simply stated that actual exposure levels for the years in question could not be determined; they did agree, however, that their study should *not* be taken as proof of a fivefold increase in leukemia risk at 10–15 ppm. Tr. 814–815. In its explanation of the permanent standard, OSHA agreed with the NIOSH witnesses that no dose-response relationship could be inferred from the study:

"Comments at the hearing demonstrated that there were area exposures during this study period exceeding these levels [10–15 ppm], at times reaching values of hundreds of parts per million. Since no personal monitoring data are available, any conclusion regarding the actual individual time-weighted average exposure is speculative. Because of the lack of definitive exposure data, OSHA cannot derive any conclusions linking the excess leukemia risk observed with any specific exposure level." 43 Fed.Reg. 5927 (1978).

17. OSHA also sought public comment as to whether certain industries should be exempt from compliance, whether the proposed compliance procedures and labeling techniques were adequate, what the environmental and economic consequences of the regulation would be, and whether it was feasible to replace benzene in solvents and other products of which it constituted more than 1%.

18. It became clear at the hearing that OSHA had not promulgated the proposed standard in response to any new concern about the non-

nogen is involved, OSHA will presume that no safe level of exposure exists in the absence of clear proof establishing such a level and will accordingly set the exposure limit at the lowest level feasible.[19] The
1625 proposed 1 ppm exposure limit in this case thus was established not on the basis of a proven hazard at 10 ppm, but rather on the basis of "OSHA's best judgement at the time of the proposal of the feasibility of compliance with the proposed standard by the [a]ffected industries." Tr. 30. Given OSHA's cancer policy, it was in fact irrelevant whether there was any evidence at all of a leukemia risk at 10 ppm. The important point was that there was no evidence that there was *not* some risk, however small, at that level. The fact that OSHA did not ask for comments on whether there was a safe level of exposure for benzene was indicative of its further view that a demonstration of such absolute safety simply could not be made.[20]

Public hearings were held on the proposed standard, commencing on July 19, 1977. The final standard was issued on February 10, 1978. 29 CFR § 1910.1028 (1979).[21] In its final form, the benzene standard is designed to protect workers from whatever hazards are associated with low-level benzene exposures by requiring 1626
employers to monitor workplaces to determine the level of exposure, to provide medical examinations when the level rises above 0.5 ppm, and to institute whatever engi-

malignant effects of low-level benzene exposure. See Tr. 126–127:

"Is it accurate to say that the reason why the—why OSHA has proposed to reduce the exposure limits in the standard below the current levels is because of a perceived risk of leukemia, and not because of any new evidence it has received that the current standards are inadequate to protect against acute or chronic benzene toxicity, other than leukemia?

"MR. WRENN: I think I will simply refer the part of my statement you were referring to, in which it says, it is however benzene's leukemogenicity which is of greatest concern to OSHA. That is certainly the central issue within the ETS [emergency temporary standard] and the proposed standard."

19. Mr. Wrenn testified:

"The proposed standard requires that employee exposure to benzene in air be reduced to one part per million, with a five part per million ceiling allowable over any fifteen minute period during an eight hour work shift, and prohibits eye or prolonged skin contact with liquid benzene.

"This airborne exposure limit is based on OSHA's established regulatory policy, that in the absence of a demonstrated safe level, or a no effect level for a carcinogen, it will be assumed that none exist, and that the agency will attempt to limit employee exposure to the lowest level feasible." *Id.*, at 29–30.

See also:

"MR. WARREN: Mr. Wrenn, in promulgating the emergency temporary, and proposed permanent, benzene standards, OSHA relies heavily, and I am quoting from your testimony now, on the regulatory policy that there is no safe level for carcinogens at any—for any exposed population, and the fact that leukemia, and a leukemogen is a carcinogen, is that correct?

"MR. WRENN: I believe that I stated that slightly differently in my oral summary of the statement than it is stated in the statement itself. I said that in the absence of a known or demonstrated safe level or no effect level, our policy is to assume that none exists, and to regulate accordingly." *Id.*, at 48–49.

"MR. WRENN: I would prefer to state it as I have on a couple of occasions already this morning, and that in the absence of a demonstrated safe level of exposure, we will assume that none exists for the purpose of regulatory policy." *Id.*, at 50.

20. In answer to the question of what demonstration would suffice to establish a "safe level," Mr. Wrenn stated:

"I would like to draw a distinction, however, between what I have referred to as the demonstration that a safe level exists, and speculation or elaborate theories that one may make, and I think that the agency in its history and very likely its future regulatory policy, would, in the face of evidence demonstrating that a carcinogenic hazard does exist or did exist, in this particular set of circumstances, would be very reluctant to accept as the basis for its regulatory decisions, a theoretical argument that a safe level may, in fact, exist for a particular substance." *Id.*, at 51–52.

A NIOSH representative who testified later put it more succinctly, stating that ". . . if benzene causes leukemia, and if leukemia is a cancer, then exposure really is almost moot." *Id.*, at 1007.

21. An amendment to the standard was promulgated on June 27, 1978. 43 Fed.Reg. 27962. See n. 22, *infra*.

neering or other controls are necessary to keep exposures at or below 1 ppm.

In the standard as originally proposed by OSHA, the employer's duty to monitor, keep records, and provide medical examinations arose whenever *any* benzene was present in a workplace covered by the rule.[22] Because benzene is omnipresent in small quantities, NIOSH and the President's Council on Wage and Price Stability recommended the use of an "action level" to trigger monitoring and medical examination requirements. Tr. 1030–1032; App. 121–133. OSHA accepted this recommendation, providing under the final standard that, if initial monitoring discloses benzene concentrations below 0.5 ppm averaged over an 8-hour work day, no further action is required unless there is a change in the company's practices.[23] If exposures are [1637] above the action level, but below the 1 ppm exposure limit, employers are required to monitor exposure levels on a quarterly basis and to provide semiannual medical examinations for their exposed employees. Neither the concept of an action level, nor the specific level selected by OSHA, is challenged in this proceeding.

Whenever initial monitoring indicates that employees are subject to airborne concentrations of benzene above 1 ppm averaged over an 8-hour workday, with a ceiling of 5 ppm for any 15-minute period, employers are required to modify their plants or institute work practice controls to reduce exposures within permissible limits. Consistent with OSHA's general policy, the regulation does not allow respirators to be used if engineering modifications are technologically feasible.[24] Employers in this category are also required to perform monthly monitoring so long as their workplaces remain above 1 ppm, provide semiannual medical examinations to exposed workers, post signs in and restrict access to "regulated areas" where the permissible exposure limit is exceeded, and conduct employee training programs where necessary.

The standard also places strict limits on exposure to liquid benzene. As originally [1638] framed, the standard totally prohibited any skin or eye contact with any liquid contain-

22. Apart from its exclusion of gasoline storage and distribution facilities (an exclusion retained in the final rule, see text, at n. 25, *infra*), the proposed rule also excluded from coverage work operations in which liquid mixtures containing 1% or less benzene were used. After a year this exclusion was to be narrowed to operations where 0.1% benzene solutions were used. The rationale for the exclusion was that airborne exposures from such liquids would generally be within the 1 ppm limit. However, testimony at the hearing on the proposed rule indicated that there was no "consistent predictable relationship" between benzene content in a liquid and the resulting airborne exposure. Therefore, OSHA abandoned the idea of a percentage exclusion for liquid benzene in its final standard. 43 Fed.Reg.5942 (1978).

OSHA later reconsidered its position and, in an amendment to the permanent standard, reinstated an exclusion for liquids, setting the level at 0.5%, to be reduced to 0.1% after three years, *id.*, at 27962.

23. The exemption from the monitoring and medical testing portions of the standard for workplaces with benzene exposure levels below 0.5 ppm was not predicated on any finding that regulation of such workplaces was not feasible. OSHA's consultant, Arthur D. Little, Inc., concluded that 1 ppm was a feasible exposure limit even assuming that there was no action level (or, to put it another way, assuming that the action level was zero). Rather, it was, as NIOSH witnesses stated, a practical decision based on a determination that, where benzene exposures are below 0.5 ppm, they will be unlikely ever to rise above the permissible exposure level of 1 ppm. NIOSH was also concerned that, in the absence of an action level, employers who used sophisticated analytical equipment might be required to monitor and provide medical examinations simply because of the presence of benzene in the ambient air. Tr. 1030–1032, 1133–1134.

24. Indeed, in its explanation of the standard OSHA states that an employer is required to institute engineering controls (for example, installing new ventilation hoods) even if those controls are insufficient, by themselves, to achieve compliance and respirators must therefore be used as well. 43 Fed.Reg. 5952 (1978). OSHA's preference for engineering modifications is based on its opinion that respirators are rarely used properly (because they are uncomfortable, are often not properly fitted, etc.) and therefore cannot be considered adequate protective measures.

ing any benzene. Ultimately, after the standard was challenged, OSHA modified this prohibition by excluding liquids containing less than 0.5% benzene. After three years, that exclusion will be narrowed to liquids containing less than 0.1% benzene.

The permanent standard is expressly inapplicable to the storage, transportation, distribution, sale, or use of gasoline or other fuels subsequent to discharge from bulk terminals.[25] This exception is particularly significant in light of the fact that over 795,000 gas station employees, who are exposed to an average of 102,700 gallons of gasoline (containing up to 2% benzene) annually, are thus excluded from the protection of the standard.[26]

As presently formulated, the benzene standard is an expensive way of providing some additional protection for a relatively small number of employees. According to OSHA's figures, the standard will require capital investments in engineering controls of approximately $266 million, first-year operating costs (for monitoring, medical testing, employee training, and respirators) of [629] $187 million to $205 million and recurring annual costs of approximately $34 million.[27] 43 Fed.Reg. 5934 (1978). The figures outlined in OSHA's explanation of the costs of compliance to various industries indicate that only 35,000 employees would gain any benefit from the regulation in terms of a reduction in their exposure to benzene.[28] Over two-thirds of these workers (24,450) are employed in the rubber-manufacturing industry. Compliance costs in that industry are estimated to be rather low, with no capital costs and initial operating expenses estimated at only $34 million ($1,390 per employee); recurring annual costs would also be rather low, totalling less than $1 million. By contrast, the segment of the petroleum refining industry that produces benzene would be required to incur $24 million in capital costs and $600,000 in first-year operating expenses to provide additional protection for 300 workers ($82,000 per employee), while the petrochemical industry would be required to incur $20.9 million in capital costs and $1 million in initial operating expenses for the benefit of 552 employees ($39,675 per employee).[29] *Id.*, at 5936–5938.

25. It is also inapplicable to work operations involving 0.5% liquid benzene (0.1% after three years), see n. 22, *supra*, and to the handling of benzene in sealed containers or systems, except insofar as employers are required to provide cautionary notices and appropriate employee training.

26. Prior to the introduction of the action-level concept, A. D. Little estimated that compliance costs for the service station industry might be as high as $4 billion. Tr. 508–509. Moreover, A. D. Little's Economic Impact Statement indicated that service station employees were generally exposed to very low levels of benzene. 1 Economic Impact Statement, p. 4–21; 11 Record, Ex. 5A, p. 4–21. Still, in its explanation accompanying the permanent standard OSHA did not rule out regulation of this industry entirely, stating that it was in the process of studying whether and to what extent it should regulate exposures to gasoline in general. 43 Fed.Reg. 5943 (1978).

27. OSHA's estimate of recurring annual costs was based on the assumption that the exposure levels it had projected would be confirmed by initial monitoring and that, after the first year, engineering controls would be successful in bringing most exposures within the 1 ppm limit. Under these circumstances, the need for monitoring, medical examinations, and respirators would, of course, be drastically reduced.

28. Three hundred of these employees work in benzene plants, 5,000 in other petroleum refineries, 4,000 in light oil plants, 552 in the petrochemical industry, 156 in benzene transportation, 1,250 in laboratories, 11,400 in tire-manufacturing plants, and 13,050 in other rubber-manufacturing plants. OSHA also estimated that another 16,216 workers (5,000 in petroleum refineries, 1,104 in the petrochemical industry, 7,300 in bulk terminals, 312 in benzene transportation, and 2,500 in laboratories) would be exposed to 0.5 to 1 ppm of benzene and thus would receive a benefit in terms of more comprehensive medical examinations. *Id.*, at 5936–5938.

29. The high cost per employee in the latter two industries is attributable to OSHA's policy of requiring engineering controls rather than allowing respirators to be used to reduce exposures to the permissible limit. The relatively low estimated cost per employee in the rubber industry is based on OSHA's assumption that other solvents and adhesives can be substituted

[630] [Although OSHA did not quantify the benefits to each category of worker in terms of decreased exposure to benzene, it appears from the economic impact study done at OSHA's direction that those benefits may be relatively small. Thus, although the current exposure limit is 10 ppm, the actual exposures outlined in that study are often considerably lower. For example, for the period 1970–1975 the petrochemical industry reported that, out of a total of 496 employees exposed to benzene, only 53 were exposed to levels between 1 and 5 ppm and only 7 (all at the same plant) were exposed to between 5 and 10 ppm. 1 Economic Impact Statement, p. 4–6, Table 4–2, 11 Record, Ex 5A, p. 4–6, Table 4–2. See also *id.*, Tables 4.3–4.8 (indicating sample exposure levels in various industries).

II

[2] The critical issue at this point in the litigation is whether the Court of Appeals was correct in refusing to enforce the 1 ppm exposure limit on the ground that it was not supported by appropriate findings.[30]

[631] [3] Any discussion of the 1 ppm exposure limit must, of course, begin with the Agency's rationale for imposing that limit.[31] The written explanation of the standard fills 184 pages of the printed appendix. Much of it is devoted to a discussion of the voluminous evidence of the adverse effects of exposure to benzene at levels of concentration well above 10 ppm. This discussion demonstrates that there is ample justification for regulating occupational exposure to benzene and that the prior limit of 10 ppm, with a ceiling of 25 ppm (or a peak of 50 ppm) was reasonable. It does not, however, provide direct support for the Agency's conclusion that the limit should be reduced from 10 ppm to 1 ppm.

The evidence in the administrative record of adverse effects of benzene exposure at 10 ppm is sketchy at best. OSHA noted that there was "no dispute" that certain nonmalignant blood disorders, evidenced by a reduction in the level of red or white cells or platelets in the blood, could result from exposures of 25–40 ppm. It then stated that several studies had indicated that relatively slight changes in normal blood values could result from exposures below 25 ppm and perhaps below 10 ppm. OSHA did not attempt to make any estimate based on these studies of how significant the risk of nonmalignant disease would be at exposures of 10 ppm or less.[32] Rather, it stated that because of the lack of data concerning the linkage between low-level exposures and blood abnormalities, it was impossible to construct a dose-response curve at this [632]

for those that contain benzene and that capital costs will therefore not be required.

30. The other issue before us is whether the Court of Appeals correctly refused to enforce the dermal contact ban. That issue is discussed in Part IV, *infra*.

In the court below respondents also challenged the monitoring and medical testing requirements, arguing that certain industries should have been totally exempt from them and that, as to other industries, the Agency had not demonstrated that all the requirements were reasonably necessary to ensure worker health and safety. They also argued that OSHA's requirement that the permissible exposure limit be met through engineering controls rather than through respirators was not reasonably necessary under the Act. Because it invalidated the 1 ppm exposure limit, the Fifth Circuit had no occasion to deal with these issues, and they are not now before this Court.

31. As we have often held, the validity of an agency's determination must be judged on the basis of the agency's stated reasons for making that determination. See *SEC v. Chenery Corp.*, 318 U.S. 80, 95, 63 S.Ct. 454, 462, 87 L.Ed. 626 ("[A]n administrative order cannot be upheld unless the grounds upon which the agency acted in exercising its powers were those upon which its action can be sustained"); *FPC v. Texaco Inc.*, 417 U.S. 380, 397, 94 S.Ct. 2315, 2326, 41 L.Ed.2d 141; *FTC v. Sperry & Hutchinson Co.*, 405 U.S. 233, 249, 92 S.Ct. 898, 907, 31 L.Ed.2d 170.

32. As OSHA itself noted, some blood abnormalities caused by benzene exposure may not have any discernible health effects, while others may lead to significant impairment and even death. 43 Fed.Reg. 5921 (1978).

time.[33] OSHA did conclude, however, that the studies demonstrated that the current 10 ppm exposure limit was inadequate to ensure that no single worker would suffer a nonmalignant blood disorder as a result of benzene exposure. Noting that it is "customary" to set a permissible exposure limit by applying a safety factor of 10–100 to the lowest level at which adverse effects had been observed, the Agency stated that the evidence supported the conclusion that the limit should be set at a point "substantially less than 10 ppm" even if benzene's leukemic effects were not considered. 43 Fed.Reg. 5924–5925 (1978). OSHA did not state, however, that the nonmalignant effects of benzene exposure justified a reduction in the permissible exposure limit to 1 ppm.[34]

OSHA also noted some studies indicating an increase in chromosomal aberrations in ⟨633 workers chronically exposed to ⟩concentrations of benzene "probably less than 25 ppm."[35] However, the Agency took no definitive position as to what these aberrations meant in terms of demonstrable health effects and stated that no quantitative dose-response relationship had yet been established. Under these circumstances, chromosomal effects were categorized by OSHA as an "adverse biological event of serious concern which may pose or reflect a potential health risk and as such, must be considered in the larger purview of adverse health effects associated with benzene." *Id.*, at 5932–5934.

With respect to leukemia, evidence of an increased risk (*i. e.*, a risk greater than that borne by the general population) due to benzene exposures at or below 10 ppm was even sketchier. Once OSHA acknowledged that the NIOSH study it had relied upon in promulgating the emergency standard did not support its earlier view that benzene had been shown to cause leukemia at concentrations below 25 ppm, see 2853, *supra*, there was only one study that provided any evidence of such an increased risk. That study, conducted by the Dow Chemical Co., uncovered three leukemia deaths, versus 0.2 expected deaths, out of a population of 594 workers; it appeared that the three workers had never been exposed to more than 2 to 9 ppm of benzene. The authors of the study, however, concluded that it could not be viewed as proof of a relationship between low-level benzene exposure and leukemia because all three workers had probably been occupationally exposed to a number of other potentially carcinogenic chemicals at other points in their careers and because no leukemia deaths had been uncovered among workers who had been exposed to much higher levels of benzene. In its explanation of the permanent standard, OSHA stated that the possibility that these three leukemias had been caused by benzene exposure could not be ⟨ruled out and ⟩634

33. "A dose-response curve shows the relationship between different exposure levels and the risk of cancer [or any other disease] associated with those exposure levels. Generally, exposure to higher levels carries with it a higher risk, and exposure to lower levels is accompanied by a reduced risk." 581 F.2d, at 504, n. 24.

OSHA's comments with respect to the insufficiency of the data were addressed primarily to the lack of data at low exposure levels. OSHA did not discuss whether it was possible to make a rough estimate, based on the more complete epidemiological and animal studies done at higher exposure levels, of the significance of the risks attributable to those levels, nor did it discuss whether it was possible to extrapolate from such estimates to derive a risk estimate for low-level exposures.

34. OSHA did not invoke the automatic rule of reducing exposures to the lowest limit feasible that it applies to cancer risks. Instead, the Secretary reasoned that prudent health policy merely required that the permissible exposure limit be set "sufficiently below the levels at which adverse effects have been observed to assure adequate protection for all exposed employees." 43 Fed.Reg. 5925 (1978). While OSHA concluded that application of this rule would lead to an exposure limit "substantially less than 10 ppm," it did not state either what exposure level it considered to present a significant risk of harm or what safety factor should be applied to that level to establish a permissible exposure limit.

35. While citing these studies, OSHA also noted that other studies of similarly exposed workers had not indicated any increased level of chromosome damage.

that the study, although not evidence of an increased risk of leukemia at 10 ppm, was therefore "consistent with the findings of many studies that there is an excess leukemia risk among benzene exposed employees." 43 Fed.Reg. 5928 (1978). The Agency made no finding that the Dow study, any other empirical evidence, or any opinion testimony demonstrated that exposure to benzene at or below the 10 ppm level had ever in fact caused leukemia. See 581 F.2d, at 503, where the Court of Appeals noted that OSHA was "unable to point to any empirical evidence documenting a leukemia risk at 10 ppm . . . ."

In the end OSHA's rationale for lowering the permissible exposure limit to 1 ppm was based, not on any finding that leukemia has ever been caused by exposure to 10 ppm of benzene and that it will *not* be caused by exposure to 1 ppm, but rather on a series of assumptions indicating that some leukemias might result from exposure to 10 ppm and that the number of cases might be reduced by reducing the exposure level to 1 ppm. In reaching that result, the Agency first unequivocally concluded that benzene is a human carcinogen.[36] Second, it concluded that industry had failed to prove that there is a safe threshold level of exposure to benzene below which no excess leukemia cases would occur. In reaching this conclusion OSHA rejected industry contentions that certain epidemiological studies indicating no excess risk of leukemia among workers exposed at levels below 10 ppm were sufficient to establish that the threshold level of safe exposure was at or above 10 ppm.[37] It also rejected an industry witness' testimony that a dose-response curve could be constructed on the basis of the reported epidemiological studies and that this curve indicated that reducing the permissible exposure limit from 10 to 1 ppm would prevent at most one leukemia and one other cancer death every six years.[38] 1635

Third, the Agency applied its standard policy with respect to carcinogens,[39] con-

36. "The evidence in the record conclusively establishes that benzene is a human carcinogen. The determination of benzene's leukemogenicity is derived from the evaluation of all the evidence in totality and is not based on any one particular study. OSHA recognizes, as indicated above that individual reports vary considerably in quality, and that some investigations have significant methodological deficiencies. While recognizing the strengths and weaknesses in individual studies, OSHA nevertheless concludes that the benzene record as a whole clearly establishes a causal relationship between benzene and leukemia." *Id.*, at 5931.

37. In rejecting these studies, OSHA stated that: "Although the epidemiological method can provide strong evidence of a causal relationship between exposure and disease in the case of positive findings, it is by its very nature relatively crude and an insensitive measure." After noting a number of specific ways in which such studies are often defective, the Agency stated that it is "OSHA's policy when evaluating negative studies, to hold them to higher standards of methodological accuracy." *Id.*, at 5931–5932. Viewing the industry studies in this light, OSHA concluded that each of them had sufficient methodological defects to make them unreliable indicators of the safety of low-level exposures to benzene.

38. OSHA rejected this testimony in part because it believed the exposure data in the epidemiological studies to be inadequate to formulate a dose-response curve. It also indicated that even if the testimony was accepted—indeed as long as there was any increase in the risk of cancer—the Agency was under an obligation to "select the level of exposure which is most protective of exposed employees." *Id.*, at 5941.

39. In his dissenting opinion, Mr. Justice MARSHALL states that the Agency did not rely "blindly on some Draconian carcinogen 'policy'" in setting a permissible exposure limit for benzene. He points to the large number of witnesses the Agency heard and the voluminous record it compiled as evidence that it relied instead on the particular facts concerning benzene. With all due respect, we disagree with Mr. Justice MARSHALL's interpretation of the Agency's rationale for its decision. After hearing the evidence, the Agency relied on the same policy view it had stated at the outset, see *supra*, at 2855, namely, that, in the absence of clear evidence to the contrary, it must be assumed that no safe level exists for exposure to a carcinogen. The Agency also reached the entirely predictable conclusion that industry had not carried its concededly impossible burden, see n. 41, *infra*, of proving that a safe level of exposure exists for benzene. As the Agency made clear later in its proposed generic cancer policy, see n. 51, *infra*, it felt compelled to allow

cluding that, in the absence of definitive [636] proof of a safe level, it must be assumed that *any* level above zero presents *some* increased risk of cancer.[40] As the federal parties point out in their brief, there are a number of scientists and public health specialists who subscribe to this view, theorizing that a susceptible person may contract cancer from the absorption of even one molecule of a carcinogen like benzene. Brief for Federal Parties 18–19.[41]

[637] Fourth, the Agency reiterated its view of the Act, stating that it was required by § 6(b)(5) to set the standard either at the level that has been demonstrated to be safe or at the lowest level feasible, whichever is higher. If no safe level is established, as in this case, the Secretary's interpretation of the statute automatically leads to the selection of an exposure limit that is the lowest feasible.[42] Because of benzene's importance to the economy, no one has ever suggested that it would be feasible to eliminate its use entirely, or to try to limit exposures to the small amounts that are omnipresent. Rather, the Agency selected 1 ppm as a workable exposure level, see n. 14, *supra*, and then determined that compliance with that level was technologically feasible and that "the economic impact of . . . [compliance] will not be such as to threaten the financial welfare of the affected firms or the general economy." 43 Fed.Reg. 5939 (1978). It therefore held that 1 ppm was the minimum feasible exposure level within the meaning of § 6(b)(5) of the Act.

Finally, although the Agency did not refer in its discussion of the pertinent legal authority to any duty to identify the anticipated benefits of the new standard, it did conclude that some benefits were likely to result from reducing the exposure limit from 10 ppm to 1 ppm. This conclusion was based, again, not on evidence, but rather on

industry witnesses to go over the same ground in each regulation dealing with a carcinogen, despite its policy view. The generic policy, which has not yet gone into effect, was specifically designed to eliminate this duplication of effort in each case by foreclosing industry from arguing that there is a safe level for the particular carcinogen being regulated. 42 Fed.Reg. 54154–54155 (1977).

40. "As stated above, the positive studies on benzene demonstrate the causal relationship of benzene to the induction of leukemia. Although these studies, for the most part involve high exposure levels, it is OSHA's view that once the carcinogenicity of a substance has been established qualitatively, any exposure must be considered to be attended by risk when considering any given population. OSHA therefore believes that occupational exposure to benzene at low levels poses a carcinogenic risk to workers." 43 Fed.Reg. 5932 (1978).

41. The so-called "one hit" theory is based on laboratory studies indicating that one molecule of a carcinogen may react in the test tube with one molecule of DNA to produce a mutation. The theory is that, if this occurred in the human body, the mutated molecule could replicate over a period of years and eventually develop into a cancerous tumor. See OSHA's Proposed Rule on the Identification, Classification and Regulation of Toxic Substances Posing a Potential Carcinogenic Risk, 42 Fed.Reg. 54148, 54165–54167 (1977). Industry witnesses challenged this theory, arguing that the presence of several different defense mechanisms in the human body make it unlikely that a person would actually contract cancer as a result of absorbing one carcinogenic molecule. Thus, the molecule might be detoxified before reaching a critical site, damage to a DNA molecule might be repaired, or a mutated DNA molecule might be destroyed by the body's immunological defenses before it could develop into a cancer. Tr. 2836.

In light of the improbability of a person's contracting cancer as a result of a single hit, a number of the scientists testifying on both sides of the issue agreed that every individual probably does have a threshold exposure limit below which he or she will not contract cancer. See, *e. g., id.*, at 1179–1181. The problem, however, is that individual susceptibility appears to vary greatly and there is at present no way to calculate each and every person's threshold. Thus, even industry witnesses agreed that if the standard must ensure with absolute certainty that every single worker is protected from any risk of leukemia, only a zero exposure limit would suffice. *Id.*, at 2492, 2830.

42. "There is no doubt that benzene is a carcinogen and must, for the protection and safety of workers, be regulated as such. Given the inability to demonstrate a threshold or establish a safe level, it is appropriate that OSHA prescribe that the permissible exposure to benzene be reduced to the lowest level feasible." 43 Fed.Reg. 5932 (1978).

the assumption that the risk of leukemia will decrease as exposure levels decrease. Although the Agency had found it impossible to construct a dose-response curve that ⌊638 would predict with any accuracy the ⌊number of leukemias that could be expected to result from exposures at 10 ppm, at 1 ppm, or at any intermediate level, it nevertheless "determined that the benefits of the proposed standard are likely to be appreciable." [43] 43 Fed.Reg. 5941 (1978). In light of the Agency's disavowal of any ability to determine the numbers of employees likely to be adversely affected by exposures of 10 ppm, the Court of Appeals held this finding to be unsupported by the record. 581 F.2d, at 503.[44]

It is noteworthy that at no point in its lengthy explanation did the Agency quote or even cite § 3(8) of the Act. It made no finding that any of the provisions of the new standard were "reasonably necessary or appropriate to provide safe or healthful employment and places of employment." Nor did it allude to the possibility that any such finding might have been appropriate.

⌊639

⌊III

Our resolution of the issues in these cases turns, to a large extent, on the meaning of and the relationship between § 3(8), which defines a health and safety standard as a standard that is "reasonably necessary and appropriate to provide safe or healthful employment," and § 6(b)(5), which directs the Secretary in promulgating a health and safety standard for toxic materials to "set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity . . . ."

In the Government's view, § 3(8)'s definition of the term "standard" has no legal significance or at best merely requires that a standard not be totally irrational. It takes the position that § 6(b)(5) is controlling and that it requires OSHA to promulgate a standard that either gives an absolute assurance of safety for each and every worker or reduces exposures to the lowest level feasible. The Government interprets "feasible" as meaning technologically achievable at a cost that would not impair the viability of the industries subject to the regulation. The respondent industry representatives, on the other hand, argue that the Court of Appeals was correct in holding that the "reasonably necessary and appropriate" language of § 3(8), along with the feasibility requirement of § 6(b)(5), requires the Agency to quantify both the costs and the benefits of a proposed rule and to conclude that they are roughly commensurate.

[4] In our view, it is not necessary to decide whether either the Government or industry is entirely correct. For we think it is clear that § 3(8) does apply to all permanent standards promulgated under the Act and that it requires the Secretary, before issuing any standard, to determine that it is

43. At an earlier point in its explanation, OSHA stated:

"There is general agreement that benzene exposure causes leukemia as well as other fatal diseases of the bloodforming organs. In spite of the certainty of this conclusion, there does not exist an adequate scientific basis for establishing the quantitative dose response relationship between exposure to benzene and the induction of leukemia and other blood diseases. The uncertainty in both the actual magnitude of expected deaths and in the theory of extrapolation from existing data to the OSHA exposure levels places the estimation of benefits on 'the frontiers of scientific knowledge.' While the actual estimation of the number of cancers to be prevented is highly uncertain, the evidence indicates that the number may be appreciable. There is general agreement that even in the absence of the ability to establish a 'threshold' or 'safe' level for benzene and other carcinogens, a dose response relationship is likely to exist; that is, exposure to higher doses carries with it a higher risk of cancer, and conversely, exposure to lower levels is accompanied by a reduced risk, even though a precise quantitative relationship cannot be established." *Id.*, at 5940.

44. The court did, however, hold that the Agency's other conclusions—that there is *some* risk of leukemia at 10 ppm and that the risk would decrease by decreasing the exposure limit to 1 ppm—were supported by substantial evidence. 581 F.2d, at 503.

reasonably necessary and appropriate to remedy a significant risk of material health impairment. Only after the Secretary has made the threshold determination that such [640] a risk exists [with respect to a toxic substance, would it be necessary to decide whether § 6(b)(5) requires him to select the most protective standard he can consistent with economic and technological feasibility, or whether, as respondents argue, the benefits of the regulation must be commensurate with the costs of its implementation. Because the Secretary did not make the required threshold finding in these cases, we have no occasion to determine whether costs must be weighed against benefits in an appropriate case.

A

Under the Government's view, § 3(8), if it has any substantive content at all,[45] merely [641] requires OSHA to issue standards that are reasonably calculated to produce a safer or more healthy work environment. Tr. of Oral Arg. 18, 20. Apart from this minimal requirement of rationality, the Government argues that § 3(8) imposes no limits on the Agency's power, and thus would not prevent it from requiring employers to do whatever would be "reasonably necessary" to eliminate all risks of any harm from their workplaces.[46] With respect to toxic substances and harmful physical agents, the Government takes an even more extreme position. Relying on § 6(b)(5)'s direction to set a standard "which most adequately assures . . . . that no employee will suffer material impairment of health or functional capacity," the Government contends that the Secretary is required to impose standards that either guarantee workplaces that are free from any risk of material health impairment, however small, or that come as close as possible to doing so without ruining entire industries.

[5] If the purpose of the statute were to eliminate completely and with absolute certainty any risk of serious harm, we would agree that it would be proper for the Secretary to interpret §§ 3(8) and 6(b)(5) in this fashion. But we think it is clear that the statute was not designed to require employers to provide absolutely risk-free workplaces whenever it is technologically feasible to do so, so long as the cost is not great

45. We cannot accept the argument that § 3(8) is totally meaningless. The Act authorized the Secretary to promulgate three different kinds of standards—national consensus standards, permanent standards, and temporary emergency standards. The only substantive criteria given for two of these—national consensus standards and permanent standards for safety hazards not covered by § 6(b)(5)—are set forth in § 3. While it is true that § 3 is entitled "definitions," that fact does not drain each definition of substantive content. For otherwise there would be no purpose in defining the critical terms of the statute. Moreover, if the definitions were ignored, there would be no statutory criteria at all to guide the Secretary in promulgating either national consensus standards or permanent standards other than those dealing with toxic materials and harmful physical agents. We may not expect Congress to display perfect craftsmanship, but it is unrealistic to assume that it intended to give no direction whatsoever to the Secretary in promulgating most of his standards.

The structure of the separate subsection describing emergency temporary standards, 29 U.S.C. § 655(c), quoted in n. 13, *supra*, supports this conclusion. It authorizes the Secretary to bypass the normal procedures for setting permanent standards if he makes two findings: (A) that employees are exposed to "grave danger" from exposure to toxic substances and (B) that an emergency standard is "necessary" to protect the employees from that danger. Those findings are to be compared with those that are implicitly required by the definition of the permanent standard—(A) that there be a significant—as opposed to a "grave"—risk, and (B) that additional regulation is "reasonably necessary or appropriate"—as opposed to "necessary." It would be anomalous for Congress to require specific findings for temporary standards but to give the Secretary a *carte blanche* for permanent standards.

46. The Government does not concede that the feasibility requirement in the second sentence of § 6(b)(5) applies to health and safety standards other than toxic substances standards. See n. 1, *supra*. However, even if it did the Government's interpretation of the term "feasible," when coupled with its view of § 3(8), would still allow the Agency to require the elimination of even insignificant risks at great cost, so long as an entire industry's viability would not be jeopardized.

enough to destroy an entire industry. Rather, both the language and structure of the Act, as well as its legislative history, indicate that it was intended to require the elimination, as far as feasible, of significant risks of harm.

⊥642 ⊥B

[6] By empowering the Secretary to promulgate standards that are "reasonably necessary or appropriate to provide safe or healthful employment and places of employment," the Act implies that, before promulgating any standard, the Secretary must make a finding that the workplaces in question are not safe. But "safe" is not the equivalent of "risk-free." There are many activities that we engage in every day—such as driving a car or even breathing city air—that entail some risk of accident or material health impairment; nevertheless, few people would consider these activities "unsafe." Similarly, a workplace can hardly be considered "unsafe" unless it threatens the workers with a significant risk of harm.

[7, 8] Therefore, before he can promulgate *any* permanent health or safety standard, the Secretary is required to make a threshold finding that a place of employment is unsafe—in the sense that significant risks are present and can be eliminated or lessened by a change in practices. This requirement applies to permanent standards promulgated pursuant to § 6(b)(5), as well as to other types of permanent standards. For there is no reason why § 3(8)'s definition of a standard should not be deemed incorporated by reference into § 6(b)(5). The standards promulgated pursuant to § 6(b)(5) are just one species of the genus of standards governed by the basic requirement. That section repeatedly uses the term "standard" without suggesting any exception from, or qualification of, the general definition; on the contrary, its directs the Secretary to select "*the* standard"—that is to say, one of various possible alternatives that satisfy the basic definition in § 3(8)—that is most protective.[47] Moreover, requiring the ⊥Secretary to make a threshold finding of significant risk is consistent with the scope of the regulatory power granted to him by § 6(b)(5), which empowers the Secretary to promulgate standards, not for chemicals and physical agents generally, but for "*toxic* materials" and "*harmful* physical agents."[48] ⊥643

This interpretation of §§ 3(8) and 6(b)(5) is supported by the other provisions of the

47. Section 6(b)(5) parallels § 6(a) in this respect. Section 6(a) requires the Secretary, when faced with a choice between two national consensus standards, to choose the more protective standard, see n. 7, *supra*. Just as § 6(a) does not suggest that this more protective standard need not meet the definition of a national consensus standard set forth in § 3(9), so § 6(b)(5) does not suggest that the most protective toxic material standard need not conform to the definition of a "standard" in § 3(8).

48. The rest of § 6(b)(5), while requiring the Secretary to promulgate the standard that "most adequately assures . . . that no employee will suffer material impairment of health or functional capacity," also contains phrases implying that the Secretary should consider differences in degrees of significance rather than simply a total elimination of all risks. Thus, the standard to be selected is one that "most adequately assures, to the extent feasible, on the basis of the best available evidence," that no such harm will result. The Secretary is also directed to take into account "research, demonstrations, experiments, and such other information as may be appropriate" and to consider "[i]n addition to the attainment of the highest degree of health and safety protection for the employee . . . the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws."

Mr. Justice MARSHALL states that our view of § 3(8) would make the first sentence in § 6(b)(5) superfluous. We disagree. The first sentence of § 6(b)(5) requires the Secretary to select a highly protective standard once he has determined that a standard should be promulgated. The threshold finding that there is a need for such a standard in the sense that there is a significant risk in the workplace is not unlike the threshold finding that a chemical is toxic or a physical agent is harmful. Once the Secretary has made the requisite threshold finding, § 6(b)(5) directs him to choose the most protective standard that still meets the definition of a standard under § 3(8), consistent with feasibility.

Act. Thus, for example, § 6(g) provides in part that

> "[i]n determining the priority for establishing standards under this section, the Secretary shall give due regard to the urgency of the need for mandatory safety and health standards for particular industries, trades, crafts, occupations, businesses, workplaces or work environments."

The Government has expressly acknowledged that this section requires the Secretary to undertake some cost-benefit analysis before he promulgates any standard, requiring the elimination of the most serious hazards first.[49] If such an analysis must precede the promulgation of any standard, it seems manifest that Congress intended, at a bare minimum, that the Secretary find a significant risk of harm and therefore a probability of significant benefits before establishing a new standard.

Section 6(b)(8) lends additional support to this analysis. That subsection requires that, when the Secretary substantially alters an existing consensus standard, he must explain how the new rule will "better effectuate" the purposes of the Act.[50] If this requirement was intended to be more than a meaningless formality, it must be read to impose upon the Secretary the duty to find that an existing national consensus standard is not adequate to protect workers from a continuing and significant risk of harm. Thus, in this case, the Secretary was required to find that exposures at the current permissible exposure level of 10 ppm present a significant risk of harm in the workplace.

In the absence of a clear mandate in the Act, it is unreasonable to assume that Congress intended to give the Secretary the unprecedented power over American industry that would result from the Government's view of §§ 3(8) and 6(b)(5), coupled with OSHA's cancer policy. Expert testimony that a substance is probably a human carcinogen—either because it has caused cancer in animals or because individuals have contracted cancer following extremely high exposures—would justify the conclusion that the substance poses some risk of serious harm no matter how minute the exposure and no matter how many experts testified that they regarded the risk as insignificant. That conclusion would in turn justify pervasive regulation limited only by the constraint of feasibility. In light of the fact that there are literally thousands of substances used in the workplace that have been identified as carcinogens or suspect carcinogens, the Government's theory would give OSHA power to impose enormous costs that might produce little, if any, discernible benefit.[51]

49. "First, 29 U.S.C. § 655(g) requires the Secretary to establish priorities in setting occupational health and safety standards so that the more serious hazards are addressed first. In setting such priorities the Secretary must, of course, consider the relative costs, benefits and risks." Reply Brief for Federal Parties 13. The Government argues that the Secretary's setting of priorities under this section is not subject to judicial review. Tr. of Oral Arg. 23. While we agree that a court cannot tell the Secretary which of two admittedly significant risks he should act to regulate first, this section, along with §§ 3(8) and 6(b)(5), indicates that the Act does limit the Secretary's power to requiring the elimination of significant risks.

50. Section 6(b)(8), as set forth in 29 U.S.C. § 655(b)(8), provides:

> "Whenever a rule promulgated by the Secretary differs substantially from an existing national consensus standard, the Secretary shall, at the same time, publish in the Federal Register a statement of the reasons why the rule as adopted will better effectuate the purposes of this chapter than the national consensus standard."

51. OSHA's proposed generic cancer policy, 42 Fed.Reg. 54148 (1977), indicates that this possibility is not merely hypothetical. Under its proposal, whenever there is a certain quantum of proof—either from animal experiments, or, less frequently, from epidemiological studies—that a substance causes cancer at any exposure level, an emergency temporary standard would be promulgated immediately, requiring employers to provide monitoring and medical examinations and to reduce exposures to the lowest feasible level. A proposed rule would then be issued along the same lines, with objecting employers effectively foreclosed from presenting evidence that there is little or no risk associated with current exposure levels. *Id.*, at 54154–54155; 29 CFR, Part 1990 (1977).

[646] If the Government was correct in arguing that neither § 3(8) nor § 6(b)(5) requires that the risk from a toxic substance be quantified sufficiently to enable the Secretary to characterize it as significant in an understandable way, the statute would make such a "sweeping delegation of legislative power" that it might be unconstitutional under the Court's reasoning in *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495, 539, 55 S.Ct. 837, 847, 79 L.Ed. 1570, and *Panama Refining Co. v. Ryan*, 293 U.S. 388, 55 S.Ct. 241, 79 L.Ed. 446. A construction of the statute that avoids this kind of open-ended grant should certainly be favored.

C

[9] The legislative history also supports the conclusion that Congress was concerned, not with absolute safety, but with the elimination of significant harm. The examples of industrial hazards referred to in the Committee hearings and debates all involved situations in which the risk was unquestionably significant. For example, the Senate Committee on Labor and Public Welfare noted that byssinosis, a disabling lung disease caused by breathing cotton dust, affected as many as 30% of the workers in carding or spinning rooms in some American cotton mills and that as many as 100,000 active or retired workers were then suffering from the disease. It also noted that statistics indicated that 20,000 out of 50,000 workers who had performed insulation work were likely to die of asbestosis, lung cancer, or mesothelyioma as a result of breathing asbestos fibers. Another example given of an occupational health hazard that would be controlled by the Act was betanaphthylamine, a "chemical so toxic that any exposure at all is likely to cause the development of bladder cancer over a period of years." S.Rep.No.91-1282, pp. 3-4 (1970); Legislative History of the Occupational Safety and Health Act of 1970 (Committee Print compiled for the Senate Committee on Labor and Public Welfare), pp. 143-144 (1971) (hereafter Leg.Hist.); U.S.Code Cong. & Admin.News 1970, pp. 5177, 5180.

Moreover, Congress specifically amended § 6(b)(5) to make it perfectly clear that it [647] does not require the Secretary to promulgate standards that would assure an absolutely risk-free workplace. Section 6(b)(5) of the initial Committee bill provided that

> "[t]he Secretary, in promulgating standards under this subsection, shall set the standard which most adequately and feasibly assures, on the basis of the best available evidence, that no employee will suffer *any* impairment of health or functional capacity, or diminished life expectancy even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life." (Emphasis supplied.) S. 2193, 91st Cong., 2d Sess., p. 39 (1970), Leg.Hist. 242.

On the floor of the Senate, Senator Dominick questioned the wisdom of this provision, stating:

> "How in the world are we ever going to live up to that? What are we going to do about a place in Florida where mosquitoes are getting at the employee—perish the thought that there may be mosquitoes in Florida? But there are black flies in Minnesota and Wisconsin. Are we going to say that if employees get bitten by those for the rest of their lives they will not have been done any harm at all? Probably they will not be, but do we know?" 116 Cong.Rec. 36522 (1970), Leg. Hist. 345.

The scope of the proposed regulation is indicated by the fact that NIOSH has published a list of 2,415 potential occupational carcinogens, NIOSH, Suspected Carcinogens: A Subfile of the Registry of Toxic Effects of Chemical Substances (HEW Pub. No. 77-149, 2d ed. 1976).

OSHA has tentatively concluded that 269 of these substances have been proved to be carcinogens and therefore should be subject to full regulation. See OSHA Press Release, USDL 78-625 (July 14, 1978).

He then offered an amendment deleting the ⟨648 entire subsection.[52] ⟨After discussions with the sponsors of the Committee bill, Senator Dominick revised his amendment. Instead of deleting the first sentence of § 6(b)(5) entirely, his new amendment limited the application of that subsection to toxic materials and harmful physical agents and changed "any" impairment of health to "material" impairment.[53] In discussing this change, Senator Dominick noted that the Committee's bill read as if a standard had to "assure that, no matter what anybody was doing, the standard would protect him for the rest of his life against any foreseeable hazard." Such an "unrealistic standard," he stated, had not been intended by the sponsors of the bill. Rather, he explained that the intention of the bill, as implemented by the amendment, was to require the Secretary

> "to use his best efforts to promulgate the best available standards, and in so doing, . . . he should take into account that anyone working in toxic agents and physical ⟨agents which might be harmful ⟨649 may be subjected to such conditions for the rest of his working life, so that we can get at something which might not be toxic now, if he works in it a short time, but if he works in it the rest of his life might be very dangerous; and we want to make sure that such things are taken into consideration in establishing standards." 116 Cong.Rec., at 37622–37623, Leg.Hist. 502–503.[54]

52. In criticizing the Committee bill, Senator Dominick also made the following observations:

"It is unrealistic to attempt, as this section apparently does, to establish a utopia free from any hazards. Absolute safety is an impossibility and it will only create confusion in the administration of this act for the Congress to set clearly unattainable goals." 116 Cong.Rec. 37614 (1970), Leg.Hist. 480.

"But I ask, Mr. President, just thinking about that language, let us take a fellow who is a streetcar conductor or a bus conductor at the present time. How in the world, in the process of the pollution we have in the streets or in the process of the automobile accidents that we have all during a working day of any one driving a bus or trolley car, or whatever it may be, can we set standards that will make sure he will not have any risk to his life for the rest of his life? It is totally impossible for this to be put in a bill; and yet it is in the committee bill." 116 Cong.Rec., at 37337, Leg.Hist. 423.

As an opponent of the legislation, Senator Dominick may have exaggerated the significance of the problem since the language in § 3(8) already was sufficient to prevent the Secretary from trying "to establish a utopia free from any hazards." Nevertheless, the fact that Congress amended the bill to allay Senator Dominick's concern demonstrates that it did not intend the statute to achieve "clearly unattainable goals."

53. Senator Dominick had also been concerned that the placement of the word "feasibly" could be read to require the Secretary to "ban all occupations in which there remains *some* risk of injury, impaired health, or life expectancy," since the way to most "adequately" and "feasibly" assure absolute protection might well be to prohibit the occupation entirely. 116 Cong. Rec., at 36530, Leg.Hist. 366–367. In his final amendment, he attempted to cure this problem by relocating the feasibility requirement, changing "the standard which most adequately and feasibly assures" to "the standard which most adequately assures, to the extent feasible."

54. Mr. Justice MARSHALL argues that Congress could not have thought § 3(8) had any substantive meaning inasmuch as § 6(b)(5), as originally drafted, applied to all standards and not simply to standards for toxic materials and harmful physical substances. However, as this legislative history indicates, it appears that the omission of the words "toxic substances" and "harmful physical agents" from the original draft of § 6(b)(5) was entirely inadvertent. As Senator Dominick noted, the Committee had always intended that subsection to apply only to that limited category of substances. The reason that Congress drafted a special section for these substances was not, as Mr. Justice MARSHALL suggests, because it thought that there was a need for special protection in these areas. Rather, it was because Congress recognized that there were special problems in regulating health risks as opposed to safety risks. In the latter case, the risks are generally immediate and obvious, while in the former, the risks may not be evident until a worker has been exposed for long periods of time to particular substances. It was to ensure that the Secretary took account of these long-term risks that Congress enacted § 6(b)(5).

Senator Williams, one of the sponsors of the Committee bill, agreed with the interpretation, and the amendment was adopted.

In their reply brief the federal parties argue that the Dominick amendment simply means that the Secretary is not required to eliminate threats of insignificant harm; they argue that § 6(b)(5) still requires the Secretary to set standards that ensure that not even one employee will be subject to any risk of serious harm—no matter how small that risk may be.[55] ⊥650 This interpretation is at odds with Congress' express recognition of the futility of trying to make all workplaces totally risk-free. Moreover, not even OSHA follows this interpretation of § 6(b)(5) to its logical conclusion. Thus, if OSHA is correct that the only no-risk level for leukemia due to benzene exposure is zero and if its interpretation of § 6(b)(5) is correct, OSHA should have set the exposure limit as close to zero as feasible. But OSHA did not go about its task in that way. Rather, it began with a 1 ppm level, selected at least in part to ensure that employers would not be required to eliminate benzene concentrations that were little greater than the so-called "background" exposures experienced by the population at large. See n. 14, *supra*. Then, despite suggestions by some labor unions that it was feasible for at least some industries to reduce exposures to well below 1 ppm,[56] OSHA decided to apply the same limit to all, largely as a matter of administrative convenience. 43 Fed.Reg. 5947 (1978).

OSHA also deviated from its own interpretation of § 6(b)(5) in adopting an action level of 0.5 ppm below which monitoring and medical examinations are not required. In light of OSHA's cancer policy, it must have assumed that some employees would be at risk because of exposures below 0.5 ppm. These employees would thus presumably benefit from medical examinations, which might uncover any benzene-related problems. OSHA's consultant advised the Agency that it was technologically and economically feasible to require that such examinations be provided. Nevertheless, OSHA adopted an action level, largely because the insignificant benefits of giving ⊥651 such examinations and performing the necessary monitoring did not justify the substantial cost.[57]

OSHA's concessions to practicality in beginning with a 1 ppm exposure limit and using an action level concept implicitly adopt an interpretation of the statute as not requiring regulation of insignificant risks.[58] It is entirely consistent with this interpretation to hold that the Act also

55. Reply Brief for Federal Parties 24–26. While it is true that some of Senator Dominick's comments were concerned with the relative unimportance of minor injuries (see his "fly" example quoted *supra*, at 2867), it is clear that he was also concerned with the remote possibility of major injuries, see n. 52, *supra*.

56. One union suggested a 0.5 ppm permissible exposure limit for oil refineries and a 1 ppm ceiling (rather than a time-weighted average) exposure for all other industries, with no use of an action level, Tr. 1250, 1257. Another wanted a 1 ppm ceiling limit for all industries, *id.*, at 3375–3376.

57. "A need for an action level is also suggested by the record evidence that some minimal exposure to benzene occurs naturally from animal and plant matter (Tr. 749–750; 759–760). Naturally occurring benzene concentrations, it appears, may range from 0.02 to 15 parts per billion (Ex. 117, p. 1). Additionally, it was suggested by certain employers that their operations be exempted from the requirements of the standard because those operations involve only intermittent and low level exposures to benzene. The use of the action level concept should accommodate these concerns in all cases where exposures are indeed extremely low since it substantially reduces the monitoring of employees who are below the action level and removes for these employees the requirements for medical surveillance. At the same time, employees with *significant* overexposure are afforded the full protection of the standard." (Emphasis added.) 43 Fed.Reg. 5942 (1978).

58. The Government also states that it is OSHA's policy to attempt to quantify benefits wherever possible. While this is certainly a reasonable position, it is not consistent with OSHA's own view of its duty under § 6(b)(5). In light of the inconsistencies in OSHA's position and the legislative history of the Act, we decline to defer to the Agency's interpretation.

requires the Agency to limit its endeavors in the standard-setting area to eliminating significant risks of harm.

Finally, with respect to the legislative history, it is important to note that Congress repeatedly expressed its concern about allowing the Secretary to have too much power over American industry. Thus, Congress refused to give the Secretary the power to shut down plants unilaterally because of an imminent danger, see *Whirlpool Corp. v. Marshall*, 445 U.S. 1, 100 S.Ct. 883, 63 L.Ed.2d 154, and narrowly circumscribed the Secretary's power to issue temporary emergency standards.[59] This ef-]652 fort by]Congress to limit the Secretary's power is not consistent with a view that the mere possibility that some employee somewhere in the country may confront some risk of cancer is a sufficient basis for the exercise of the Secretary's power to require the expenditure of hundreds of millions of dollars to minimize that risk.

D

Given the conclusion that the Act empowers the Secretary to promulgate health and safety standards only where a significant risk of harm exists, the critical issue becomes how to define and allocate the burden of proving the significance of the risk in a case such as this, where scientific knowledge is imperfect and the precise quantification of risks is therefore impossible. The Agency's position is that there is substantial evidence in the record to support its conclusion that there is no absolutely safe level for a carcinogen and that, therefore, the burden is properly on industry to prove, apparently beyond a shadow of a doubt, that there *is* a safe level for benzene exposure. The Agency argues that, because of the uncertainties in this area, any other approach would render it helpless, forcing it to wait for the leukemia deaths that it believes are likely to occur[60] before taking any regulatory action.

]We disagree. As we read the statute, the]653 burden was on the Agency to show, on the basis of substantial evidence, that it is at least more likely than not that long-term exposure to 10 ppm of benzene presents a significant risk of material health impairment. Ordinarily, it is the proponent of a rule or order who has the burden of proof in administrative proceedings. See 5 U.S.C. § 556(d). In some cases involving toxic substances, Congress has shifted the burden of proving that a particular substance is safe onto the party opposing the proposed rule.[61] The fact that Congress did not fol-

59. In *Florida Peach Growers Assn., Inc. v. U. S. Dept. of Labor*, 489 F.2d 120, 130, and n. 16 (CA5 1974), the court noted that Congress intended to restrict the use of emergency standards, which are promulgated without any notice or hearing. It held that, in promulgating an emergency standard, OSHA must find not only a danger *of* exposure or even some danger *from* exposure, but also a grave danger from exposure necessitating emergency action. Accord, *Dry Color Mfrs. Assn., Inc. v. U. S. Dept. of Labor*, 486 F.2d 98, 100 (CA3 1973) (an emergency standard must be supported by something more than a possibility that a substance may cause cancer in man).

Congress also carefully circumscribed the Secretary's enforcement powers by creating a new, independent board to handle appeals from citations issued by the Secretary for noncompliance with health and safety standards. See 29 U.S.C. §§ 659–661.

60. As noted above, OSHA acknowledged that there was no empirical evidence to support the conclusion that there was any risk whatsoever of deaths due to exposures at 10 ppm. What OSHA relied upon was a theory that, because leukemia deaths had occurred at much higher exposures, some (although fewer) were also likely to occur at relatively low exposures. The Court of Appeals specifically held that its conclusion that the number was "likely" to be appreciable was unsupported by the record. See *supra*, at 2862.

61. See *Environmental Defense Fund, Inc. v. EPA*, 179 U.S.App.D.C. 43, 49, 57–63, 548 F.2d 998, 1004, 1012–1018 (1977), cert. denied, 431 U.S. 925, 97 S.Ct. 2199, 53 L.Ed.2d 239, where the court rejected the argument that the EPA has the burden of proving that a pesticide is unsafe in order to suspend its registration under the Federal Insecticide, Fungicide, and Rodenticide Act. The court noted that Congress had deliberately shifted the ordinary burden of proof under the Administrative Procedure Act, requiring manufacturers to establish the continued safety of their products.

low this course in enacting the Occupational Safety and Health Act indicates that it intended the Agency to bear the normal burden of establishing the need for a proposed standard.

In this case OSHA did not even attempt to carry its burden of proof. The closest it came to making a finding that benzene presented a significant risk of harm in the workplace was its statement that the benefits to be derived from lowering the permissible exposure level from 10 to 1 ppm were "likely" to be "appreciable." The Court of Appeals held that this finding was not supported by substantial evidence. Of greater importance, even if it were supported by substantial evidence, such a finding would not be sufficient to satisfy the Agency's obligations under the Act.

The inadequacy of the Agency's findings ⊥654 can perhaps be illustrated best by its rejection of industry testimony that a dose-response curve can be formulated on the basis of current epidemiological evidence and that, even under the most conservative extrapolation theory, current exposure levels would cause at most two deaths out of a population of about 30,000 workers every six years. See n. 38, *supra*. In rejecting this testimony, OSHA made the following statement:

> "In the face of the record evidence of numerous actual deaths attributable to benzene-induced leukemia and other fatal blood diseases, OSHA is unwilling to rely on the hypothesis that at most two cancers every six years would be prevented by the proposed standard. By way of example, the Infante study disclosed seven excess leukemia deaths in a population of about 600 people over a 25-year period. While the Infante study involved higher exposures then those currently encountered, the incidence rates found by Infante, together with the numerous other cases reported in the literature of benzene leukemia and other fatal blood diseases, make it difficult for OSHA to rely on the [witness'] hypothesis to assure the statutorily mandated protection of employees. In any event, due to the fact that there is no safe level of exposure to benzene and that it is impossible to precisely quantify the anticipated benefits, OSHA must select the level of exposure which is most protective of exposed employees." 43 Fed.Reg. 5941 (1978).

There are three possible interpretations of OSHA's stated reason for rejecting the witness' testimony: (1) OSHA considered it probable that a greater number of lives would be saved by lowering the standard from 10 ppm; (2) OSHA thought that saving two lives every six years in a work force of 30,000 persons is a significant savings that makes it reasonable and appropriate to adopt a new standard; or (3) even if the small number is not significant and even if the savings may be even smaller, the Agency nevertheless believed it had a statutory ⊥655 duty to select the level of exposure that is most protective of the exposed employees if it is economically and technologically feasible to do so. Even if the Secretary did not intend to rely entirely on this third theory, his construction of the statute would make it proper for him to do so. Moreover, he made no express findings of fact that would support his 1 ppm standard on any less drastic theory. Under these circumstances, we can hardly agree with the Government that OSHA discharged its duty under the Act.

Contrary to the Government's contentions, imposing a burden on the Agency of demonstrating a significant risk of harm will not strip it of its ability to regulate carcinogens, nor will it require the Agency to wait for deaths to occur before taking any action. First, the requirement that a "significant" risk be identified is not a mathematical straitjacket. It is the Agency's responsibility to determine, in the first instance, what it considers to be a "significant" risk. Some risks are plainly acceptable and others are plainly unacceptable. If, for example, the odds are one in a billion that a person will die from cancer by taking a drink of chlorinated water, the risk clearly could not be considered significant. On the other hand, if the odds are one in a

thousand that regular inhalation of gasoline vapors that are 2% benzene will be fatal, a reasonable person might well consider the risk significant and take appropriate steps to decrease or eliminate it. Although the Agency has no duty to calculate the exact probability of harm, it does have an obligation to find that a significant risk is present before it can characterize a place of employment as "unsafe." [62]

[656] Second, OSHA is not required to support its finding that a significant risk exists with anything approaching scientific certainty. Although the Agency's findings must be supported by substantial evidence, 29 U.S.C. § 655(f), § 6(b)(5) specifically allows the Secretary to regulate on the basis of the "best available evidence." As several Courts of Appeals have held, this provision requires a reviewing court to give OSHA some leeway where its findings must be made on the frontiers of scientific knowledge. See *Industrial Union Dept., AFL-CIO v. Hodgson*, 162 U.S.App.D.C. 331, 340, 499 F.2d 467, 476 (1974); *Society of the Plastics Industry, Inc. v. OSHA*, 509 F.2d 1301, 1308 (CA2 1975), cert. denied, 421 U.S. 992, 95 S.Ct. 1998, 44 L.Ed.2d 482. Thus, so long as they are supported by a body of reputable scientific thought, the Agency is free to use conservative assumptions in interpreting the data with respect to carcinogens, risking error on the side of overprotection rather than underprotection.[63]

Finally, the record in this case and OSHA's own rulings on other carcinogens indicate that there are a number of ways in which the Agency can make a rational judgment about the relative significance of [657] the risks associated with exposure to a particular carcinogen.[64]

62. In his dissenting opinion, *post*, at 2896, Mr. Justice MARSHALL states: "[W]hen the question involves determination of the acceptable level of risk, the ultimate decision must necessarily be based on considerations of policy as well as empirically verifiable facts. Factual determinations can at most define the risk in some statistical way; the judgment whether that risk is tolerable cannot be based solely on a resolution of the facts." We agree. Thus, while the Agency must support its finding that a certain level of risk exists by substantial evidence, we recognize that its determination that a particular level of risk is "significant" will be based largely on policy considerations. At this point we have no need to reach the issue of what level of scrutiny a reviewing court should apply to the latter type of determination.

63. Mr. Justice MARSHALL states that, under our approach, the Agency must either wait for deaths to occur or must "deceive the public" by making a basically meaningless determination of significance based on totally inadequate evidence. Mr. Justice MARSHALL's view, however, rests on the erroneous premise that the only reason OSHA did not attempt to quantify benefits in this case was because it could not do so in any reasonable manner. As the discussion of the Agency's rejection of an industry attempt at formulating a dose-response curve demonstrates, however, see *supra*, at 2870, the Agency's rejection of methods such as dose-response curves was based at least in part on its view that nothing less than absolute safety would suffice.

64. For example, in the coke-oven emissions standard, OSHA had calculated that 21,000 exposed coke-oven workers had an annual excess mortality of over 200 and that the proposed standard might well eliminate the risk entirely. 41 Fed.Reg. 46742, 46750 (1976), upheld in *American Iron & Steel Inst. v. OSHA*, 577 F.2d 825 (CA3 1978), cert. granted 448 U.S. 909, 100 S.Ct. 3054, 65 L.Ed.2d 1139. In hearings on the coke-oven emissions standard the Council on Wage and Price Stability estimated that 8 to 35 lives would be saved each year, out of an estimated population of 14,000 workers, as a result of the proposed standard. Although noting that the range of benefits would vary depending on the assumptions used, OSHA did not make a finding as to whether its own staff estimate or CWPS's was correct, on the ground that it was not required to quantify the expected benefits of the standard or to weigh those benefits against the projected costs.

In other proceedings, the Agency has had a good deal of data from animal experiments on which it could base a conclusion on the significance of the risk. For example, the record on the vinyl chloride standard indicated that a significant number of animals had developed tumors of the liver, lung, and skin when they were exposed to 50 ppm of vinyl chloride over a period of 11 months. One hundred out of 200 animals died during that period. 39 Fed.Reg. 35890, 35891 (1974). Similarly, in a 1974 standard regulating 14 carcinogens, OSHA found that one of the substances had caused lung cancer in mice or rats at 1 ppm and even 0.1 ppm, while another had caused tumors in 80% of the animals subjected to high doses. *Id.*, at

It should also be noted that, in setting a permissible exposure level in reliance on less-than-perfect methods, OSHA would have the benefit of a backstop in the form ⊥658 of monitoring and medical testing. Thus, if OSHA properly determined that the permissible exposure limit should be set at 5 ppm, it could still require monitoring and medical testing for employees exposed to lower levels.[65] By doing so, it could keep a constant check on the validity of the assumptions made in developing the permissible exposure limit, giving it a sound evidentiary basis for decreasing the limit if it was initially set too high.[66] Moreover, in this way it could ensure that workers who were unusually susceptible to benzene could be removed from exposure before they had suffered any permanent damage.[67]

E

Because our review of these cases has involved a more detailed examination of the ⊥659 record than is customary, it must be emphasized that we have neither made any factual determinations of our own, nor have we rejected any factual findings made by the Secretary. We express no opinion on what factual findings this record might support, either on the basis of empirical evidence or on the basis of expert testimony; nor do we express any opinion on the more difficult question of what factual determinations would warrant a conclusion that significant risks are present which make promulgation of a new standard reasonably necessary or appropriate. The standard must, of course, be supported by the findings actually made by the Secretary, not merely by findings that we believe he might have made.

[10] In this case the record makes it perfectly clear that the Secretary relied squarely on a special policy for carcinogens that imposed the burden on industry of proving the existence of a safe level of exposure, thereby avoiding the Secretary's threshold responsibility of establishing the need for more stringent standards. In so interpreting his statutory authority, the Secretary exceeded his power.

3756, 3757, upheld in *Synthetic Organic Chemical Mfrs. Assn. v. Brennan*, 503 F.2d 1155 (CA3 1974), cert. denied, 420 U.S. 973, 95 S.Ct. 1396, 43 L.Ed.2d 653, *Synthetic Organic Chemical Mfrs. Assn. v. Brennan*, 506 F.2d 385 (CA3 1974), cert. denied, 423 U.S. 830, 96 S.Ct. 50, 46 L.Ed.2d 48.

In this case the Agency did not have the benefit of animal studies, because scientists have been unable as yet to induce leukemia in experimental animals as a result of benzene exposure. It did, however, have a fair amount of epidemiological evidence, including both positive and negative studies. Although the Agency stated that this evidence was insufficient to construct a precise correlation between exposure levels and cancer risks, it would at least be helpful in determining whether it is more likely than not that there is a significant risk at 10 ppm.

65. See *GAF Corp. v. Occupational Safety and Health Review Comm'n*, 183 U.S.App.D.C. 20, 561 F.2d 913 (1977), where the court upheld the asbestos standard insofar as it required employers to provide medical examinations for employees exposed to any asbestos fibers, even if they were exposed to concentrations below the permissible exposure limit.

The respondent industry representatives have never disputed OSHA's power to require monitoring and medical examinations in general, although they did object to some of the specific requirements imposed in this case. See n. 30, *supra*. Because of our disposition of the case, we have no occasion to pass on these specific objections or to determine what cost-benefit considerations, if any, should govern the Agency's imposition of such requirements.

66. This is precisely the type of information-gathering function that Congress had in mind when it enacted § 6(b)(7), which empowers the Secretary to require medical examinations to be furnished to employees exposed to certain hazards and potential hazards "in order to most effectively determine whether the health of such employees is adversely affected by such exposure." See S.Rep. No. 91-1282, p. 7 (1970), Leg.Hist. 147.

67. In its explanation of the final standard OSHA noted that there was some testimony that blood abnormalities would disappear after exposure had ceased. 43 Fed.Reg. 5946 (1978). Again, however, OSHA refused to rely on the hypothesis that this would always occur. Yet, in requiring medical examinations of employees exposed to between 0.5 ppm and 1 ppm, OSHA was essentially providing itself with the same kind of backstop.

IV

Throughout the administrative proceedings, the dermal contact issue received relatively little attention. In its proposed rule OSHA recommended a total ban on skin and eye contact with liquid benzene on the basis of its policy that "in dealing with a carcinogen, all potential routes of exposure (i. e., inhalation, ingestion, and skin absorption) [should] be limited to the extent feasible." 43 Fed.Reg. 5948 (1978). There was little opposition to this requirement at the hearing on the proposed rule, apparently because the proposed rule also excluded from both the permissible exposure level and the dermal contact ban work operations involving liquid mixtures containing 1% (and after one year, 0.1%) or less benzene.

In its final standard, however, OSHA eliminated the percentage exclusion for liquid benzene, on the ground that there was no predictable correlation between the percentage of benzene in a liquid and the airborne exposure arising from it. See n. 22, *supra*. Although the extent to which liquid benzene is absorbed through the skin is concededly unknown, OSHA also refused to exempt any liquids, no matter how little benzene they contained, from the ban on dermal contact. In support of this position it stated that there was no evidence to "suggest that the absorption rate depends on the amount of benzene present in the liquid." 43 Fed.Reg. 5948–5949 (1978).

After the permanent standard was promulgated, OSHA received a number of requests from various industries that the percentage exclusion for liquids containing small amounts of benzene be reinstated. Those concerned with airborne exposures argued that they should not be required to monitor workplaces simply because they handled petroleum-based products in which benzene is an unavoidable contaminant. Others concerned with the dermal contact ban made similar arguments. In particular, tire manufacturers argued that it was impossible for them to comply with the ban because gloves cannot be worn during certain tire-building operations in which solvents are used and solvents containing absolutely no benzene are not commercially available.

Because of these requests, OSHA held a new series of hearings and promulgated an amendment to the rule, reinstating the percentage exclusion, but lowering it from the proposed 1% to 0.5%. The Agency did, however, provide for a 3-year grace period before the exclusion dropped to 0.1%, rather than the one year that had originally been proposed. In explaining its amendment, OSHA reiterated its policy with respect to carcinogens, stating that, because there is no absolutely safe level for any type of exposure, exposures by whatever route must be limited to the extent feasible. For airborne exposures, a zero permissible exposure limit had not been feasible. However, in most industries a ban on any dermal contact was feasible since compliance could be achieved simply by the use of protective clothing, such as impermeable gloves. The Agency recognized that the dermal contact ban could present a problem for tire manufacturers, but stated that the percentage exclusion would alleviate the problem, because solvents containing 0.5% or less benzene were available in sufficient quantities. Although it noted that solvents containing 0.1% or less benzene were not then available in quantity, the Agency stated that a 3-year grace period would be sufficient to "allow time for increased production of solvents containing lower amounts of benzene and for development and evaluation of alternative methods of compliance with the standard's dermal provision." *Id.*, at 27968–27969.

The Court of Appeals struck down the dermal contact prohibition on two grounds. First, it held that the record did not support a finding that the ban would result in quantifiable benefits in terms of a reduced leukemia risk; therefore, it was not "reasonably necessary" within the meaning of § 3(8) of the Act. Second, the court held that the Agency's conclusion that benzene may be absorbed through the skin was not based on the best available evidence as re-

quired by § 6(b)(5). 581 F.2d, at 505–506. On the second ground, the court noted that the evidence on the issue of absorption of benzene through the skin was equivocal, with some studies indicating that it could be absorbed and some indicating that it could not. All of these studies were relatively old and the only expert who had testified on the issue stated that a simple test was now available to determine, with a great deal of accuracy, whether and to what extent absorption will result. In light of § 6(b)(5), which requires the Agency to promulgate standards on the basis of the "best available evidence" and "the latest available scientific data in the field," the court held that where there is uncontradicted testimony that a simple test will resolve the issue, the Agency is required to acquire that information before "promulgating regulations which would require an established industry to change long-followed work processes that are not demonstrably unsafe." 581 F.2d, at 508.

[662] While the court below may have been correct in holding that, under the peculiar circumstances of this case, OSHA was required to obtain more information, there is no need for us to reach that issue. For, in order to justify a ban on dermal contact, the Agency must find that such a ban is "reasonably necessary and appropriate" to remove a significant risk of harm from such contact. The Agency did not make such a finding, but rather acted on the basis of the absolute, no-risk policy that it applies to carcinogens. Indeed, on this issue the Agency's position is even more untenable, inasmuch as it was required to assume not only that benzene in small doses is a carcinogen, but also that it can be absorbed through the skin in sufficient amounts to present a carcinogenic risk. These assumptions are not a proper substitute for the findings of a significant risk of harm required by the Act.

The judgment of the Court of Appeals remanding the petition for review to the Secretary for further proceedings is affirmed.

It is so ordered.

Mr. Chief Justice BURGER, concurring.

These cases press upon the Court difficult unanswered questions on the frontiers of science and medicine. The statute and the legislative history give ambiguous signals as to how the Secretary is directed to operate in this area. The opinion by Mr. Justice STEVENS takes on a difficult task to decode the message of the statute as to guidelines for administrative action.

To comply with statutory requirements, the Secretary must bear the burden of "finding" that a proposed health and safety standard is "reasonably necessary or appropriate to provide safe or healthful employment and places of employment." This policy judgment entails the subsidiary finding that the pre-existing standard presents a "significant risk" of material health impairment for a worker who spends his entire employment life in a working environment where exposure remains at maximum permissible levels. [663] The Secretary's factual finding of "risk" must be "quantified sufficiently to enable the Secretary to characterize it as significant in an understandable way." *Ante*, at 2866. Precisely what this means is difficult to say. But because these mandated findings were not made by the Secretary, I agree that the 1 ppm benzene standard must be invalidated. However, I would stress the differing functions of the courts and the administrative agency with respect to such health and safety regulation.

The Congress is the ultimate regulator, and the narrow function of the courts is to discern the meaning of the statute and the implementing regulations with the objective of ensuring that in promulgating health and safety standards the Secretary "has given reasoned consideration to each of the pertinent factors" and has complied with statutory commands. *Permian Basin Area Rate Cases*, 390 U.S. 747, 792, 88 S.Ct. 1344, 1373, 20 L.Ed.2d 312 (1968). Our holding that the Secretary must retrace his steps with greater care and consideration is

not to be taken in derogation of the scope of legitimate agency discretion. When the facts and arguments have been presented and duly considered, the Secretary must make a policy judgment as to whether a specific risk of health impairment is significant in terms of the policy objectives of the statute. When he acts in this capacity, pursuant to the legislative authority delegated by Congress, he exercises the prerogatives of the legislature—to focus on only one aspect of a larger problem, or to promulgate regulations that, to some, may appear as imprudent policy or inefficient allocation of resources. The judicial function does not extend to substantive revision of regulatory policy. That function lies elsewhere—in Congressional and Executive oversight or amendatory legislation—although to be sure the boundaries are often ill-defined and indistinct.

Nevertheless, when discharging his duties under the statute, the Secretary is well admonished to remember that a heavy responsibility burdens his authority. Inherent in this statutory scheme is authority to]664 refrain from regulation of [1]insignificant or *de minimis* risks. See *Alabama Power Co. v. Costle*, 204 U.S.App.D.C. 51, 81–89, 636 F.2d 323, 360–361 (1979) (opinion of Leventhal, J.). When the administrative record reveals only scant or minimal risk of material health impairment, responsible administration calls for avoidance of extravagant, comprehensive regulation. Perfect safety is a chimera; regulation must not strangle human activity in the search for the impossible.

Mr. Justice POWELL, concurring in part and concurring in the judgment.

I join Parts I, II, III–A III–B, III–C, and III–E of the plurality opinion.[1] The Occupational Safety and Health Administration relied in large part on its "carcinogen policy"—which had not been adopted formally—in promulgating the benzene exposure and dermal contact regulation at issue of these cases.[2] For the reasons stated by the plurality, I agree that §§ 6(b)(5) and 3(8) of the Occupational Safety and Health Act of 1970, 29 U.S.C. §§ 655(b)(5) and 652(8), must be read together. They require OSHA to make a threshold finding that proposed occupational health standards are reasonably necessary to provide safe workplaces. When OSHA acts to reduce existing national consensus standards,]665 [1]therefore, it must find that (i) currently permissible exposure levels create a significant risk of material health impairment; and (ii) a reduction of those levels would significantly reduce the hazard.

Although I would not rule out the possibility that the necessary findings could rest in part on generic policies properly adopted by OSHA, see McGarity, Substantive and Procedural Discretion in Administrative Resolution of Science Policy Questions: Regulating Carcinogens in EPA and OSHA, 67 Geo.L.J. 729, 754–759 (1979), no properly supported agency policies are before us in this case.[3] I therefore agree with the plurality that the regulation is invalid to the

1. These portions of the plurality opinion primarily address OSHA's special carcinogen policy, rather than OSHA's argument that it also made evidentiary findings. I do not necessarily agree with every observation in the plurality opinion concerning the presence or absence of such findings. I also express no view on the question whether a different interpretation of the statute would violate the nondelegation doctrine of *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495, 55 S.Ct. 837, 79 L.Ed. 1570 (1935), and *Panama Refining Co. v. Ryan*, 293 U.S. 388, 55 S.Ct. 241, 79 L.Ed. 446 (1935). See *post*, at 2879–2887 (REHNQUIST, J., concurring in judgment).

2. The Secretary of Labor promulgated the relevant standard pursuant to his statutory authority. Since OSHA is the agency responsible for developing such regulations under the Secretary's direction, this opinion refers to "OSHA" or "the agency" as the decisionmaker most directly concerned.

3. OSHA has adopted a formal policy for regulating carcinogens effective April 21, 1980. 45 Fed.Reg. 5282 (1980) (to be codified at 29 CFR, Part 1990). But no such policy was in effect when the agency promulgated its benzene regulation. Moreover, neither the factual determinations nor the administrative judgments upon which the policy rests are supported adequate-

extent it rests upon the assumption that exposure to known carcinogens always should be reduced to a level proved to be safe or, if no such level is found, to the lowest level that the affected industry can achieve with available technology.

I

If the disputed regulation were based exclusively on this "carcinogen policy," I also would agree that we need not consider whether the Act requires OSHA to determine that the benefits of a proposed standard are reasonably related to the costs of compliance. *Ante*, at 2850. As the Court of Appeals for the Fifth Circuit recognized, however, OSHA takes the "fall-back position" that its regulation is justified by specific findings based upon the voluminous evidentiary record compiled in this case. *American Petroleum Institute v. OSHA*, 581 F.2d 493, 503. OSHA found, for example, that the number of cancers prevented by reducing permissible exposure levels from 10 ppm to 1 ppm "may be appreciable," that "the benefits of the proposed standard are likely to be appreciable," and that the "substantial costs [of the new standard] are justified in light of the hazards." 43 Fed.Reg. 5940–5941 (1978). Thus, OSHA found—at least generally—that the hazards of benzene exposure at currently permissible levels are serious enough to justify an expenditure of hundreds of millions of dollars. For me, that finding necessarily subsumes the conclusion that the health risk is "significant." If OSHA's conclusion is supported by substantial evidence, the threshold requirement discussed in the plurality opinion would be satisfied.

As I read its opinion, the plurality does not consider whether the agency's findings are supported by substantial evidence. The Court of Appeals found them insufficient because OSHA failed "to estimate the extent of expected benefits . . . ." 581 F.2d, at 504. That court apparently would have required OSHA to supply a specific numerical estimate of benefits derived through mathematical techniques for "risk quantification" or "cost-effectiveness analysis." *Id.*, at 504, n. 23; see *id.*, at 504–505. I do not agree with the Court of Appeals' conclusion that the statute requires quantification of risk in every case.

The statutory preference for the "best available evidence," 29 U.S.C. § 655(b)(5), implies that OSHA must use the best known techniques for the accurate estimation of risks and benefits when such techniques are available. But neither the statute nor the legislative history suggests that OSHA's hands are tied when reasonable quantification cannot be accomplished by any known methods. See *post*, at 2889 (MARSHALL, J., dissenting). In this litigation, OSHA found that "it is impossible to precisely quantify the anticipated benefits. . . ." 43 Fed.Reg. 5941 (1978). If this finding is supported by substantial evidence, the statute does not prevent the Secretary from finding a significant health hazard on the basis of the weight of expert testimony and opinion. I do not understand the plurality to hold otherwise. See *ante*, at 2874.

For the foregoing reasons, I would not hold that "OSHA did not even attempt to carry its burden of proof" on the threshold question whether exposure to benzene at 10 ppm presents a significant risk to human health. *Ante*, at 2870. In my view, the question is whether OSHA successfully carried its burden on the basis of record evidence. That question in turn reduces to two principal issues. First, is there substantial evidence supporting OSHA's determination that available quantification techniques are too imprecise to permit a reasonable numerical estimate of risks? If not, then OSHA has failed to show that its regulation rests on the "best available evidence." Second, is OSHA's finding of significant risks at current exposure levels

ly on this record alone. Accordingly, we have no occasion to consider the extent to which valid agency policies may supply a basis for a finding that health risks exist in particular cases.

supported by substantial evidence? If not, then OSHA has failed to show that the new regulation is reasonably necessary to provide safe and healthful workplaces.

II

Although I regard the question as close, I do not disagree with the plurality's view that OSHA has failed, on this record, to carry its burden of proof on the threshold issues summarized above. But even if one assumes that OSHA properly met this burden, see *post*, at 2892–2893, 2900 (MARSHALL, J., dissenting), I conclude that the statute also requires the agency to determine that the economic effects of its standard bear a reasonable relationship to the expected benefits. An occupational health standard is neither "reasonably necessary" nor "feasible," as required by statute, if it calls for expenditures wholly disproportionate to the expected health and safety benefits.

OSHA contends that § 6(b)(5) not only permits but actually requires it to promulgate standards that reduce health risks without regard to economic effects, unless those effects ⊥668 would cause widespread dislocation throughout an entire industry.[4] Under the threshold test adopted by the plurality today, this authority will exist only with respect to "significant" risks. But the plurality does not reject OSHA's claim that it must reduce such risks without considering economic consequences less serious than massive dislocation. In my view, that claim is untenable.

Although one might wish that Congress had spoken with greater clarity, the legislative history and purposes of the statute do not support OSHA's interpretation of the Act.[5] ⊥It is simply unreasonable to believe ⊥669

4. OSHA argues that § 6(b)(5) requires it to promulgate standards that are "feasible" only in the sense that they are "capable of achievement"; that is, achievable "at bearable cost with available technology." Brief for Federal Parties 57. The lower courts have indicated that a standard is not "infeasible" under OSHA's test unless it would precipitate "massive economic dislocation" in the affected industry. See, *e. g., American Federation of Labor v. Brennan*, 530 F.2d 109, 123 (CA3 1975). In this case, OSHA simply asked a consulting firm to ascertain the costs of complying with a 1 ppm standard. See *ante*, at 2854. OSHA then concluded that "the economic impact of [compliance] will not . . . threaten the financial welfare of the affected firms or the general economy." 43 Fed.Reg. 5939 (1978). The cost of complying with a standard may be "bearable" and still not reasonably related to the benefits expected. A manufacturing company, for example, may have financial resources that enable it to pay the OSHA-ordered costs. But expenditures for unproductive purposes may limit seriously its financial ability to remain competitive and provide jobs.

5. I will not repeat the detailed summary of the legislative history contained in the plurality opinion. *Ante*, at 2866–2869. Many of the considerations that the plurality relies upon to show Congress' concern with significant harms persuade me that Congress did not intend OSHA to reduce each significant hazard without regard to economic consequences. Senator Williams, a sponsor of the legislation, stated: "Our bill is fair and reasonable. It is a good-faith effort to balance the need of workers to have a sa[f]e and healthy work environment against the requirement of industry to function without undue interference." 116 Cong.Rec. 37342 (1970), Legislative History of the Occupational Safety and Health Act of 1970 (Committee Print compiled for the Senate Committee on Labor and Public Welfare), p. 435 (1971). There could no such "balance" if OSHA were authorized to impose standards without regard to economic consequences short of serious dislocation.

Senator Dominick described a preliminary version of § 6(b)(5) as follows:

"What we were trying to do in the bill . . . was to say that when we are dealing with toxic agents or physical agents, we ought to take such steps as are *feasible and practical* to provide an atmosphere within which a person's health or safety would not be affected. Unfortunately, we had language providing that anyone [*sic*] would be assured that no one would have a hazard. . . .

"It was an unrealistic standard. . . ." 116 Cong.Rec. 37622 (1970), Legislative History, *supra*, at 502 (emphasis added).

Senator Dominick's objection to the "unrealistic" standard of the forerunner of § 6(b)(5) does not imply that he thought § 3(8) of the Act lacked substantive content. See *post*, at 2898–2899 (MARSHALL, J., dissenting). The Senator hardly would have proposed that § 6(b)(5) be deleted entirely, see *ante*, at 2867, if he had not thought that other sections of the Act required health regulations that were reasonable and practical.

that Congress intended OSHA to pursue the desirable goal of risk-free workplaces to the extent that the economic viability of particular industries—or significant segments thereof—is threatened. As the plurality observes, OSHA itself has not chosen to carry out such a self-defeating policy in all instances. *Ante*, at 2868. If it did, OSHA regulations would impair the ability of American industries to compete effectively with foreign businesses and to provide employment for American workers.[6]

I therefore would not lightly assume that Congress intended OSHA to require reduction of health risks found to be significant *whenever* it also finds that the affected ⟨670⟩ industry can bear the costs. See n. 4, *supra*. Perhaps more significantly, however, OSHA's interpretation of § 6(b)(5) would force it to regulate in a manner inconsistent with the important health and safety purposes of the legislation we construe today. Thousands of toxic substances present risks that fairly could be characterized as "significant." Cf. *ante*, at 2866, n. 51. Even if OSHA succeeded in selecting the gravest risks for earliest regulation, a standard-setting process that ignored economic considerations would result in a serious misallocation of resources and a lower effective level of safety than could be achieved under standards set with reference to the comparative benefits available at a lower cost.[7] I would not attribute such an irrational intention to Congress.

In these cases, OSHA did find that the "substantial costs" of the benzene regulations are justified. See *supra*, at 2876. But the record before us contains neither adequate documentation of this conclusion, nor any evidence that OSHA weighed the relevant considerations. The agency simply announced its finding of cost-justification without explaining the method by which it determines that the benefits justify the costs and their economic effects. No rational system of regulation can permit its administrators to make policy judgments without explaining how their decisions effectuate the purposes of the governing law, and nothing in the statute authorizes such laxity in these cases.[8] Since neither the airborne concentration standard nor the ⟨671⟩ dermal contact standard for exposure to benzene satisfies the requirements of the governing statute, I join the Court's judgment affirming the judgment of the Court of Appeals.

Mr. Justice REHNQUIST, concurring in the judgment.

The statutory provision at the center of the present controversy, § 6(b)(5) of the Occupational Safety and Health Act of 1970, states, in relevant part, that the Secretary of Labor

> ". . . in promulgating standards dealing with toxic materials or harmful

6. Congress has assigned OSHA an extremely difficult and complex task, and the guidance afforded OSHA is considerably less than clear. The agency's primary responsibility, reflected in its title, is to minimize health and safety risks in the workplace. Yet the economic health of our highly industrialized society requires a high rate of employment and an adequate response to increasingly vigorous foreign competition. There can be little doubt that Congress intended OSHA to balance reasonably the societal interest in health and safety with the often conflicting goal of maintaining a strong national economy.

7. For example, OSHA's reading of § 6(b)(5) could force the depletion of an industry's resources in an effort to reduce a single risk by some speculative amount, even though other significant risks remain unregulated.

8. The decision that costs justify benefits is largely a policy judgment delegated to OSHA by Congress. When a court reviews such judgments under the "substantial evidence" standard mandated by 29 U.S.C. § 655(f), the court must determine whether the responsible agency has "careful[ly] identifi[ed] . . . the reasons why [it] chooses to follow one course rather than another" as the most reasonable method of effectuating the purposes of the applicable law. *Industrial Union Dept. v. Hodgson*, 162 U.S.App.D.C. 331, 339–340, 499 F.2d 467, 475–476 (1974). Since OSHA failed to identify its reasons in these cases, I express no opinion as to the standard of review that may be appropriate in other situations.

physical agents . . . shall set the standard which most adequately assures, *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." 84 Stat. 1594, 29 U.S.C. § 655(b)(5) (emphasis added).

According to the Secretary, who is one of the petitioners herein, § 6(b)(5) imposes upon him an absolute duty, in regulating harmful substances like benzene for which no safe level is known, to set the standard for permissible exposure at the lowest level that "can be achieved at bearable cost with available technology." Brief for Federal Parties 57. While the Secretary does not attempt to refine the concept of "bearable cost," he apparently believes that a proposed standard is economically feasible so long as its impact "will not be such as to threaten the financial welfare of the affected firms or the general economy." 43 Fed. Reg. 5939 (1978).

Respondents reply, and the lower court agreed, that § 6(b)(5) must be read in light of another provision in the same Act, § 3(8), which defines an "occupational health and safety standard" as

> ". . . a standard which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment." 84 Stat. 1591, 29 U.S.C. § 652(8).

According to respondents, § 6(b)(5), as tempered by § 3(8), requires the Secretary to demonstrate that any particular health standard is justifiable on the basis of a rough balancing of costs and benefits.

In considering these alternative interpretations, my colleagues manifest a good deal of uncertainty, and ultimately divide over whether the Secretary produced sufficient evidence that the proposed standard for benzene will result in any appreciable benefits at all. This uncertainty, I would suggest, is eminently justified, since I believe that this litigation presents the Court with what has to be one of the most difficult issues that could confront a decisionmaker: whether the statistical possibility of future deaths should ever be disregarded in light of the economic costs of preventing those deaths. I would also suggest that the widely varying positions advanced in the briefs of the parties and in the opinions of Mr. Justice STEVENS, THE CHIEF JUSTICE, Mr. Justice POWELL, and Mr. Justice MARSHALL demonstrate, perhaps better than any other fact, that Congress, the governmental body best suited and most obligated to make the choice confronting us in this litigation, has improperly delegated that choice to the Secretary of Labor and, derivatively, to this Court.

I

In his Second Treatise of Civil Government, published in 1690, John Locke wrote that "[t]he power of the legislative, being derived from the people by a positive voluntary grant and institution, can be no other than what that positive grant conveyed, which being only to make laws, and not to make legislators, the legislative can have no power to transfer their authority of making laws and place it in other hands."[1] Two hundred years later, this Court expressly recognized the existence of and the necessity for limits on Congress' ability to delegate its authority to representatives of the Executive Branch: "That Congress cannot delegate legislative power to the president is a principle universally recognized as vital to the integrity and maintenance of the system of government ordained by the Consti-

1. J. Locke, Second Treatise of Civil Government, in the Tradition of Freedom, ¶ 141, p. 244 (M. Mayer ed. 1957). In the same treatise, Locke also wrote that "[t]he legislative cannot transfer the power of making laws to any other hands; for it being but a delegated power from the people, they who have it cannot pass it over to others." *Ibid.*

tution." *Field v. Clark*, 143 U.S. 649, 692, 12 S.Ct. 495, 504, 36 L.Ed. 294 (1892).[2]

The rule against delegation of legislative power is not, however, so cardinal of principle as to allow for no exception. The Framers of the Constitution were practical statesmen, who saw that the doctrine of separation of powers was a two-sided coin. James Madison, in Federalist Paper No. 48, for example, recognized that while the division of authority among the various branches of government was a useful principle, "the degree of separation which the maxim requires, as essential to a free government, can never in practice be duly maintained." The Federalist No. 48, p. 308 (H. Lodge ed. 1888).

This Court also has recognized that a hermetic sealing-off of the three branches of government from one another could easily frustrate the establishment of a National ⊥674 Government ⊥capable of effectively exercising the substantive powers granted to the various branches by the Constitution. Mr. Chief Justice Taft, writing for the Court in *J. W. Hampton & Co. v. United States*, 276 U.S. 394, 48 S.Ct. 348, 72 L.Ed. 624 (1928), noted the practicalities of the balance that has to be struck:

> "[T]he rule is that in the actual administration of the government Congress or the Legislature should exercise the legislative power, the President or the state executive, the Governor, the executive power, and the courts or the judiciary the judicial power, and in carrying out that constitutional division into three branches it is a breach of the national fundamental law if Congress gives up its legislative power and transfers it to the President, or to the Judicial branch, or if by law it attempts to invest itself or its members with either executive power or judicial power. This is not to say that the three branches are not coordinate parts of one government and that each in the field of its duties may not invoke the action of the two other branches in so far as the action invoked shall not be an assumption of the constitutional field of action of another branch. In determining what it may do in seeking assistance from another branch, the extent and character of that assistance must be fixed according to common sense and the inherent necessities of the governmental co-ordination." *Id.*, at 406, 48 S.Ct., at 351.

During the third and fourth decades of this century, this Court within a relatively short period of time struck down several Acts of Congress on the grounds that they exceeded the authority of Congress under the Commerce Clause or under the nondelegation principle of separation of powers, and at the same time struck down state statutes because they violated "substantive" due process or interfered with interstate commerce. See generally R. Jackson, The Struggle for Judicial Supremacy 48–123 (1949). When many of these decisions were later overruled, the principle that Congress ⊥could not simply transfer its leg- ⊥675 islative authority to the Executive fell under a cloud. Yet in my opinion decisions such as *Panama Refining Co. v. Ryan*, 293 U.S. 388, 55 S.Ct. 241, 79 L.Ed. 446 (1935), suffer from none of the excesses of judicial policymaking that plagued some of the other decisions of that era. The many later decisions that have upheld congressional delegations of authority to the Executive Branch have done so largely on the theory that Congress may wish to exercise its authority in a particular field, but because the field is sufficiently technical, the ground to be covered sufficiently large, and the Members of Congress themselves not necessarily expert in the area in which they choose to legislate, the most that may be asked under the separation-of-powers doctrine is that Congress lay down the general policy and

2. As early as 1812, this Court had considered and rejected an argument that a statute authorizing the President to terminate a trade embargo on Britain and France if those two nations ceased violating "the neutral commerce of the United States" delegated too much discretion to the Executive Branch. See *The Brig Aurora v. United States*, 7 Cranch 382, 383, 386, 388, 11 U.S. 382, 3 L.Ed. 378.

standards that animate the law, leaving the agency to refine those standards, "fill in the blanks," or apply the standards to particular cases. These decisions, to my mind, simply illustrate the above-quoted principle stated more than 50 years ago by Mr. Chief Justice Taft that delegations of legislative authority must be judged "according to common sense and the inherent necessities of the governmental co-ordination."

Viewing the legislation at issue here in light of these principles, I believe that it fails to pass muster. Read literally, the relevant portion of § 6(b)(5) is completely precatory, admonishing the Secretary to adopt the most protective standard if he can, but excusing him from that duty if he cannot. In the case of a hazardous substance for which a "safe" level is either unknown or impractical, the language of § 6(b)(5) gives the Secretary absolutely no indication where on the continuum of relative safety he should draw his line. Especially in light of the importance of the interests at stake, I have no doubt that the provision at issue, standing alone, would violate the doctrine against uncanalized delegations of legislative power. For me the remaining question, then, is whether additional standards are ascertainable from the legislative history or statutory context of
1676 § 6(b)(5) or, if not, whether such a standardless delegation was justifiable in light of the "inherent necessities" of the situation.

II

One of the primary sources looked to by this Court in adding gloss to an otherwise broad grant of legislative authority is the legislative history of the statute in question. The opinions of Mr. Justice STEVENS and Mr. Justice MARSHALL, however, give little more than a tip of the hat to the legislative origins of § 6(b)(5). Such treatment is perhaps understandable, since the legislative history of that section, far from shedding light on what important policy choices Congress was making in the statute, gives one the feeling of viewing the congressional purpose "by the dawn's early light."

The precursor of § 6(b)(5) was placed in the Occupational Safety and Health Act of 1970 while that bill was pending in the House Committee on Education and Labor. At that time, the section read:

> "The Secretary, in promulgating standards under this subsection, shall set the standard which most adequately assures, on the basis of the best available professional evidence, that no employee will suffer any impairment of health, or functional capacity, or diminished life expectancy even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life." § 7(a)(4), H.R. 16785, 91st Cong., 2d Sess. 49 (1970), Legislative History of the Occupational Safety and Health Act of 1970 (Committee Print compiled for the Senate Committee on Labor and Public Welfare), p. 943 (1971) (hereinafter Leg.Hist.).

Three aspects of this original proposal are particularly significant. First, and perhaps most importantly, as originally introduced the provision contained no feasibility limitation, providing instead that the Secretary "shall set the standard which most adequately assures" that no employee will suffer harm. Second, it would have required 1677
the Secretary to protect employees from "any" impairment of health or functional capacity. Third, on its face, although perhaps not in its intent, the provision applied to both health and safety standards promulgated under the Act.[3]

3. Respondents argue that, despite its seemingly general application, the original version of § 6(b)(5) actually referred only to health hazards as opposed to safety hazards. See Addendum B to Brief for Respondents American Petroleum Institute et al. 5b–6b. In support of this proposition, they cite a portion of the legislative history where the House Committee on Education and Labor stated that the proposed version of § 6(b)(5) would apply when the Secretary set an "occupational health standard." H.R.Rep. No. 91–1291, p. 18 (1970), Leg.Hist. 848.

There can be little doubt that, at this point in its journey through Congress, § 6(b)(5) would have required the Secretary, in regulating toxic substances, to set the permissible level of exposure at a safe level or, if no safe level was known, at zero. When the Senate Committee on Labor and Public Welfare considered a provision identical in almost all respects to the House version, however, Senator Javits objected that the provision in question "might be interpreted to require absolute health and safety in all cases, regardless of feasibility. . . ." S.Rep. No. 91-1282, p. 58 (1970), Leg.Hist. 197. See also 116 Cong.Rec. 37327 (1970), Leg.Hist. 418. The Committee therefore amended the bill to provide that the Secretary "shall set the standard which most adequately *and feasibly*" assured that no employee would suffer any impairment of health. S. 2193, 91st Cong., 2d Sess., p. 39 (1970), Leg.Hist. 242 (emphasis added). The only additional explanation for this change appeared in the Senate Report accompanying the bill to the Senate floor. There, the Committee explained:

"[S]tandards promulgated under section 6(b) shall represent *feasible requirements*, which, where appropriate, shall be based on research, experiments, demonstrations, past experience, and the latest available scientific data. Such standards should be directed at assuring, *so far as possible*, that no employee will suffer impaired health of functional capacity or diminished life expectancy, by reason of the exposure to the hazard involved, even though such exposure may be over the period of his entire working life." S.Rep. No. 91-1282, p. 7 (1970), Leg.Hist. 147 (emphasis added).

Despite Senator Javits' inclusion of the words "and feasibly" in the provision, participants in the floor debate immediately characterized § 6(b)(5) as requiring the Secretary "to establish a utopia free from any hazards" and to "assure that there will not be any risk at all." 116 Cong.Rec. 37614 (1970), Leg.Hist. 480-481 (remarks of Sen. Dominick). Senator Saxbe stated:

"When we come to saying that an employer must guarantee that such an employee is protected from any possible harm, I think it will be one of the most difficult areas we are going to have to ascertain. . . .

"I believe the terms that we are passing back and forth are going to have to be identified." 116 Cong.Rec., at 26522, Leg.Hist. 345.

In response to these concerns, Senator Dominick introduced a substitute for the proposed provision, deleting the sentence at issue here entirely. He explained that his amendment would delete

"the requirement in section 6(b)(5) that the Secretary will establish occupational safety and health standards which most adequately and feasibly assure to the extent possible that *no* employee will suffer *any* impairment of health or functional capacity, or diminished life expectancy even if the employee has regular exposure to the hazard dealt with by the standard for the period of his working life.

"This requirement is inherently confusing and unrealistic. It could be read to require the Secretary to ban all occupations in which there remains *some* risk of injury, impaired health, or life expectancy. In the case of all occupations, it will be impossible to eliminate all risks to safety and health. Thus, the present criteria could, if literally applied, close every business in this nation. In addition, in many cases, the standard which might most 'adequately' and 'feasibly' assure the elimination of the danger would be the prohibition of the occupation itself.

"If the provision is intended as no more than an admonition to the Secretary to do his duty, it seems unnecessary and could, if deemed advisable be included in the legislative history." (Emphasis in original.) 116 Cong.Rec., at 36530, Leg.Hist. 367.

Eventually, Senator Dominick and his supporters settled for the present language of § 6(b)(5). This agreement resulted in

three changes from the original version of the provision as amended by Senator Javits. First, the provision was altered to state explicitly that it applied only to standards for "toxic materials or harmful physical agents," in apparent contrast with safety standards. Second, the Secretary was no longer admonished to protect employees from "any" impairment of their health, but rather only from "material" impairments. Third, and most importantly for our purposes, the phrase "most adequately and feasibly assures" was revamped to read "most adequately assures, to the extent feasible."

We have been presented with a number of different interpretations of this shift. According to the Secretary, Senator Dominick recognized that he could not delete the seemingly absolute requirements of § 6(b)(5) entirely, and instead agreed to limit its application to toxic materials or harmful physical agents and to specify that the Secretary was only to protect employees from material impairment of their health. Significantly, the Secretary asserts that his mandate to set such standards at the safest ⟨680 level technologically and economically achievable remained unchanged by the Dominick amendment. According to the Secretary, the change in language from "most adequately and feasibly assures" to "most adequately assures, to the extent feasible," represented only a slight shift in emphasis, perhaps suggesting "a preference for health protection over cost." App. to Brief for Federal Parties 7a, n. 2. See also Brief for Federal Parties 59.

Mr. Justice MARSHALL reads this history quite differently. In his view, the version of § 6(b)(5) that reached the Senate floor did not "clearly embod[y] the feasibility requirement" and thus was soundly criticized as being unrealistic. See *post*, at 2890. It was only as a result of the floor amendments, which replaced "most adequately and feasibly assures" with "most adequately assures, to the extent feasible," that the Secretary clearly was authorized to reject a standard if it proved technologically or economically infeasible. See also *post*, at 2898, and 2903, n. 34.

Respondents cast yet a third light on these events, focusing upon a few places in the legislative history where the words "feasible" and "reasonable" were used more or less interchangeably. See S.Rep. No. 91-2193, pp. 8-10 (1969), Leg.Hist. 38-40; 115 Cong.Rec. 22517 (1969) (Sen. Javits). It is their contention that, when Congress said "feasible," it meant cost-justified. According to respondents, who agree in this regard with the Secretary, the meaning of the feasibility requirement did not change substantially between the version that left the Senate Committee on Labor and Public Welfare and the version that was ultimately adopted as part of the Act.

To my mind, there are several lessons to be gleaned from this somewhat cryptic legislative history. First, as pointed out by Mr. Justice MARSHALL, to the extent that Senator Javits, Senator Dominick, and other Members were worried about imposing upon the Secretary the impossible burden of assuring absolute safety, they did not view § 3(8) of the Act ⟨681 as a limitation on that duty. I therefore find it difficult to accept the conclusion of the lower court, as embellished by respondents, that § 3(8) acts as a general check upon the Secretary's duty under § 6(b)(5) to adopt the most protective standard feasible.

Second, and more importantly, I believe that the legislative history demonstrates that the feasibility requirement, as employed in § 6(b)(5), is a legislative mirage, appearing to some Members but not to others, and assuming any form desired by the beholder. I am unable to accept Mr. Justice MARSHALL's argument that, by changing the phrasing of § 6(b)(5) from "most adequately and feasibly assures" to "most adequately assures, to the extent feasible," the Senate injected into that section something that was not already there.[4] If I am cor-

4. The legislative history indicates strongly that Senator Dominick himself saw little, if any, difference between the phrases "most adequately and feasibly assures" and "most ade-

rect in this regard, then the amendment introduced by Senator Javits to relieve the Secretary of the duty to create a risk-free workplace left Senator Dominick free to object to the amended provision on the same grounds. Perhaps Senator Dominick himself offered the aptest description of the feasibility requirement as "no more than an admonition to the Secretary to do his duty. . . ." 116 Cong.Rec. 36530 (1970); Leg. Hist. 367.

In sum, the legislative history contains nothing to indicate that the language "to the extent feasible" does anything other ⟨683 than render what had been a clear, if somewhat unrealistic, standard largely, if not entirely, precatory. There is certainly nothing to indicate that these words, as used in § 6(b)(5), are limited to technological and economic feasibility. When Congress has wanted to limit the concept of feasibility in this fashion, it has said so, as is evidenced in a statute enacted the same week as the provision at issue here.[5] I also question whether the Secretary wants to assume the duties such an interpretation would impose upon him. In these cases, for example, the Secretary actually declined to adopt a standard lower than 1 ppm for some industries, not because it was economically or technologically infeasible, but rather because "different levels for different industries would result in serious administrative difficulties." 43 Fed.Reg. 5947 (1978). See also *ante*, at 2868 (plurality opinion). If § 6(b)(5) authorizes the Secretary to reject a more protective standard in the interest of administrative feasibility, I have little doubt that he could reject such standards for any reason whatsoever, including even political feasibility.

III

In prior cases this Court has looked to sources other than the legislative history to breathe life into otherwise vague delegations of legislative power. In *American Power & Light Co. v. SEC*, 329 U.S. 90, 104, 67 S.Ct. 133, 141, 91 L.Ed. 103 (1946), for example, this Court concluded that certain seemingly vague delegations "derive[d] much meaningful content from the purpose of the Act, its factual background and the statutory context in which they appear." Here, however, there is little or nothing in the ⟨remaining provisions of the Occupational Safety and Health Act to provide specificity to the feasibility criterion in § 6(b)(5). It may be true, as suggested by Mr. Justice MARSHALL, that the Act as a whole expresses a distinct preference for safety over dollars. But that expression of preference, as I read it, falls far short of the proposition that the Secretary must eliminate marginal or insignificant risks of material harm right down to an industry's breaking point. ⟨683

Nor are these cases like *Lichter v. United States*, 334 U.S. 742, 783, 68 S.Ct. 1294, 1315, 92 L.Ed. 1694 (1948), where this Court upheld delegation of authority to recapture "excessive profits" in light of a pre-existing administrative practice. Here, the Secretary's approach to toxic substances like benzene could not have predated the enactment of § 6(b)(5) itself. Moreover, there are indications that the postenactment administrative practice has been less than uniform.

quately assures, to the extent feasible." In the course of his earlier attempt to delete the first sentence of § 6(b)(5) entirely, he paraphrased the unamended version of that section as requiring the Secretary to promulgate standards that "most adequately and feasibly assure *to the extent possible*" that no employee would suffer harm. 116 Cong.Rec. 36530 (1970), Leg. Hist. 367 (emphasis added). Unless Senator Dominick found a significant difference between the words "possible" and "feasible," it is clear that there is little difference between Senator Dominick's perception of what the unamended section required in the way of feasibility and what that section required after his amendment.

5. Sections 211(c)(2)(A) and (B) of the Clean Air Act, as amended on Dec. 31, 1970, 84 Stat. 1698, authorize the Environmental Protection Agency to regulate, control, or prohibit automotive fuel additives after "consideration of other *technologically or economically feasible* means of achieving emission standards . . ." 42 U.S.C. § 7545(c)(2)(A) (1976 ed., Supp.II) (emphasis added).

For example, the Occupational Safety and Health Review Commission (OSHRC), the body charged with adjudicating citations issued by the Secretary under the Act, apparently does not agree with the definition of "feasibility," advanced in these cases by the Secretary. In *Continental Can Co.*, 4 OSHC 1541, 1976–1977 OSHD ¶21,009 (1976), the Commission reasoned:

> "Clearly, employers have finite resources available for use to abate health hazards. And just as clearly if they are to be made to spend without limit for abatement of this hazard their financial ability to abate other hazards, including life threatening hazards, is reduced." *Id.*, at 1547, 1976–1977 OSHD, p. 25,256.

Furthermore, the record in these cases contains at least one indication that the Secretary himself was, at one time, quite uncertain what limits § 6(b)(5) placed upon him. In announcing the proposed 1 ppm standard and discussing its economic ramifications, the Secretary explained that "[w]hile the precise meaning of feasibility is not clear
[684] from the Act, it is OSHA's view that the term may include the economic ramifications of requirements imposed by standards." 43 Fed.Reg. 5934 (1978). This candid and tentative statement falls far short of the Secretary's present position that economic and technological considerations set the only limits on his duty to adopt the most protective standard. Finally, as noted earlier, the Secretary has failed to apply his present stringent view uniformly, rejecting in these cases a lower standard for some industries on the grounds of administrative convenience.

In some cases where broad delegations of power have been examined, this Court has upheld those delegations because of the delegatee's residual authority over particular subjects of regulation. In *United States v. Curtiss-Wright Export Corp.*, 299 U.S. 304, 307, 57 S.Ct. 216, 81 L.Ed. 255 (1936), this Court upheld a statute authorizing the President to prohibit the sale of arms to certain countries if he found that such a prohibition would "contribute to the reestablishment of peace." This Court reasoned that, in the area of foreign affairs, Congress "must often accord to the President a degree of discretion and freedom from statutory restriction which would not be admissible were domestic affairs alone involved." *Id.*, at 320, 57 S.Ct., at 221. Similarly, *United States v. Mazurie*, 419 U.S. 544, 95 S.Ct. 710, 42 L.Ed.2d 706 (1975), upheld a broad delegation of authority to various Indian tribes to regulate the introduction of liquor into Indian country. According to *Mazurie*, limitations on Congress' authority to delegate legislative power are "less stringent in cases where the entity exercising the delegated authority itself possesses independent authority over the subject matter." *Id.*, at 556–557, 95 S.Ct., at 717. In the present cases, however, neither the Executive Branch in general nor the Secretary in particular enjoys any independent authority over the subject matter at issue.

Finally, as indicated earlier, in some cases this Court has abided by a rule of necessity, upholding broad delegations of authority where it would be "unreasonable and impracticable to compel Congress to prescribe [685] detailed rules" regarding a particular policy or situation. *American Power & Light Co. v. SEC*, 329 U.S., at 105, 67 S.Ct., at 142. See also *Buttfield v. Stranahan*, 192 U.S. 470, 496, 24 S.Ct. 349, 355, 48 L.Ed. 525 (1904). But no need for such an evasive standard as "feasibility" is apparent in the present cases. In drafting § 6(b)(5), Congress was faced with a clear, if difficult, choice between balancing statistical lives and industrial resources or authorizing the Secretary to elevate human life above all concerns save massive dislocation in an affected industry. That Congress recognized the difficulty of this choice is clear from the previously noted remark of Senator Saxbe, who stated that "[w]hen we come to saying that an employer must guarantee that such an employee is protected from any possible harm, I think it will be one of the most difficult areas we are going to have to ascertain." 116 Cong.Rec. 36522 (1970); Leg.Hist. 345. That Congress chose, intentionally or unintentionally, to pass this dif-

ficult choice on to the Secretary is evident from the spectral quality of the standard it selected and is capsulized in Senator Saxbe's unfulfilled promise that "the terms that we are passing back and forth are going to have to be identified." *Ibid.*

IV

As formulated and enforced by this Court, the nondelegation doctrine serves three important functions. First, and most abstractly, it ensures to the extent consistent with orderly governmental administration that important choices of social policy are made by Congress, the branch of our Government most responsive to the popular will. See *Arizona v. California*, 373 U.S. 546, 626, 83 S.Ct. 1468, 1511, 10 L.Ed.2d 542 (1963) (Harlan, J., dissenting in part); *United States v. Robel*, 389 U.S. 258, 276, 88 S.Ct. 419, 430, 19 L.Ed.2d 508 (1967) (BRENNAN, J., concurring in result). Second, the doctrine guarantees that, to the extent Congress finds it necessary to delegate authority, it provides the recipient of]686 that authority with an ["intelligible principle" to guide the exercise of the delegated discretion. See *J. W. Hampton & Co. v. United States*, 276 U.S., at 409, 48 S.Ct., at 352; 72 L.Ed. 624 (1928); *Panama Refining Co. v. Ryan*, 293 U.S., at 430, 55 S.Ct., at 252. Third, and derivative of the second, the doctrine ensures that courts charged with reviewing the exercise of delegated legislative discretion will be able to test that exercise against ascertainable standards. See *Arizona v. California, supra*, 373 U.S., at 626, 83 S.Ct., at 1511 (Harlan, J., dissenting in part); *American Power & Light Co. v. SEC, supra*, at 106, 67 S.Ct., at 142.

I believe the legislation at issue here fails on all three counts. The decision whether the law of diminishing returns should have any place in the regulation of toxic substances is quintessentially one of legislative policy. For Congress to pass that decision on to the Secretary in the manner it did violates, in my mind, John Locke's caveat—reflected in the cases cited earlier in this opinion—that legislatures are to make laws, not legislators. Nor, as I think the prior discussion amply demonstrates, do the provisions at issue or their legislative history provide the Secretary with any guidance that might lead him to his somewhat tentative conclusion that he must eliminate exposure to benzene as far as technologically and economically possible. Finally, I would suggest that the standard of "feasibility" renders meaningful judicial review impossible.

We ought not to shy away from our judicial duty to invalidate unconstitutional delegations of legislative authority solely out of concern that we should thereby reinvigorate discredited constitutional doctrines of the pre-New Deal era. If the nondelegation doctrine has fallen into the same desuetude as have substantive due process and restrictive interpretations of the Commerce Clause, it is, as one writer has phrased it, "a case of death by association." J. Ely, Democracy and Distrust, A Theory of Judicial Review 133 (1980). Indeed, a number of observers have suggested that this Court should once more take up its burden of ensuring that Congress does not unnecessarily delegate important choices of social policy to politically unresponsive administrators.[6] Other observers, as might be imagined, have disagreed.[7]]687

6. See J. Ely, Democracy and Distrust, A Theory of Judicial Review 131–134 (1980); J. Freedman, Crisis and Legitimacy, The Administrative Process and American Government 78–94 (1978); T. Lowi, The End of Liberalism: Ideology, Policy, and the Crisis of Public Authority 129–146, 297–299 (1969); Wright, Beyond Discretionary Justice, 81 Yale L.J. 575, 582–587 (1972); Waist-Deep in Regulation, Washington Post, Nov. 3, 1979, p. A10, col. 1. Cf. W. Douglas, Go East, Young Man 217 (1974).

7. See K. Davis, Discretionary Justice: A Preliminary Inquiry 49–51 (1969); Stewart, The Reformation of American Administrative Law, 88 Harv.L.Rev. 1669, 1693–1697 (1975). Cf. Jaffe, The Illusion of the Ideal Administration, 86 Harv.L.Rev. 1183, 1190, n. 37 (1973).

If we are ever to reshoulder the burden of ensuring that Congress itself make the critical policy decisions, these are surely the cases in which to do it. It is difficult to imagine a more obvious example of Congress simply avoiding a choice which was both fundamental for purposes of the statute and yet politically so divisive that the necessary decision or compromise was difficult, if not impossible, to hammer out in the legislative forge. Far from detracting from the substantive authority of Congress, a declaration that the first sentence of § 6(b)(5) of the Occupational Safety and Health Act constitutes an invalid delegation to the Secretary of Labor would preserve the authority of Congress. If Congress wishes to legislate in an area which it has not previously sought to enter, it will in today's political world undoubtedly run into opposition no matter how the legislation is formulated. But that is the very essence of legislative authority under our system. It is the hard choices, and not the filling in of the blanks, which must be made by the elected representatives of the people. When fundamental policy decisions underlying important legislation about to be enacted are to be made, the buck stops with Congress and the President insofar as he exercises his constitutional role in the legislative process.

I would invalidate the first sentence of § 6(b)(5) of the Occupational Safety and]689 Health Act of 1970 as it applies to]any toxic substance or harmful physical agent for which a safe level, that is, a level at which "no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to [that hazard] for the period of his working life," is, according to the Secretary, unknown or otherwise "infeasible." Absent further congressional action, the Secretary would then have to choose, when acting pursuant to § 6(b)(5), between setting a safe standard or setting no standard at all.[8]

Accordingly, for the reasons stated above, I concur in the judgment of the Court affirming the judgment of the Court of Appeals.

Mr. Justice MARSHALL, with whom Mr. Justice BRENNAN, Mr. Justice WHITE, and Mr. Justice BLACKMUN join, dissenting.

In cases of statutory construction, this Court's authority is limited. If the statutory language and legislative intent are plain, the judicial inquiry is at an end. Under our jurisprudence, it is presumed that ill-considered or unwise legislation will be corrected through the democratic process; a court is not permitted to distort a statute's meaning in order to make it conform with the Justices' own views of sound social policy. See *TVA v. Hill*, 437 U.S. 153, 98 S.Ct. 2279, 57 L.Ed.2d 117 (1978).

Today's decision flagrantly disregards these restrictions on judicial authority. The plurality ignores the plain meaning of the Occupational Safety and Health Act of 1970 in order to bring the authority of the Secretary of Labor in line with the plurality's own views of proper regulatory policy. The unfortunate consequence is that the Federal Government's efforts to protect American workers from cancer and other crippling diseases may be substantially impaired.

]The first sentence of § 6(b)(5) of the Act]689 provides:

> "The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, 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." 29 U.S.C. § 655(b)(5).

8. This ruling would not have any effect upon standards governing toxic substances or harmful physical agents for which safe levels are feasible, upon extant standards promulgated as "national consensus standards" under § 6(a), nor upon the Secretary's authority to promulgate "emergency temporary standards" under § 6(c).

In this case the Secretary of Labor found, on the basis of substantial evidence, that (1) exposure to benzene creates a risk of cancer, chromosomal damage, and a variety of nonmalignant but potentially fatal blood disorders, even at the level of 1 ppm; (2) no safe level of exposure has been shown; (3) benefits in the form of saved lives would be derived from the permanent standard; (4) the number of lives that would be saved could turn out to be either substantial or relatively small; (5) under the present state of scientific knowledge, it is impossible to calculate even in a rough way the number of lives that would be saved, at least without making assumptions that would appear absurd to much of the medical community; and (6) the standard would not materially harm the financial condition of the covered industries. The Court does not set aside any of these findings. Thus, it could not be plainer that the Secretary's decision was fully in accord with his statutory mandate "most adequately [to] assur[e] . . . that no employee will suffer material impairment of health or functional capacity . . . ."

The plurality's conclusion to the contrary is based on its interpretation of 29 U.S.C. § 652(8), which defines an occupational safety and health standard as one "which requires conditions . . . reasonably necessary or appropriate to provide safe or healthful employment. . . ." According to the plurality, a standard is not "rea- ⟨690 sonably necessary or appropriate" ⟨unless the Secretary is able to show that it is "at least more likely than not," *ante*, at 2869, that the risk he seeks to regulate is a "significant" one. *Ibid.* Nothing in the statute's language or legislative history, however, indicates that the "reasonably necessary or appropriate" language should be given this meaning. Indeed, both demonstrate that the plurality's standard bears no connection with the acts or intentions of Congress and is based only on the plurality's solicitude for the welfare of regulated industries. And the plurality uses this standard to evaluate not the agency's decision in this case, but a strawman of its own creation.

Unlike the plurality, I do not purport to know whether the actions taken by Congress and its delegates to ensure occupational safety represent sound or unsound regulatory policy. The critical problem in cases like the ones at bar is scientific uncertainty. While science has determined that exposure to benzene at levels above 1 ppm creates a definite risk of health impairment, the magnitude of the risk cannot be quantified at the present time. The risk at issue has hardly been shown to be insignificant; indeed, future research may reveal that the risk is in fact considerable. But the existing evidence may frequently be inadequate to enable the Secretary to make the threshold finding of "significance" that the Court requires today. If so, the consequence of the plurality's approach would be to subject American workers to a continuing risk of cancer and other fatal diseases, and to render the Federal Government powerless to take protective action on their behalf. Such an approach would place the burden of medical uncertainty squarely on the shoulders of the American worker, the intended beneficiary of the Occupational Safety and Health Act. It is fortunate indeed that at least a majority of the Justices reject the view that the Secretary is prevented from taking regulatory action when the magnitude of a health risk cannot be quantified on the basis of current techniques. See *ante*, at 2876 (POWELL, J., concurring in part ⟨and concurring in judg- ⟨691 ment); see also *ante*, at 2871, and n. 63 (plurality opinion).

Because today's holding has no basis in the Act, and because the Court has no authority to impose its own regulatory policies on the Nation, I dissent.

I

Congress enacted the Occupational Safety and Health Act as a response to what was characterized as "the grim history of our failure to heed the occupational health

needs of our workers."[1] The failure of voluntary action and legislation at the state level, see S.Rep. No. 91-1282, p. 4 (1970), Leg.Hist. 144, had resulted in a "bleak" and "worsening"[2] situation in which 14,500 persons had died annually as a result of conditions in the workplace. In the four years preceding the Act's passage, more Americans were killed in the workplace than in the contemporaneous Vietnam War. S.Rep.No. 91-1283, at 2, Leg.Hist. 142; U.S. Code Cong. & Admin.News, p. 5177. The Act was designed as "a safety bill of rights for close to 60 million workers."[3] Its stated purpose is "to assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources." 29 U.S.C. § 651(b). See *Atlas Roofing Co. v. Occupational Safety and Health Review Comm'n*, 430 U.S. 442, 444-445, 97 S.Ct. 1261, 1263-64, 51 L.Ed.2d 464 (1977).

The Act is enforced primarily through two provisions. First, a "general duty" is imposed upon employers to furnish employment and places of employment "free from recognized hazards that are causing or are likely to cause death or serious physical harm . . . ." 29 U.S.C. § 654(a)(1). Second, the Secretary of Labor is authorized to set "occupational safety and health standards," defined as standards requiring "conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment." 29 U.S.C. § 652(8).

The legislative history of the Act reveals Congress' particular concern for health hazards of "unprecedented complexity" that had resulted from chemicals whose toxic effects "are only now being discovered." S.Rep.No. 91-1282, *supra*, at 2, Leg.Hist. 142. "Recent scientific knowledge points to hitherto unsuspected cause-and-effect relationships between occupational exposures and many of the so-called chronic diseases—cancer, respiratory ailments, allergies, heart disease, and others." *Ibid.*, U.S.Code Cong. & Admin.News, p. 5178. Members of Congress made repeated references to the dangers posed by carcinogens and to the defects in our knowledge of their operation and effect.[4] One of the primary purposes of the Act was to ensure regulation of these "insidious 'silent' killers."[5]

This special concern led to the enactment of the first sentence of 29 U.S.C. § 655(b)(5), which, as noted above, provides:

> "The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, 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."

This directive is designed to implement three legislative purposes. First, Congress recognized that there may be substances that become dangerous only upon repeated or frequent exposure.[6] The Secretary was therefore required to provide protection even from substances that would cause material impairment only upon exposure occurring throughout an employee's working

1. Legislative History of the Occupational Safety and Health Act of 1970 (Committee Print compiled for the Senate Committee on Labor and Public Welfare), p. iii (1971) (Foreword by Sen. Williams) (hereinafter Leg.Hist.).

2. S.Rep.No. 91-1282, p. 2 (1970), Leg.Hist. 142.

3. Leg.Hist. iii.

4. S.Rep.No. 91-1282, p. 2 (1970), Leg.Hist. 142; 116 Cong.Rec. 37326 (1970), Leg.Hist. 415 (Sen. Williams); H.R.Rep.No. 91-1291, p. 19 (1970), Leg.Hist. 849; 116 Cong.Rec. 38392-38393 (1970), Leg.Hist. 1049 (Rep. Karth).

5. 116 Cong.Rec. 38375 (1970), Leg.Hist. 1003 (Sen. Daniels).

6. 116 Cong.Rec., at 37623, Leg.Hist. 503 (Sen. Dominick); H.R.No. 91-1291, p. 28 (1970), Leg. Hist. 858.

life. Second, the requirement that the Secretary act on the basis of "the best *available* evidence" was intended to ensure that the standard-setting process would not be destroyed by the uncertainty of scientific views. Recognizing that existing knowledge may be inadequate, Congress did not require the Secretary to wait until definitive information could be obtained. Thus "it is not intended that the Secretary be paralyzed by debate surrounding diverse medical opinions." H.R.Rep.No. 91-1291, p. 18 (1970), Leg.Hist. 848. Third, Congress' special concern for the "silent killers" was felt to justify an especially strong directive to the Secretary in the standard-setting process. 116 Cong.Rec. 37622 (1970), Leg. Hist. 502 (Sen. Dominick).

The authority conferred by § 655(b)(5), however, is not absolute. The subsection itself contains two primary limitations. The requirement of "material" impairment was designed to prohibit the Secretary from regulating substances that create a trivial hazard to affected employees.[7] Moreover, all standards promulgated under the subsection must be "feasible." During the floor debates Congress expressed concern that a prior version of the bill, not clearly embodying the feasibility requirement, would require the Secretary to close down whole industries in order to eliminate risks of impairment. This standard was criticized as unrealistic.[8] The feasibility requirement was imposed as an affirmative limit on the standard-setting power. 1694

The remainder of § 655(b)(5), applicable to all safety and health standards, requires the Secretary to base his standards "upon research, demonstrations, experiments, and such other information as may be appropriate." In setting standards, the Secretary is directed to consider "the attainment of the highest degree of health and safety protection for the employee" and also "the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws."

The Act makes provision for judicial review of occupational safety and health standards promulgated pursuant to § 655(b)(5). The reviewing court must uphold the Secretary's determinations if they are supported by "substantial evidence in the record considered as a whole." 29 U.S.C. § 655(f). It is to that evidence that I now turn. 1695

II

The plurality's discussion of the record in this case is both extraordinarily arrogant and extraordinarily unfair. It is arrogant

7. See n. 34, *infra*.

8. An earlier version of the bill had provided: "The Secretary, in promulgating standards under this subsection, shall set the standard which most adequately and feasibly assures, on the basis of the best available evidence, that no employee will suffer any impairment of health or functional capacity, or diminished life expectancy even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life." S. 2193, 91st Cong., 2d Sess., 39 (1970), Leg.Hist. 242.

This standard, it was feared, "could be read to require the Secretary to ban all occupations in which there remains *some* risk of injury, impaired health, or life expectancy. In the case of all occupations, it will be impossible to eliminate all risks to safety and health. Thus, the present criteria could, if literally applied, close every business in this nation. In addition, in many cases, the standard which might most 'adequately' and 'feasibly' assure the elimination of the danger would be the prohibition of the occupation itself." 116 Cong.Rec. 36530 (1970), Leg.Hist. 367 (Statement on Amendment of Sen. Dominick). In explaining the present language, Senator Dominick stated:

"What we were trying to do in the bill—unfortunately, we did not have the proper wording or the proper drafting—was to say that when we are dealing with toxic agents or physical agents, we ought to take such steps as are feasible and practical to provide an atmosphere within which a person's health or safety would not be affected. Unfortunately, we had language providing that anyone would be assured that no one would have a hazard . . . so that no one would have any problem for the rest of his working life.

"It was an unrealistic standard. As modified, we would be approaching the problem by looking at the problem and setting a standard or criterion which would not result in harm." 116 Cong.Rec., at 37622; Leg.Hist. 502.

because the plurality presumes to make its own factual findings with respect to a variety of disputed issues relating to carcinogen regulation. See, e. g., *ante*, at 2871–2872, and n. 64. It should not be necessary to remind the Members of this Court that they were not appointed to undertake independent review of adequately supported scientific findings made by a technically expert agency.[9] And the plurality's discussion is unfair because its characterization of the Secretary's report bears practically no resemblance to what the Secretary actually did in this case. Contrary to the plurality's suggestion, the Secretary did not rely blindly on some Draconian carcinogen "policy." See *ante*, at 2855, 2861. If he had, it would have been sufficient for him to have ob- ⊥598 served that benzene is a carcinogen, a proposition that respondents do not dispute. Instead, the Secretary gathered over 50 volumes of exhibits and testimony and offered a detailed and evenhanded discussion of the relationship between exposure to benzene at all recorded exposure levels and chromosomal damage, aplastic anemia, and leukemia. In that discussion he evaluated, and took seriously, respondents' evidence of a safe exposure level. See also *ante*, at 2876 (POWELL, J., concurring in part and in judgment).

The hearings on the proposed standard were extensive, encompassing 17 days from July 19 through August 10, 1977. The 95 witnesses included epidemiologists, toxicologists, physicians, political economists, industry representatives, and members of the affected work force. Witnesses were subjected to exhaustive questioning by representatives from a variety of interested groups and organizations.

Three basic positions were presented at the hearings. The first position was that the proposed 1 ppm standard was necessary because exposure to benzene would cause material impairment of the health of workers no matter how low the exposure level. Some direct evidence indicated that exposure to benzene had caused chromosomal damage, blood disorders, and leukemia at or below the 10 ppm level itself. More important, it was suggested that the recorded effects of benzene at higher levels required an inference that leukemia and other disorders would result at levels of 1 ppm and lower, especially after the prolonged exposure typical in industrial settings. Therefore, the standard should be set at the lowest feasible level, which was 1 ppm.

The second position was at a 1 ppm exposure level would itself pose an unwarranted threat to employee health and safety and that the available evidence necessitated a significantly lower level. An exposure limit below 1 ppm, it was argued, would be feasible. There were suggestions that benzene was gradually being replaced in many of the affected industries and that most com- ⊥597 panies were already operating at or below the 1 ppm level.

The third position was that the 1971 standard should be retained. Proponents of this position suggested that evidence linking low levels of benzene exposure to leukemia was

9. I do not, of course, suggest that it is appropriate for a federal court reviewing agency action blindly to defer to the agency's findings of fact and determinations of policy. Under *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416, 91 S.Ct. 814, 823, 28 L.Ed.2d 136 (1971), courts must undertake a "searching and careful" judicial inquiry into those factors. Such an inquiry is designed to require the agency to take a "hard look," *Kleppe v. Sierra Club*, 427 U.S. 390, 410, n. 21, 96 S.Ct. 2718, 2730, n. 21, 49 L.Ed.2d 576 (1976) (citation omitted), by considering the proper factors and weighing them in a reasonable manner. There is also room for especially rigorous judicial scrutiny of agency decisions under a rationale akin to that offered in *United States v. Carolene Products Co.*, 304 U.S. 144, 152, n. 4, 58 S.Ct. 778, 783, 82 L.Ed. 1234 (1938). See *Environmental Defense Fund v. Ruckelshaus*, 142 U.S.App.D.C. 74, 439 F.2d 584 (1971).

I see no basis, however, for the approach taken by the plurality today, which amounts to nearly *de novo* review of questions of fact and of regulatory policy on behalf of institutions that are by no means unable to protect themselves in the political process. Such review is especially inappropriate when the factual questions at issue are ones about which the Court cannot reasonably be expected to have expertise.

uncertain, that the current exposure limit was sufficiently safe, and that the benefits of the proposed standard would be insufficient to justify the standard's costs. In addition, there was testimony that the expenses required by the proposed standard would be prohibitive.

The regulations announcing the permanent standard for benzene are accompanied by an extensive statement of reasons summarizing and evaluating the results of the hearings. The Secretary found that the evidence showed that exposure to benzene causes chromosomal damage, a variety of nonmalignant blood disorders, and leukemia. 43 Fed.Reg. 5921 (1978). He concluded that low concentrations imposed a hazard that was sufficiently grave to call for regulatory action under the Act.

Evidence of deleterious effects. The Secretary referred to studies which conclusively demonstrated that benzene could damage chromosomes in blood-forming cells. *Id.*, at 5932. There was testimony suggesting a causal relationship between chromosomal damage and leukemia, although it could not be determined whether and to what extent such damage would impair health. *Id.*, at 5933.[10] Some studies had suggested chromosomal damage at exposure levels of 10–25 ppm and lower.[11] No quantitative dose-response curve, showing the relationship between exposure levels and incidence of chromosomal damage could yet be established. *Id.*, at 5933–5934. The evidence of chromosomal damage was, in the Secretary's view, a cause for "serious concern." *Id.*, at 5933.

The most common effect of benzene ex- ⟨698 posure was a decrease in the levels of blood platelets and red and white blood cells. If sufficiently severe, the result could be pancytopenia or aplastic anemia, noncancerous but potentially fatal diseases. There was testimony that some of the nonmalignant blood disorders caused by benzene exposure could progress to, or represented, a preleukemic stage which might eventually evolve into a frank leukemia. *Id.*, at 5922.[12]

Considerable evidence showed an association between benzene and nonmalignant blood disorders at low exposure levels. Such an association had been established in one study in which the levels frequently ranged from zero to 25 ppm with some concentrations above 100 ppm, *ibid.*; in another they ranged from 5 to 30 ppm, *id.*, at 5923. Because of the absence of adequate data, a dose-response curve showing the relationship between benzene exposure and blood disorders could not be constructed. There was considerable testimony, however, that such disorders had resulted from exposure to benzene at or near the current level of 10 ppm and lower.[13] The Secretary concluded that the current standard did not provide adequate protection. He observed that a "safety factor" of 10 to 100 was generally used to discount the level at which a causal connection had been found in existing studies.[14] Under this approach, he concluded that, quite apart from any leukemia risk, the permissible exposure limit should be set at a level considerably lower than 10 ppm.

Finally, there was substantial evidence that exposure to benzene caused leukemia. The Secretary concluded that the evidence established that benzene was a carcinogen. A causal relationship between benzene and leukemia was first reported in France in 1897, and since that time similar results had been found in a number of countries, including Italy, Turkey, Japan, Switzerland, the Soviet Union, and the United States. ⟨699 The latest study, undertaken by the National Institute for Occupational Safety and Health (NIOSH) in the 1970's, reported a fivefold excess over the normal incidence of leukemia among workers exposed to ben-

10. Tr. 258–259, 1039.

11. *Id.*, at 148, 200–201, 258.

12. *Id.*, at 145, 173–174, 352, 1227, 1928, 3206; 15 Record, Ex. 43B, p. 166.

13. *Id.*, at 149, 360–361, 997, 1023, 2543, 2689, 3203; 11 Record, Ex. 3.

14. Tr. 149, 1218, 2692, 2847.

zene at industrial plants in Ohio. There was testimony that this study seriously understated the risk.[15]

The Secretary reviewed certain studies suggesting that low exposure levels of 10 ppm and more did not cause any excess incidence of leukemia. Those studies, he suggested, suffered from severe methodological defects, as their authors frankly acknowledged.[16] Finally, the Secretary discussed a study suggesting a statistically significant excess in leukemia at levels of 2 to 9 ppm. *Ibid.*[17] He found that, despite certain deficiencies in the study, it should be considered as consistent with other studies demonstrating an excess leukemia risk among employees exposed to benzene. *Id.*, at 5928.

Areas of uncertainty. The Secretary ex- ⊥700 amined three areas of uncertainty that had particular relevance to his decision. First, he pointed to evidence that the latency period for benzene-induced leukemia could range from 2 to over 20 years. *Id.*, at 5930. Since lower exposure levels lead to an increase in the latency period, it would be extremely difficult to obtain evidence showing the dose-response relationship between leukemia and exposure to low levels of benzene. Because there has been no adequate monitoring in the past, it would be practically impossible to determine what the exposure levels were at a time sufficiently distant so that the latency period would have elapsed. The problem was compounded by the difficulty of conducting a suitable study. Because exposure levels approaching 10 ppm had been required only recently, direct evidence showing the relationship between leukemia and exposure levels between 1 and 10 ppm would be unavailable in the foreseeable future.

Second, the Secretary observed that individuals had differences in their susceptibility to leukemia. *Ibid.*. Among those exposed to benzene was a group of unknown but possibly substantial size having various "predisposing factors" whose members were especially vulnerable to the disease. *Id.*, at 5930, 5946. The permanent standard was designed to minimize the effects of exposure for these susceptible individuals as well as for the relatively insensitive, *id.*, at 5946, and also to facilitate early diagnosis and treatment. *Id.*, at 5930.

The Secretary discussed the contention that a safe level of exposure to benzene had been demonstrated. From the testimony of numerous scientists, he concluded that it had not. *Id.*, at 5932.[18] He also found that although no dose-response curve could be plotted, *id.*, at 5946,[19] the extent of the risk ⊥would decline with the exposure level. ⊥701

15. *Id.*, at 308, 314, 747, 768, 769–770, 874, 2445. As the Secretary observed, the issue of the exposure level in the NIOSH study was extensively debated during the hearings. A report from the Industrial Commission of Ohio suggested that concentrations generally ranged from zero to 10 or 15 ppm. But the Secretary concluded that evidence at the hearings showed that area exposures during the study period had sometimes substantially exceeded that level. Because of the conflicting evidence and the absence of monitoring data, he found that the excess leukemia risk observed in the NIOSH study could not be linked to any particular exposure level.

16. As to the study on which industry relied most heavily, for example, the Secretary, largely repeating the author's own admissions, observed that (1) a number of employees included in the sample may not have been exposed to benzene at any time; (2) there was inadequate followup of numerous employees, so that persons who may have contracted leukemia were not included in the data; (3) the diagnoses were subject to serious question, and cases of leukemia may have gone unnoticed; (4) no determination of exposure levels had been made; and (5) the occupational histories of the workers were admittedly incomplete. 43 Fed. Reg. 5928 (1978).

17. Tr. 1023–1024, 1227; 22A Record, Ex. 154.

18. The testimony of Dr. Aksoy, one of the world's leading experts, was typical: "[E]ven one ppm . . . causes leukemia." Tr. 204. See also *id.*, at 30, 150, 262, 328, 351–352, 363–364, 394, 745–746, 1057, 1210, 2420; 9 Record, Ex. 2.8–272, p. 1.

19. Tr. 130, 360, 414–415, 416–417, 760–761, 781–782, 925, 1055–1056; 17 Record, Ex. 75, p. 2; 1 Record, Ex. 2–4, p. 11.

Ibid.[20] Exposure at a level of 1 ppm would therefore be less dangerous than exposure at one of 10 ppm. The Secretary found that the existing evidence justified the conclusion that he should not "wait for answers" while employees continued to be exposed to benzene at hazardous levels.

Finally, the Secretary responded to the argument that the permissible exposure level should be zero or lower than 1 ppm. *Id.*, at 5947.[21] Even though many industries had already achieved the 1 ppm level, he found that a lower level would not be feasible. *Ibid.*

Costs and benefits. The Secretary offered a detailed discussion of the role that economic considerations should play in his determination. He observed that standards must be "feasible," both economically and technologically. In his view the permanent standard for benzene was feasible under both tests. The economic impact would fall primarily on the more stable industries, such as petroleum refining and petrochemical production. *Id.*, at 5934. These industries would be able readily to absorb the costs or to pass them on to consumers. None of the 20 affected industries, involving 157,000 facilities and 629,000 exposed employees, *id.*, at 5935, would be unable to bear the required expenditures, *id.*, at 5934. He concluded that the compliance costs were "well within the financial capability of the covered industries." *Id.*, at 5941. An extensive survey of the national economic impact of the standard, undertaken by a private contractor, found first-year operating costs of between $187 and $205 million, recurring annual costs of $34 million, and investment in engineering controls of about $266 million.[22] Since respondents have not attacked the Secretary's basic conclusions as to cost, the Secretary's extensive discussion need not be summarized here.]702

Finally, the Secretary discussed the benefits to be derived from the permanent standard. During the hearings, it had been argued that the Secretary should estimate the health benefits of the proposed regulation. To do this he would be required to construct a dose-response curve showing, at least in a rough way, the number of lives that would be saved at each possible exposure level. Without some estimate of benefits, it was argued, the Secretary's decision-making would be defective. During the hearings an industry witness attempted to construct such a dose-response curve. Restricting himself to carcinogenic effects, he estimated that the proposed standard would save two lives every six years and suggested that this relatively minor benefit would not justify the regulation's costs.

The Secretary rejected the hypothesis that the standard would save only two lives in six years. This estimate, he concluded, was impossible to reconcile with the evidence in the record. *Ibid.*[23] He determined

20. Tr. 382, 401, 405, 1372, 2846, 2842–2843.

21. *Id.*, at 148–149 ("the permissible exposure limit for benzene should be zero") (testimony of Dr. Aksoy). See also *id.*, at 1251 *et seq.*, 3506 *et seq.*

22. The plurality's estimate of the amount of expenditure per employee, see *ante*, at 2858, is highly misleading. Most of the costs of the benzene standard would be incurred only once and would thus protect an unascertainable number of employees in the future; that number will be much higher than the number of employees currently employed.

23. The projection, designed as an extrapolation from an amalgamation of existing studies, was dependent on a number of assumptions which the Secretary could reasonably view as questionable. Indeed, the witness himself stated that his estimate was based on "a lousy set of data," was "slightly better than a guess," Tr. 2772, and that there was "no real basis," *id.*, at 2719, for a dose-response curve on which the estimate was wholly dependent.

The witness' assumptions were severely tested during the hearings, see *id.*, at 2795 *et seq.*, and the Secretary could reasonably reject them on the basis of the evidence in the record. For example: (1) The witness appeared to assume that in previous tests leukemia had been contracted after a lifetime of exposure; the evidence afforded no basis for that assumption, and the duration of exposure may have been quite short for particular employees. If the duration period was short, the witness' estimate would have been much too low. (2) The witness assumed that exposure levels in the NIOSH study were around 100 ppm. The Secretary found, however, that no such assump-

⊥703 that, because of numerous uncertainties in the existing data, it was impossible to construct a dose-response curve by extrapolating from those data to lower exposure lev-
⊥704 els.[24] More generally, the Secretary observed that it had not been established that there was a safe level of exposure for benzene. Since there was considerable testimony that the risk would decline with the exposure level, *id.*, at 5940, the new standard would save lives. The number of lives saved "may be appreciable," but there was no way to make a more precise determination.[25] The question was "on the frontiers of scientific knowledge." *Ibid.*

The Secretary concluded that, in light of the scientific uncertainty, he was not required to calculate benefits more precisely. *Id.*, at 5941. In any event he gave "careful consideration" to the question of whether the admittedly substantial costs were justified in light of the hazards of benzene exposure. He concluded that those costs were "necessary" in order to promote the purposes of the Act.

III

A

This is not a case in which the Secretary found, or respondents established, that no benefits would be derived from a permanent standard, or that the likelihood of benefits was insignificant. Nor was it shown that a quantitative estimate of benefits could be made on the basis of "the best available evidence." Instead, the Secretary concluded that benefits will result, that those benefits "may" be appreciable, but that the dose-response relationship of low levels of benzene exposure and leukemia, ⊥705

tion could be made, and there was evidence that exposure levels had generally been between zero and 10–15 ppm. (3) The witness assumed that the dose-response curve was linear at all levels, but there was no basis for that assumption. In the case of vinyl chloride (another carcinogen for which the Secretary has promulgated exposure standards), recent evidence suggested that the dose-response curve rises steeply at low doses and becomes less steep as the levels are increased. (4) Twenty-five percent of the workers in the NIOSH study had not been found, and the witness assumed that they were still alive and would not contract leukemia. Six hundred additional workers exposed in that study were still alive; the witness assumed they too would not contract leukemia. There was considerable testimony that, for these and other reasons, the NIOSH study significantly underestimated the risk. The witness assumes that it had not. (5) The NIOSH study found a fivefold excess risk from benzene exposure; the witness assumed that the excess was much lower, despite the NIOSH finding and the testimony that that finding was a significant understatement of the risk. In light of these uncertainties, the Secretary could conclude that the witness' estimate was unsupportable.

24. Witnesses testifying to the inability to construct a dose-response curve referred primarily to the impossibility of correlating the incidence of leukemia, blood disorders, and chromosomal damage with the levels and duration of exposure in past studies. Thus Dr. Herman Kraybill of the National Cancer Institute testified:

"[W]e like to estimate risk factors. This has been done, as many of you recall, with vinyl chloride several years ago.

". . . [T]o estimate the risk factors on [the basis of] experimental data, this presupposes if you have good toxicity data. When I say toxicity data, I mean good dose-response data on vinyl chloride, which indeed we did have that.

"But with benzene, it appeared that we didn't have this situation, so therefore, most of us gave up. . . .

". . . With benzene, we sort of struck out." *Id.*, at 760–761.

Because of the enormous uncertainties in levels and duration of exposure in prior studies, any assumptions would necessarily be arbitrary. The possible range of assumptions was so great that the ultimate conclusion would be entirely uninformative. See *id.*, at 360, 415, 1055–1056.

25. At one point the Secretary did indicate that appreciable benefits were "likely" to result. The Court of Appeals held that this conclusion was unsupported by substantial evidence. The Secretary's suggestion, however, was made in the context of a lengthy discussion intended to show that appreciable benefits "may" be predicted but that their likelihood could not be quantified. The suggestion should not be taken as a definitive statement that appreciable benefits were more probable than not.

For reasons stated *infra*, there is nothing in the Act to prohibit the Secretary from acting when he is unable to conclude that appreciable benefits are more probable than not.

nonmalignant blood disorders, and chromosomal damage was impossible to determine. The question presented is whether, in these circumstances, the Act permits the Secretary to take regulatory action, or whether he must allow continued exposure until more definitive information becomes available.

As noted above, the Secretary's determinations must be upheld if supported by "substantial evidence in the record considered as a whole." 29 U.S.C. § 655(f). This standard represents a legislative judgment that regulatory action should be subject to review more stringent than the traditional "arbitrary and capricious" standard for informal rulemaking. We have observed that the arbitrary and capricious standard itself contemplates a searching "inquiry into the facts" in order to determine "whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 416, 91 S.Ct. 814, 824, 28 L.Ed.2d 136 (1971). Careful performance of this task is especially important when Congress has imposed the comparatively more rigorous "substantial evidence" requirement. As we have emphasized, however, judicial review under the substantial evidence test is ultimately deferential. See, *e. g., Richardson v. Perales*, 402 U.S. 389, 401, 91 S.Ct. 1420, 1427, 28 L.Ed.2d 842 (1971); *Consolo v. Federal Maritime Comm'n*, 383 U.S. 607, 618–621, 86 S.Ct. 1018, 1025–27, 16 L.Ed.2d 131 (1966). The agency's decision is entitled to the traditional presumption of validity, and the court is not authorized to substitute its judgment for that of the Secretary. If the Secretary has considered the decisional factors and acted in conformance with the statute, his ultimate decision must be given a large measure of respect. *Id.*, at 621, 86 S.Ct., at 1027.

The plurality is insensitive to three factors which, in my view, make judicial review of occupational safety and health standards under the substantial evidence test particularly difficult. First, the issues often reach a high level of technical complexity. In such circumstances the courts are required to immerse themselves in matters to which they are unaccustomed by training 1706 or experience. Second, the factual issues with which the Secretary must deal are frequently not subject to any definitive resolution. Often "the factual finger points, it does not conclude." *Society of Plastics Industry, Inc. v. OSHA*, 509 F.2d 1301, 1308 (CA2) (Clark, J.), cert. denied, 421 U.S. 992, 95 S.Ct. 1998, 44 L.Ed.2d 482 (1975). Causal connections and theoretical extrapolations may be uncertain. Third, when the question involves determination of the acceptable level of risk, the ultimate decision must necessarily be based on considerations of policy as well as empirically verifiable facts. Factual determinations can at most define the risk in some statistical way; the judgment whether that risk is tolerable cannot be based solely on a resolution of the facts.

The decision to take action in conditions of uncertainty bears little resemblance to the sort of empirically verifiable factual conclusions to which the substantial evidence test is normally applied. Such decisions were not intended to be unreviewable; they too must be scrutinized to ensure that the Secretary has acted reasonably and within the boundaries set by Congress. But a reviewing court must be mindful of the limited nature of its role. See *Vermont Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519, 98 S.Ct. 1197, 55 L.Ed.2d 460 (1978). It must recognize that the ultimate decision cannot be based solely on determinations of fact, and that those factual conclusions that have been reached are ones which the courts are ill-equipped to resolve on their own.

Under this standard of review, the decision to reduce the permissible exposure level to 1 ppm was well within the Secretary's authority. The Court of Appeals upheld the Secretary's conclusions that benzene causes leukemia, blood disorders, and chromosomal damage even at low levels, that an exposure level of 10 ppm is more dangerous

than one of 1 ppm, and that benefits will result from the proposed standard. It did not set aside his finding that the number of lives that would be saved was not subject to ⊥707 quantification. ⊥Nor did it question his conclusion that the reduction was "feasible."

In these circumstances, the Secretary's decision was reasonable and in full conformance with the statutory language requiring that he "set the standard which most adequately assures, 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." 29 U.S.C. § 655(b)(5). On this record, the Secretary could conclude that regular exposure above the 1 ppm level would pose a definite risk resulting in material impairment to some indeterminate but possibly substantial number of employees. Studies revealed hundreds of deaths attributable to benzene exposure. Expert after expert testified that no safe level of exposure had been shown and that the extent of the risk declined with the exposure level. There was some direct evidence of incidence of leukemia, nonmalignant blood disorders, and chromosomal damage at exposure levels of 10 ppm and below. Moreover, numerous experts testified that existing evidence required an inference that an exposure level above 1 ppm was hazardous. We have stated that "well-reasoned expert testimony—based on what is known and uncontradicted by empirical evidence—may in and of itself be 'substantial evidence' when first-hand evidence on the question . . . is unavailable." *FPC v. Florida Power & Light Co.*, 404 U.S. 453, 464–465, 92 S.Ct. 637, 644, 30 L.Ed.2d 600 (1972). Nothing in the Act purports to prevent the Secretary from acting when definitive information as to the quantity of a standard's benefits is unavailable.[26] Where, as here, the deficiency in ⊥knowledge relates to the extent of ⊥708 the benefits rather than their existence, I see no reason to hold that the Secretary has exceeded his statutory authority.

B

The plurality avoids this conclusion through reasoning that may charitably be described as obscure. According to the plurality, the definition of occupational safety and health standards as those "reasonably necessary or appropriate to provide safe or healthful . . . working conditions" requires the Secretary to show that it is "more likely than not" that the risk he seeks to regulate is a "significant" one. *Ante*, at 2869. The plurality does not show how this requirement can be plausibly derived from the "reasonably necessary or appropriate" clause. Indeed, the plurality's reasoning is refuted by the Act's language, structure, and legislative history, and it is foreclosed by every applicable guide to statutory construction. In short, the plurality's standard is a fabrication bearing no connection with the acts or intentions of Congress.

At the outset, it is important to observe that "reasonably necessary or appropriate" clauses are routinely inserted in regulatory legislation, and in the past such clauses have uniformly been interpreted as general provisos that regulatory actions must bear a reasonable relation to those statutory purposes set forth in the statute's substantive provisions. See, e. *g., FCC v. National Citi-*

26. This is not to say that the Secretary is prohibited from examining relative costs and benefits in the process of setting priorities among hazardous substances, or that systematic consideration of costs and benefits is not to be attempted in the standard-setting process. Efforts to quantify costs and benefits, like statements of reasons generally, may help to promote informed consideration of decisional factors and facilitate judicial review. See *Dunlop v. Bachowski*, 421 U.S. 560, 571–574, 95 S.Ct. 1851, 1859–61, 44 L.Ed.2d 377 (1975). The Secretary indicates that he has attempted to quantify costs and benefits in the past. See 43 Fed.Reg. 54354, 54427–54431 (1978) (lead); *Id.*, at 27350, 27378–27379 (cotton dust).

It is not necessary in the present litigation to say whether the Secretary must show a reasonable relation between costs and benefits. Discounting for the scientific uncertainty, the Secretary expressly—and reasonably—found such a relation here.

zens Committee for Broadcasting, 436 U.S. 775, 796–797, 98 S.Ct. 2096, 2112–13, 56 L.Ed.2d 697 (1978); *Mourning v. Family Publications Service, Inc.*, 411 U.S. 356, 369, 93 S.Ct. 1652, 1660, 36 L.Ed.2d 318 (1973); ⊥709 *Thorpe* ⊥*v. Housing Authority of City of Durham*, 393 U.S. 268, 280–281, 89 S.Ct. 518, 525–26, 21 L.Ed.2d 474 (1969). The Court has never—until today—interpreted a "reasonably necessary or appropriate" clause as having a substantive content that supersedes a specific congressional directive embodied in a provision that is focused more particularly on an agency's authority. This principle, of course, reflects the common understanding that the determination of whether regulations are "reasonably necessary" may be made only by reference to the legislative judgment reflected in the statute; it must not be based on a court's own, inevitably subjective view of what steps should be taken to promote perceived statutory goals.

The plurality suggests that under the "reasonably necessary" clause, a workplace is not "unsafe" unless the Secretary is able to convince a reviewing court that a "significant" risk is at issue. *Ante*, at 2864. That approach is particularly embarrassing in this case, for it is contradicted by the plain language of the Act. The plurality's interpretation renders utterly superfluous the first sentence of § 655(b)(5), which, as noted above, requires the Secretary to set the standard "which most adequately assures . . . that no employee will suffer material impairment of health." Indeed, the plurality's interpretation reads that sentence out of the Act. By so doing, the plurality makes the test for standards regulating toxic substances and harmful physical agents substantially identical to the test for standards generally—plainly the opposite of what Congress intended. And it is an odd canon of construction that would insert in a vague and general definitional clause a threshold requirement that overcomes the specific language placed in a standard-setting provision. The most elementary principles of statutory construction demonstrate that precisely the opposite interpretation is appropriate. See *e. g., FPC v. Texaco Inc.*, 417 U.S. 380, 394–395, 94 S.Ct. 2315, 2324–25, 41 L.Ed.2d 141 (1974); *Clark v. Uebersee Finanz-Korp.*, 332 U.S. 480, 488–489, 68 S.Ct. 174, 177–78, 92 L.Ed. 88 (1947). In short, Congress could have provided that the Secretary may not take regulatory action until the existing ⊥scien- ⊥710 tific evidence proves the risk as issue to be "significant," [27] but it chose not to do so.

The plurality's interpretation of the "reasonably necessary or appropriate" clause is also conclusively refuted by the legislative history. While the standard-setting provision that the plurality ignores received extensive legislative attention, the definitional clause received *none at all.* An earlier version of the Act, see n. 8, *supra*, did not embody a clear feasibility constraint and was not restricted to toxic substances or to "material" impairments. The "reasonably necessary or appropriate" clause was con-

27. It is useful to compare the Act with other regulatory statutes in which Congress has required a showing of a relationship between costs and benefits or of an "unreasonable risk." In some statutes Congress has expressly required cost-benefit analysis or a demonstration of some reasonable relation between costs and benefits. See 33 U.S.C. § 701a (Flood Control Act of 1936); 42 U.S.C. § 7545(c)(2)(B) (1976 ed., Supp.II) (Clean Air Act); 33 U.S.C. § 1314(b)(4)(B) (1976 ed., Supp.II) (Clean Water Act). In others Congress has imposed two independent requirements: that administrative action be "feasible" and justified by a balancing of costs and benefits, *e. g.*, 43 U.S.C. § 1347(b) (1976 ed., Supp.II) (Outer Continental Shelf Lands Act); 42 U.S.C. § 6295(a)(2)(D) (1976 ed., Supp.II) (Energy Policy and Conservation Act). This approach demonstrates a legislative awareness of the difference between a feasibility constraint and a constraint based on weighing costs and benefits. See *infra*, at 2903. In still others Congress has authorized regulation of "unreasonable risk," a term which has been read by some courts to require a balancing of costs and benefits. See, *e. g., Aqua Slide 'N' Dive Corp. v. Consumer Product Safety Comm'n*, 569 F.2d 831 (CA5 1978) (construing 15 U.S.C. § 2058(c)(2)(A) (Consumer Product Safety Act)); *Forester v. Consumer Product Safety Comm'n*, 182 U.S.App.D.C. 153, 559 F.2d 774 (1977) (construing 15 U.S.C. § 1261(s) (Child Protection and Toy Safety Act)).

tained in this prior version of the bill, as it was at all relevant times. In debating this version, Members of Congress repeatedly expressed concern that it would require a risk-free universe. See, *e. g., ante*, at 2866–2867. The definitional clause was not mentioned at all, an omission that would be ⌊711 incomprehensible if Congress intended ⌊by that clause to require the Secretary to quantify the risk he sought to regulate in order to demonstrate that it was "significant."

The only portions of the legislative history on which the plurality relies, see *ibid.*, have nothing to do with the "reasonably necessary or appropriate" clause from which the "threshold finding" requirement is derived. Those portions consisted of criticisms directed toward the earlier version of the statute, *which already contained the definitional clause.* These criticisms, in turn, were met by subsequent amendments that limited application of the strict "no employee will suffer" clause to toxic substances, inserted an explicit feasibility constraint, and modified the word "impairment" by the adjective "material." It is disingenuous at best for the plurality to suggest that isolated statements in the legislative history, expressing concerns that were met by subsequent amendments not requiring any "threshold" finding, can justify reading such a requirement into a "reasonably necessary" clause that was in the Act all along.[28]

⌊The plurality's various structural arguments are also unconvincing. The fact that a finding of "grave danger" is required for temporary standards, see *ante*, at 2863, n. 45, hardly implies that the Secretary must show for permanent standards that it is more probable than not that the substance to be regulated poses a "significant" risk. Nor is the reference to "*toxic* materials," *ante*, at 2864, in any way informative. And the priority-setting provision, *ante*, 2865, cannot plausibly be read to condition the Secretary's standard-setting authority on an ability to meet the Court's "threshold" requirement. ⌊712

The plurality ignores applicable canons of construction, apparently because it finds their existence inconvenient. But as we stated quite recently, the inquiry into statutory purposes should be "informed by an awareness that the regulation is entitled to deference unless it can be said not to be a reasoned and supportable interpretation of the Act." *Whirlpool Corp. v. Marshall*, 445 U.S. 1, 11, 100 S.Ct. 883, 890, 63 L.Ed.2d 154 (1980). Can it honestly be said that the Secretary's interpretation of the Act is "unreasoned" or "unsupportable"? And as we stated in the same case, "safety legislation is to be liberally construed to effectuate the congressional purpose." *Id.*, at 13, 100 S.Ct., at 891. The plurality's disregard of these principles gives credence to the frequently voiced criticism that they are hon-

28. The plurality also relies on its perception that if the "reasonably necessary" clause were not given the meaning it ascribes to it, there would be no guidance for "standards other than those dealing with toxic materials and harmful physical agents." *Ante*, at 2863, n. 45. For two reasons this argument is without force. First, even if the "reasonably necessary" clause does have independent content, and even if that content is as the plurality describes it, it cannot under any fairminded reading supersede the express language of § 655(b)(5) for toxic substances and harmful physical agents.

Second, as noted above, an earlier version of the bill applied the "no employee will suffer" language to all substances. At that time, there was no "gap," and accordingly it could not be argued that the "reasonably necessary or appropriate" clause had the content the plurality ascribes to it. In this light, the plurality's reasoning must be that when Congress amended the bill to apply the strict § 655(b)(5) requirements only to toxic substances, the definitional clause gained an independent meaning that in turn comprehended all standards. But surely this argument turns congressional purposes on their head. It reasons that when Congress singled out toxic substances for special regulation, it simultaneously created a more lenient ("reasonably necessary") test for standards generally, and that once that more lenient test was applicable, it somehow superseded the strict requirements for toxic substances. That reasoning is both illogical and circular. Nor is there any basis for the plurality's suggestion, see *ante*, at 2867–2868, n. 54, that the original bill's application to all standards was "entirely inadvertent."

ored only when the Court finds itself in substantive agreement with the agency action at issue.

In short, today's decision represents a usurpation of decisionmaking authority that has been exercised by and properly belongs with Congress and its authorized representatives. ⊥713 The plurality's construction has no support in the statute's language, structure, or legislative history. The threshold finding that the plurality requires is the plurality's own invention. It bears no relationship to the acts or intentions of Congress, and it can be understood only as reflecting the personal views of the plurality as to the proper allocation of resources for safety in the American workplace.

C

The plurality is obviously more interested in the consequences of its decision than in discerning the intention of Congress. But since the language and legislative history of the Act are plain, there is no need for conjecture about the effects of today's decision. "It is not for us to speculate, much less act, on whether Congress would have altered its stance had the specific events of this case been anticipated." *TVA v. Hill*, 437 U.S., at 185, 98 S.Ct., at 2297. I do not pretend to know whether the test the plurality erects today is, as a matter of policy, preferable to that created by Congress and its delegates: the area is too fraught with scientific uncertainty, and too dependent on considerations of policy, for a court to be able to determine whether it is desirable to require identification of a "significant" risk before allowing an administrative agency to take regulatory action. But in light of the tenor of the plurality opinion, it is necessary to point out that the question is not one-sided, and that Congress' decision to authorize the Secretary to promulgate the regulation at issue here was a reasonable one.

In this case the Secretary found that exposure to benzene at levels above 1 ppm posed a definite albeit unquantifiable risk of chromosomal damage, nonmalignant blood disorders, and leukemia. The existing evidence was sufficient to justify the conclusion that such a risk was presented, but it did not permit even rough quantification of that risk. Discounting for the various scientific uncertainties, the Secretary gave ⊥714 "careful consideration to the question of whether the[ ] substantial costs" of the standard "are justified in light of the hazards of exposure to benzene," and concluded that "these costs are necessary in order to effectuate the statutory purpose . . . and to adequately protect employees from the hazards of exposure to benzene." 43 Fed.Reg. 5941 (1978).

In these circumstances it seems clear that the Secretary found a risk that is "significant" in the sense that the word is normally used. There was some direct evidence of chromosomal damage, nonmalignant blood disorders, and leukemia at exposures at or near 10 ppm and below. In addition, expert after expert testified that the recorded effects of benzene exposure at higher levels justified an inference that an exposure level above 1 ppm was dangerous. The plurality's extraordinarily searching scrutiny of this factual record reveals no basis for a conclusion that quantification is, on the basis of "the best available evidence," possible at the present time. If the Secretary decided to wait until definitive information was available, American workers would be subjected for the indefinite future to a possibly substantial risk of benzene-induced leukemia and other illnesses. It is unsurprising, at least to me, that he concluded that the statute authorized him to take regulatory action now.

Under these circumstances, the plurality's requirement of identification of a "significant" risk will have one of two consequences. If the plurality means to require the Secretary realistically to "quantify" the risk in order to satisfy a court that it is "significant," the record shows that the plurality means to require him to do the impossible. But the regulatory inaction has very significant costs of its own. The adoption of such a test would subject American workers to a continuing risk of cancer and

other serious diseases; it would disable the Secretary from regulating a wide variety of carcinogens for which quantification simply cannot be undertaken at the present time. ⌊715 ⌊There are encouraging signs that today's decision does not extend that far.[29] My Brother POWELL concludes that the Secretary is not prevented from taking regulatory action "when reasonable quantification cannot be accomplished by any known methods." See *ante*, at 2876. The plurality also indicates that it would not prohibit the Secretary from promulgating safety standards when quantification of the benefits is impossible. See *ante*, at 2871, and n. 63. The Court might thus allow the Secretary to attempt to make a very rough quantification of the risk imposed by a carcinogenic substance, and give considerable deference to his finding that the risk was significant. If so, the Court would permit the Secretary to promulgate precisely the same regulation involved in these cases if he had not relied on a carcinogen "policy," but undertaken a ⌊716 review of the evidence and the ⌊expert testimony and concluded, on the basis of conservative assumptions, that the risk addressed is a significant one. Any other interpretation of the plurality's approach would allow a court to displace the agency's judgment with its own subjective conception of "significance," a duty to be performed without statutory guidance.

The consequences of this second approach would hardly be disastrous; indeed, it differs from my own principally in its assessment of the basis for the Secretary's decision in these cases. It is objectionable, however, for three reasons. First, the requirement of identification of a "significant" risk simply has no relationship to the statute that the Court today purports to construe. Second, if the "threshold finding" requirement means only that the Secretary must find "that there is a need for such a standard," *ante*, at 2864–2865, n. 48, the requirement was plainly satisfied by the Secretary's express statement that the standard's costs "are necessary in order to effectuate the statutory purpose . . . and to adequately protect employees from the hazards of exposure to benzene." 43 Fed.Reg. 5941 (1978). Third, the record amply demonstrates that in light of existing scientific knowledge, no purpose would be served by requiring the Secretary to take steps to quantify the risk of exposure to benzene at low levels. Any such quantification would be based not on scientific "knowledge" as that term is normally understood, but on considerations of policy. For carcinogens like benzene, the assumptions on which a dose-response curve must be based are necessarily arbitrary. To require a quantitative showing of a "significant" risk, therefore, would either paralyze the Secretary into inaction or force him to deceive the public by acting on the basis of assumptions that must be considered too speculative to support any realistic assess-

29. The plurality suggests that it is for the agency "to determine, in the first instance, what it considers to be a 'significant' risk," and that the agency "is free to use conservative assumptions in interpreting the data. . . ." *Ante*, at 2871. Moreover, my Brother POWELL would not require "quantification of risk in every case." *Ante*, at 2876 (opinion concurring in part and concurring in judgment). As I read his opinion, Mr. Justice POWELL would have permitted the Secretary to promulgate the standard at issue here if the Secretary had provided a more carefully reasoned explanation of his conclusion that the risk at issue justified the admittedly significant costs of the benzene standard. Mr. Justice POWELL also suggests that such a conclusion would be subject to relatively deferential review. *Ante*, at 2878, n. 8.

In this respect, the differences between my approach and that of Mr. Justice POWELL may be comparatively narrow. We are agreed on two propositions that I regard as critical to a fairminded interpretation of the Act: (1) the Secretary may regulate risks that are not subject to quantification on the basis of the "best available evidence"; and (2) the Secretary's judgment that a particular health risk merits regulatory action is subject to limited judicial scrutiny. It is encouraging that at least five Members of the Court accept these basic propositions.

For reasons stated in the text, however, I disagree with my Brother POWELL's conclusion that it is appropriate to hold in these cases that the Act requires the Secretary to show a reasonable relationship between costs and benefits.

ment of the relevant risk. See McGarity, Substantive and Procedural Discretion in Administrative Resolution of Science Policy Questions: Regulating Carcinogens in EPA and OSHA, 67 Geo.L.J. 729, 806 (1979). It is encouraging that the Court appears will- ⊥717 ing ⊥not to require quantification when it is not fairly possible. See *ante*, at 2871, and n. 63.

Though it is difficult to see how a future Congress could be any more explicit on the matter than was the Congress that passed the Act in 1970, it is important to remember that today's decision is subject to legislative reversal. Congress may continue to believe that the Secretary should not be prevented from protecting American workers from cancer and other fatal diseases until scientific evidence has progressed to a point where he can convince a federal court that the risk is "significant." Today's decision is objectionable not because it is final, but because it places the burden of legislative inertia on the beneficiaries of the safety and health legislation in question in these cases. By allocating the burden in this fashion, the Court requires the American worker to return to the political arena and to win a victory that he won once before in 1970. I am unable to discern any justification for that result.

D

Since the plurality's construction of the "reasonably necessary or appropriate" clause is unsupportable, I turn to a brief discussion of the other arguments that respondents offer in support of the judgment below.

First, respondents characterize the Act as a pragmatic statute designed to balance the benefits of a safety and health regulation against its costs. Respondents observe that the statute speaks in terms of relative protection by providing that safety must be assured "so far as possible," 29 U.S.C. § 651(b), and by stating that the "no material impairment" requirement is to be imposed only "to the extent feasible." [30] ⊥Re- ⊥718 spondents contend that the term feasible should be read to require consideration of the economic burden of a standard, not merely its technological achievability. I do not understand the Secretary to disagree. But respondents present no argument that the expenditure required by the benzene standard is not feasible in that respect. The Secretary concluded on the basis of substantial evidence that the costs of the standard would be readily absorbed by the 20 affected industries. One need not define the feasibility requirement with precision in order to conclude that the benzene standard is "feasible" in the sense that it will not

30. Finding obscurity in the word "feasible," my Brother REHNQUIST invokes the nondelegation doctrine, which was last used to invalidate an Act of Congress in 1935. *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495, 55 S.Ct. 837, 79 L.Ed. 1570 (1935). While my Brother REHNQUIST eloquently argues that there remains a place for such a doctrine in our jurisprudence, I am frankly puzzled as to why the issue is thought to be of any relevance here. The nondelegation doctrine is designed to assure that the most fundamental decisions will be made by Congress, the elected representatives of the people, rather than by administrators. Some minimal definiteness is therefore required in order for Congress to delegate its authority to administrative agencies.

Congress has been sufficiently definite here. The word "feasible" has a reasonably plain meaning, and its interpretation can be informed by other contexts in which Congress has used it. See n. 27, *supra*. Since the term is placed in the same sentence with the "no employee will suffer" language, it is clear that "feasible" means technologically and economically achievable. Under the Act, the Secretary is afforded considerably more guidance than are other administrators acting under different regulatory statutes. In short, Congress has made "the critical policy decisions" in these cases, see *ante*, at 2886 (REHNQUIST, J., concurring in the judgment).

The plurality's apparent suggestion, see *ante*, at 2866, that the nondelegation doctrine might be violated if the Secretary were permitted to regulate definite but nonquantifiable risks is plainly wrong. Such a statute would be quite definite and would thus raise no constitutional question under *Schechter Poultry*. Moreover, Congress could rationally decide that it would be better to require industry to bear "feasible" costs than to subject American workers to an indeterminate risk of cancer and other fatal diseases.

materially harm the financial condition of the regulated industries.

Respondents suggest that the feasibility requirement should be understood not merely to refer to a standard's expense, but also to mandate a finding that the benefits of an occupational safety and health stan-]719 dard bear a reasonable relation [to its costs. I believe that the statute's language, structure, and legislative history foreclose respondents' position. In its ordinary meaning an activity is "feasible" if it is capable of achievement, not if its benefits outweigh its costs. See Webster's Third New International Dictionary 831 (1976). Moreover, respondents' interpretation would render § 655(b)(5) internally inconsistent by reading into the term "feasible" a requirement irreconcilable with the express language authorizing the Secretary to set standards assuring that "no employee will suffer material impairment . . . ." Respondents' position would render that language merely hortatory. As noted above, no cost-benefit analysis is referred to at any point in the statute or its legislative history, an omission which cannot be deemed inadvertent in light of the explicit cost-benefit requirements inserted into other regulatory legislation.[31] Finally, the legislative history of the feasibility requirement, see n. 8, *supra*, demonstrates that Congress' sole concern was that standards be economically and technologically achievable. The legislative intent was to prevent the Secretary from materially harming the financial condition of regulated industries in order to eliminate risks of impairment. Congress did not intend to preclude the Secretary from taking regulatory action where, as here, no such threat to industry is posed.[32]

[In order to decide these cases, however, it]720 is not necessary to resolve the question whether the term "feasible" may contemplate some balancing of the costs and benefits of regulatory action.[33] Taking into account the uncertainties in existing knowledge, the Secretary made an express finding that the hazards of benzene exposure were sufficient to justify the regulation's costs. 43 Fed.Reg. 5941 (1978). Any requirement to balance costs and benefits cannot be read to invalidate this wholly rational conclusion. A contrary result, forcing the Secretary to wait for quantitative data that may not be available in the foreseeable future, would run directly counter to the protective purposes of the Act.[34]

31. See n. 27, *supra*.

32. Congress' antipathy toward cost-benefit balancing is evident throughout the legislative history of the Act. For example:

"The costs that will be incurred by employers in meeting the standards of health and safety to be established under this bill are, in my view, reasonable and necessary costs of doing business. Whether we, as individuals, are motivated by simple humanity or by simple economics, we can no longer permit profits to be dependent upon an unsafe or unhealthy worksite." 116 Cong.Rec. 41766 (1970), Leg.Hist. 1150–1151 (Sen. Eagleton).

Similarly, Senator Yarborough stated:

"We are talking about people's lives, not the indifference of some cost accountants. We are talking about assuring the men and women who work in our plants and factories that they will go home after a day's work with their bodies intact. We are talking about assuring our American workers who wo[r]k with deadly chemicals that when they have accumulated a few year's seniority they will not have accumulated lung congestion and poison in their bodies, or something that will strike them down before they reach retirement age." 116 Cong. Rec., at 37625; Leg.Hist. 510.

33. Nor need I discuss the possibility, raised by counsel for the federal parties in oral argument, that a decision to regulate a substance posing a negligible threat to health and safety could itself be challenged as arbitrary and capricious under the Administrative Procedure Act. See Tr. of Oral Arg. 23.

34. Respondents also rely on the statutory requirement that the Secretary may act only to prevent "material" impairment. They contend that the standard promulgated here does not fall within that category because the risk is so low. This interpretation derives no support from the statute or its legislative history. The statute itself states that standards should ensure that no employee will suffer "material impairment," not material *risk* of impairment.

The language is consistent with the legislative history. In an early version of the Act, the word "impairment" was modified by "any" rather than "material." See n. 8, *supra*. The feasibility and materiality requirements were

[721] Finally, respondents suggest broadly that the Secretary did not fulfill his statutory responsibility to act on the basis of "research, demonstrations, experiments," and to consider "the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws." 29 U.S.C. § 655(b)(5). Here, they contend, the Secretary based his decision solely on "views and arguments." Brief for Respondents American Petroleum Institute et al. 52. I disagree. The Secretary compiled an extensive record composed of over 50 volumes of exhibits. Most of those exhibits are the reported results of research and demonstrations representing "the latest available scientific data." The Secretary offered a careful discussion of these data in the statement accompanying the permanent standard. His ultimate conclusions were grounded in extensive findings of fact. Where, as here, there are gaps in existing knowledge, the Secretary's decision must necessarily be based on considerations of policy as well as on empirically verifiable facts.

In passing the Occupational Safety and Health Act of 1970, Congress was aware that it was authorizing the Secretary to regulate in areas of scientific uncertainty. But it intended to require stringent regulation even when definitive information was unavailable. In reducing the permissible level of exposure to benzene, the Secretary applied proper legal standards. His determinations are supported by substantial evidence. The Secretary's decision was one, [722] then, which the governing legislation authorized him to make.[35]

IV

In recent years there has been increasing recognition that the products of technological development may have harmful effects whose incidence and severity cannot be predicted with certainty. The responsibility to regulate such products has fallen to administrative agencies. Their task is not an enviable one. Frequently no clear causal link can be established between the regulated substance and the harm to be averted. Risks of harm are often uncertain, but inaction has considerable costs of its own. The agency must decide whether to take regula-

added simultaneously as part of an effort to qualify the original language authorizing the Secretary to ensure that "no employee will suffer any impairment of health or functional capacity, or diminished life expectancy." Senator Dominick was concerned that the phrase "any" impairment would require the Secretary to prevent insect bites. 116 Cong.Rec. 36522 (1970), Leg.Hist. 345.

The respondents' construction would pose an enormous obstacle to efforts to regulate toxic substances under § 655(b)(5). The probability of contracting cancer will in most contexts be quite small with respect to any particular employee. If the statute were read to authorize the Secretary to act only to assure that "no employee will suffer material risk of impairment," the Secretary would be disabled from regulating substances which poses a small risk with respect to any particular employee but which will nonetheless result in the death of numerous members of the employee pool.

35. Although the Court of Appeals accepted the Secretary's finding that dermal contact with benzene could cause leukemia, it set aside the dermal contact standard because of the Secretary's failure to perform an experiment recommended by an industry witness. The failure to conduct this test, according to the court, violated the statutory requirement that the Secretary act on the basis of "the best available evidence" and "the latest available scientific data in the field."

In the hearings before the agency, respondents presented no substantial challenge to the position that benzene could be absorbed through the skin, and there was evidence in the record to support that position. Both animal and human studies had found such absorption. In these circumstances, the Secretary was not obligated to undertake additional studies simply because a witness testified that such studies would be informative. The imposition of such a requirement would paralyze the standard-setting process. The Secretary's mandate is to act on the basis of "available" evidence, not evidence which may become available in the future.

In setting aside the dermal contact standard, the Court of Appeals also relied on its conclusion that the Secretary had not shown that quantifiable benefits would result from the standard. As the discussion above indicates, the court applied incorrect legal standards in so holding.

tory action against possibly substantial risks or to wait until more definitive information becomes available—a judgment which by its very nature cannot be based solely on determinations of fact.[36]

Those delegations, in turn, have been made on the understanding that judicial review would be available to ensure that the agency's determinations are supported by substantial evidence and that its actions do not exceed the limits set by Congress. In the Occupational Safety and Health Act, Congress expressed confidence that the courts would carry out this important responsibility. But in these cases the plurality has far exceeded its authority. The plurality's "threshold finding" requirement is nowhere to be found in the Act and is antithetical to its basic purposes. "The fundamental policy questions appropriately resolved in Congress . . . are *not* subject to re-examination in the federal courts under the guise of judicial review of agency action." *Vermont Yankee Nuclear Power Corp. v. NRDC*, 435 U.S., at 558, 98 S.Ct., at 1219 (emphasis in original). Surely this is no less true of the decision to ensure safety for the American worker than the decision to proceed with nuclear power. See *ibid.*

Because the approach taken by the plurality is so plainly irreconcilable with the Court's proper institutional role, I am certain that it will not stand the test of time. In all likelihood, today's decision will come to be regarded as an extreme reaction to a regulatory scheme that, as the Members of the plurality perceived it, imposed an unduly harsh burden on regulated industries. But as the Constitution "does not enact Mr. Herbert Spencer's Social Statics," *Lochner v. New York*, 198 U.S. 45, 75, 25 S.Ct. 539, 546, 49 L.Ed. 937 (1905) (Holmes, J., dissenting), so the responsibility to scrutinize federal administrative action does not authorize this Court to strike its own balance between the costs and benefits of occupational safety standards. I am confident that the approach taken by the plurality today, like that in *Lochner* itself, will eventually be abandoned, and that the representative branches of government will once again be allowed to determine the level of safety and health protection to be accorded to the American worker.

36. See W. Lowrance, Of Acceptable Risk: Science and the Determination of Safety (1976); Stewart, Paradoxes of Liberty, Integrity and Fraternity: The Collective Nature of Environmental Quality and Judicial Review of Administrative Action, 7 Environ.L. 463, 469–472 (1977).

448 U.S. 725, 65 L.Ed.2d 1086

William Jack HAMMETT

v.

State of TEXAS.

No. 79-5050.

July 2, 1980.

Defendant's conviction for murder and sentence to death were affirmed by the Texas Court of Criminal Appeals, 578 S.W.2d 699. After attorney filed petition for writ of certiorari, defendant filed motion to dismiss. The Supreme Court held that in absence of any issue as to defendant's competence to withdraw the petition which had been filed against his will, the motion would be granted.

Motion granted.

Mr. Justice Marshall dissented and filed an opinion in which Mr. Justice Brennan joined.

Mr. Justice Blackmun filed a dissenting opinion.

Federal Courts ⇐510

Where petitioner had moved to withdraw petition for certiorari, where state did not oppose the motion, and where there was

where the agreement was formed or an overt act occurred." *United States v. Winship*, 724 F.2d 1116, 1125 (5th Cir. 1984). Therefore, the district court clearly had proper venue over the conspiracy charges because there was clearly an overt act committed there; i.e., the importation of cocaine. Crimes based on a *Pinkerton* theory may be tried where the co-conspirator committed the crime. *United States v. Parrish*, 736 F.2d 152, 158 (5th Cir.1984) Therefore, the district court had proper venue over the cocaine importation charges as well.

VI

In summary, we find no basis for reversal of the district court. There was sufficient evidence to support the jury's finding that one conspiracy existed and to support each of the convictions. Neither the deliberate ignorance instruction nor the admission of evidence of Bauman's personal use of cocaine and of Cary's distribution of cocaine was reversible error. Defendants' remaining claims lack even colorable merit. The trial court was correct in denying the defendants' motions for judgment of acquittal. Therefore, the decision of the district court is

AFFIRMED.

CORROSION PROOF FITTINGS, et al., Petitioners,

v.

The ENVIRONMENTAL PROTECTION AGENCY and William K. Reilly, Administrator, Respondents.

No. 89-4596.

United States Court of Appeals, Fifth Circuit.

Oct. 18, 1991.

On Motion for Clarification Nov. 15, 1991.

Rehearing Denied Nov. 27, 1991.

Petition was filed for review of final rule promulgated by Environmental Protection Agency (EPA) under Toxic Substances Control Act section prohibiting future manufacture, importation, processing, and distribution of asbestos in almost all products. The Court of Appeals, Jerry E. Smith, Circuit Judge, held that: (1) foreign entities lacked standing under Act to challenge rule; (2) EPA failed to give required notice to public, before conclusion of hearings, that it intended to use "analogous exposure" data to calculate expected benefits of product bans; and (3) EPA failed to give adequate weight to statutory language requiring it to promulgate least burdensome, reasonable regulation required to protect environment adequately.

Petition granted, regulation vacated, matter remanded.

1. Administrative Law and Procedure ⚷669

Health and Environment ⚷25.15(3.3)

To extent that briefs of amici curiae raised new issues before Court of Appeals on challenge to Environmental Protection Agency's (EPA) promulgation of rule, Court would not consider those arguments; however, when those briefs raised variations of arguments also raised by petitioners, court would draw on those briefs if helpful in consideration of other issues properly brought before court.

2. Administrative Law and Procedure ⚷677

Health and Environment ⚷25.15(3.3)

On challenge to Environmental Protection Agency's (EPA) promulgation of final rule prohibiting future manufacture, importation, processing, and distribution of asbestos in almost all products, Court of Appeals could consider arguments raised by amici that related to differences in fiber types, sizes, and manufacturing processes even if those differences only were raised by petitioners within context of prohibiting specific friction products, such as gasket sheets and roof coating; role of amici was intended to bridge gaps in issues initially and properly raised by parties.

3. Health and Environment ⇐25.15(4)

Issue of whether foreign entities had standing to contest Environmental Protection Agency's (EPA) final asbestos rule was question of prudential standing, which was of less than constitutional dimensions; thus, touchstone of analysis was statutory language used by Congress in conferring standing upon general public.

4. Administrative Law and Procedure ⇐668

Health and Environment ⇐25.15(4)

Only those who come within zone of interests to be protected or regulated by Toxic Substances Control Act have prudential standing to bring challenges to regulations under Act; when party's interests are inconsistent with purposes implicit in Act, it can reasonably be assumed that Congress did not intend to permit suit. Toxic Substances Control Act, § 19(a), 15 U.S.C.A. § 2618(a).

5. Administrative Law and Procedure ⇐668

Under "zone of interests" test, Court of Appeals liberally construes congressional acts to favor plaintiff's standing to challenge administrative actions; however, if plaintiff is not itself subject of contested regulatory action, test denies right of review when plaintiff's interests are so marginally related to or inconsistent with purposes implicit in statute that it cannot reasonably be assumed that Congress intended to permit suit.

6. Administrative Law and Procedure ⇐668

Health and Environment ⇐25.15(4)

Canadian mine workers lacked standing to contest Environmental Protection Agency's (EPA) promulgation of final rule under Toxic Substances Control Act section prohibiting future manufacture, importation, processing, and distribution of asbestos in almost all products; mine workers argued that EPA erred by not considering effects of ban on foreign countries and workers, but, while Act speaks of necessity of cleaning up national environment and protecting United States workers, it is largely silent concerning international effects of agency action. Toxic Substances Control Act, § 6, 15 U.S.C.A. § 2605.

7. Administrative Law and Procedure ⇐668

Health and Environment ⇐25.15(4)

Because Toxic Substances Control Act did not require Environmental Protection Agency (EPA) to consider foreign effects when promulgating final rule prohibiting future manufacture, importation, processing, and distribution of asbestos in almost all products, Canadian asbestos mine operator lacked standing to challenge that rule, despite argument that its status as vendor to American vendee gave it right to contest administrative decisions that affected economic well-being of vendee; vendee was independent entity, fully capable of asserting its own rights. Toxic Substances Control Act, § 6, 15 U.S.C.A. § 2605.

8. Statutes ⇐219(1)

Courts should give great weight to any reasonable construction of regulatory statute adopted by agency charged with enforcement of that statute; thus, only where congressional intent is pellucid is court entitled to reject reasonable administrative construction of statute.

9. Health and Environment ⇐25.5(3)

In promulgating final rule under Toxic Substances Control Act section prohibiting future manufacture, importation, processing, and distribution of asbestos in almost all products, Environmental Protection Agency's (EPA) decision to ignore international effects of rule was rational construction of Act. Toxic Substances Control Act, § 6, 15 U.S.C.A. § 2605.

10. Administrative Law and Procedure ⇐398

Health and Environment ⇐25.5(9)

During rule-making procedure which resulted in Environmental Protection Agency's (EPA) promulgation of final rule pertaining to asbestos, EPA was not required to cross-examine witnesses of opponents of rule.

11. Administrative Law and Procedure ⚷401

Health and Environment ⚷25.5(9)

It was within Environmental Protection Agency's (EPA) discretion to designate hearing officer, rather than administrative law judge, to preside at hearings on rule under Toxic Substances Control Act to prohibit future manufacture, importation, processing, and distribution of asbestos in almost all products. Toxic Substances Control Act, § 6, 15 U.S.C.A. § 2605.

12. Administrative Law and Procedure ⚷398

Health and Environment ⚷25.5(9)

During rule-making procedure which resulted in Environmental Protection Agency's (EPA) promulgation of final rule under Toxic Substances Control Act section prohibiting future manufacture, importation, processing, and distribution of asbestos in almost all products, EPA was not required to assemble panel of experts on asbestos disease risks; EPA already possessed abundance of information on subject. Toxic Substances Control Act, § 6, 15 U.S.C.A. § 2605.

13. Administrative Law and Procedure ⚷416

Agency's choices concerning its rule-making procedures are entitled to great deference, as agencies are best suited to determine how they should allocate their finite resources.

14. Administrative Law and Procedure ⚷398

Health and Environment ⚷25.5(9)

In rule-making proceedings which resulted in Environmental Protection Agency's (EPA) issuance of final rule under Toxic Substances Control Act section prohibiting future manufacture, importation, processing, and distribution of asbestos in almost all products, EPA's general failure to accord interested parties adequate cross-examination of all of EPA's major witnesses, while improper, was insufficient by itself to mandate overturning rule. Toxic Substances Control Act, §§ 6(c)(3), 19(c)(1)(B)(ii), 15 U.S.C.A. §§ 2605(c)(3), 2618(c)(1)(B)(ii).

15. Administrative Law and Procedure ⚷394, 817

Health and Environment ⚷25.5(9), 25.15(12)

Environmental Protection Agency's (EPA) failure to give notice to public, before conclusion of hearings on rule under Toxic Substances Control Act to prohibit future manufacture, importation, processing, and distribution of asbestos in almost all products, that EPA intended to use "analogous exposure" data to calculate expected benefits of product bans required vacation of rule and remand to EPA for further proceedings; analogous exposure estimates supported substantial part of rule finally promulgated by EPA. Toxic Substances Control Act, § 6, 15 U.S.C.A. § 2605.

16. Administrative Law and Procedure ⚷797

Court of Appeals uses relatively lenient standard in judging administrative rule-making proceedings.

17. Administrative Law and Procedure ⚷791

Substantial evidence to support final agency rule requires something less than the weight of the evidence, and possibility of drawing two inconsistent conclusions from evidence does not prevent agency's finding from being supported by substantial evidence; this standard requires that agency's decision be based on entire record, taking into account whatever in record detracts from weight of agency's decision, and that agency's decision be what reasonable mind might accept as adequate to support its conclusion.

18. Administrative Law and Procedure ⚷763, 791

Health and Environment ⚷25.15(7)

Arbitrary and capricious standard found in Administrative Procedure Act and substantial evidence standard found in Toxic Substances Control Act (TSCA) are different standards, even in context of informal rule making; substantial evidence standard mandated by TSCA is generally considered to be more rigorous than arbi-

trary and capricious standard normally applied to informal rule making, and affords considerably more generous judicial review than arbitrary and capricious test. 5 U.S.C.A. § 551 et seq.; Toxic Substances Control Act, § 19(c)(1)(B)(i), 15 U.S.C.A. § 2618(c)(1)(B)(i).

19. Administrative Law and Procedure ⇐791

Health and Environment ⇐25.15(7)

Substantial evidence standard mandated by Toxic Substances Control Act imposes considerable burden on agency and limits its discretion in arriving at factual predicate. Toxic Substances Control Act, § 19(c)(1)(B)(i), 15 U.S.C.A. § 2618(c)(1)(B)(i).

20. Administrative Law and Procedure ⇐791

Health and Environment ⇐25.15(7)

Under substantial evidence standard of Toxic Substances Control Act, reviewing court must give careful scrutiny to agency findings and, at same time, accord appropriate deference to administrative decisions that are based on agency experience and expertise. Toxic Substances Control Act, § 19(c)(1)(B)(i), 15 U.S.C.A. § 2618(c)(1)(B)(i).

21. Administrative Law and Procedure ⇐791

Health and Environment ⇐25.15(7)

In evaluating whether Environmental Protection Agency (EPA) has presented substantial evidence to support final rule regulating substance under Toxic Substances Control Act, court examines whether quantities of regulated chemical entering into environment are "substantial" and whether human exposure to chemical is "substantial" or "significant." Toxic Substances Control Act, § 6, 15 U.S.C.A. § 2605.

22. Administrative Law and Procedure ⇐402

Agency may exercise its judgment without strictly relying on quantifiable risks, costs, and benefits, but it must cogently explain why it has exercised its discretion in given manner and must offer rational connection between facts found and choice made.

23. Administrative Law and Procedure ⇐391

All agency rules are given presumption of validity, and it is up to challenger to any rule to show that agency action is invalid.

24. Administrative Law and Procedure ⇐750

Health and Environment ⇐25.15(5.1)

Upon judicial review, burden remains on Environmental Protection Agency (EPA) to justify that products it bans under Toxic Substances Control Act present unreasonable risk, no matter how regulated. Toxic Substances Control Act, § 6, 15 U.S.C.A. § 2605.

25. Health and Environment ⇐25.5(3)

Environmental Protection Agency (EPA) presented insufficient evidence to justify its final rule under Toxic Substances Control Act section prohibiting future manufacture, importation, processing, and distribution of asbestos in almost all products; EPA failed to consider all necessary evidence and failed to give adequate weight to statutory language requiring it to promulgate least burdensome, reasonable regulation required to protect environment adequately. Toxic Substances Control Act, § 6(a), 15 U.S.C.A. § 2605(a).

26. Health and Environment ⇐25.5(3)

In promulgating final rule under Toxic Substances Control Act section banning asbestos, Environmental Protection Agency (EPA) failed to show it met requirement under Act that EPA use least burdensome regulation to achieve its goals of minimum reasonable risk; EPA rejected calculating how many lives less burdensome regulation would save, and at what cost, and, when calculating benefits of its ban, explicitly refused to compare it to improved workplace in which currently available control technology was utilized. Toxic Substances Control Act, § 6(a), 15 U.S.C.A. § 2605(a).

27. Health and Environment ⇐25.5(3)

In order to impose regulation totally banning substance under Toxic Substances

Control Act, Environmental Protection Agency (EPA) must show not only that its proposed action reduces risk of product to adequate level, but also that actions Congress identified as less burdensome also would not do job. Toxic Substances Control Act, § 2 et seq., 15 U.S.C.A. § 2601 et seq.

28. Health and Environment ⚷25.5(3)

In promulgating rule under Toxic Substances Control Act section banning asbestos, Environmental Protection Agency (EPA) properly discounted perceived nonmonetary benefits of rule in saving human lives; however, EPA's choice of 13-year period of its calculations was so short as to make unquantified period so unreasonably large that any EPA reliance upon it had to be displaced. Toxic Substances Control Act, § 6(a), 15 U.S.C.A. § 2605(a).

29. Health and Environment ⚷25.5(9)

Waiver provision allowing Environmental Protection Agency (EPA) to extend temporarily the planned phase-out of banned products if hoped-for substitutes fail to materialize in time may not be used by EPA to lessen its burden when justifying banning products under Toxic Substances Control Act without existing substitutes; by its own terms, exemption shifts burden onto waiver proponent to convince EPA that waiver is justified, and waiver only may be granted by EPA in very limited circumstances. Toxic Substances Control Act, § 6(c)(1)(C), 15 U.S.C.A. § 2605(c)(1)(C).

30. Health and Environment ⚷25.5(3)

Under Toxic Substances Control Act, agency is empowered to issue safety standards which require improvements in existing technology or which require development of new technology; however, where no substitutes presently exist, agency bears heavier burden to show that product ban is justified. Toxic Substances Control Act, § 6(c)(1)(C), 15 U.S.C.A. § 2605(c)(1)(C).

31. Health and Environment ⚷25.5(3)

Environmental Protection Agency's (EPA) ban of asbestos under Toxic Substances Control Act lacked reasonable basis required by Act, as EPA did not consider harm that could flow from increased use of products designed to substitute for asbestos, even where probable substitutes themselves were known carcinogens. Toxic Substances Control Act, § 6(a), 15 U.S.C.A. § 2605(a).

32. Health and Environment ⚷25.5(3)

Once interested party brings forth credible evidence suggesting toxicity of probable or only alternatives to substance which Environmental Protection Agency (EPA) proposes to ban under Toxic Substances Control Act, EPA must consider comparative toxic costs of each. Toxic Substances Control Act, § 6(c)(1)(C), 15 U.S.C.A. § 2605(c)(1)(C).

33. Health and Environment ⚷25.5(3)

Requirement that risk be "unreasonable" before Environmental Protection Agency (EPA) may engage in rule making under Toxic Substances Control Act necessarily involves balancing test like that familiar in tort law; regulation may issue if severity of injury that may result from product, factored by likelihood of injury, offsets harm regulation itself imposes upon manufacturers and consumers. Toxic Substances Control Act, § 2(c), 15 U.S.C.A. § 2601(c).

34. Health and Environment ⚷25.5(3)

Environmental Protection Agency (EPA) must articulate "understandable basis" to support its Toxic Substances Control Act action with respect to each substance or application of substance banned; to make finding of unreasonable risk based upon this assessment, EPA must balance probability that harm will occur from activities against effects of proposed regulatory action on availability to society of benefits of banned substance. Toxic Substances Control Act, §§ 6(a), 19(c)(1)(B)(i), 15 U.S.C.A. §§ 2605(a), 2618(c)(1)(B)(i).

35. Health and Environment ⚷25.5(3)

Environmental Protection Agency's (EPA) final rule under Toxic Substances Control Act banning friction products such as brakes, which constituted most of proposed benefits of asbestos ban, was unrea-

sonable due to EPA's failure to examine effect of nonasbestos brakes on automotive safety in light of credible evidence that nonasbestos brakes could increase significantly the number of highway fatalities, and due to EPA's failure to evaluate toxicity of likely brake substitutes. Toxic Substances Control Act, § 19(c)(1)(B)(i), 15 U.S.C.A. § 2618(c)(1)(B)(i).

36. Health and Environment ⚷25.5(3)

Environmental Protection Agency (EPA) failed to present substantial evidence to support its ban of asbestos pipe under Toxic Substances Control Act; EPA refused to assess risks of substitutes to asbestos pipe, despite EPA's concession that most likely substitutes for asbestos pipe also contained known carcinogens. Toxic Substances Control Act, §§ 6(c)(1)(C), 19(c)(1)(B)(i), 15 U.S.C.A. §§ 2605(c)(1)(C), 2618(c)(1)(B)(i).

37. Health and Environment ⚷25.5(3)

In those cases in which complete ban of substance under Toxic Substances Control Act would save less than one statistical life, such as those affecting asbestos paper products and certain roofing materials, Environmental Protection Agency (EPA) has particular need to examine less burdensome alternatives to complete ban. Toxic Substances Control Act, § 6(a), 15 U.S.C.A. § 2605(a).

38. Health and Environment ⚷25.5(3)

Under Toxic Substances Control Act, Environmental Protection Agency (EPA) could properly attempt to promulgate "cleanup" ban precluding future uses of asbestos even in products not yet on market. Toxic Substances Control Act, §§ 5, 6, 15 U.S.C.A. §§ 2604, 2605.

39. Health and Environment ⚷25.5(3)

Under sections of Toxic Substances Control Act which allow Environmental Protection Agency (EPA) to ban product "that presents or will present" significant risk, EPA had authority to ban products that once were, but no longer are, being produced in United States; this applies only to products that were not being manufactured, imported, or processed on July 12, 1989, date of rule's promulgation. Toxic Substances Control Act §§ 5, 6; 15 U.S.C.A. §§ 2604, 2605.

Wm. K. Reilly, Adm'r, E.P.A., Charles Edward Breece, Mary Elizabeth Ward, Richard Thornburgh, Atty. Gen., U.S. Dept. of Justice, Washington, D.C., for E.P.A.

Eve C. Gartner, Berle, Kass & Case, New York City, Karen Florini, Environmental Defense Fund, Washington, D.C., for Natural Resources Defense Council, Inc.

Jacqueline M. Warren, Natural Resources Defense Council, New York City, for Environmental Defense Fund.

Richard J. Fiesta, Robert J. Connerton, Connerton, Ray & Simon, Washington, D.C., for Laborers' Intern. Union of North America, AFL–CIO and Laborers' Nat. Health and Safety Fund.

Martha A. Churchill, Gen. Counsel, Chicago, Ill., for Mid-America Legal Foundation.

Donald N. Dewees, Toronto, Canada, for Federal Government of Canada.

Arthur Kahn, Schnader, Harrison, Segal & Lewis, Philadelphia, Pa., for amici-applicant The Province of Quebec, Canada.

Robert E. Holden, Mary S. Johnson, Liskow & Lewis, New Orleans, La., for Corrosion Proof Fittings, et al.

Edward W. Warren, Timothy S. Hardy, Susan M. O'Sullivan, Kathleen L. Blaner, Kirkland & Ellis, Washington, D.C., for Abestor Information Ass'n & Asbestor Cement, and the Asbestos Institute, et al.

Michael M. Levy, Levy & Smith, Washington, D.C., for United Steel Workers of America (Canada), et al.

Frederick C. Schafrick, Thomas J. Mikula, David Booth Beers, Michael S. Giannotto, Shea & Gardner, Washington, D.C., for Cassiar Min. Corp.

Duane A. Siler, Patton Boggs & Blow, Washington, D.C. for Institute of Scrap Recycling Ind., Inc.

Jeryl Dezelick, Robert E. Mann, Seyfarth, Shaw, Fairweather & Geraldson, Chicago, Ill., for Caterpillar Tractor Co.

Jane B. McAllister, Ahlers, Cooney, Dorweiler, Des Moines, Iowa, for Grinnell College.

Donald Elisburg, Brian M. Hechinger, OHF, Edward J. Gorman, III, Orrin Baird, Washington, D.C., for Occ. Health Found. United Broth. of Carp. & Joinders and Service Employees Intern. Union.

On Petition for Review of a Rule of the Environmental Protection Agency.

Before BROWN, SMITH, and WIENER, Circuit Judges.

JERRY E. SMITH, Circuit Judge:

The Environmental Protection Agency (EPA) issued a final rule under section 6 of the Toxic Substances Control Act (TSCA) to prohibit the future manufacture, importation, processing, and distribution of asbestos in almost all products. Petitioners claim that the EPA's rulemaking procedure was flawed and that the rule was not promulgated on the basis of substantial evidence. Certain petitioners and amici curiae contend that the EPA rule is invalid because it conflicts with international trade agreements and may have adverse economic effects on Canada and other foreign countries. Because the EPA failed to muster substantial evidence to support its rule, we remand this matter to the EPA for further consideration in light of this opinion.

I.

Facts and Procedural History.

Asbestos is a naturally occurring fibrous material that resists fire and most solvents. Its major uses include heat-resistant insulators, cements, building materials, fireproof gloves and clothing, and motor vehicle brake linings. Asbestos is a toxic material, and occupational exposure to asbestos dust can result in mesothelioma, asbestosis, and lung cancer.

The EPA began these proceedings in 1979, when it issued an Advanced Notice of Proposed Rulemaking announcing its intent to explore the use of TSCA "to reduce the risk to human health posed by exposure to asbestos." *See* 54 Fed.Reg. 29,460 (1989). While these proceedings were pending, other agencies continued their regulation of asbestos uses, in particular the Occupational Safety and Health Administration (OSHA), which in 1983 and 1984 involved itself with lowering standards for workplace asbestos exposure.[1]

An EPA-appointed panel reviewed over one hundred studies of asbestos and conducted several public meetings. Based upon its studies and the public comments, the EPA concluded that asbestos is a potential carcinogen at all levels of exposure, regardless of the type of asbestos or the size of the fiber. The EPA concluded in 1986 that exposure to asbestos "poses an unreasonable risk to human health" and thus proposed at least four regulatory options for prohibiting or restricting the use of asbestos, including a mixed ban and phase-out of asbestos over ten years; a two-stage ban of asbestos, depending upon product usage; a three-stage ban on all asbestos products leading to a total ban in ten years; and labeling of all products containing asbestos. *Id.* at 29,460–61.

Over the next two years, the EPA updated its data, received further comments, and allowed cross-examination on the updated documents. In 1989, the EPA issued a final rule prohibiting the manufacture, im-

1. OSHA began to regulate asbestos in the workplace in 1971. At that time, the permissible exposure limit was 12 fibers per cubic centimeter (f/cc), which OSHA lowered several times until today it stands at 0.2 f/cc. OSHA currently is considering lowering the limit to 0.1 f/cc, following a challenge to the regulation in *Building & Constr. Trades Dep't v. Brock*, 838 F.2d 1258, 1267–69 (D.C.Cir.1988). The Mine Safety and Health Administration (MSHA) since 1976 has limited mine worker asbestos exposure to 2 f/cc. *See* 30 C.F.R. § 71.702 (1990).

The Consumer Product Safety Commission (CPSC) has banned consumer patching compounds containing respirable asbestos, *see* 16 C.F.R. §§ 1304–05 (1990), and also requires labeling for other products containing respirable asbestos. Similarly, the Food and Drug Administration has banned general-use garments containing asbestos unless used for protection against fire. *See* 16 C.F.R. § 1500.17 (1990).

portation, processing, and distribution in commerce of most asbestos-containing products. Finding that asbestos constituted an unreasonable risk to health and the environment, the EPA promulgated a staged ban of most commercial uses of asbestos. The EPA estimates that this rule will save either 202 or 148 lives, depending upon whether the benefits are discounted, at a cost of approximately $450–800 million, depending upon the price of substitutes. *Id.* at 29,468.

The rule is to take effect in three stages, depending upon the EPA's assessment of how toxic each substance is and how soon adequate substitutes will be available.[2] The rule allows affected persons one more year at each stage to sell existing stocks of prohibited products. The rule also imposes labeling requirements on stage 2 or stage 3 products and allows for exemptions from the rule in certain cases.

Section 19(a) of TSCA, 15 U.S.C. § 2618(a), grants interested parties the right to appeal a final rule promulgated under section 6(a) directly to this or any other regional circuit court of appeals. Pursuant to this section, petitioners challenge the EPA's final rule, claiming that the EPA's rulemaking procedure was flawed and that the rule was not promulgated based upon substantial evidence. Some amici curiae also contend that the rule is invalid because it conflicts with international trade agreements and may have adverse economic effects on Canada and other foreign countries. We deal with each of these contentions *seriatim*.

2. The main products covered by each ban stage are as follows:

(1) Stage 1: August 27, 1990: ban on asbestos-containing floor materials, clothing, roofing felt, corrugated and flat sheet materials, pipeline wrap, and new asbestos uses;
(2) Stage 2: August 25, 1993: ban on asbestos-containing "friction products" and certain automotive products or uses;
(3) Stage 3: August 26, 1996: ban on other asbestos-containing automotive products or uses, asbestos-containing building materials including non-roof and roof coatings, and asbestos cement shingles.

See 54 Fed.Reg. at 29,461–62.

3. *See Bell v. Wolfish*, 441 U.S. 520, 531 n. 13, 99 S.Ct. 1861, 1870 n. 13, 60 L.Ed.2d 447 (1979).

II.

Standing.

A.

Issues Raised Solely by Amici Curiae.

[1] The EPA argues that the briefs of two of the amici curiae, Quebec and Canada, should be stricken because they improperly raise arguments not mentioned by any petitioner. To the extent that these briefs raise new issues, such as the EPA's decision not to consider the adverse impacts of the asbestos ban on the development of the economies of third-world countries, we disregard these arguments.[3] At times, however, the briefs raise variations of arguments also raised by petitioners. We thus draw on these briefs where helpful in our consideration of other issues properly brought before this court by the parties.

[2] The EPA also asserts that we cannot consider arguments raised by the two amici that relate to the differences in fiber types, sizes, and manufacturing processes because these differences only are raised by the petitioners within the context of prohibiting specific friction products, such as sheet gaskets and roof coating. This is, however, a role that amici are intended to fill: to bridge gaps in issues initially and properly raised by parties. Because various petitioners urge arguments similar to these, we properly can consider these specific issues articulated in the amici briefs.[4]

While it is true that the joint brief of petitioners Centrale des Syndicats Democratiques, Confederation des Syndicats Nationaux, and United Steel Workers of America (Canada) (collectively along with petitioner Cassiar Mining Corp. (Cassiar), the "Canadian petitioners") also deal with some of the same issues raised by amici, we hold in part II.B, *infra*, that these petitioners lack standing. The arguments of amici cannot be bootstrapped into this case based upon the arguments of petitioners who themselves lack standing.

4. The EPA also seeks to bar the brief of Grinnell College. That brief, however, presents arguments directly related to the arguments raised by the parties seeking to prevent the ban of asbestos shingles.

B.

Standing of Foreign Entities Under TSCA.

The EPA also contends that certain foreign petitioners and amici do not have standing to contest the EPA's final rule. In its final rulemaking, the EPA decided to exclude foreign effects from its analysis. Cassiar Mining Corporation, a Canadian mining company that operates an asbestos mine, and the other Canadian petitioners believe that the EPA erred by not considering the effects of the ban on foreign countries and workers.

[3] At issue in this case is a question of prudential standing, which is of less than constitutional dimensions. The touchstone of the analysis, therefore, is the statutory language used by Congress in conferring standing upon the general public. *Warth v. Seldin*, 422 U.S. 490, 501, 95 S.Ct. 2197, 2206, 45 L.Ed.2d 343 (1975).

[4] Only those who come within the "zone of interests to be protected or regulated by the statute" have prudential standing to bring challenges to regulations under the statute at issue.[5] Indeed, when a party's interests are "inconsistent with the purposes implicit in the statute," it can "reasonably be assumed that Congress [did not] intend[ ] to permit the suit." *Clarke*, 479 U.S. at 399, 107 S.Ct. at 757.

The Canadian petitioners believe that Congress, by granting the right of judicial review to "any person," 15 U.S.C.A. § 2618(a)(1)(A) (West Supp.1991), meant to confer standing on anyone who could arrange transportation to the courthouse door. The actual language of TSCA, however, belies the broad meaning the petitioners attempt to impart to the act, for the EPA was not required to consider the effects on people or entities outside the United States. TSCA provides a laundry list of factors to consider when promulgating a rule under section 6, including "the effect [of the rule] on the *national* economy." *Id.* § 2605(c)(1)(D) (emphasis added). International concerns are conspicuously absent from the statute.

[5] Under the "zone of interests" test, we liberally construe Congressional acts to favor a plaintiff's standing to challenge administrative actions. *Warth*, 422 U.S. at 501, 95 S.Ct. at 2206. This is not to say, however, that all plaintiffs affected by a regulation or order have standing to sue; "[i]n cases where the plaintiff is not itself the subject of the contested regulatory action, the test denies a right of review if the plaintiff's interests are so marginally related to or inconsistent with the purposes implicit in the statute that it cannot reasonably be assumed that Congress intended to permit the suit." *Clarke*, 479 U.S. at 399, 107 S.Ct. at 757.

[6] The Canadian petitioners do not have standing to contest the EPA's actions. Nothing in the statute requires the EPA to consider the effects of its actions in areas outside the scope of section 6. TSCA speaks of the necessity of cleaning up the national environment and protecting United States workers but largely is silent concerning the international effects of agency action. Because of this national emphasis, we are reluctant to ascribe international standing rights to foreign workers affected by the loss of economic sales within this country. We note that the Supreme Court, using similar analysis, recently denied standing rights to workers only incidentally affected by a postal regulation. *Air Courier Conference of Am. v. American Postal Workers Union*, — U.S. —, 111 S.Ct. 913, 112 L.Ed.2d 1125 (1991). Indeed, to "proceed[ ] at the behest of interests that

5. *Association of Data Processing Serv. Orgs. v. Camp*, 397 U.S. 150, 153, 90 S.Ct. 827, 829, 25 L.Ed.2d 184 (1970); *accord Panhandle Producers & Royalty Owners Ass'n v. Economic Regulatory Admin.*, 847 F.2d 1168, 1173–74 (5th Cir. 1988); *Hazardous Waste Treatment Council v. EPA*, 861 F.2d 277, 282 (D.C.Cir.1988) (per curiam), *cert. denied*, 490 U.S. 1106, 109 S.Ct. 3157, 104 L.Ed.2d 1020 (1989). We note that the zone of interest test is not one universally applied outside the context of the Administrative Procedure Act (APA), *see Clarke v. Securities Indus. Ass'n*, 479 U.S. 388, 400 n. 16, 107 S.Ct. 750, 757 n. 16, 93 L.Ed.2d 757 (1987), but because it is the most useful factor in considering Congressional intent on the question of standing, we invoke it as an aid to our decisionmaking today, as we sometimes have in the past. *Cf. Moses v. Banco Mortgage Co.*, 778 F.2d 267, 271 (5th Cir.1985).

coincide only accidentally with [the statutory] goals" of TSCA actually may work to defeat those goals. *Hazardous Waste Treatment Council,* 861 F.2d at 283. We therefore do not consider the arguments raised by the Canadian petitioners.

[7] Cassiar separately asserts even closer contacts with the United States and believes that its status as a vendor to an American vendee gives it the right to contest administrative decisions that affect the economic well-being of the vendee. Some courts recognize that vendors can stand as third parties in the shoes of their vendees in order to contest administrative decisions.[6]

Even if we were to accept this line of reasoning, however, the result would be unavailing. Cassiar's vendee is an independent entity, fully capable of asserting its own rights. Given the purely national scope of TSCA, Cassiar cannot bootstrap from its vendee simply because it sells asbestos to an American company. Merely inserting a product into the stream of commerce is not sufficient to confer standing under TSCA. If the rule were otherwise, the concept of standing would lose all meaning, for the only parties who would not have standing would be those who sell nothing in the United States and thus are indifferent to federal government actions. There is no indication that Congress intended to enact so loose a concept of standing, and we do not import that intent into the act today.[7]

Hence, Cassiar does not have prudential standing to bring this claim, because TSCA expressly concerns itself with national economic concerns. Cassiar brings forth no evidence that it actually controls, and does not just deal with, the American vendee. We thus conclude, along the lines of *Moses,* 778 F.2d at 271–72, that parties that Congress specifically did not intend to participate in, or benefit from, an administrative decision have no right to challenge the legitimacy of that decision.

[8] We draw support for our holding from the decision of the EPA to give a similar construction to TSCA. "It is settled that courts should give great weight to any reasonable construction of a regulatory statute adopted by the agency charged with the enforcement of that statute." *Investment Co. Inst. v. Camp,* 401 U.S. 617, 626–27, 91 S.Ct. 1091, 1097, 28 L.Ed.2d 367 (1971). "Thus, only where congressional intent is pellucid are we entitled to reject reasonable administrative construction of a statute." *National Grain & Feed Ass'n v. OSHA,* 866 F.2d 717, 733 (5th Cir.1989).

[9] We find the EPA's decision to ignore the international effects of its decision to be a rational construction of the statute. *Chemical Mfrs. Ass'n v. Natural Resources Defense Council,* 470 U.S. 116, 125, 134, 105 S.Ct. 1102, 1107, 1112, 84 L.Ed.2d 90 (1985). Because it is unlikely that these foreign entities were "intended [by Congress] to be relied upon to challenge agency disregard of the law," *Clarke,* 479 U.S. at 399, 107 S.Ct. at 757 (citations omitted), we hold that they are

6. *See, e.g., Carey v. Population Serv. Int'l,* 431 U.S. 678, 683–84 & n. 4, 97 S.Ct. 2010, 2015 & n. 4, 52 L.Ed.2d 675 (1977); *National Cottonseed Prods. Ass'n v. Brock,* 825 F.2d 482, 489–92 (D.C.Cir.1987), *cert. denied,* 485 U.S. 1020, 108 S.Ct. 1573, 99 L.Ed.2d 889 (1988); *FAIC Sec. v. United States,* 768 F.2d 352, 357–61 (D.C.Cir. 1985). *Carey,* however, gives *jus tertii* standing to a party only if the party directly affected is incapable of asserting its own interests, which is not true in the instant case. *See Carey,* 431 U.S. at 683–84, 97 S.Ct. at 2015; *accord Craig v. Boren,* 429 U.S. 190, 195–96, 97 S.Ct. 451, 456, 50 L.Ed.2d 397 (1976). The cases from the District of Columbia Circuit, represented by *National Cottonseed* and *FAIC Securities,* appear to go too far in expanding the exception in the vendor-vendee relationship, at least when evaluating a statute so purely national in scope.

7. *See Warth,* 422 U.S. at 501, 95 S.Ct. at 2206 (noting that courts generally are reluctant "to extend judicial power when the plaintiff's claim to relief rests on the legal rights of third parties"). Cassiar mentions only one case, *Constructores Civiles de Centroamerica, S.A. v. Hannah,* 459 F.2d 1183, 1190–91 (D.C.Cir.1972), in which a foreign vendor was able to borrow its domestic vendee's standing rights to pursue its own claim. That case, however, involved the APA, which, unlike TSCA, does not confine itself to matters concerning national economic interests.

outside the zone of interests encompassed by TSCA and thus lack standing to protest the EPA's rulemaking.[8]

III.

Rulemaking Defects.

[10-12] The petitioners allege that the EPA's rulemaking procedure was flawed. Specifically, the petitioners contend that the EPA erred by not cross-examining petitioner's witnesses, by not assembling a panel of experts on asbestos disease risks, by designating a hearing officer, rather than an administrative law judge (ALJ), to preside at the hearings on the rule, and by not swearing in witnesses who testified. Petitioners also complain that the EPA did not allow cross-examination of some of its witnesses and did not notify anyone until after the hearings were over that it intended to use "analogous exposure" estimates and a substitute pricing assumption to support its rule. Most of these contentions lack merit and are part of the petitioners' "protest everything" approach,[9] but we address specifically the two EPA actions of most concern to us, the failure of the EPA to afford cross-examination of its own witnesses and its failure to provide notice of the analogous exposure estimates.

[13] Administrative agencies acting under TSCA are not required to adhere to all of the procedural requirements we might require of an adjudicative body. *See* 15 U.S.C. § 2605(c)(3). In evaluating petitioners' claims, we are guided by our long-held view that an agency's choices concerning its rulemaking procedures are entitled to great deference, as the agencies are "best situated to determine how they should allocate their finite resources." *Superior Oil Co. v. FERC*, 563 F.2d 191, 201 (5th Cir. 1977).

[14] Section 19(c)(1)(B)(ii) of TSCA requires that we hold unlawful any rule promulgated where EPA restrictions on cross-examination "precluded disclosure of disputed material facts which [were] necessary to a fair determination by the Administrator." 15 U.S.C. § 2618(c)(1)(B)(ii). In promulgating this rule, the EPA allowed substantial cross-examination of most, but not all, of its witnesses. Considering the importance TSCA accords to cross-examination, the EPA should have afforded interested parties full cross-examination on all of its major witnesses. We are mindful of the length of the asbestos regulatory process in this case, but Congress, in enacting the rules governing the informal hearing process under TSCA, specifically reserved a place for proper cross-examination on issues of disputed material fact. *See id.* §§ 2605(c)(3), 2618(c)(1)(B)(ii). Precluding cross-examination of EPA witnesses—even a minority of them—is not the proper way to expedite the finish of a lengthy rulemaking procedure.

The EPA's general failure to accord the petitioners adequate cross-examination, however, is not sufficient by itself to mandate overturning the rule. The "foundational question is whether any procedural flaw so subverts the process of judicial review that invalidation of the regulation is warranted." *Superior Oil Co.*, 563 F.2d at

8. The Canadian petitioners also allege that United States treaty obligations, such as the provisions of the General Agreement on Tariffs and Trade (GATT), award them the right to protest the EPA's actions. GATT requires nations to indicate that their environmental decisions meet international standards, thus preventing countries from using arbitrary environmental rulings as *de facto* trade barriers. GATT, however, establishes trade dispute procedures of its own. These Canadian parties therefore have no standing here to challenge the EPA's decision.

9. These complaints include the failure of the EPA to cross-examine petitioners' witnesses, which it was not required to do, and the EPA's decision not to designate an ALJ, which also was within its discretion under 40 C.F.R. §§ 750.7 and 750.8 (1990). Similarly, the EPA's failure to issue subpoenas was of little moment, as the petitioners in fact suffered no injury from the lack of subpoenas. *See id.* § 750.5.

We also note that while an independent panel of experts often might be needed, in this case the EPA was not required to assemble such a panel on asbestos disease risks, as it already possessed an abundance of information on the subject, including a report by the members of the Ontario Royal Commission, a study often cited by the petitioners themselves. Considering the number of studies available, the EPA was not required to assemble its own panel to duplicate them, except to fill in any gaps.

201 (quoting *Alabama Ass'n of Ins. Agents v. Board of Governors of the Fed. Reserve Sys.*, 533 F.2d 224, 236–37 (5th Cir.1976)). Under this standard, the EPA's denial of cross-examination, by itself, is insufficient to force us to overturn the EPA's asbestos regulation.

[15] We cannot reach the same conclusion in another area, however. The EPA failed to give notice to the public, before the conclusion of the hearings, that it intended to use "analogous exposure" data to calculate the expected benefits of certain product bans. In general, the EPA should give notice as to its intended methodology while the public still has an opportunity to analyze, comment, and influence the proceedings. The EPA's use of the analogous exposure estimates, apart from their merits, thus should have been subjected to public scrutiny *before* the record was closed. While it is true that "[t]he public need not have an opportunity to comment on every bit of information influencing an agency's decision," *Texas v. Lyng*, 868 F.2d 795, 799 (5th Cir.1989), this cannot be used as a defense to the late adoption of the analogous exposure estimates, as they are used to support a substantial part of the regulation finally promulgated by the EPA.[10]

We draw support for this conclusion from *Aqua Slide 'N' Dive v. CPSC*, 569 F.2d 831 (5th Cir.1978), in which the CPSC decided, without granting interested parties the opportunity to comment, that its proposed regulation merely would slow the industry's rate of growth rather than actually cut sales. We rejected the CPSC's rule, and our reasons there are similar to those that require us to reject the EPA's reliance upon the analogous exposure data today:

> [T]he evidence on which the Commission relies was only made public after the period for public comment on the standard had closed. Consequently, critics had no realistic chance to rebut it.... It matters not that the late submission probably did not violate the notice requirement of 5 U.S.C.A. § 553.... *The statute requires that the Commission's findings be supported by substantial evidence, and that requirement is not met when the only evidence on a crucial finding is alleged to be unreliable and the Commission has not exposed it to the full public scrutiny which would encourage confidence in its accuracy.*

Id. at 842–43 (citations omitted) (emphasis added).

In short, the EPA should not hold critical analysis in reserve and then use it to justify its regulation despite the lack of public comment on the validity of its basis. Failure to seek public comment on such an important part of the EPA's analysis deprived its rule of the substantial evidence required to survive judicial scrutiny, as in *Aqua Slide*.

[16] We reach this conclusion despite the relatively lenient standard by which we judge administrative rulemaking proceedings. E.g., *Superior Oil Co.*, 563 F.2d at 201. The EPA seeks to avert this result by contending that the petitioners had constructive notice that the EPA might adopt the analogous exposure theory because it included, among its published data, certain information that might be manipulated to support such an analysis. We hold, however, that considering that for some products the analogous exposure estimates constituted the bulk of the EPA's analysis, constructive notice was insufficient notice.[11] In summary, on an issue of this import, the EPA should have announced

10. According to the EPA, if the analogous exposure estimates were not included, the benefits of the rule would decrease from 168 to 120 deaths avoided, discounted at 3%. 54 Fed.Reg. at 29,469, 29,485. The analogous exposure estimates, adopted after hearings were concluded, thus increase the purported benefits of the rule by more than one-third.

11. For some of the products, such as the beater-add and sheet gaskets, the analogous exposure analysis completely altered the EPA's calculus and multiplied four- or five-fold the anticipated benefits of the proposed regulation. This was a change sufficient to make the proceedings unfair to the petitioners and was of sufficient importance that the EPA's failure to afford any cross-examination on this issue was an abuse of discretion.

during the years in which the hearings were ongoing, rather than in the subsequent weeks after which they were closed, that it intended to use the analogous exposure estimates. On reconsideration, the EPA should open to public comment the validity of its analogous exposure estimates and methodology.

IV.

The Language of TSCA.

A.

Standard of Review.

Our inquiry into the legitimacy of the EPA rulemaking begins with a discussion of the standard of review governing this case. EPA's phase-out ban of most commercial uses of asbestos is a TSCA § 6(a) rulemaking. TSCA provides that a reviewing court "shall hold unlawful and set aside" a final rule promulgated under § 6(a) "if the court finds that the rule is not supported by substantial evidence in the rulemaking record ... taken as a whole." 15 U.S.C. § 2618(c)(1)(B)(i).

[17] Substantial evidence requires "something less than the weight of the evidence, and the possibility of drawing two inconsistent conclusions from the evidence does not prevent an administrative agency's finding from being supported by substantial evidence." *Consolo v. Federal Maritime Comm'n*, 383 U.S. 607, 620, 86 S.Ct. 1018, 1026, 16 L.Ed.2d 131 (1966). This standard requires (1) that the agency's decision be based upon the entire record,[12] taking into account whatever in the record detracts from the weight of the agency's decision; and (2) that the agency's decision be what " 'a reasonable mind might accept as adequate to support [its] conclusion.' " *American Textile Mfrs. Inst. v. Donovan*, 452 U.S. 490, 522, 101 S.Ct. 2478, 2497, 69 L.Ed.2d 185 (1981) (quoting *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 477, 71 S.Ct. 456, 459, 95 L.Ed. 456 (1951)). Thus, even if there is enough evidence in the record to support the petitioners' assertions, we will not reverse if there is substantial evidence to support the agency's decision. *See, e.g., Villa v. Sullivan*, 895 F.2d 1019, 1021–22 (5th Cir.1990); *Singletary v. Bowen*, 798 F.2d 818, 822–23 (5th Cir.1986); *accord Fort Valley State College v. Bennett*, 853 F.2d 862, 864 (11th Cir.1988) (reviewing court examines the entire record but defers to the agency's choice between two conflicting views).

[18, 19] Contrary to the EPA's assertions, the arbitrary and capricious standard found in the APA and the substantial evidence standard found in TSCA are different standards, even in the context of an informal rulemaking.[13] Congress specifically went out of its way to provide that "the standard of review prescribed by paragraph (2)(E) of section 706 [of the APA] shall not apply and the court shall hold unlawful and set aside such rule if the court finds that the rule is not supported by substantial evidence in the rulemaking

12. The term "rulemaking record" means (A) the rule being reviewed; (B) all commentary received in response to the (EPA) Administrator's notice of proposed rulemaking, and the Administrator's own published statement of the effects of exposure of the substance on health and the environment, the benefits of the substance for various uses and the availability of substitutes for such uses, and "the reasonably ascertainable economic consequences of the rule" on the national economy, small business, technological innovation, the environment, and public health; (C) transcripts of hearings on promulgation of the rule; (D) written submissions of interested parties; and (E) any other information the Administrator deems relevant. *See* 15 U.S.C. § 2618(a)(3) (referring to §§ 2604(f) and 2605(c)(1) in regard to component (B) above).

13. The EPA cites *Superior Oil Co.*, 563 F.2d at 199, an APA case, for the proposition that in informal rulemaking, the arbitrary and capricious standard and the substantial evidence standard "tend to converge." While it certainly is true that the requirement of substantial evidence within formal rulemaking is more strenuous, we acknowledged in *Superior Oil* that when comparing arbitrary and capricious to substantial evidence, "[i]t is generally accepted that the latter standard allows for 'a considerably more generous judicial review' than does the former." *Id.* (quoting *Abbott Laboratories*, 387 U.S. at 143, 87 S.Ct. at 1512). Considering that Congress specifically rejected the arbitrary and capricious standard in the TSCA context, we will not act now to read that same standard back in by holding that the two standards are in fact one and the same.

record ... taken as a whole." 15 U.S.C. § 2618(c)(1)(B)(i). "The substantial evidence standard mandated by [TSCA] is generally considered to be more rigorous than the arbitrary and capricious standard normally applied to informal rulemaking," *Environmental Defense Fund v. EPA*, 636 F.2d 1267, 1277 (D.C.Cir.1980), and "afford[s] a considerably more generous judicial review" than the arbitrary and capricious test. *Abbott Laboratories v. Gardner*, 387 U.S. 136, 143, 87 S.Ct. 1507, 1512, 18 L.Ed.2d 681 (1967), *overruled on other grounds, Califano v. Sanders*, 430 U.S. 99, 97 S.Ct. 980, 51 L.Ed.2d 192 (1977). The test "imposes a considerable burden on the agency and limits its discretion in arriving at a factual predicate." *Mobil Oil Corp. v. FPC*, 483 F.2d 1238, 1258 (D.C.Cir.1973).

[20] "Under the substantial evidence standard, a reviewing court must give careful scrutiny to agency findings and, at the same time, accord appropriate deference to administrative decisions that are based on agency experience and expertise." *Environmental Defense Fund*, 636 F.2d at 1277. As with consumer product legislation, "Congress put the substantial evidence test in the statute because it wanted the courts to scrutinize the Commission's actions more closely than an 'arbitrary and capricious' standard would allow." *Aqua Slide*, 569 F.2d at 837.

[21, 22] The recent case of *Chemical Mfrs. Ass'n v. EPA*, 899 F.2d 344 (5th Cir.1990), provides our basic framework for reviewing the EPA's actions. In evaluating whether the EPA has presented substantial evidence, we examine (1) whether the quantities of the regulated chemical entering into the environment are "substantial" and (2) whether human exposure to the chemical is "substantial" or "significant." *Id.* at 359. An agency may exercise its judgment without strictly relying upon quantifiable risks, costs, and benefits, but it must "cogently explain why it has exercised its discretion in a given manner" and "must offer a 'rational connection between the facts found and the choice made.'" *Id.* (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins.*, 463 U.S. 29, 103 S.Ct. 2856, 77 L.Ed.2d 443 (1983)).

[23, 24] We note that in undertaking our review, we give all agency rules a presumption of validity, and it is up to the challenger to any rule to show that the agency action is invalid. *Alabama Nursing Home Ass'n v. Harris*, 617 F.2d 388, 393-94 (5th Cir.1980). The burden remains on the EPA, however, to justify that the products it bans present an unreasonable risk, no matter how regulated. *See Industrial Union Dep't v. American Petroleum Inst.*, 448 U.S. 607, 662, 100 S.Ct. 2844, 2874, 65 L.Ed.2d 1010 (1980); *cf. National Lime Ass'n v. EPA*, 627 F.2d 416, 433 (D.C.Cir.1980) ("an initial burden of promulgating and explaining a non-arbitrary, non-capricious rule rests with the Agency"). Finally, as we discuss in detail *infra*, because TSCA instructs the EPA to undertake the least burdensome regulation sufficient to regulate the substance at issue, the agency bears a heavier burden when it seeks a partial or total ban of a substance than when it merely seeks to regulate that product. *See* 15 U.S.C. § 2605(a).

B.

The EPA's Burden Under TSCA.

TSCA provides, in pertinent part, as follows:

(a) Scope of regulation.—If the Administrator finds that there is a *reasonable basis* to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents or will present an *unreasonable risk of injury* to health or the environment, the Administrator shall by rule apply one or more of the following requirements to such substance or mixture to the extent necessary *to protect adequately* against such risk

using the *least burdensome* requirements.

Id. (emphasis added). As the highlighted language shows, Congress did not enact TSCA as a zero-risk statute.[14] The EPA, rather, was required to consider both alternatives to a ban and the costs of any proposed actions and to "carry out this chapter in a reasonable and prudent manner [after considering] the environmental, economic, and social impact of any action." 15 U.S.C. § 2601(c).

[25] We conclude that the EPA has presented insufficient evidence to justify its asbestos ban. We base this conclusion upon two grounds: the failure of the EPA to consider all necessary evidence and its failure to give adequate weight to statutory language requiring it to promulgate the least burdensome, reasonable regulation required to protect the environment adequately. Because the EPA failed to address these concerns, and because the EPA is required to articulate a "reasoned basis" for its rules, we are compelled to return the regulation to the agency for reconsideration.

1.

Least Burdensome and Reasonable.

[26] TSCA requires that the EPA use the least burdensome regulation to achieve its goal of minimum reasonable risk. This statutory requirement can create problems in evaluating just what is a "reasonable risk." Congress's rejection of a no-risk policy, however, also means that in certain cases, the least burdensome yet still adequate solution may entail somewhat more risk than would other, known regulations that are far more burdensome on the industry and the economy. The very language of TSCA requires that the EPA, once it has determined what an acceptable level of non-zero risk is, choose the least burdensome method of reaching that level.

In this case, the EPA banned, for all practical purposes, all present and future uses of asbestos—a position the petitioners characterize as the "death penalty alternative," as this is the *most* burdensome of all possible alternatives listed as open to the EPA under TSCA. TSCA not only provides the EPA with a list of alternative actions, but also provides those alternatives in order of how burdensome they are.[15] The

14. *Cf. Southland Mower Co. v. CPSC*, 619 F.2d 499, 510 (5th Cir.1980) ("It must be remembered that '[t]he statutory term "unreasonable risk" presupposes that a real, and not a speculative, risk be found to exist and that the Commission bear the burden of demonstrating the existence of such a risk before proceeding to regulate.'" (Citation omitted.)).

15. The statute provides, in order, the possible regulatory schemes as follows:

(1) A requirement (A) prohibiting the manufacturing, processing, or distribution in commerce of such substance or mixture, or (B) limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce.

(2) A requirement—

(A) prohibiting the manufacture, processing, or distribution in commerce of such substance or mixture for (i) a particular use or (ii) a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement, or

(B) limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce for (i) a particular use or (ii) a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement.

(3) A requirement that such substance or mixture or any article containing such substance or mixture be marked with or accompanied by clear and adequate warnings and instructions with respect to its use, distribution in commerce, or disposal or with respect to any combination of such activities. The form and content of such warnings and instructions shall be prescribed by the Administrator.

(4) A requirement that manufacturers and processors of such substance or mixture make and retain records of the processes used to manufacture or process such substance or mixture and monitor or conduct tests which are reasonable and necessary to assure compliance with the requirements of any rule applicable under this subsection.

(5) A requirement prohibiting or otherwise regulating any manner or method of commercial use of such substance or mixture.

(6) (A) A requirement prohibiting or otherwise regulating any manner or method of disposal of such substance or mixture, or of any article containing such substance or mixture, by its manufacturer or processor or by any other person who uses, or disposes of, it for commercial purposes.

(B) A requirement under subparagraph (A) may not require any person to take any action which would be in violation of any law or requirement of, or in effect for, a State or

regulations thus provide for EPA regulation ranging from labeling the least toxic chemicals to limiting the total amount of chemicals an industry may use. Total bans head the list as the most burdensome regulatory option.

By choosing the harshest remedy given to it under TSCA, the EPA assigned to itself the toughest burden in satisfying TSCA's requirement that its alternative be the least burdensome of all those offered to it. Since, both by definition and by the terms of TSCA, the complete ban of manufacturing is the most burdensome alternative—for even stringent regulation at least allows a manufacturer the chance to invest and meet the new, higher standard—the EPA's regulation cannot stand if there is any other regulation that would achieve an acceptable level of risk as mandated by TSCA.

We reserve until a later part of the opinion a product-by-product review of the regulation. Before reaching this analysis, however, we lay down the inquiry that the EPA should undertake whenever it seeks total ban of a product.

The EPA considered, and rejected, such options as labeling asbestos products, thereby warning users and workers involved in the manufacture of asbestos-containing products of the chemical's dangers, and stricter workplace rules. EPA also rejected controlled use of asbestos in the workplace and deferral to other government agencies charged with worker and consumer exposure to industrial and product hazards, such as OSHA, the CPSC, and the MSHA. The EPA determined that deferral to these other agencies was inappropriate because no one other authority could address all the risks posed "throughout the life cycle" by asbestos, and any action by one or more of the other agencies still would leave an unacceptable residual risk.[16]

Much of the EPA's analysis is correct, and the EPA's basic decision to use TSCA as a comprehensive statute designed to fight a multi-industry problem was a proper one that we uphold today on review. What concerns us, however, is the manner in which the EPA conducted some of its analysis. TSCA requires the EPA to consider, along with the effects of toxic substances on human health and the environment, "the benefits of such substance[s] or mixture[s] for various uses and the availability of substitutes for such uses," as well as "the reasonably ascertainable economic consequences of the rule, after consideration for the effect on the national economy, small business, technological innovation, the environment, and public health." *Id.* § 2605(c)(1)(C–D).

The EPA presented two comparisons in the record: a world with no further regulation under TSCA, and a world in which no manufacture of asbestos takes place. The EPA rejected calculating how many lives a less burdensome regulation would save, and at what cost. Furthermore the EPA, when calculating the benefits of its ban, explicitly refused to compare it to an improved workplace in which currently available control technology is utilized. *See* 54 Fed.Reg. at 29,474. This decision artificially inflated the purported benefits of the rule by using a baseline comparison sub-

political subdivision, and shall require each person subject to it to notify each State and political subdivision in which a required disposal may occur of such disposal.

(7) A requirement directing manufacturers or processors of such substance or mixture (A) to give notice of such unreasonable risk of injury to distributors in commerce of such substance or mixture and, to the extent reasonably ascertainable, to other persons in possession of such substance or mixture or exposed to such substance or mixture, (B) to give public notice of such risk of injury, and (C) to replace or repurchase such substance or mixture as elected by the person to which the requirement is directed.

15 U.S.C. § 2605(a). As is plain from the order in which they are listed, options at the top of the list are the most burdensome regulatory options, progressively declining to the least burdensome option.

16. EPA argues that OSHA can only deal with workplace exposures to asbestos and that the CPSC and MSHA cannot take up the slack, as the CPSC can impose safety standards for asbestos products based only upon the risk to consumers, and MSHA can protect against exposure only in the mining and milling process. These agencies leave unaddressed dangers posed by asbestos exposure through product repair, installation, wear and tear, and the like.

stantially lower than what currently available technology could yield.

[27] Under TSCA, the EPA was required to evaluate, rather than ignore, less burdensome regulatory alternatives. TSCA imposes a least-to-most-burdensome hierarchy. In order to impose a regulation at the top of the hierarchy—a total ban of asbestos—the EPA must show not only that its proposed action reduces the risk of the product to an adequate level, but also that the actions Congress identified as less burdensome also would not do the job.[17] The failure of the EPA to do this constitutes a failure to meet its burden of showing that its actions not only reduce the risk but do so in the Congressionally-mandated *least burdensome* fashion.

Thus it was not enough for the EPA to show, as it did in this case, that banning some asbestos products might reduce the harm that could occur from the use of these products. If that were the standard, it would be no standard at all, for few indeed are the products that are so safe that a complete ban of them would not make the world still safer.

This comparison of two static worlds is insufficient to satisfy the dictates of TSCA. While the EPA may have shown that a world with a complete ban of asbestos might be preferable to one in which there is only the current amount of regulation, the EPA has failed to show that there is not some intermediate state of regulation that would be superior to both the currently-regulated and the completely-banned world. Without showing that asbestos regulation would be ineffective, the EPA cannot discharge its TSCA burden of showing that its regulation is the least burdensome available to it.

Upon an initial showing of product danger, the proper course for the EPA to follow is to consider each regulatory option, beginning with the least burdensome, and the costs and benefits of regulation under each option. The EPA cannot simply skip several rungs, as it did in this case, for in doing so, it may skip a less-burdensome alternative mandated by TSCA. Here, although the EPA mentions the problems posed by intermediate levels of regulation, it takes no steps to calculate the costs and benefits of these intermediate levels. *See* 54 Fed.Reg. at 29,462, 29,474. Without doing this it is impossible, both for the EPA and for this court on review, to know that none of these alternatives was less burdensome than the ban in fact chosen by the agency.

The EPA's offhand rejection of these intermediate regulatory steps is "not the stuff of which substantial evidence is made." *Aqua Slide*, 569 F.2d at 843. While it is true that the EPA considered five different ban options, these differed solely with respect to their effective dates. The EPA did not calculate the risk levels for intermediate levels of regulation, as it believed that there was no asbestos exposure level for which the risk of injury or death was zero. Reducing risk to zero, however, was not the task that Congress set for the EPA in enacting TSCA. The EPA thus has failed "cogently [to] explain why it has exercised its discretion in a given manner," *Chemical Mfrs. Ass'n*, 899 F.2d at 349, by failing to explore in more than a cursory way the less burdensome alternatives to a total ban.

17. Although we, as always, rely mainly upon the language of the statute to determine Congress's intent, we also note that the legislative history of TSCA supports the notion of TSCA's least-to-most-burdensome hierarchy. As the Senate sponsor of the "least burdensome" requirement stated, Congress did "not want to give the Administrator unlimited authority and let him say, 'I will impose this control, if there are other controls that are effective and are less burdensome on the industry.'" 122 Cong.Rec. 8295 (1976) (statement of Sen. Cannon).

In addition, the EPA itself acknowledges this hierarchy when it states in its brief that "TSCA authorizes and directs [the] EPA to impose that burden [of a total ban] *if the risks of a substance cannot be adequately addressed in another way.*" (Emphasis added.) The EPA does not explain how it can determine that the risks of a substance cannot be addressed in another way if it refuses to make a finding that the alternatives will not discharge the EPA's TSCA burden. It cannot simply state that there is no level of zero risk asbestos use and then impose the most burdensome alternative on that sole basis.

2.

The EPA's Calculations.

Furthermore, we are concerned about some of the methodology employed by the EPA in making various of the calculations that it did perform. In order to aid the EPA's reconsideration of this and other cases, we present our concerns here.

[28] First, we note that there was some dispute in the record regarding the appropriateness of discounting the perceived benefits of the EPA's rule. In choosing between the calculated costs and benefits, the EPA presented variations in which it discounted only the costs, and counter-variations in which it discounted both the costs and the benefits, measured in both monetary and human injury terms. As between these two variations, we choose to evaluate the EPA's work using its discounted benefits calculations.

Although various commentators dispute whether it ever is appropriate to discount benefits when they are measured in human lives, we note that it would skew the results to discount only costs without according similar treatment to the benefits side of the equation. Adopting the position of the commentators who advocate not discounting benefits would force the EPA similarly not to calculate costs in present discounted real terms, making comparisons difficult. Furthermore, in evaluating situations in which different options incur costs at varying time intervals, the EPA would not be able to take into account that soon-to-be-incurred costs are more harmful than postponable costs. Because the EPA must discount costs to perform its evaluations properly, the EPA also should discount benefits to preserve an apples-to-apples comparison, even if this entails discounting benefits of a non-monetary nature. *See What Price Posterity?*, The Economist, March 23, 1991, at 73 (explaining use of discount rates for non-monetary goods).

When the EPA does discount costs or benefits, however, it cannot choose an unreasonable time upon which to base its discount calculation. Instead of using the time of injury as the appropriate time from which to discount, as one might expect, the EPA instead used the time of exposure.

The difficulties inherent in the EPA's approach can be illustrated by an example. Suppose two workers will be exposed to asbestos in 1995, with worker X subjected to a tiny amount of asbestos that will have no adverse health effects, and worker Y exposed to massive amounts of asbestos that quickly will lead to an asbestos-related disease. Under the EPA's approach, which takes into account only the time of exposure rather than the time at which any injury manifests itself, both examples would be treated the same. The EPA's approach implicitly assumes that the day on which the risk of injury occurs is the same day the injury actually occurs.[18] Such an approach might be proper when the exposure and injury are one and the same, such as when a person is exposed to an immediately fatal poison, but is inappropriate for discounting toxins in which exposure often is followed by a substantial lag time before manifestation of injuries.[19]

Of more concern to us is the failure of the EPA to compute the costs and benefits of its proposed rule past the year 2000, and its double-counting of the costs of asbestos use. In performing its calculus, the EPA only included the number of lives saved over the next thirteen years, and counted any additional lives saved as simply "unquantified benefits." 54 Fed.Reg. at 29,-

18. Recently, in a different context, we observed the important distinction between present and future injury. *See Willett v. Baxter Int'l, Inc.*, 929 F.2d 1094, 1099-1100 & n. 20 (5th Cir.1991).

19. We also note that the EPA chose to use a real discount rate of 3%. Because historically the real rate of interest has tended to vary between 2% and 4%, this figure was not inaccurate.

The EPA also did not err by calculating that the price of substitute goods is likely to decline at a rate of 1% per year, resulting from economies of scale and increasing manufacturing prowess. Because the EPA properly limited the scope of these declines in its models so that the cost of substitutes would not decline so far as to make the price of the substitutes less than the cost of the asbestos they were forced to replace, this was not an unreasonable real rate of price decline to adopt.

486. The EPA and intervenors now seek to use these unquantified lives saved to justify calculations as to which the benefits seem far outweighed by the astronomical costs. For example, the EPA plans to save about three lives with its ban of asbestos pipe, at a cost of $128–227 million (*i.e.*, approximately $43–76 million per life saved). Although the EPA admits that the price tag is high, it claims that the lives saved past the year 2000 justify the price. *See generally id.* at 29,473 (explaining use of unquantified benefits).

Such calculations not only lessen the value of the EPA's cost analysis, but also make any meaningful judicial review impossible. While TSCA contemplates a useful place for unquantified benefits beyond the EPA's calculation, unquantified benefits never were intended as a trump card allowing the EPA to justify any cost calculus, no matter how high.

The concept of unquantified benefits, rather, is intended to allow the EPA to provide a rightful place for any remaining benefits that are impossible to quantify after the EPA's best attempt, but which still are of some concern. But the allowance for unquantified costs is not intended to allow the EPA to perform its calculations over an arbitrarily short period so as to preserve a large unquantified portion.

Unquantified benefits can, at times, permissibly tip the balance in close cases. They cannot, however, be used to effect a wholesale shift on the balance beam. Such a use makes a mockery of the requirements of TSCA that the EPA weigh the costs of its actions before it chooses the least burdensome alternative.[20]

We do not today determine what an appropriate period for the EPA's calculations would be, as this is a matter better left for agency discretion. *See Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 53, 103 S.Ct. at 2872. We do note, however, that the choice of a thirteen-year period is so short as to make the unquantified period so unreasonably large that any EPA reliance upon it must be displaced.

Under the EPA's calculations, a twenty-year-old worker entering employment today still would be at risk from workplace dangers for more than thirty years after the EPA's analysis period had ended. The true benefits of regulating asbestos under such calculations remain unknown. The EPA cannot choose to leave these benefits high and then use the high unknown benefits as a major factor justifying EPA action.

We also note that the EPA appears to place too great a reliance upon the concept of population exposure. While a high population exposure certainly is a factor that the EPA must consider in making its calculations, the agency cannot count such problems more than once. For example, in the case of asbestos brake products, the EPA used factors such as risk and exposure to calculate the probable harm of the brakes, and then used, as an *additional* reason to ban the products, the fact that the exposure levels were high. Considering that calculations of the probable harm level, when reduced to basics, simply are a calculation of population risk multiplied by population exposure, the EPA's redundant use of population exposure to justify its actions cannot stand.

20. We thus reject the arguments made by the Natural Resources Defense Council, Inc., and the Environmental Defense Fund, Inc., that the EPA's decision can be justified because the EPA "relied on many serious risks that were understated or not quantified in the final rule," presented figures in which the "benefits are calculated only for a limited time period," and undercounted the risks to the general population from low-level asbestos exposure. In addition, the intervenors argue that the EPA rejected using upper estimates, *see* 54 Fed.Reg. at 29,473, and that this court now should use the rejected limits as evidence to support the EPA. They thus would have us reject the upper limit concerns when they are not needed, but use them if necessary.

We agree that these all are valid concerns that the EPA legitimately should take into account when considering regulatory action. What we disagree with, however, is the manner in which the EPA incorporated these concerns. By not using such concerns in its quantitative analysis, even where doing so was not difficult, and reserving them as additional factors to buttress the ban, the EPA improperly transformed permissible considerations into determinative factors.

3.

Reasonable Basis.

In addition to showing that its regulation is the least burdensome one necessary to protect the environment adequately, the EPA also must show that it has a reasonable basis for the regulation. 15 U.S.C. § 2605(a). To some extent, our inquiry in this area mirrors that used above, for many of the methodological problems we have noted also indicate that the EPA did not have a reasonable basis. We here take the opportunity to highlight some areas of additional concern.

[29] Most problematical to us is the EPA's ban of products for which no substitutes presently are available. In these cases, the EPA bears a tough burden indeed to show that under TSCA a ban is the least burdensome alternative, as TSCA explicitly instructs the EPA to consider "the benefits of such substance or mixture for various uses and the availability of substitutes for such uses." *Id.* § 2605(c)(1)(C). These words are particularly appropriate where the EPA actually has decided to ban a product, rather than simply restrict its use, for it is in these cases that the lack of an adequate substitute is most troubling under TSCA.

As the EPA itself states, "[w]hen no information is available for a product indicating that cost-effective substitutes exist, the estimated cost of a product ban is very high." 54 Fed.Reg. at 29,468. Because of this, the EPA did not ban certain uses of asbestos, such as its use in rocket engines and battery separators. The EPA, however, in several other instances, ignores its own arguments and attempts to justify its ban by stating that the ban itself will cause the development of low-cost, adequate substitute products.

[30] As a general matter, we agree with the EPA that a product ban can lead to great innovation, and it is true that an agency under TSCA, as under other regulatory statutes, "is empowered to issue safety standards which require improvements in existing technology or which require the development of new technology." *Chrysler Corp. v. Department of Transp.*, 472 F.2d 659, 673 (6th Cir.1972). As even the EPA acknowledges, however, when no adequate substitutes currently exist, the EPA cannot fail to consider this lack when formulating its own guidelines. Under TSCA, therefore, the EPA must present a stronger case to justify the ban, as opposed to regulation, of products with no substitutes.

We note that the EPA does provide a waiver provision for industries where the hoped-for substitutes fail to materialize in time. *See* 54 Fed.Reg. at 29,464. Under this provision, if no adequate substitutes develop, the EPA temporarily may extend the planned phase-out.

The EPA uses this provision to argue that it can ban any product, regardless of whether it has an adequate substitute, because inventive companies soon will develop good substitutes. The EPA contends that if they do not, the waiver provision will allow the continued use of asbestos in these areas, just as if the ban had not occurred at all.

The EPA errs, however, in asserting that the waiver provision will allow a continuation of the status quo in those cases in which no substitutes materialize. By its own terms, the exemption shifts the burden onto the waiver proponent to convince the EPA that the waiver is justified. *See id.* As even the EPA acknowledges, the waiver only "may be granted by [the] EPA in very limited circumstances." *Id.* at 29,460.

The EPA thus cannot use the waiver provision to lessen its burden when justifying banning products without existing substitutes. While TSCA gives the EPA the power to ban such products, the EPA must bear its heavier burden of justifying its total ban in the face of inadequate substitutes. Thus, the agency cannot use its waiver provision to argue that the ban of products with no substitutes should be treated the same as the ban of those for which adequate substitutes are available now.

[31] We also are concerned with the EPA's evaluation of substitutes even in those instances in which the record shows

that they are available. The EPA explicitly rejects considering the harm that may flow from the increased use of products designed to substitute for asbestos, even where the probable substitutes themselves are known carcinogens. *Id.* at 29,481–83. The EPA justifies this by stating that it has "more concern about the continued use and exposure to asbestos than it has for the future replacement of asbestos in the products subject to this rule with other fibrous substitutes." *Id.* at 29,481. The agency thus concludes that any "[r]egulatory decisions about asbestos which poses well-recognized, serious risks should not be delayed until the risk of all replacement materials are fully quantified." *Id.* at 29,-483.

This presents two problems. First, TSCA instructs the EPA to consider the relative merits of its ban, as compared to the economic effects of its actions. The EPA cannot make this calculation if it fails to consider the effects that alternate substitutes will pose after a ban.

Second, the EPA cannot say with any assurance that its regulation will increase workplace safety when it refuses to evaluate the harm that will result from the increased use of substitute products. While the EPA may be correct in its conclusion that the alternate materials pose less risk than asbestos, we cannot say with any more assurance than that flowing from an educated guess that this conclusion is true.

Considering that many of the substitutes that the EPA itself concedes will be used in the place of asbestos have known carcinogenic effects, the EPA not only cannot assure this court that it has taken the least burdensome alternative, but cannot even prove that its regulations will increase workplace safety. Eager to douse the dangers of asbestos, the agency inadvertently actually may increase the risk of injury Americans face. The EPA's explicit failure to consider the toxicity of likely substitutes thus deprives its order of a reasonable basis. *Cf. American Petroleum Inst. v. OSHA*, 581 F.2d 493, 504 (5th Cir.1978) (An agency is required to "regulate on the basis of knowledge rather than the unknown.").

Our opinion should not be construed to state that the EPA has an affirmative duty to seek out and test every workplace substitute for any product it seeks to regulate. TSCA does not place such a burden upon the agency. We do not think it unreasonable, however, once interested parties introduce credible studies and evidence showing the toxicity of workplace substitutes, or the decreased effectiveness of safety alternatives such as non-asbestos brakes, that the EPA then consider whether its regulations are even increasing workplace safety, and whether the increased risk occasioned by dangerous substitutes makes the proposed regulation no longer reasonable. In the words of the EPA's own release that initiated the asbestos rulemaking, we direct that the agency consider the adverse health effects of asbestos substitute "for comparison with the known hazards of asbestos," so that it can conduct, as it promised in 1979, a "balanced consideration of the environmental, economic, and social impact of any action taken by the agency." 44 Fed. Reg. at 60,065 (1979).

[32] In short, a death is a death, whether occasioned by asbestos or by a toxic substitute product, and the EPA's decision not to evaluate the toxicity of known carcinogenic substitutes is not a reasonable action under TSCA. Once an interested party brings forth credible evidence suggesting the toxicity of the probable or only alternatives to a substance, the EPA must consider the comparative toxic costs of each.[21] Its failure to do so in this case thus

21. This is not to say that an interested party can introduce just any evidence of a suspected carcinogen or other toxin in its efforts to slow down a valid EPA regulation. The agency may, within its discretion, consider the probable merits of such dilatory tactics and act appropriately. *Cf. National Grain & Feed Ass'n*, 866 F.2d at 734 ("[W]e do not require the agency to respond in detail to every imaginable proposal for tighter standards."). Where, however, the health risks of substitutes, such as non-asbestos brakes and polyvinyl chloride (PVC) pipe, are both plausible and known, the EPA must consider not only the probable costs of continued use of the product it is considering, but also the harm that

deprived its regulation of a reasonable basis, at least in regard to those products as to which petitioners introduced credible evidence of the dangers of the likely substitutes.[22]

4.

Unreasonable Risk of Injury.

The final requirement the EPA must satisfy before engaging in any TSCA rulemaking is that it only take steps designed to prevent "unreasonable" risks. In evaluating what is "unreasonable," the EPA is required to consider the costs of any proposed actions and to "carry out this chapter in a reasonable and prudent manner [after considering] the environmental, economic, and social impact of any action." 15 U.S.C. § 2601(c).

[33] As the District of Columbia Circuit stated when evaluating similar language governing the Federal Hazardous Substances Act, "[t]he requirement that the risk be 'unreasonable' necessarily involves a balancing test like that familiar in tort law: The regulation may issue if the severity of the injury that may result from the product, factored by the likelihood of the injury, offsets the harm the regulation itself imposes upon manufacturers and consumers." *Forester v. CPSC*, 559 F.2d 774, 789 (D.C.Cir.1977). We have quoted this language approvingly when evaluating other statutes using similar language. *See, e.g., Aqua Slide*, 569 F.2d at 839.

That the EPA must balance the costs of its regulations against their benefits further is reinforced by the requirement that it seek the least burdensome regulation. While Congress did not dictate that the EPA engage in an exhaustive, full-scale cost-benefit analysis, it did require the EPA to consider both sides of the regulatory equation, and it rejected the notion that the EPA should pursue the reduction of workplace risk at any cost. *See American Textile Mfrs. Inst.*, 452 U.S. at 510 n. 30, 101 S.Ct. at 2491 n. 30 ("unreasonable risk" statutes require "a generalized balancing of costs and benefits" (citing *Aqua Slide*, 569 F.2d at 839)). Thus, "Congress also plainly intended the EPA to consider the economic impact of *any* actions taken by it under ... TSCA." *Chemical Mfrs. Ass'n*, 899 F.2d at 348.

Even taking all of the EPA's figures as true, and evaluating them in the light most favorable to the agency's decision (non-discounted benefits, discounted costs, analogous exposure estimates included), the agency's analysis results in figures as high as $74 million per life saved. For example, the EPA states that its ban of asbestos pipe will save three lives over the next thirteen years, at a cost of $128–227 million ($43–76 million per life saved), depending upon the price of substitutes; that its ban of asbestos shingles will cost $23–34 million to save 0.32 statistical lives ($72–106 million per life saved); that its ban of asbestos coatings will cost $46–181 million to save 3.33 lives ($14–54 million per life saved); and that its ban of asbestos paper products will save 0.60 lives at a cost of $4–5 million ($7–8 million per life saved). *See* 54 Fed.Reg. at 29,484–85. Were the analogous exposure estimates not included, the cancer risks from substitutes such as ductile iron pipe factored in, and the benefits of the ban appropriately discounted from the time of the manifestation of an injury rather than the time of exposure, the costs would shift even more sharply against the EPA's position.

While we do not sit as a regulatory agency that must make the difficult decision as to what an appropriate expenditure is to prevent someone from incurring the risk of

would follow from its regulation and increased use of an alternate, harmful product.

22. We note that at least part of the EPA's arguments rest on the assumption that regulation will not work because the federal government will not adequately enforce any workplace standards that the EPA might promulgate. This is an improper assumption. The EPA should assume reasonable efforts by the government to implement its own regulations. A governmental agency cannot point to how poorly the government will implement regulations as a reason to reject regulation. Rather, the solution to poor enforcement of regulations is better enforcement, not more burdensome alternative solutions under TSCA.

an asbestos-related death, we do note that the EPA, in its zeal to ban any and all asbestos products, basically ignored the cost side of the TSCA equation. The EPA would have this court believe that Congress, when it enacted its requirement that the EPA consider the economic impacts of its regulations, thought that spending $200–300 million to save approximately seven lives (approximately $30–40 million per life) over thirteen years is reasonable.

As we stated in the OSHA context, until an agency "can provide substantial evidence that the benefits to be achieved by [a regulation] bear a reasonable relationship to the costs imposed by the reduction, it cannot show that the standard is reasonably necessary to provide safe or healthful workplaces." *American Petroleum Inst.*, 581 F.2d at 504. Although the OSHA statute differs in major respects from TSCA, the statute does require substantial evidence to support the EPA's contentions that its regulations both have a reasonable basis and are the least burdensome means to a reasonably safe workplace.

The EPA's willingness to argue that spending $23.7 million to save less than one-third of a life reveals that its economic review of its regulations, as required by TSCA, was meaningless. As the petitioners' brief and our review of EPA caselaw reveals, such high costs are rarely, if ever, used to support a safety regulation. If we were to allow such cavalier treatment of the EPA's duty to consider the economic effects of its decisions, we would have to excise entire sections and phrases from the language of TSCA. Because we are judges, not surgeons, we decline to do so.[23]

V.

Substantial Evidence Regarding Least Burdensome, Adequate Regulation.

TSCA provides that a reviewing court "shall hold unlawful and set aside" a final rule promulgated under section 6(a) "if the court finds that the rule is not supported by substantial evidence in the rulemaking record ... taken as a whole." 15 U.S.C. § 2618(c)(1)(B)(i). The substantial evidence standard "afford[s] a considerably more generous judicial review" than the arbitrary or capricious test, *Abbott Laboratories*, 387 U.S. at 143, 87 S.Ct. at 1513, and "imposes a considerable burden on the agency and limits its discretion in arriving at a factual predicate." *Mobil Oil Corp. v. FPC*, 483 F.2d 1238, 1258 (D.C.Cir.1973).

[34] We have declared that the EPA must articulate an "understandable basis" to support its TSCA action with respect to each substance or application of the substance banned. *Chemical Mfrs. Ass'n*, 899 F.2d at 357. To make a finding of unreasonable risk based upon this assessment, the "EPA must balance the probability that harm will occur from the activities against the effects of the proposed regulatory action on the availability to society of the benefits of asbestos." 54 Fed.Reg. at 29,467. With these edicts in mind, we now examine each product against the TSCA criteria.[24]

23. *See Environmental Defense Fund*, 636 F.2d at 1275 n. 17 ("[W]e must construe the statute 'so that no provision will be inoperative or superfluous'" (quoting *Motor & Equip. Mfrs. Ass'n v. EPA*, 627 F.2d 1095, 1108 (D.C.Cir.1979), *cert. denied*, 446 U.S. 952, 100 S.Ct. 2917, 64 L.Ed.2d 808 (1980))); *see also Old Colony R.R. v. Commissioner*, 284 U.S. 552, 560, 52 S.Ct. 211, 213, 76 L.Ed. 484 (1932) (in interpreting statutory language, "the plain, obvious and rational meaning of a statute is to be preferred to any curious, narrow, hidden sense").

As the petitioners point out, the EPA regularly rejects, as unjustified, regulations that would save more lives at less cost. For example, over the next 13 years, we can expect more than a dozen deaths from ingested *toothpicks*—a death toll more than twice what the EPA predicts will flow from the quarter-billion-dollar bans of asbestos pipe, shingles, and roof coatings. *See* L. Budnick, *Toothpick-Related Injuries in the United States, 1979 Through 1982*, 252 J. Am. Med. Ass'n, Aug. 10, 1984, at 796 (study showing that toothpick-related deaths average approximately one per year).

24. In large part, our analysis draws upon our general discussion already concluded. Where necessary, however, we develop specific themes more appropriately addressed in the context of a specific product. The EPA on subsequent review should consider these specific comments as applicable to its procedures dealing with other products, where necessary. In other words, by presenting a concern in the context of one

A.

Friction Products.

[35] We begin our analysis with the EPA's ban of friction products, which constitutes the lion's share of the proposed benefits of the asbestos regulation—nearly three-fourths of the anticipated asbestos deaths. The friction products in question, although primarily made up of drum and disk brakes, also include brake blocks and other friction products.

Workers are exposed to asbestos during the manufacture, use, repair, and disposal of these products. The EPA banned most of these products with a stage 2 ban, which would require companies to cease manufacturing or importing the products by August 25, 1993, with distribution to end one year later. The final stage 3 ban would han any remaining friction products on August 26, 1996, with distribution again ceasing one year later. *See id.* at 29,461–62.

We note that of all the asbestos bans, the EPA did the most impressive job in this area, both in conducting its studies and in supporting its contention that banning asbestos products would save over 102 discounted lives. *Id.* at 29,485. Furthermore, the EPA demonstrates that the population exposure to asbestos in this area is great, while the estimated cost of the measure is low, at least in comparison to the cost-per-life of its other bans. Were the petitioners only questioning the EPA's decision to ban friction products based upon disputing these figures, we would be tempted to uphold the EPA, even in the face of petitioners' arguments that workplace exposure to friction product asbestos could be decreased by as much as ninety percent using stricter workplace controls and in light of studies supporting the conclusion that some forms of asbestos present less danger. Decisions such as these are better left to the agency's expertise.

Such expertise, however, is not a universal talisman affording the EPA unbridled latitude to act as it chooses under TSCA. What we cannot ignore is that the EPA failed to study the effect of non-asbestos brakes on automotive safety, despite credible evidence that non-asbestos brakes could increase significantly the number of highway fatalities, and that the EPA failed to evaluate the toxicity of likely brake substitutes. As we already mentioned, the EPA, in its zeal to ban asbestos, cannot overlook, with only cursory study, credible contentions that substitute products actually might increase fatalities.

The EPA commissioned an American Society of Mechanical Engineers (ASME) study that concluded that while more research was needed, it appeared that many of the proposed substitutes for friction products are not, and will, not soon be available, especially in the replacement brake market, and that the substitutes may or may not assure safety.[25] Despite this credible record evidence, by a study specifically commissioned by the EPA, that substitute products actually might cause more deaths than those asbestos deaths predicted by the EPA, the agency did not evaluate the dangers posed by the substitutes, including cancer deaths from the other fibers used and highway deaths occasioned by less effective, non-asbestos brakes. This failure to examine the likely consequence of the EPA's regulation renders the ban of asbestos friction products unreasonable.

This failure would be of little moment, were the relevant market confined to original equipment disk brakes and pads. For these original equipment brakes, it appears that manufacturers already have developed safe substitutes for asbestos, considering

product, we do not mean to imply that it arises only in that area.

25. One of the study's authors, Mr. Anderson, submitted written testimony that the "replacement/substitution of asbestos-based with non-asbestos brake linings will produce grave risks" and that "the expected increase of skid-related highway accidents and resultant traffic deaths would certainly be expected to overshadow any potential health-related benefits of fiber substitution." The ASME report itself concludes only that "[i]f the eventual elimination of all asbestos in friction products is to be accomplished, additional future studies are required." This is an insufficient basis upon which to support the EPA's judgment that non-asbestos brakes are just as safe as asbestos brakes.

that nearly all new vehicles come with non-asbestos disk brakes, with non-asbestos drum brakes apparently soon to follow. *See id.* at 29,493. The ASME Report concluded that "at the present rate of technological progress, most new passenger cars could be equipped with totally non-asbestos frictional systems by 1991, and most light trucks and heavy trucks with S-cam brakes, by 1992." *See id.* at 29,494.

Although the petitioners dispute the evidence, we find particularly telling the fact that manufacturers already are producing most vehicles with newly designed, non-asbestos brakes. The ban of asbestos brakes for these uses here appears reasonable and, had the EPA taken the proper steps to consider and reject the less burdensome alternatives, we might find the ban of these products supported by substantial evidence.

With respect to the aftermarket replacement market, however, the EPA's failure to consider the safety ramifications of its decisions is problematic. Original equipment, non-asbestos brakes are designed from the start to work without the superior insulating properties of asbestos. The replacement market brakes, on the other hand, were designed with asbestos, rather than substitutes, in mind. As the EPA itself states, "[c]ommenters generally agreed that it is easier to develop replacement asbestos-free friction materials for use in vehicles that are intentionally designed to use such materials than it is to develop asbestos-free friction materials for use as after-market replacement products in vehicles currently in use that have brake systems designed to use asbestos." *Id.* Because of these difficulties, the EPA decided to use a stage 3 ban for replacement brakes.

Despite acknowledging the difficulty of retrofitting current asbestos brakes, however, the EPA decided that the problem with non-asbestos brakes was not that they are inferior, but that they are less safe because the government does not regulate them. Based upon this conclusion, the EPA decided that it need not consider the safety of alternative brakes because, after consultation with the National Highway Traffic Safety Administration (NHTSA), the EPA concluded that regulation of non-asbestos brakes soon would be forthcoming. *Id.*

This determination is insufficient to discharge the EPA's duties under TSCA. The EPA failed to settle whether alternative brakes will be as safe as current brakes, even though, by its own admission, the "EPA also acknowledges that a ban on asbestos in the brake friction product categories may increase the uncertainty about brake performance." *Id.* at 29,495. The EPA contends that it can rely upon NHTSA to discharge its regulatory burdens, but it ignores the fact that the problem with non-asbestos brakes may be technical, rather than regulatory, in nature.

Future consideration by the NHTSA cannot support a present ban by the EPA when the record contains conflicting and non-conclusive evidence regarding the safety of non-asbestos brake replacement parts. After being presented with credible evidence "that a ban on asbestos use in the aftermarket for brake systems designed for asbestos friction products will compromise the performance of braking systems designed for asbestos brakes," *id.* at 29,494, the EPA under TSCA had to consider whether its proposed ban not only was reasonable, but also whether the increased deaths caused by less efficient brakes made the ban of asbestos in the replacement brake market unreasonable.

In short, while it is apparent that non-asbestos brake products either are available or soon will be available on new vehicles, there is no evidence indicating that forcing consumers to replace their asbestos brakes with new non-asbestos brakes as they wear out on their present vehicles will decrease fatalities or that such a ban will produce other benefits that outweigh its costs. Furthermore, many of the EPA's own witnesses conceded on cross-examination that the non-asbestos fibrous substitutes also pose a cancer risk upon inhalation, yet the EPA failed to examine in more than a cursory fashion the toxicity of these alternatives. Under these circumstances,

the EPA has failed to support its ban with the substantial evidence needed to provide it with a reasonable basis.

Finally, as we already have noted, the structure of TSCA requires the EPA to consider, and reject, the less burdensome alternatives in the TSCA hierarchy before it can invoke its power to ban a product completely. It may well be true, as the EPA contends, that workplace controls are insufficient measures under TSCA and that only a ban will discharge the EPA's TSCA-imposed duty to seek the safest, reasonable environment. The EPA's failure to consider the regulatory alternatives, however, cannot be substantiated by conclusory statements that regulation would be insufficient. *See Texas Indep. Ginners Ass'n v. Marshall,* 630 F.2d 398, 411–12 (5th Cir. 1980); *Aqua Slide,* 569 F.2d at 843. We thus conclude that while the EPA may have presented sufficient evidence to underpin the dangers of asbestos brakes, its failure to consider whether the ban is the least burdensome alternative, and its refusal to consider the toxicity and danger of substitute brake products, in regard to both highway and workplace safety, deprived its regulation of the reasonable basis required by TSCA.

B.

Asbestos-Cement Pipe Products.

[36] The EPA's analysis supporting its ban of asbestos-cement (A/C") pipe is more troublesome than its action in regard to friction products. Asbestos pipe primarily is used to convey water in mains, sewage under pressure, and materials in various industrial process lines. Unlike most uses of asbestos, asbestos pipe is valued primarily for its strength and resistance to corrosion, rather than for its heat-resistant qualities. The EPA imposed a stage 3 ban on asbestos pipe. 54 Fed.Reg. at 29,462.

Petitioners question EPA's cost/benefit balancing, noting that by the EPA's own predictions, the ban of asbestos pipe will save only 3–4 discounted lives, at a cost ranging from $128–227 million ($43–76 million per life saved), depending upon the price of substitutes. *Id.* at 29,484. Furthermore, much of EPA's data regarding this product and others depends upon data received from exposures observed during activities similar to the ones to be regulated—the "analogous exposure" analysis that the EPA adopted subsequent to the public comment period, which thus was not subjected to cross-examination or other critical testing.[26] Finally, the petitioners protest that the EPA acted unreasonably because the most likely substitutes for the asbestos pipe, PVC and ductile iron pipe, also contain known carcinogens.

Once again we are troubled by the EPA's methodology and its evaluation of the substitute products. Many of the objections raised by the asbestos cement pipe producers are general protests about the EPA's studies and other similar complaints. We will not disturb such agency inquiries, as it is not our role to delve into matters better left for agency expertise. We do, however, examine the EPA's methodology in places to determine whether it has presented substantial evidence to support its regulation.

As with friction products, the EPA refused to assess the risks of substitutes to asbestos pipe. *Id.* at 29,497–98. Unlike non-asbestos brakes, which the EPA contends are safe, the EPA here admits that vinyl chloride, used in PVC, is a human carcinogen that is especially potent during the manufacture of PVC pipe. As for the EPA's defense of the ductile iron pipe substitute, the EPA also acknowledges evidence that it will cause cancer deaths but rejects these deaths as overestimated, even though it can present no more support for this assumption than its own *ipse dixit.*

The EPA presented several plausible, albeit untested, reasons why PVC and ductile iron pipe might be less of a health risk than asbestos pipe. It did not, however, actually evaluate the health risk flowing from these substitute products, even though the

26. In this case, the EPA extrapolated data regarding asbestos exposure during installation of asbestos pipe products and estimated, by formula, how often workers would be exposed to asbestos during repair and disposal.

"EPA acknowledges that the individual lifetime cancer risk associated with the production of PVC may be equivalent to that associated with the production of A/C pipe." *Id.* at 29,497. The agency concedes that "[t]he population cancer risk for the production of ductile iron pipe could be comparable to the population cancer risk for production of A/C pipe." *Id.*

It was insufficient for the EPA to conclude that while its data showed that "the number of cancer cases associated with production of equivalent amounts of ductile iron pipe and A/C pipe 'may be similar,' the estimate of cancer risk for ductile iron pipe 'is most likely an overestimate,'" *see* 54 Fed.Reg. at 29,498, unless the agency can present something more concrete than its own speculation to refute these earlier iron pipe cancer studies. Musings and conjecture are "not the stuff of which substantial evidence is made," *Aqua Slide,* 569 F.2d at 843, and "[u]narticulated reliance on Commission 'experience' may satisfy an 'arbitrary, capricious' standard of review, but it does not add one jot to the record evidence." *Id.* at 841–42 (citations omitted). "While expert opinion deserves to be heeded, it must be based on more than casual observation and speculation, particularly where a risk of fatal injury is being evaluated." *Id.* These concerns are of special note where the increased carcinogen risk occasioned by the EPA's proposed substitutes is both credible and known.

This conclusion only is strengthened when we consider the EPA's failure to analyze the health risks of PVC pipe, the most likely substitute for asbestos pipe, which the EPA concedes poses a cancer risk similar to that presented by asbestos pipe. The failure of the EPA to make a record finding on the risks of PVC pipe is particularly inexplicable, as the EPA *already is studying* increasing the stringency of PVC regulation in separate rulemaking proceedings, an action that one of the very intervenors in the instant case has been urging for years. *See NRDC v. EPA,* 824 F.2d 1146, 1148–49 (D.C.Cir.1987) (en banc).

The EPA, in these separate proceedings, has estimated the cancer risk from PVC plants to be as high as twenty deaths *per year,* a death rate that stringent controls might be able to reduce to one *per year, see id.* at 1149, *far in excess of the fractions of a life that the asbestos pipe ban may save each year, by the EPA's own calculations.* Considering that the EPA concedes that there is no evidence showing that *ingested,* as opposed to *inhaled,* asbestos is a health risk, while the EPA's own studies show that ingested vinyl chloride is a significant cancer risk that could cause up to 260 cancer deaths over the next thirteen years, *see id.;* 54 Fed.Reg. at 29,498, the EPA's failure to consider the risks of substitute products in the asbestos pipe area is particularly troublesome. The agency cannot simply choose to note the similar cancer risks of asbestos and iron pipe and then reject the data underpinning the iron and PVC pipe without more than its own conclusory statements.

We also express concern with the EPA's cavalier attitude toward the use of its own data. The asbestos pipe industry argues that the exposure times the EPA used to calculate its figures are much higher than experience would warrant, a contention that the EPA now basically concedes. Rather than recalculate its figures, however, based upon the best data available to it, the EPA merely responds that while the one figure may be too high, it undoubtedly underestimated the exposure levels, because contractors seldom comply with OSHA regulations. In the words of its brief, "[t]hus, EPA concluded that its estimates contain both over- and underestimates, but nevertheless represented a reasonable picture of aggregate exposure."

The EPA is required to support its analysis with substantial evidence under TSCA. When one figure is challenged, it cannot back up its position by changing an unrelated figure to yield the same result. Allowing such behavior would require us only to focus on the final numbers provided by an agency, and to ignore how it arrives at that number. Because a conclusion is no better than the methodology used to reach it, such a result cannot survive the substantial evidence test.

Finally, we once again note that the EPA failed to discharge its TSCA-mandated burden that it consider and reject less burdensome alternatives before it impose a more burdensome alternative such as a complete ban. The EPA instead jumped immediately to the ban provision, without calculating whether a less burdensome alternative might accomplish TSCA's goals. *See* 54 Fed.Reg. at 29,489. We therefore conclude that the EPA failed to present substantial evidence to support its ban of asbestos pipe.

C.

Gaskets, Roofing, Shingles, and Paper Products.

We here deal with the remaining products affected by the EPA ban. Petitioners challenge the basis for the EPA's finding that beater-add and sheet gaskets, primarily used in automotive parts, should be banned. The agency estimated its ban would save thirty-two lives over a thirteen-year time span, at an overall cost of $207–263 million ($6–8 million per life saved). *Id.* at 29,484.

We have little to add in this area, beyond our general discussion and comments on other products, apart from a brief highlight of the EPA's use of analogous exposure data to support its gasket ban. For these products, the analogous exposure estimate constituted almost eighty percent of the anticipated total benefits—a proportion so large that the EPA's duty to give interested parties notice that it intended to use analogous exposure estimates was particularly acute.[27] Considering some of the EPA's support for its analogous exposure estimates—such as its assumption that *none* of the same workers who install beater-add and sheet gaskets *ever* is involved in repairing or disposing of them, and the unexplained discrepancy between its present conclusion that over 50,000 workers are involved in this area and its 1984 estimate that only 768 workers are involved in "gasket removal and installation," *see* 51 Fed.Reg. 22,612, 22,665 (1986)—the petitioners' complaint that they never were afforded the opportunity to comment publicly upon these figures, or to cross-examine any EPA witnesses regarding them, is particularly telling.

[37] The EPA also banned roof coatings, roof shingles, non-roof coatings, and asbestos paper products. Again, we have little to add beyond our discussions already concluded, especially regarding TSCA's requirement that the EPA always choose the least burdensome alternative, whether it be workplace regulation, labeling, or only a partial ban. We note, however, that in those cases in which a complete ban would save less than one statistical life, such as those affecting asbestos paper products and certain roofing materials, the EPA has a particular need to examine the less burdensome alternatives to a complete ban.

Where appropriate, the EPA should consider our preceding discussion as applicable to their bans of these products. By following the dictates of *Chemical Mfrs. Ass'n*, 899 F.2d at 359, that the quantities of the regulated chemical entering into the environment be "substantial," and that the human exposure to the chemical also must be "substantial" or "significant," as well as our concerns expressed in this opinion, the EPA should be able to determine the proper procedures to follow on its reconsideration of its rule and present the cogent explanation of its actions as required under *Chemical Manufacturers Association.*

D.

Ban of Products Not Being Produced in the United States.

Petitioners also contend that the EPA overstepped TSCA's bounds by seeking to ban products that once were, but no longer are, being produced in the United States. We find little merit to this claim, considering that sections 5 and 6 of TSCA allow the EPA to ban a product "that presents *or*

27. The EPA estimates drop from 32.24 discounted lives to 6.68 discounted lives without the analogous exposure data.

will present" a significant risk. (Emphasis added.)

Although petitioners correctly point out that the value of a product not being produced is not zero, as it may find some future use, and that the EPA here has banned items where the estimated risk is zero, this was not error on the part of the EPA. The numbers appear to favor petitioners only because even products with known high risks temporarily show no risk because they are not part of this country's present stream of commerce. This would soon change if the product returned, which is precisely what the EPA is trying to avoid.

Should some unlikely future use arise for these products, the manufacturers and importers have access to the waiver provision established by the EPA for just these contingencies. Under such circumstances, we will not disturb the agency's decision to ban products that no longer are being produced in or imported into the United States.

[38] Similarly, we also decide that the EPA properly can attempt to promulgate a "clean up" ban under TSCA, providing it takes the proper steps in doing so. A clean-up ban, like the asbestos ban in this case, seeks to ban all uses of a certain toxic substance, including unknown, future uses of the substance. Although there is some merit to petitioners' argument that the EPA cannot possibly evaluate the costs and benefits of banning unknown, uninvented products, we hold that the nebulousness of these future products, combined with TSCA's language authorizing the EPA to ban products that "will" create a public risk, allows the EPA to ban future uses of asbestos even in products not yet on the market.

E.

Fundamental EPA Choices.

Finally, we note that there are many other issues raised by petitioners, such as the EPA's decision to treat all types of asbestos the same, its conclusion that various lengths of fibers present similar toxic risks, and its decision that asbestos presents similar risks even in different industries. *See generally* 54 Fed.Reg. at 29,470–71 (detailing differences in potency of chrysotile and other forms of asbestos and toxicity of various fiber lengths). We mention these concerns now only to reject them.

On these, and many similar points, the petitioners merely seek to have us reevaluate the EPA's initial evaluation of the evidence. While we can, and in this opinion do, question the agency's reliance upon flawed methodology and its failure to consider factors and alternatives that TSCA explicitly requires it to consider, we do not sit as a regulatory agency ourselves. Decisions such as the EPA's decision to treat various types of asbestos as presenting similar health risks properly are better left for agency determination and, while the EPA is free to reconsider its data should it so choose when it revisits this area, it also is free to adopt similar reasoning in the future.

VI.

Conclusion.

In summary, of most concern to us is that the EPA has failed to implement the dictates of TSCA and the prior decisions of this and other courts that, before it impose a ban on a product, it first evaluate and then reject the less burdensome alternatives laid out for it by Congress. While the EPA spent much time and care crafting its asbestos regulation, its explicit failure to consider the alternatives required of it by Congress deprived its final rule of the reasonable basis it needed to survive judicial scrutiny.

Furthermore, the EPA's adoption of the analogous exposure estimates during the final weeks of its rulemaking process, after public comment was concluded, rather than during the ten years during which it was considering the asbestos ban, was unreasonable and deprived the petitioners of the notice that they required in order to present their own evidence on the validity of the estimates and its data bases. By depriving the petitioners of their right to

cross-examine EPA witnesses on methodology and data used to support as much as eighty percent of the proposed benefits in some areas, the EPA also violated the dictates of TSCA.

Finally, the EPA failed to provide a reasonable basis for the purported benefits of its proposed rule by refusing to evaluate the toxicity of likely substitute products that will be used to replace asbestos goods. While the EPA does not have the duty under TSCA of affirmatively seeking out and testing all possible substitutes, when an interested party comes forward with credible evidence that the planned substitutes present a significant, or even greater, toxic risk than the substance in question, the agency must make a formal finding on the record that its proposed action still is both reasonable and warranted under TSCA.

We regret that this matter must continue to take up the valuable time of the agency, parties and, undoubtedly, future courts. The requirements of TSCA, however, are plain, and the EPA cannot deviate from them to reach its desired result. We therefore GRANT the petition for review, VACATE the EPA's proposed regulation, and REMAND to the EPA for further proceedings in light of this opinion.[28]

On Petition for Review of a Rule of the Environmental Protection Agency.

ON MOTION FOR CLARIFICATION

Before BROWN, SMITH, and WIENER, Circuit Judges.

PER CURIAM:

[39] Respondents, the Environmental Protection Agency (EPA) and William K. Reilly, seek a clarification of the status of the phase 1, or stage 1, provisions in the challenged rule, which provisions ban, effective August 27, 1990, the manufacture, importation, and processing of asbestos-containing corrugated and flat sheet, asbestos clothing, flooring felt, pipeline wrap, roofing felt, and vinyl/asbestos floor tile, and any new uses of asbestos. See 40 C.F.R. §§ 763.165(a)-.167(a). The rule also requires labeling of phase 1 products after August 27, 1990, *see id.* § 763.171(a), and prohibits the distribution in commerce of such products after August 27, 1992, *see id.* § 763.169(a). *See Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1208 & n. 2 (5th Cir.1991).

Respondents assert that the clarification is needed because, in part V.D of our opinion, *id.* at 1228-29, we have held that the EPA may "ban products that once were, but no longer are, being produced in the United States." Thus, the motion seeks clarification of the status of any products that still were being manufactured, imported, or processed on July 12, 1989, which is the date on which the final rule was issued, *see* 54 Fed.Reg. 29,459 (1989), but which no longer were being manufactured, imported, or processed, as a result of the phase 1 ban, on the date of our opinion, which is October 18, 1991.

The motion for clarification is GRANTED. The holding in part V.D of our opinion applies only to products that were not being manufactured, imported, or processed on July 12, 1989, the date of the rule's promulgation. To the extent, if any, that there is doubt as to whether particular products are in that category, the EPA may resolve the factual dispute on remand.

G.W. GREEN, Petitioner-Appellant,

v.

James A. COLLINS, Director, Institutional Division Texas Department of Criminal Justice, Respondent-Appellee.

No. 91-6203.

United States Court of Appeals, Fifth Circuit.

Nov. 9, 1991.

Defendant's capital murder conviction and death sentence were affirmed by the

28. Pursuant to the Internal Operating Procedures accompanying Fifth Cir.Loc.R. 47, Judge Brown reserves the right to file a separate opinion.

Mr. GOWDY. Next we are pleased to welcome Mr. Noel Francisco. I hope I pronounced it somewhat close to being correct. Mr. Francisco leads the government regulation practice at Jones Day. Prior to joining Jones Day, Mr. Francisco served as the deputy assistant

attorney general in the Department of Justice Office of Legal Counsel and as associate counsel to the President of the United States. Mr. Francisco earned a B.A. In economics from the University of Chicago. He also earned his J.D. From the University of Chicago with high honors. He clerked for Judge Luttig on the United States Court of Appeals for the fourth circuit in Richmond and for Justice Scalia on the Supreme Court of the United States. At Jones Day, Mr. Francisco regularly interacts with administrative agencies at every step of the regulatory process. He knows from personal experience how the Administrative Procedure Act works and how it does not work. And we look forward to his insights. With that, welcome, Mr. Francisco.

TESTIMONY OF NOEL J. FRANCISCO, ESQ., JONES DAY LLP

Mr. FRANCISCO. Thank you, Mr. Chairman and Members of the Subcommittee. It is an honor to appear before you today to discuss the important issue of judicial review of agency action.

In the modern administrative state, it is necessary for courts to defer to agencies' interpretation and implementation of laws passed by Congress. In complex regulatory regimes, Congress simply cannot anticipate every problem that may arise, nor can courts be expected to fill the policy gaps. That is the role of the agencies.

Rigorous judicial oversight, however, is also required, for if judicial deference goes too far, we risk undermining the basic structure of our system of government. Take, for example, a common feature of the modern administrative state. At the front end, Congress passes a broad and open-ended law. Agencies then fill in the gaps through implementing regulations. This is no ministerial function. In these implementing regulations, the agencies are not just interpreting a broad law. In addition, they are making fundamental policy choices similar to those made by this body every day. Then at the back end, courts largely defer to the agencies' interpretation and implementation of broad law. As a result, we see the agencies not only executing the law, which is their primary function, but also both making and interpreting the law through their implementing regulations.

The primary check on this agency discretion is judicial review. It is the judiciary's job to ensure that the agency's policy choices ultimately reflect those made by this body, the Congress, in the original legislation. The point here, of course, is not judicial power. Rather, the court's role in this process is to protect Congress' power by ensuring that at the end of the day, the agency's policy choices reflect Congress' policy choices. And if courts accord agencies too much discretion, then we remove this fundamental check and the result is an undue concentration in the executive branch of all three powers of our national government.

This ultimately is the dilemma of modern administrative law: how to balance agency discretion against judicial oversight. And striking the right balance is vital to preserving the separation of powers on which our government was founded.

In light of this, there are three basic areas where in my view we should consider whether legal doctrine is tilted too far in favor of agency discretion and away from judicial review.

The first is the one that was just touched upon by my friend and former law professor, Ed Warren, and that is the issue of formal versus informal rulemaking. I agree that we should carefully ask ourselves whether or not we have struck the right balance here.

It is true, it is true that in many contexts, it is important for agencies to act expeditiously. And that is primarily the benefit of the notice and comment rulemaking process. But I would submit that in the vast majority of contexts, it is much more important to get the right answer than it is to get the quick answer. And in light of that, it is eminently reasonable to ask whether we have struck the right balance by making the more formal procedures as embodied in formal rulemaking a virtual dinosaur in the area of administrative law.

The other area where I think that reconsideration of whether we have struck the right balance is important is in the area of judicial deference to the agencies' interpretation and implementation of laws. Here, too, the law is tilted strongly in favor of agency discretion and against judicial oversight. To give more deference where courts defer to the agency's views, to the extent those views are persuasive, makes a lot of sense. So does Chevron deference, if not taken too far. Agencies, after all, have technical expertise that courts do not. And courts by and large should defer to that expertise.

In addition to those decisions, however, the courts have adopted various other and even more deferential doctrines as embodied by cases like as Power and Baltimore Gas and Electric. This development raises an important and fundamental policy question. Have these doctrines tipped the balance too far in favor of agency discretion and away from judicial review? If so, then recalibration of that balance is eminently warranted.

There are many ways to do that. The bottom line, however, is that in this context, judicial review is not about judicial power. It is about ensuring that the agencies are adhering to Congress' policy choices so that Congress is not effectively cut out of the policymaking process.

The last area—and I will just defer to my written remarks on this, on which I think it warrants reconsideration of the right balance is in the area of specific statutes aimed at improving the regulatory process, primarily the Information Quality Act and the Regulatory Flexibility Act. Thank you, Mr. Chairman.

Mr. GOWDY. Thank you, Mr. Francisco.

[The prepared statement of Mr. Francisco follows:]

Written Statement of Noel J. Francisco
Partner, Jones Day

Before

The Committee on the Judiciary
Subcommittee on Courts, Commercial and Administrative Law
House of Representatives

May 31, 2011

on

"Formal Rulemaking and Judicial Review: Protecting Jobs and the Economy with Greater Regulatory Transparency and Accountability"

Mr. Chairman, Ranking Member, and Members of the Subcommittee:

My name is Noel John Francisco. I am a partner at the law firm of Jones Day, where I chair the firm's Government Regulation practice. I served as Associate Counsel to President George W. Bush from 2001 to 2003, and as Deputy Assistant Attorney General in the Department of Justice's Office of Legal Counsel from 2003 to 2005. It is an honor to appear before you to discuss the important issue of ensuring effective judicial review of agency action.

Every student of high school civics understands the basic contours of our system of separated powers: The Legislative Branch makes the law. The Executive Branch enforces the law. And the Judicial Branch interprets the law. But consider how this often plays out in the modern administrative state: Congress passes a broad and open-ended law, leaving it to an Executive Branch administrative agency to "fill in the gaps" through administrative regulation. The agency then promulgates regulations interpreting and implementing that open-ended law. And when the issue gets to the judiciary, the courts, as a general matter, defer to Congress's decision to delegate to the agency the policy-making functions in the first place, *see Mistretta v. United States*, 488 U.S. 361, 372-74 (1989), and defer to the agency's interpretation and implementation of the law that Congress passed, *see Mayo Foundation for Medical Education and Research v. United States*, 131 S. Ct. 704, 714-16 (2011). As a result, we often see the administrative agencies making, interpreting, *and* enforcing the law.

To a large extent, this is necessary to the proper functioning of the modern administrative state. In complex regulatory regimes, Congress cannot anticipate every problem that might arise. Nor can courts fill in the policy gaps that Congress leaves open. As a result, it is necessary that Congress be able to delegate a certain amount of its policy-making function to administrative agencies, particularly on matters that involve agency expertise. And it is equally necessary for courts to accord a certain amount of deference to the agencies' exercise of that delegated power. But at the same time, there *must* be some kind of judicial check. For otherwise, we risk unduly concentrating all three powers of government in the Executive Branch alone.

This, in a nutshell, is the dilemma of administrative law: how to balance the dual needs for judicial deference to, and judicial oversight of, the political branches of our government. At first blush, this might appear to be a dry topic best left to judges and academics. But in truth, it goes to the heart of our system of separated powers. If we strike the wrong balance—if we allow excessive and unchecked delegation to administrative agencies—we risk transforming our system of government into something it was never meant to be. It is, therefore, both necessary and appropriate for Congress in general—and this Subcommittee in particular—to continually review the balance that we have struck and, where necessary, recalibrate and adjust that balance.

With that basic background in mind, I would like to focus on three areas of administrative law where, in my view, recalibration and readjustment may be warranted: (1) formal versus informal rulemaking; (2) judicial deference to agency interpretations of law; and (3) judicial enforceability of statutes designed to ensure that agencies engage in reliable rulemaking that considers the burdens of regulation. In each of these cases, the pendulum has swung far in the direction of increased agency power.

1. Formal Versus Informal Rulemaking. Today, informal rulemaking has become the norm. Congress passes a general law. The President, through an administrative agency, implements that law through informal rulemaking procedures, pursuant to which it notifies the public of the proposed regulation and allows for a period of written public comment. The agency then finalizes the rule. And the judiciary upholds it unless it is "arbitrary and capricious." *See* The Administrative Procedure Act ("APA"), 5 U.S.C. § 706(2)(A). This regulatory scheme thus gives the judiciary a limited role in policing the power of the regulatory agencies.

Consider, however, the formal rulemaking alternative, which provides a more rigorous and transparent administrative process followed by increased, yet still deferential, judicial review. Under the formal rulemaking process, the agency holds an open hearing on its proposed regulation, during which interested parties may not only submit their views in writing, but may also testify and question witnesses. After the agency finalizes the rule, the judiciary reviews it to ensure the agency's factual conclusions are supported by "substantial evidence." APA § 706(2)(E). This is hardly an intrusive standard of review, as courts must uphold the regulation if the agency's decision is supported by "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Consol. Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938). Yet formal rulemaking is rarely, if ever, used.

In my view, this balance—where nearly all agency rulemaking is subject only to "arbitrary and capricious" review—warrants reconsideration. Under formal rulemaking, agencies *still* have broad leeway to implement Congress's mandates, and courts *still* defer to agencies' judgments. But formal rulemaking provides a greater level of transparency and accountability and closer judicial oversight. It is therefore worth considering whether (a) formal rulemaking should be used more, or (b) the "substantial evidence" standard should be extended to informal rulemaking proceedings.

2. Judicial Deference to Agency Interpretations of Law. Another area in which the scale has tipped far in the direction of deference is the standards courts apply when reviewing agency interpretations of law. In 1944, the Supreme Court acknowledged the common-sense principle that the level of deference a court should accord to an agency interpretation is proportional to the

interpretation's persuasiveness, as demonstrated by the agency's thoroughness, level of expertise, formality, and consistency. *See Skidmore v. Swift & Co.*, 323 U.S. 134, 139-40 (1944). Since then, however, the Supreme Court has progressively increased the level of deference accorded to agencies and also expanded the circumstances in which such deference is warranted.

Under the most common rule, articulated by the Supreme Court in *Chevron, U.S.A., Inc. v. Natural Resources Defense Council*, 467 U.S. 837, 842-44 (1984), courts may ask whether the statute at issue is ambiguous and, if so, whether the agency's interpretation reflects a "permissible" interpretation of the law. Even more deferential than *Chevron*, however, is the standard established in *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410, 414 (1945), and *Auer v. Robbins*, 519 U.S. 452, 461 (1997), which holds that an agency's interpretation of its own regulation is "controlling . . . unless it is plainly erroneous or inconsistent with the regulation." *Seminole Rock*, 325 U.S. at 414. Similarly, the Court held in *Baltimore Gas & Electric Co. v. Natural Resources Defense Council*, 462 U.S. 87, 103 (1983) ("*BGE*"), that a reviewing court must be "at its most deferential" when reviewing an agency's scientific conclusions. *Skidmore*, in contrast, is now considered the *lowest* level of deference applicable to agency interpretations of law, rather than the standard rule it was intended to be.

Again, judicial deference is both important and appropriate. The question, however, is whether the balance has tilted too far in favor of unchecked agency discretion.

In light of this, it merits considering whether administrative law has struck the right balance between judicial deference and oversight and how the applicable standards could be clarified. For example, Congress might consider: (a) clarifying that *Skidmore* deference applies where an agency fails to adhere rigorously to its own procedures or those required by the APA; (b) clarifying the standard courts should apply when determining whether a regulation is "permissible" under *Chevron*'s second step; or (c) streamlining the applicable levels of deference, such that *Skidmore* applies unless Congress has explicitly delegated lawmaking authority, in which case *Chevron* applies. There are, undoubtedly, other possibilities. It is, moreover, entirely appropriate for Congress to undertake this assessment. After all, the varying deference doctrines are, at bottom, rules of interpretation—mechanisms by which courts assess what *Congress* intended when passing a law. It is therefore appropriate for Congress to provide the judiciary with guidance on how, going forward, courts should discern this legislative intent.

3. Judicial Enforceability of Certain Statutes. Finally, Congress has, from time to time, enacted specific statutes aimed at ensuring that agencies engage in more rigorous and transparent analysis before promulgating burdensome regulations. For example, the Information Quality Act ("IQA"), Pub. L. No. 106-554, § 515 (2001), seeks to ensure that the information on which agencies rely meets standards of reliability. Likewise, the Regulatory Flexibility Act ("RFA"), 5 U.S.C. §§ 601 *et seq.*, aims to ensure that agencies consider the economic impact of regulation on small businesses. These targeted statutory regimes are thus intended to ensure that, in specified areas, agencies engage in the rigorous analysis that the public expects before the government imposes potentially burdensome and costly regulations. The problem, however, is that while these statutes serve the most salutary of purposes, their effectiveness is limited. As construed by the courts, the ability of parties to enforce the IQA is very limited. And the RFA's terms accord agencies wide discretion to determine when and how it applies. These too, therefore, are areas where recalibration and readjustment may be warranted.

In sum, in the modern administrative state, courts must accord deference to the discretion of agencies if they are to fulfill their congressionally delegated task of interpreting and enforcing laws enacted by Congress. But in order to ensure that our basic system of government is preserved, Congress must, at the same time, ensure effective judicial oversight of agency discretion. In recent years, the balance has tipped decisively in favor of agency discretion. I therefore believe that some form of legislative recalibration should be considered.

I elaborate on these issues in more detail in the discussion below.

A. Formal Versus Informal Rulemaking

The APA provides for two types of procedures for promulgating substantive rules: formal procedures and informal ones. Both allow for significant judicial deference to an agency's ultimate conclusion. The formal procedures, however, provide greater transparency into the agency's decision-making process by requiring on-the-record hearings during which witnesses testify and may be cross-examined, as well as a higher (though still deferential) standard for judicial review. In contrast, in informal proceedings, the agency's rationale and analysis is often difficult to discern, and regulations are subject to a lower standard of review. In modern administrative law, however, formal rulemaking has all but disappeared. In my view, this is an instance where Congress should consider whether the pendulum has swung too far in favor of agency discretion.

1. Formal Versus Informal Rulemaking. There are two primary differences between formal and informal rulemaking, one procedural, and the other relating to the standard for judicial review.

First, as a procedural matter, formal rulemaking is more rigorous and transparent than informal rulemaking. The formal rulemaking procedures, which are governed by APA §§ 556 and 557, require an open hearing where interested parties can testify and can cross-examine adverse witnesses. Formal rulemaking is often called "rulemaking on a record" because these trial-type proceedings provide much more opportunity for the agency to develop a formal record before issuing a final rule. In contrast, informal rulemaking, also called "notice-and-comment" rulemaking, does not require an agency to hold oral hearings, nor do agencies typically do so. Instead, an agency must give written notice of "either the terms or substance of the proposed rule or a description of the subjects and issues involved," APA § 553(b)(3); allow "interested persons an opportunity to participate" in the rulemaking through submission of written comments, APA § 553(c); and, when an agency issues a final rule, include "a concise general statement of . . . basis and purpose," *id.* Thus, formal rulemaking allows interested parties to have greater input into the rulemaking process.

Second, and relatedly, informal rules are subject to a more deferential standard of review than formal rules. Under APA § 706(2)(A), courts may set aside informal rules only if they are "arbitrary and capricious." This standard requires that the agency engage in "reasoned decision-making," *Professional Drivers Council v. Bureau of Motor Carrier Safety*, 706 F.2d 1216, 1220 (D.C. Cir. 1983), and courts must "consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment," though the court "is not empowered to substitute its judgment for that of the agency," *Citizens to Preserve Overton*

Park, Inc. v. Volpe, 401 U.S. 402, 416 (1971). As the Supreme Court has explained, "[n]ormally an agency rule would be arbitrary and capricious 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." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

In contrast, for rules adopted through formal procedures, the APA provides an additional layer of review. In addition to "arbitrary and capricious" review under APA § 706(2)(A), courts must also examine the evidentiary basis for formal rules to ensure that they are supported by "substantial evidence." APA § 706(2)(E). This "substantial evidence" standard is also deferential—though less so than the "arbitrary and capricious" standard—and requires a court to ask whether the agency's decision is supported by "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Consol. Edison Co.*, 305 U.S. at 229. This standard thus allows a court to look at the whole record and assess whether there is evidentiary support for the conclusions drawn by the agency. Consequently, formal rules are more likely to be supported by the evidentiary record than informal ones, since agencies know that a formal rule that lacks evidentiary support will be more vulnerable to legal attack.

In light of these differences, and the apparent benefits of the formal rulemaking process, one might expect to see a fair number of rules promulgated pursuant to the formal procedures. That, however, is most certainly not the case. The formal procedures only apply when the agency's authorizing statute explicitly requires them, *see United States v. Florida East Coast Railway Co.*, 410 U.S. 224 (1973), which is quite rare. Consequently, virtually all agency rulemakings today take place through informal "notice-and-comment" rulemaking.

2. Recalibrating the Balance. Although informal rulemaking procedures give agencies a means by which they can issue rules quickly and efficiently, it should go without saying that enacting rules quickly is often far less important than striking the right policy balance. Indeed, while there are surely some areas where expeditious agency action is paramount, I would expect that for the great majority of rules, striking the right policy balance is more important that reaching a quick result. Thus, administrative efficiency cannot, in my view, justify the virtual extinction of the formal rulemaking process. The balance between formal and informal rulemaking is therefore an area where a recalibration is warranted.

There are, of course, numerous ways in which the balance could be adjusted. One possibility would be a renewed emphasis on formal rulemaking procedures by Congress. This would serve to enhance both public participation in the rulemaking process and judicial oversight through "substantial evidence" review. Another possibility would be to expand the "substantial evidence" standard of review to informal rulemakings. This would preserve the more streamlined "notice and comment" structure but, by increasing the level of judicial oversight, incentivize agencies to engage in more rigorous analysis in order to ensure that their regulations survive increased judicial scrutiny. Or some combination of these approaches could be considered. But regardless of how the balance is struck, the important point is that Congress should be vigilant to ensure that the regulatory process is both rigorous and transparent, so that

agency determinations receive the level of scrutiny commensurate with the administrative agencies' responsibility to Congress and the public.

B. Judicial Deference to Agency Interpretations of Law

When an agency interprets a law that the agency is charged with administering, courts normally defer to the agency's interpretation. Currently, courts employ different standards of deference to agency interpretations, depending on the type of interpretation under review—what some scholars have referred to as a "continuum of deference."[1] Over time, however, the balance between deference and judicial oversight has tended strongly toward deference and away from rigorous judicial review. This shift toward ever-increasing deference weakens the primary check on agency discretion. This too, then, is an area where Congress should consider whether current administrative law standards have struck the proper balance between agency discretion and judicial oversight.

1. Standards of Deference. In *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944), the Supreme Court established the common-sense principle that agency interpretations of law "constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance." *Id.* at 140. The level of deference a court should show to an agency interpretation, the *Skidmore* court explained, "depend[s] upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control." *Id.* *Skidmore* thus called for a sliding-scale approach to deference, whereby the level of respect a court accorded to an agency interpretation was proportional to the interpretation's persuasiveness.

Since *Skidmore*, however, the Supreme Court has recognized several categories of agency interpretation to which it has accorded heightened deference—deference that, unlike *Skidmore* deference, does, in fact, give agency interpretations the "power to control." *Id.* The most well-known of these categories is the two-step analysis first developed in *Chevron, U.S.A., Inc. v. Natural Resources Defense Council*, 467 U.S. 837, 842-44 (1984). This so-called "*Chevron* deference" applies whenever an agency interprets its statutory delegation of lawmaking authority. *United States v. Mead Corp.*, 533 U.S. 218, 229-30 (2001). Under *Chevron*, a court first determines "whether Congress has directly spoken to the precise question at issue." *Id.* at 843. Next, if "the statute is silent or ambiguous with respect to the specific issue," courts ask whether the agency's interpretation of the ambiguous statute is "permissible." *Id.* If so, the court is to defer to the agency's determination. *Id.*

Even more deferential than *Chevron* is the standard established in *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410, 414 (1945) and *Auer v. Robbins*, 519 U.S. 452, 461 (1997), which applies when a court is reviewing an agency's interpretation of one of its own regulations. When applying *Auer* deference, an agency's interpretation of its own properly issued regulation is "controlling . . . unless it is plainly erroneous or inconsistent with the regulation." *Seminole Rock*, 325 U.S. at 414. One commentator has described this doctrine as providing that

[1] William N. Eskridge, Jr. & Lauren E. Baer, *The Continuum of Deference: Supreme Court Treatment of Agency Statutory Interpretations from* Chevron *to* Hamdan, 96 Geo. L.J. 1083 (2008).

"whenever an agency applies a regulation—whether to seek a civil penalty through an enforcement proceeding, to adjudicate a claim for federal benefits, or even to determine the means of calculating a prisoner's incarceration—the governing regulation means what the agency says it means unless the reviewing court can conclude that the agency is 'plainly wrong,'" thereby "mak[ing] it easier for the agency simply to issue vague regulations and then put off difficult policy questions until the relatively less demanding implementation stage."[2]

Similarly, in *Baltimore Gas & Electric Co. v. Natural Resources Defense Council*, 462 U.S. 87, 103 (1983), the Supreme Court adopted a yet more deferential standard governing agency judgments on scientific matters. Called "super deference" by some,[3] the Court held that a reviewing court must be "at its most deferential" when reviewing agency interpretations that involve judgments "within its area of special expertise, at the frontiers of science." *BGE*, 462 U.S. at 103. Finally, some courts have held that courts should defer to an agency's determination of whether it has regulatory jurisdiction in the first place. *See, e.g.*, *United Transp. Union v. Surface Transp. Bd.*, 183 F.3d 606, 612-13 (7th Cir. 1999).[4]

As these developments show, since *Skidmore*, courts have become increasingly deferential to agency interpretations of law. Comparing *Skidmore* with *Chevron*, for example, reveals the greater degree to which courts defer to agency interpretations under the *Chevron* analysis. Under *Skidmore*, the level of deference given to an agency's interpretation is proportional to the persuasiveness of the agency's interpretation. Courts thus consider the agency's interpretive process in light of the text under consideration. Under *Chevron*, however, agencies may get *Chevron* deference even when the agency's interpretation has been inconsistent over time, *see National Cable & Telecommunications Ass'n v. Brand X Internet Services*, 545 U.S. 967, 981 (2005), the agency's interpretation was made significantly after enactment of the statute, *see Smiley v. Citibank (South Dakota), N. A.*, 517 U.S. 735, 740 (1996), or the interpretation was prompted by litigation, *see id.* at 741. The question for the court under *Chevron* is not whether the agency's interpretation is the best, or even the most sensible, reading of the statute, but whether it is a "permissible" one. To be sure, this does not eliminate judicial review; courts can and do invalidate regulations under *Chevron*. *See, e.g.*, *AT & T Corp. v. Iowa Utils. Bd.*, 525 U.S. 366, 388-92 (1999). Compared to *Skidmore*, however, *Chevron* does significantly constrain such review.

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[2] *See* John F. Manning, *Constitutional Structure and Judicial Deference to Agency Interpretations of Agency Rules*, 96 Colum. L. Rev. 612, 615-16 (1996). For example, regulations direct that payments for health services covered by Medicare must be "reasonable," defining "reasonable" to include those costs that are "necessary and proper" or "appropriate and helpful," and leaving further elaboration to other agency pronouncements. 42 C.F.R. § 413.9(a), (b)(2). Likewise, regulations under HIPAA governing notice to an individual of a breach of private health information require notice if the risk of harm to the individual is "significant," leaving clarification of the situations where notice is required to further agency action. 45 C.F.R. § 164.402(1)(i).

[3] *See* Emily Hammond Meazell, *Super Deference, the Science Obsession, and Judicial Review as Translation of Agency Science*, 109 Mich. L. Rev. 733 (2011).

[4] One commentator has noted that "[t]o accord such power to agencies would be to allow them to be judges in their own cause, in which they are of course susceptible to bias." Cass R. Sunstein, *Law and Administration after* Chevron, 90 Colum. L. Rev. 2071, 2099 (1990); *see also* Nathan Alexander Sales & Jonathan H. Adler, *The Rest is Silence:* Chevron *Deference, Agency Jurisdiction, and Statutory Silences*, 2009 U. Ill. L. Rev. 1497, 1518 (describing different approaches taken by the federal courts of appeals).

Auer and *BGE* deference, moreover, go even further. Indeed, *Auer* potentially allows an agency to insulate its interpretation from judicial review by interpreting an ambiguous statute with its own ambiguous regulation and then interpreting the ambiguous regulation. *See Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 525 (1994) (Thomas, J., dissenting); *Christensen v. Harris Cnty.*, 529 U.S. 576, 587-88 (2000).[5] Likewise, some commentators have noted that the highly deferential *BGE* standard "incentivizes agencies to cloak their true reasoning behind an unassailable mantle of science."[6]

To be sure, some level of deference serves important purposes. For example, agency decisions often involve technical and complex issues that require the balancing of competing priorities and which courts are not equipped to handle appropriately. In such circumstances, where agencies promulgate rules through transparent and rigorous administrative processes, it is necessary and appropriate to defer to their resolution of these issues. Nonetheless, effective judicial review of agency action is also essential to the proper functioning of the modern administrative state, since it ensures that Congress has the ultimate say on important matters of public policy. This, in turn, creates greater legitimacy in the administrative process by ensuring that agencies operate within the bounds of the discretion accorded them by Congress.[7]

In addition, as a practical matter, effective judicial review should increase the quality of agency action. For example, the prospect of judicial review should encourage agencies to be more attentive to policy limits imposed by Congress, thus increasing the democratic legitimacy of the regulations. Likewise, judicial review encourages thoroughness and rigor in the decision-making process, making it more likely that the regulations will in fact solve the problems at which they are aimed without creating new and/or unintended ones. If agencies are aware that unsupported conclusions will face skepticism in the courts, they will be more likely to spend the time and resources necessary to ensure that their conclusions are well-founded. Excessive deference, on the other hand, diminishes an agency's incentives to adhere closely to its statutory mandate and engage in a thorough decision-making process.

Consequently, it is important to constantly assess whether administrative law doctrine reflects the proper balance between agency discretion and judicial review.

2. Recalibrating the Balance. Because the pendulum has swung far in favor of agency deference, now may be an appropriate time for Congress to consider whether it should increase, to some extent, the role of the courts in this process. As in other areas, there are numerous ways to accomplish this goal.

One possibility that some commentators have suggested would be to streamline the applicable standards of deference. Under this approach, *Chevron* deference would apply only where Congress has explicitly delegated lawmaking authority, rather than a general authority to

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[5] *See* Manning, *supra* note 2, at 615-17.

[6] Meazell, *supra* note 3, at 763-64.

[7] *See* Cass R. Sunstein, *On the Costs and Benefits of Aggressive Judicial Review of Agency Action*, 1989 Duke L.J. 522, 525.

implement and interpret a statute. In other cases, *Skidmore* deference would apply, as it is not clear that additional standards, such as those articulated in *Auer* and *BGE*, are necessary.[8]

Another possibility is to limit *Chevron* deference to agency decisions made in strict compliance with an agency's own internal administrative processes and those required by the APA. Absent strict adherence to administrative procedure, *Skidmore* deference applies. This approach reflects the view that rigorous and transparent adherence to administrative processes serves to enhance the democratic legitimacy of regulations, and absent such adherence to procedures, closer judicial scrutiny is warranted.

Finally, with respect to *Chevron* deference itself, Congress might consider clarifying the standard of review. Currently, the "permissible" standard applied under *Chevron*'s second step is open-ended and vague. Congress could attempt to specify factors a court should consider when determining if a regulation does, in fact, reflect a "permissible" interpretation of a statute.

These are just a few possibilities, some of which may be more workable and/or effective than others. But the basic issue that warrants legislative attention is the need to ensure a proper level of judicial oversight of agency discretion. Otherwise, we risk having both Congress and the courts effectively excluded from the regulatory process.

C. Enhancing Current Statutory Controls on Agency Action

Congress has, from time to time, enacted targeted statutes aimed at ensuring that agency regulations are promulgated through more rigorous and transparent procedures. Two good examples of this are the Information Quality Act and the Regulatory Flexibility Act. The problem, however, is that the effectiveness of these statutes is limited. The IQA lacks sufficient mechanisms to allow judicial enforcement. And the RFA accords agencies wide latitude to determine whether and to what extent it applies. The benefits of such statutes, therefore, could be enhanced by creating better avenues of enforcement.

1. Information Quality Act. The Information Quality Act, also called the Data Quality Act, is designed to ensure the reliability of the information agencies use to develop regulations. It requires the Office of Management and Budget ("OMB") to issue guidelines that "provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies." 44 U.S.C. § 3516 note (a). The OMB guidelines direct agencies to ensure that the quality of the information on which they rely is at a level "appropriate to the nature and timeliness of the information to be disseminated." *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies*, Republication, 67 Fed. Reg. 8452, 8458 (Feb. 22, 2002). They require that agencies both adopt appropriate standards of quality for the types of information the agency disseminates and put in place a review process to ensure the quality of the information before it is disseminated. *Id.* at 8458-59. And, for agencies involved in disseminating "influential scientific, financial, or statistical information," the guidelines call for a "high degree of transparency" about the

[8] *See* Eskridge & Baer, *supra* note 1, at 1183-89; Manning, *supra* note 2, at 686-90.

agency's data and methods to facilitate the reproduction of the information by third parties. *Id.* at 8460.

The guidelines provide for an administrative review process through which a party can challenge the quality of an agency's information, and affected parties can appeal an unsuccessful challenge within the agency. *Id.* at 8459. The IQA, however, does not provide any mechanism of judicial review of an agency's determination, and courts thus far have held that the IQA does not create a private right of action. *See, e.g., Salt Inst. v. Leavitt*, 440 F.3d 156, 159 (4th Cir. 2006).

2. Regulatory Flexibility Act. The Regulatory Flexibility Act seeks to protect small businesses from some of the burdens of federal regulation by requiring agencies to engage in procedures designed to measure the impact on small businesses when an agency proposes a new rule. When an agency first proposes a new rule, the RFA requires it to publish in the Federal Register an "initial regulatory flexibility analysis" that includes the agency's reasoning for the proposed rule, its goals, the types and number of entities that will be affected, and a description of anticipated costs of compliance. 5 U.S.C. § 603(b). The agency must also identify any preexisting rules that might conflict or overlap with the proposed rule and any less burdensome alternatives to the proposed rule that would achieve the agency's objective. *Id.* If the agency issues a final rule, it must then include a "final regulatory flexibility analysis" which explains the need for and objectives of the rule, summarizes and evaluates the issues raised during the public comment period, lists the changes made as a result of the comments, and contains a statement as to why the agency rejected alternative proposals. 5 U.S.C. § 604(a).

An agency may avoid these requirements, however, by certifying that the regulation will not have a "significant economic impact on a substantial number of small entities." 5 U.S.C. § 605(b). The RFA, moreover, does not define when a regulation has had a "significant economic impact on a substantial number of small entities," and instead leaves to agencies the task of determining when their regulations trigger the requirements of the RFA. President Bush's Executive Order 13272 of August 2002 sought to address this issue by requiring agencies to develop procedures for determining whether a regulation has a "significant economic impact on a substantial number of small entities." Exec. Order No. 13272, Proper Consideration of Small Entities in Agency Rulemaking, 67 Fed. Reg. 53461 (Aug. 16, 2002). Still, however, Executive Order 13272 did not provide for a uniform definition or set of procedures for determining when a rule triggers the RFA's requirements, and to date no such uniform procedures exist.

3. Recalibrating the Balance. Both the IQA and RFA are salutary attempts to constrain the discretion afforded agencies to ensure that they engage in reliable rulemaking that is conscious of the burdens inflicted by regulation. Unfortunately, however, the effectiveness of each is constrained by the limitations on the ability to enforce their mandates. Here again, therefore, is another area where Congress should consider whether to strengthen these statutes to ensure that agencies work within the context of the priorities Congress has set for them.

As with the other areas discussed above, there are many different ways to effectuate this reform. For example, Congress could consider incorporating the IQA and/or the RFA into the APA itself, such that a failure to adhere to the requirements of these statutes constitutes a violation of the APA. Another possibility for the IQA would be to provide for a private right of

action and judicial review of challenges to data quality under the IQA. With respect to the RFA, Congress could expand the universe of regulations to which the RFA's procedures apply. After all, there is no obvious reason why the more rigorous analysis required by the RFA should apply only where large numbers of small businesses are affected. Or Congress could adopt a uniform procedure for determining when a rule has a "significant economic impact on a substantial number of small entities."

In short, the IQA and RFA recognize and attempt to remedy specific shortcomings of the regulatory process, but are constrained in their effectiveness by limited means of enforcement. This too, then, is an area where Congress should consider mechanisms for ensuring that the goals of these statutes are, in fact, attained.

D. Conclusion

In the modern administrative state, courts must necessarily defer to the discretion of administrative agencies if agencies are to fulfill their congressionally delegated task of interpreting and enforcing laws enacted by Congress. But effective judicial oversight is equally necessary to ensure that this discretion does not become a license to fundamentally transform our system of separated powers. To this end, administrative law must strike a delicate balance between congressional delegation, agency discretion, and judicial review. Given the importance of this mission, we must be vigilant in reviewing existing legal regimes and, where necessary, recalibrating the balance. As I have explained, in several areas, the balance has tipped far in favor of agency discretion. It is therefore appropriate to consider whether reforms are needed to increase judicial oversight of the regulatory process while, at the same time, ensuring that Congress and the Executive Branch have the tools necessary to confront and resolve the problems of the day. In my view, those two goals are not inconsistent with, but rather are and should be, mutually reinforcing of one another.

This concludes my prepared written statement. I would be happy to answer any questions you may have.

Mr. GOWDY. And third, we will have Professor Matthew Stephenson from Harvard Law School. Mr. Stephenson is a professor at Harvard where he teaches administrative law, legislation, and regulation, and political economy of public law. His research focuses on the application of positive political theory to public law, particu-

larly in the areas of administrative procedure, judicial institutions, and separation of powers.

Prior to joining the Harvard Law School faculty, Professor Stephenson clerked for senior Judge Steven Williams on the U.S. Court of Appeals for the District of Columbia circuit and for Justice Anthony Kennedy on the Supreme Court of the United States. He received his Ph.D. In political science and his J.D. from Harvard in 2003 and his B.A. From Harvard in 1997. We are glad to have you, Professor Stephenson, and we will recognize you for your 5 minutes.

TESTIMONY OF MATTHEW C. STEPHENSON, PROFESSOR, HARVARD LAW SCHOOL

Mr. STEPHENSON. Thank you Chairman Gowdy, Ranking Member Quigley, Members of the Subcommittee. I appreciate your inviting me here today to speak on these very important issues of administrative process.

These procedural issues may seem arcane and technical, but as Members of the Subcommittee are well aware, they are critically important for the welfare of the American people. I think it is important to keep in mind when we have these discussions about regulatory process, that there is an important distinction between our views about desirable regulatory policy and desirable regulatory process. The same administrative procedures that might regulate and slow down the adoption by agencies of rules and regulations that impose new mandates on the private sector would likewise regulate and perhaps slow down deregulatory initiatives or the replacement of command-and-control style regulatory schemes with more market-based incentive schemes.

The same practices of judicial review that might empower courts to strike down agency regulations that in the judge's views are not supported by sound science might also empower Federal judges to strike down agency efforts to deregulate or alter regulatory burdens and, in some circumstances, even leave Federal courts to require agencies to adopt new regulations.

I think in light of this useful example to keep in mind is President Ronald Reagan's efforts shortly after he was elected to use the notice and comment rulemaking process to implement his vision of regulatory policy. At the time, it was progressive critics who charged that there was sometimes too little process and not enough judicial scrutiny.

The more general point—and this is a point on which I believe my fellow witnesses would agree, even if we might disagree on some of the particulars—-is that we should be willing to advocate the same procedural rules today that we would have advocated in 1980.

In light of that, let me now turn to some of the more specific proposals that Members of the Committee have raised as worth exploring. One is the suggestion that more administrative rulemakings be governed by the APA's formal rulemaking procedures rather than its so-called informal or notice and comment rulemaking procedures. In my view, such a move would be likely both unnecessary and unwise; unnecessary, because the so-called informal rulemaking process is, in fact, heavily proceduralized. It

is true that it does not typically involve adversarial oral cross-examination, but there is extensive opportunity for parties to provide their views to criticize agency science, to criticize agency policy choices, and to compel agencies to respond to all reasonable such comments, criticisms, and proposed alternatives, to the point where most people would refer to this process—this notice and comment process as somewhat akin to a paper hearing.

What formal rulemaking would add principally—although there are other things as well—would be adversarial cross-examination. There is to my knowledge very little evidence that adversarial cross-examination is especially well-suited for the sorts of issues that typically come up in major rulemakings, whatever its benefits in other contexts. And what limited systematic study of the issue that there is seems to corroborate this and suggest that the principal result of more formalized procedures, as Ranking Member Quigley mentioned in his opening remarks, is greater delay; delay that, as I mentioned earlier it is important to keep in mind, would not only delay or deter the imposition of new regulatory burdens but would also delay or deter the relaxation or modification of regulatory burdens. In other words, the principal effect of requiring formal rulemaking would be to freeze the regulatory status quo—whatever that happens to be at the moment—in place or at least make it very difficult and slow to change.

With respect to judicial review, my comments would be somewhat similar. Here my views are less strongly held. I think there are important questions about judicial review as currently practiced, but it is important to recognize there does exist substantial judicial oversight of agency rulemaking right now. Imposing a more or heightened standard of judicial review would have the effect perhaps of shifting more power over regulatory policymaking from agency policy experts to agency lawyers, and more power over regulatory policymaking from administrative agencies and perhaps also this body to the Federal courts.

Now, I certainly wouldn't advocate eliminating such meaningful judicial review as some of my colleagues in the academy might. But I do think the Committee should take into account those potential drawbacks before mandating a heightened standard of review this time. Thank you very much.

Mr. GOWDY. Thank you, Professor.

[The prepared statement of Mr. Stephenson follows:]

Statement of Matthew C. Stephenson
Professor of Law, Harvard Law School

before the

Subcommittee on Courts, Commercial and Administrative Law
of the
House Committee on the Judiciary, 112th Congress

on

"Formal Rulemaking and Judicial Review: Protecting Jobs and the Economy with Greater Regulatory Transparency and Accountability"

May 31, 2011

Chairman Coble, Ranking Member Cohen, and Members of the Subcommittee, thank you for inviting me to testify on the appropriate role of formal rulemaking procedures and judicial review in the federal regulatory system. These topics may seem obscure and technical, but as the Members of this Subcommittee are well aware, the choices that our government makes about the administrative process have enormous consequences for the welfare of the American people.

Attention to questions of administrative procedure has increased over the last few years. This attention is largely due to profound disagreements among our citizens, and among our elected representatives, about federal regulatory policy. President Obama's regulatory philosophy and strategy differ from those of President Bush, and these differences are manifest in the current administration's exercise of its rulemaking authority under statutes like the Clean Air Act and the Occupational Safety and Health Act. Moreover, recent legislation – most notably the Dodd-Frank Wall Street Reform and Consumer Protection Act and the Patient Protection and Affordable Care Act – authorize federal agencies to promulgate important new regulations. Many citizens support these regulatory initiatives. Others do not. These disagreements over regulatory policy are likely to be the focus of sustained political debate for some time to come, as they should be in a healthy democracy. These differences in perspective have also led to more intense scrutiny into the *process* by which federal agencies make regulations.

While this increased attention to process is welcome, we must be careful to distinguish our views of desirable regulatory *policy* from our assessment of desirable regulatory *process*. In the current climate, those who oppose the substance of the Obama Administration's initiatives in areas like health care, financial regulation, and environmental protection may be inclined to advocate more demanding procedural restrictions and judicial oversight of agency action, while those who favor the President's initiatives might tend to take the opposite position. But when thinking about the design of regulatory institutions, it is

important to take the long view. The same procedural safeguards that slow down the adoption of rules that impose new regulatory requirements also slow down the adoption of rules that relax regulatory requirements or that replace command-and-control regulations with market-based regimes. The same judicial review provisions that empower federal judges to strike down regulations that, in the judges' view, are not supported by sound science also empower judges to strike down rules that ease economic burdens on industry, or even to compel agencies to impose new regulations, if the judges conclude that the failure to regulate is irrational.

Indeed, it is helpful to recall that thirty years ago, President Reagan, like President Obama, initiated an array of notice-and-comment rulemaking proceedings in order to align federal agency policy with the President's regulatory philosophy. Many of these rulemakings were challenged in court by progressives who argued that they were procedurally invalid, substantively irrational, or both. Then, as now, Congress, the courts, and the American people confronted difficult choices about the about the appropriate procedural requirements for agency rulemaking and the appropriate role of judicial oversight. President Reagan and President Obama may have different regulatory approaches, but the basic questions about administrative procedure and the standard of judicial review are essentially the same. When we debate these questions, then, we should be sure that the positions we take do not depend on who is in the White House at the moment. We should be willing to advocate the same institutional rules today that we would have advocated in 1980, and vice versa.

I gather that the Subcommittee is interested in whether the prevailing law on rulemaking procedure and judicial review, particularly the default rules laid out in the Administrative Procedure Act (APA), are sufficiently stringent, or whether they are instead too lax. More specifically, my understanding is that the Subcommittee is interested in exploring (1) whether it would be wise to require that some or all federal agencies use *formal rulemaking*, as opposed to informal ("notice-and-comment") rulemaking; and (2) whether it would be wise to instruct the

federal courts to review agency regulations more rigorously. Would such reforms, as the title of this hearing suggests, better protect jobs (and other aspects of the welfare of the American people) and better promote transparency and accountability?

While these are hard questions, I believe that the answer to the first question is clearly no: the additional benefits of requiring formal rulemaking rather than notice-and-comment rulemaking are minimal, and the costs are likely high – even for someone who is skeptical of the value of many of the specific rules currently under consideration in the Obama Administration.

On the second question, my answer is more tentative. Judicial review of agency regulations, as currently practiced, is far from perfect. It is not as consistent or predictable as it ought to be, and there is disturbing evidence that judges' personal policy preferences play a greater role than they should when judges review agency regulations. That said, while improvements are certainly possible, courts for the most part have struck a reasonable balance between conflicting goals, and any move toward requiring more demanding judicial review should at least take into account a number of possible drawbacks.

The balance of my written statement will flesh out these points. I will first address the question whether Congress should require greater use of formal rulemaking. I will then turn to the question whether Congress should mandate a more stringent, less deferential standard of judicial review.

I. SHOULD CONGRESS REQUIRE GREATER USE OF FORMAL RULEMAKING?

The great challenge of administrative law is to design institutions that will allow the American people to reap the advantages of delegation to administrative agencies – advantages that include greater expertise, more flexibility, and a healthy insulation from day-to-day political horse-trading – while avoiding or limiting the risks of arbitrary, ill-considered, unaccountable

bureaucratic policymaking.[1] Our system relies heavily on carefully-designed administrative procedures to try to achieve these goals.[2] But correctly calibrating the degree of procedural formality is quite difficult. If the procedural safeguards governing agency decisions are too weak, agencies may fail to give due consideration to the interests of all the parties who might be affected by agency action, and may be tempted to disregard or downplay inconvenient evidence or arguments that cut against the agencies' preferred policies. On the other hand, if procedural requirements are too demanding, agencies may find themselves unable to take effective action to fulfill their responsibilities, or may be tempted to circumvent the required procedures altogether.

For agency rulemaking, the APA lays out two basic sets of procedural requirements. So-called "informal rulemaking," also known as "notice-and-comment rulemaking," is governed by § 553 of the APA, which requires that agencies publish advance notice of any proposed rule, give all interested parties an opportunity to submit written comments, and include with every final rule a statement explaining the rule's basis and purpose.[3] So-called "formal rulemaking," governed by §§ 556 and 557 of the APA, requires extensive hearings, usually including oral testimony and cross-examination, as well as a formal record that forms the exclusive basis for final agency decisions.[4] An agency rulemaking must be formal if, but only if, the statute authorizing the rulemaking specifically requires that the rule be made "on the record after opportunity for an agency hearing."[5] The Supreme Court has interpreted that requirement stringently: a mere statutory requirement that an agency rule be made "after a

[1] *See* JOHN F. MANNING & MATTHEW C. STEPHENSON, LEGISLATION AND REGULATION 379-84 (Foundation Press 2010). Because my book with Professor Manning covers many of the topics relevant to this statement, including citations to relevant case law and scholarly literature, for convenience I will refer to the relevant sections of the book throughout these footnotes. The cited pages of the book contain additional references, which for brevity's sake I will not cite separately in the footnotes in this statement.
[2] *Id.* at 580.
[3] 5 U.S.C. § 553.
[4] 5 U.S.C. §§ 556-557.
[5] 5 U.S.C. § 553(c).

hearing" is not enough to trigger formal rulemaking under the APA. Because very few statutes use the precise "on the record after opportunity for an agency hearing" language, most agency rulemakings are informal rather than formal.[6]

Congress could require that agencies use formal rather than informal rulemaking either by amending individual statutes to include the necessary triggering language, or by amending the APA itself. But doing either would probably be unwise, for three reasons. First, the nominally "informal" notice-and-comment rulemaking process already imposes substantial procedural safeguards on agency rulemaking. Second, the formal rulemaking process, with its emphasis on adversarial proceedings, oral presentations, and cross-examination, is not especially well-suited to broad policy decisions of the sort contemplated in most major rulemakings. Third, the costs and delays associated with formal rulemaking would have an array of undesirable consequences.

A. Agency Rulemaking Is Already Subject to Extensive Procedural Requirements

On learning that most federal agencies enact major regulations through an "informal" process that requires only "notice and opportunity for comment," many lay people might naturally doubt the adequacy of the procedural safeguards. Shouldn't regulations that will affect the welfare of millions of citizens go through a more rigorous vetting process? It turns out, however, that the term "informal rulemaking" is misleading. Nominally "informal" notice-and-comment rulemaking is in fact heavily proceduralized, to the point where many commentators describe this process as a kind of "paper hearing."[7] Agencies must provide a fairly detailed and specific proposal, or set of alternatives, in their initial published notice of proposed rulemaking.[8] This notice must also disclose the scientific or evidentiary basis of the proposal, so that

[6] *See* MANNING & STEPHENSON, *supra* note 1, at 597-98.
[7] *See id.* at 624-25.
[8] *See id.* at 635-36.

the agency's evidence can be subjected to critical scrutiny.[9] Any interested party (indeed, any member of the public) may submit written comments on the agency's proposal. These submissions may criticize the agency's analysis and evidence, and may also suggest alternatives. Under Executive Order 12866, executive branch agencies must also submit proposed rules, along with a detailed cost-benefit analysis, to the Office of Management and Budget for review.[10] If the agency decides to promulgate a final rule, it must provide a detailed written explanation that includes responses to all material comments submitted by interested parties.[11] If an agency fails to respond adequately to criticisms or proposed alternatives submitted by commenters, the agency risks judicial reversal. This creates powerful incentives for agencies to take comments seriously and to provide detailed responses.[12] Furthermore, if the agency decides to change its policy substantially in response to comments, it may have to initiate a new round of notice-and-comment so that all parties have a fair opportunity to critique the new proposal.[13]

While the notice-and-comment process is hardly perfect, few would argue that it fails to provide sufficient transparency or sufficient opportunities for affected parties to compel agencies to address their concerns. Indeed, the more common criticism of notice-and-comment rulemaking is that it is *too demanding* of agencies (although there is some controversy over this point).[14] Given that the notice-and-comment rulemaking process already provides for extensive public participation and agency engagement with all serious concerns or objections, the only thing the formal rulemaking process is likely to add is red tape.

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[9] *See id.* at 614-17.
[10] *See id.* at 550-71.
[11] *See id.* at 621-24.
[12] *See id.*
[13] *See id.* at 626-35.
[14] *See id.* at 624-26.

B. Formal Rulemaking Procedures Are Not Well-Suited to Effective Regulatory Decisionmaking

The hearing requirements laid out in § 556 and 557 of the APA seem designed for individualized determinations, which turn on case-specific facts and benefit from adversarial contestation. They are not terribly well-suited to general policy decisions that require balancing the interests of a large number of potentially interested parties. Therefore, while some individualized determinations may count as "rules" under the APA's technical definition,[15] most agency rulemakings are would benefit more from the quasi-legislative procedures of notice-and-comment rulemaking than from the quasi-judicial procedures of formal rulemaking.

In his testimony at a related hearing before this Subcommittee in February 2011, Mr. Jeffrey Rosen asserted that "[t]here is no better tool than cross-examination [of the sort generally available in formal rulemaking] to expose unsupportable factual assertions and [to] assur[e] the public that only the best science underlies agency action."[16] With all due respect to Mr. Rosen's depth of experience as a litigator and the insightful points he made throughout his testimony, his statement about the purported benefits of face-to-face cross-examination is *itself* an unsupported factual assertion. To my knowledge, there is no systematic evidence demonstrating that adversarial oral cross-examination is the most effective tool for making sound scientific or policy judgments on general issues of the sort addressed in most rulemakings. Indeed, the usual justifications for oral cross-examination, such as the need to assess the demeanor of witnesses, are generally inapposite in the rulemaking context. As Judge Richard Posner explained (albeit in a different context), "[T]rials are to determine adjudicative facts rather than legislative facts. The distinction is between facts germane to the specific

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[15] 5 U.S.C. §551(4).

[16] Prepared Statement of Jeffrey A. Rosen, Hearing on "The APA at 65- Is Reform Needed to Create Jobs, Promote Economic Growth and Reduce Costs?", Subcommittee on Courts, Commercial and Administrative Law, Committee on the Judiciary, U.S. House of Representatives, Feb. 21, 2011, p. 12.

dispute, which often are best developed through testimony and cross-examination, and facts relevant to shaping a general rule, which ... more often are facts reported in books and other documents not prepared specially for litigation or refined in its fires."[17]

In one of the few close examinations of the use of oral cross-examination in agency rulemaking, Judge (then Professor) Stephen Williams found that cross-examination had little positive effect. In those cases where such cross-examination had been required, Judge Williams concluded that it was "doubtful that the use of cross-examination was necessary to clarify ... the critical issues" and, moreover, that even when cross-examination did effectively undermine certain arguments in favor of a rule, that did not matter much because the "enormous quantities of additional data" in the record meant that cross-examination "proved to be of little importance."[18] Judge Williams further pointed out that requiring cross-examination in rulemaking proceedings "may actually tend to frustrate its own supposed goal: elucidation of the issues. Cross-examination virtually assures that high-level agency decision makers will not participate, for they do not have enough time for that sort of enterprise."[19] By contrast, as Judge Williams noted, in major informal rulemaking proceedings, typically the agency head or his highest ranking assistants participate directly.[20]

Cross-examination, and other trappings associated with the formal hearing process, may appeal to lawyers and other skilled oral advocates. Indeed, some scholars have suggested that the provisions for formal procedures in the original APA may have more to do with lawyers' preferences than with anything else. As Yale Law School Professor Alan Schwartz puts it, "lawyers

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[17] Indiana Belt Harbor Railroad Co. v. American Cyanamid Co., 916 F.2d 1174 (7th Cir. 1990).
[18] Stephen F. Williams, *"Hybrid Rulemaking" under the Administrative Procedure Act: A Legal and Empirical Analysis*, 42 UNIVERSITY OF CHICAGO LAW REVIEW 401, 440 (1975).
[19] *Id.* at 444.
[20] *See id.*

[pressing for the APA] preferred generic procedural reform because that introduced a much greater amount of lawyering into the entire federal administrative process than there had been before.... [T]he more procedure there is and the more due process there is, the more money for lawyers there is."[21] Yet despite their appeal to lawyers, adversarial oral proceedings are not generally the way that most scientists, or indeed most policymakers, typically try to make sound judgments on the sorts of issues that come up in major rulemakings.[22]

C. Requiring Formal Rulemaking Would Have Perverse Effects

While there is little reason to believe that requiring formal procedures would substantially improve the quality of agency decisions, the costs and delays associated with formal rulemaking are well documented. Even a relatively minor amendment to a simple Food and Drug Administration labeling rule (one of the few contexts where, until 1990, formal rulemaking had been required) could take up to a decade, and produce thousands and thousands of pages of official documents, without any apparent positive effect on the quality of the final decision.[23] While not all formal rulemakings take quite this long, the costs and delays involved are typically substantial.[24] Such costs and delays would have a number of undesirable consequences:

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[21] Alan Schwartz, *Comment on "The Political Origins of the Administrative Procedure Act," by McNollGast*, 15 JOURNAL OF LAW, ECONOMICS & ORGANIZATION 218, 220-21 (1999).

[22] *See* Williams, *supra* note 18,at 444-45; Carl F. Cranor, *Science Courts, Evidentiary Procedures and Mixed Science-Policy Decisions*, 4 RISK 113 (1993).

[23] *See* MANNING & STEPHENSON, *supra* note 1, at 597-98.

[24] *See* Robert W. Hamilton, *Rulemaking on the Record by the Food and Drug Administration*, 50 TEXAS LAW REVIEW 1132 (1975); Richard A. Merrill & Earl M. Collier, Jr., *"Like Mother Used To Make": An Analysis of FDA Food Standards of Identity*, 74 COLUMBIA LAW REVIEW 561, 608-09 (1974).

1. Requiring Formal Rulemaking Would Impede Desirable Rule Changes

Delaying agency action by years or decades, or perhaps even deterring agencies from acting at all, might seem like a good idea to someone whose regulatory philosophy differs from that of the incumbent administration, or who is skeptical of the value of federal regulation generally. But such a view would be shortsighted, because slowing down the rulemaking process does not necessarily privilege *non-regulation*, but rather privileges the *status quo*. The same procedural requirements that make it difficult or impossible to promulgate rules that impose new mandates on the private sector also make it difficult or impossible to promulgate rules that lift such mandates, or that replace command-and-control regulatory systems with market-based systems, or that streamline existing regulatory programs so that they are more efficient and predictable for affected parties.

The over-proceduralization associated with formal rulemaking also makes it more difficult for agencies to update their rules in response to new information or changed circumstances. Often agencies are required by statute to promulgate a rule to deal with some problem. If formal rulemaking were required, presumably the agency would have no choice but to use it when enacting its initial rule. This first attempt at regulation may often turn out to have been misguided, but cumbersome formal rulemaking requirements might nonetheless deter an agency from updating or abandoning a rule that turned out not to be working as intended – even in circumstances where Democrats and Republicans could agree that change was needed. Here is it worth keeping in mind that despite controversies over the Obama Administration's regulatory initiatives in certain high-profile areas, the administration has also undertaken a range of rulemaking efforts to scale back unnecessary or overly burdensome regulations.[25] Indeed, one aspect of President Obama's recent executive order on regulatory review that ought to command broad bipartisan

[25] *See* Cass R. Sunstein, *21st Century Regulation: An Update on the President's Reforms*, WALL STREET JOURNAL, May 26, 2011.

support is his directive that agencies conduct retrospective analyses of their existing regulations, to see if experience with these regulations reveals that their benefits indeed justify their costs.[26] If formal rulemaking were required for any regulatory change, then agencies would be much less likely to alter their regulations in response to such retrospective analyses, essentially freezing the regulatory status quo in place.

Of course, if one opposes a particular regulation, or set of regulations, it might be tempting to require formal rulemaking only for *those* regulations, but not for others. Doing so would have the practical effect of delaying or blocking the targeted regulations, but would do so indirectly, and in such a way that those responsible could avoid accountability. We can and should have a vigorous debate over regulatory policy, but – as the title of this hearing implies – it is important to have this debate in a manner that promotes transparency and accountability. Those interests are ill-served when we disguise substantive decisions as procedural decisions.

2. Requiring Rulemakings To Be Formal May Lead to Other, Less Desirable Forms of Agency Regulation

While statutes sometimes require agencies to make rules, oftentimes statutes will give agencies the option either of making rules or of making policy in a piecemeal fashion through individualized, ad hoc adjudications.[27] Indeed, some agencies, such as the National Labor Relations Board, proceed almost exclusively through administrative adjudication rather than rulemaking.[28] Other agencies, like the Federal Communications Commission and the Securities and Exchange Commission, use a mix of rulemaking and adjudication.[29]

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[26] *See* Executive Order 13563, "Improving Regulation and Regulatory Review," Sec. 6 (Jan. 18, 2011).
[27] *See* MANNING & STEPHENSON, *supra* note 1, at 643, 656-61.
[28] *See id.* at 661.
[29] *See id.*

If Congress were to require that agencies use formal rulemaking procedures rather than notice-and-comment procedures, a likely consequence is that agencies would rely more on case-by-case adjudication. This would not, however, mean that agencies were not making general policy. Under governing Supreme Court doctrine, agencies are generally permitted to make broad policy pronouncements in the context of individualized orders, much as common law courts announce general rules of decision when deciding particular cases.[30] While this mode of regulatory policymaking may sometimes be appropriate, it is generally less predictable, and involves less broad-based public participation, than rulemaking.[31]

Furthermore, some agencies do not conduct their own administrative adjudications, but rather bring enforcement actions in federal court against parties that the agency believes to be in violation of the relevant statute or its implementing regulations. Many of these statutes use vague and general language. If the responsible agency does not give this statutory language more precise content through rulemaking, then that task will fall to the court. Thus over-proceduralization of agency rulemaking could result in more *judicial* lawmaking, which might also be a perverse and undesirable result.

3. Inhibiting Agency Rulemaking May Lead to Worse Legislation

Many critics of contemporary American government argue that Congress has delegated too much of its lawmaking authority to federal agencies.[32] This concern might lead one to argue for the imposition of much more demanding procedural requirements on agency rulemaking, on the logic that if rulemaking becomes more cumbersome and less efficient, delegation to agencies will become less attractive to Congress. Congress, the argument continues, will therefore be more inclined to make the hard regulatory

[30] *See id.* at 643-656, 661, 668-70.
[31] *See id.* at 659-60.
[32] *See id.* at 380-82.

choices itself by enacting more specific and detailed statutes, rather than enacting vague language and delegating the responsibility to working out the details to the agencies.

However, even if we accept the premise that greater proceduralization makes delegation to agencies less attractive, it does not necessarily follow that Congress will respond by writing more detailed statutes. There are at least two other possibilities. First, Congress might respond not by writing more detailed rules into the statute, but rather by writing cruder, blunter rules into the statute.[33] Imagine, for example, that instead of delegating to the new Consumer Financial Protection Bureau (CFPB) the authority to promulgate regulations regarding consumer credit transactions, the Democratic majorities that passed the Dodd-Frank Act had instead enacted specific substantive restrictions on consumer credit transactions. It is not at all clear that current critics of the CFPB would have been happier if Congress had opted for this alternative to delegation, yet that is what might well have happened if progressive advocates of substantive legislation could have argued, persuasively, that the rulemaking process was too cumbersome for delegation to be effective.

Second, if greater proceduralization makes agency rulemaking an unattractive option for Congress, Congress might respond by enacting vague language and leaving its implementation to the federal judiciary.[34] In other words, over-proceduralization of agency rulemaking might lead Congress to delegate to courts rather than to agencies. There are already a handful of federal regulatory programs that involve congressional delegation of de facto rulemaking authority to the judiciary rather than to an agency, including important aspects of the antitrust, bankruptcy, and patent laws. While there may be some advantages to judicial

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[33] *See id.* at 683; *see also* Matthew C. Stephenson, *Statutory Interpretation by Agencies*, in DANIEL FARBER & ANNE JOSEPH O'CONNELL EDS., RESEARCH HANDBOOK ON PUBLIC CHOICE AND PUBLIC LAW 285, 292 (Edward Elgar Publishing 2010).

[34] *See* MANNING & STEPHENSON, *supra* note 1, at 683; Stephenson, *supra* note 33, at 292.

delegation, it is far from clear that critics of delegation to agencies would be happy with more widespread delegation to federal judges.[35] Yet that is a likely consequence of procedural reforms that make agency delegation impractical.

4. Cumbersome Formal Rulemaking May Impede Effective Political Oversight

Although Congress often delegates regulatory policy decisions to administrative agencies in order to secure a healthy degree of insulation from the short-term pressures of partisan politics, it is also vitally important that agencies, staffed as they are by unelected bureaucrats, are subject to effective oversight by both Congress and the President. The formal rulemaking process tends to inhibit such oversight, for three reasons. First, the demands of the formal rulemaking process make it difficult for Congress or the President to get an agency to change course in response to the views (or a change in party control) of these elected branches of government. Indeed, in those few regulatory areas where an agency is (or believes itself to be) required to follow formal rulemaking requirements, there are often clashes between frustrated oversight committees, who want the agency to do something quickly about a pressing problem, and equally frustrated agency officials who find themselves hamstrung by the formal rulemaking requirements.[36] Second, formal rulemaking gives agencies a convenient way to "run out the clock" when they do not in fact want to do what Congress or the President want them to do. An agency can appear to comply with a congressional request by initiating a formal rulemaking proceeding, but string out the process for years. In the interim, the elected representatives pressing the agency for action might leave office, or change committee assignments, or turn their attention to other matters. Third, greater proceduralization of agency rulemaking tends to shift power within the agencies from the political appointees and senior policy staff to the agency lawyers who know how to navigate the labyrinthine procedures required to get

[35] *See* Stephenson, *supra* note 33, at 292-94.
[36] *See* MANNING & STEPHENSON, *supra* note 1, at 589-90.

anything done, but who might be less responsive to political oversight.[37]

II. SHOULD CONGRESS REQUIRE MORE STRINGENT JUDICIAL REVIEW OF AGENCY RULES?

In addition their role in enforcing procedural requirements, the federal courts provide an important independent check on agency rulemaking. Under the APA, the federal judiciary must hold unlawful and set aside agency rules that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."[38] Thus federal courts are supposed to review agency action for consistency with the statutory mandate that gives the agency the power to regulate, and the courts are also supposed to inquire into the substantive rationality of the agency's decision.[39] But how stringent a standard should the courts apply when performing these tasks?

As was true with procedural choices, setting the right standard of judicial review is something of a balancing act. Too little judicial scrutiny eliminates a potentially important check on administrative arbitrariness or disregard for legal requirements.[40] Overly demanding judicial review may lead federal judges to overstep the appropriate bounds on their authority, substituting their own policy judgments for the considered views of the agency.[41] The latter possibility is particularly troubling given that federal judges are neither experts in the relevant fields nor politically accountable for their decisions.

The current doctrine on judicial review of agency rulemakings is as follows. First, the reviewing court must decide whether the agency has a valid legal basis for its rule, and this assessment

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[37] *See id.* at 581.
[38] 5 U.S.C. § 706(2)(a).
[39] *See* MANNING & STEPHENSON, *supra* note 1, at 717.
[40] *See id.* at 719.
[41] *See id.*

often involves an evaluation of the agency's interpretation of its authorizing statute. Under the doctrine announced by the Supreme Court in *Chevron, U.S.A. v. Natural Resources Defense Council*,[42] a reviewing court must strike down agency regulations that are inconsistent with a clear statutory provision, but must uphold agency regulations that are based on a plausible reading of an ambiguous statutory provision (at least if the agency's interpretation is announced in a notice-and-comment rule, or something similarly formal).[43] The logic here is that if the statute is ambiguous, then the agency's interpretation is more of a policy decision than a legal decision, and courts should generally be reluctant to substitute their policy judgments for those of the responsible agency officials.[44] An agency's interpretation of its own regulation receives similarly deferential judicial review.[45]

Second, the reviewing court must decide whether the agency's decision is "arbitrary and capricious." Because courts are reluctant to second-guess agency policy judgments on complex technical issues, courts focus less on the *substance* of the agency's decision than on the agency's *reasoning process*. A reviewing court will ask whether the agency considered all the relevant factors, addressed all important alternatives, and offered an explanation for its decision reasonably connects the final choice made to the available evidence.[46] This form of review is known as "hard look" review. (For formal agency proceedings, the APA also requires that factual findings be supported by "substantial evidence,"[47] a standard of review that seems somewhat more stringent, but that in practice is quite similar to hard look review.)

Are these standards of review appropriate? Are they adequate? Should Congress amend the APA to make the default standard of judicial review more stringent? These are difficult questions,

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[42] 467 U.S. 837 (1984).
[43] *See* MANNING & STEPHENSON, *supra* note 1, at 814-24, 935-36.
[44] *See id.* at 824-25, 828.
[45] *See id.* at 715-16.
[46] *See id.* at 756-75.
[47] *See id.* at 718.

which are impossible to answer conclusively, or even to treat adequately in these brief comments. In contrast to my discussion of the proposal for requiring formal rulemaking procedures, where my views are strongly held and would (I believe) command wide consensus among administrative law scholars across the political spectrum, I am much less certain whether the stringency of judicial review should be ratcheted up or down (or left unchanged). It is fair to say that administrative law scholars advocate a wide range of opinions on this question (though, interestingly and importantly, these differences do not seem to correlate with political ideology). Because my understanding is that the Subcommittee is considering the possibility of imposing a more stringent (that is, less deferential) standard of judicial review, I will limit my remarks here to some questions and concerns about such a move.

First, one effect of imposing more stringent hard look review would be to make it more difficult and costly for agencies to adopt new rules (or to modify or repeal existing rules). There are two reasons for this. The first is that hard look review focuses on the agency's reasoning process, and this leads agencies to try to insulate themselves from judicial reversal by developing more detailed factual records and explanatory statements. While this can be good up to a point,[48] when judicial review of agency rulemaking becomes too demanding, the effect may be largely the same as imposing on the agency more elaborate and burdensome procedural requirements.[49] This, in turn, implicates all the concerns about over-proceduralization discussed earlier in my statement. Second, when agencies are uncertain whether or not courts will uphold their proposals, they may be deterred from regulating at all.[50] Again, this may seem superficially desirable if one dislikes the regulatory agenda of the incumbent administration, but the long-term consequences may be bad for everyone (except lawyers).

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[48] *See id.* at 775-76, 780-81.
[49] *See id.* at 778.
[50] *See id.*

A second potentially adverse effect of a more stringent standard of judicial review, especially in complicated technical policy areas, is the possibility of good faith error by judges who lack the expertise, training, and resources to fully understand and evaluate regulatory policy decisions.[51] Again, review of an expert agency decision by an independent generalist judge may have many advantages.[52] But past a certain point, such review may introduce more errors than it corrects. Even under the current hard look review standard, the case law is replete with examples of judges getting basic statistical, scientific, or economic concepts badly wrong, or misunderstanding important parts of the record, or treating trivial mistakes or omissions as a reason to invalidate a major rule.[53] A less deferential standard of review would likely lead to more such errors, and these costs might well outweigh the benefits of preventing agency errors in a handful of close cases.

Third, there is disturbing evidence that judges sometimes let their personal political ideologies influence their review of agency regulations.[54] This is not to say that judges are acting in bad faith. But they are probably susceptible to the natural human tendency to scrutinize more carefully and skeptically results they disfavor, and to gloss over problems with the evidence or analysis when they like the final result. Of course, even if this is indeed a problem, we might still want a more stringent standard of review. After all, perhaps the problem is not that judges are being too hard on agency regulations that they dislike, but rather that

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[51] *See id.* at 776.

[52] *See id.* at 775-76.

[53] *See id.* at 776. *See also* Thomas O. McGarity, *Some Thoughts on "Deossifying" the Rulemaking Process*, 41 DUKE LAW JOURNAL 1385, 1415-20 (1992); Thomas O. McGarity, *The Courts and the Ossification of Rulemaking: A Response to Professor Seidenfeld*, 75 TEXAS LAW REVIEW 525, 545-48 (1997); Howard Latin, *Good Science, Bad Regulation, and Toxic Risk Assessment*, 5 YALE JOURNAL ON REGULATION 89, 131 (1988); Frank Cross, *Pragmatic Pathologies of Judicial Review of Administrative Rulemaking*, 78 NORTH CAROLINA LAW REVIEW 1013, 1041-43, 1054-55 (2000); Richard Pierce, *Unruly Judicial Review of Rulemaking*, 5 NATURAL RESOURCES & ENVIRONMENT 23 (1990).

[54] *See* MANNING & STEPHENSON, *supra* note 1, at 777, 833-34; Stephenson, *supra* note 33, at 307-310.

judges are being too soft on agency regulations that they favor.[55] Nonetheless, an instruction to judges that they should reverse agency decisions only in extreme cases, where the agency is not just wrong but clearly wrong, is often thought to mitigate the influence of judicial ideology on judicial review of agency action, and some empirical evidence suggests that this is indeed the case.[56]

Fourth, more rigorous judicial review tends to shift power within an agency from the scientific or policy experts to the agency lawyers. The former set of employees may have a better understanding of sound regulatory policy, but the latter are more skilled at drafting "bulletproof" regulations that will survive judicial review, as well as predicting what courts are likely to do. This shift in power might undermine the *actual* rationality of regulation, even as it enhances the *appearance* of rationality to reviewing courts.[57]

Finally, overly aggressive judicial review can have the perverse effect of making agency regulations, and in particular the assumptions and political choices underlying those regulations, *less* transparent to courts, Congress, and the American people. In order to insulate their decisions from judicial second-guessing, agencies will try to make these decisions look as obscure and technical as possible.[58] Agencies may also simply revert to modes of policymaking, like ad hoc adjudication, that courts are less likely to reverse.[59]

Again, none of this is to say that the form or degree of judicial scrutiny currently applied by the federal courts is the right one. My own view is that the current doctrine probably strikes a reasonable balance between the interest in ensuring meaningful judicial oversight and the interest in preventing judicial

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[55] *Cf.* MANNING & STEPHENSON, *supra* note 1, at 834.
[56] *See id.* at 777, 834.
[57] *See id.* at 777-78.
[58] *See id.* at 777.
[59] *See id.* at 776.

overreaching. Of course, I might criticize the approach of some courts, and the results of some cases, as leaning too far in one direction or the other, but I am not aware of any systematic evidence that would justify congressionally-mandated increase in the rigor of the standard of review. More generally, any proposal to take such action should be mindful of the sorts of concerns I raised above.

It is also worth keeping in mind that *judicial* review is not the only option for increased oversight of administrative rulemaking. There is already extensive oversight by the executive branch, both internally within agencies and by the White House. Congressional oversight continues to play a vital role. While lawyers have a natural inclination to focus on courts and litigation, there are a variety of other tools and techniques that Congress or the President might employ if greater agency oversight seems warranted.

Thank you again for the opportunity to share my thoughts on these important issues, and I look forward to answering your questions.

Mr. GOWDY. At this point I would recognize the gentleman from Illinois for his 5 minutes of questioning.

Mr. QUIGLEY. Thank you, Mr. Chairman.

Professor Stephenson, I think it was in your written statement, or it might have been in your prepared statement, you indicate that there is, quote, disturbing evidence that judges' personal policy preferences play a greater role than they should in evaluating agency regulations. The first part of the question would be: What does that evidence consist of, and can you elaborate?

Mr. STEPHENSON. Yes. Thank you very much, Mr. Quigley.

The evidence to which I refer, which is—the relevant citations would appear in the portion of the book to which I cite. But there has been some evidence to look systematically at whether the composition of the typically three-judge judicial panels that evaluate major agency rulemakings affect the outcome. And when I say the "composition," I mean simply crude measures of whether the judges on that panel were appointed by Republican Presidents or Democratic Presidents.

If Republican appointees and Democratic appointees resolve administrative law cases in more or less the same way, then if you look at a sufficiently large number of cases, such that random errors wash out, the rates of affirming or reversing or remanding agency regulations ought to look about the same regardless of panel composition.

However, there is evidence that they do not look the same; that panels, for example, composed of three Republican appointees seem to decide cases in a manner systematically differently than three Democratic appointees, or even that panels composed of all judges appointed by a President of the same party behave differently from panels that have at least one member appointed by a President of a different party.

Now, we need to be careful not to exaggerate the significance of this evidence. Sometimes these academic studies are cited from the proposition that judges are purely political or ideological. The evidence doesn't support that conclusion. It does, however, suggest that like human beings, judges' strongly held views about policy might influence their judgments about, for example, whether an agency has offered enough evidence in support of a potentially debatable conclusion. Now that would be the nature of the evidence. It is certainly by no means conclusive. But there have now been numerous studies searching for these so-called ideological or panel effects, and although they are not uniform, they do seem to keep coming up over and over again in the data that exists.

Mr. QUIGLEY. Mr. Francisco you seem to have perked up when I asked that question. I just want to get your reaction, Mr. Warren, as well.

Mr. FRANCISCO. Well, Congressman Quigley, I make my living appearing before judges. I think every judge is eminently fair before I make my case. After I make my case, I think half of them are fair.

That being said, I think to the extent that there is some kind of tilt based on a judge's political preferences, it may reflect the fact that the standards that govern their decision making are simply too ambiguous. Take standard Chevron deference, for example. If

judges are to uphold an agency regulation to the extent it reflects a, quote, permissible reading of the statute, that is a quite vague and open-ended statute. And when you invite judges to engage in that kind of open-ended and discretionary review and you give that much leeway to the agencies, you invite a certain amount of other issues creeping into the judicial decision-making process.

Mr. QUIGLEY. Mr. Warren?

Mr. WARREN. Yeah. I think it is an interesting question. But I think it is more a product of how messed up the agency process is today in judicial review. As a lawyer, I want a judge who will probe and go in-depth into the record, whether he is a Democrat or a Republican. I really don't care. I just want to get to the heart of the matter.

Let me try to explain to all of you who are lawyers exactly what the administrative process today is like. To think of it as simple and straightforward and quick is just not true. It takes years and years and years, comments by the millions of pages are filed. Agencies have an obligation under this process-oriented judicial review to give an answer to every case. This takes man-years of work by agencies to assemble a record which can withstand judicial review. And then judicial review takes place under this very amorphous process that has very little to do with the heart of the matter, what is really the critical evidence.

What I am suggesting is a modification which would focus in on what is really important, and that would enhance I think judicial review and enhance the ability of the executive branch to focus in on what is really important.

I think the problem with judicial review is that it is insufficiently substantive. It is not just the question of Chevron deference but it is the question of understanding what it is that is at issue.

Let me give you another comparison. And that is, we have another form of regulation. It is called the tort system. It is civil litigation. In the tort system, the Supreme Court has now gone to great lengths to make sure that the evidence on which toxic torts or other major class-action litigation, for example, is conducted at the highest levels of scientific and technical expertise. That is one form of regulation. It seems crazy not to apply the same kinds of rigor to the evidence which is being utilized by the agencies to impose enormous costs on society.

Mr. QUIGLEY. Thank you, Mr. Chairman. My time is up.

Mr. GOWDY. I thank the gentleman from Illinois.

Mr. Warren, perhaps I was asleep during law school when the peanut butter case was taught, because my two colleagues to the left are both much more familiar with it than I. The peanut butter case, are you familiar with it? And is there another version?

Mr. WARREN. Yeah. I am aware of the peanut butter case. This has to do with aflatoxin, which is a carcinogen which naturally occurs in peanuts and in some other crops. Now I am not suggesting—and I agree with those who suggest that this kind of long, drawn-out process is inefficient and inappropriate. We have had formal proceedings, for example, under the old Federal Power Commission Act that went on for months and months and years and years. And I think that is not right and not what we want to do.

I have suggested in my testimony that what we should be focusing on is not all rules. Most rules, I think, are going to be governed by section 553 of the APA. Instead, let's talk about the major rules, the major rules that pass that $100 million hurdle that lead to scrutiny by the executive branch under the OIRA process. Then I think with respect to those rules, we should be asking the agency to say what is it really centrally that you are relying on. And I give examples in my testimony of three cases that I have litigated where it is pretty easy to see what is the central evidence.

And that is what we should be focusing our attention on. That is the evidence that parties ought to be able—and I am not just talking about regulated parties, I am talking about public interest groups and environmental groups who have an equal interest in seeing—and this goes to the question of deregulation. They have an equal interest in seeing that the public interest is served. And so they have the same opportunity to seek to cross-examine, and that process has to be governed by some hearing officer who says yes or no and gives the reasons for saying yes or no to cross-examination, so that we don't have the excesses that occurred in the 1950's and into the 1960's which gave rise to Florida East Coast Railroad and Vermont Yankee.

Mr. GOWDY. Professor Stephenson, where in the hierarchy of constitutional rights would you list the right to confront?

Mr. STEPHENSON. The right to confront in the context of a criminal trial?

Mr. GOWDY. Just the right to confront.

Mr. STEPHENSON. I am not sure how I would answer the question where in the hierarchy I would list it. Clearly, in a criminal case, the defendant has a right to confront the witnesses against him. And that is clearly an constitutional right that I would view as absolutely important.

Mr. GOWDY. And why is the right to confront so important?

Mr. STEPHENSON. Not being a constitutional historian, especially not one who focuses on the history of criminal procedure, I would be reluctant to give an off-the-cuff——

Mr. GOWDY. Oh, come on. You are a law professor. You know everything.

Mr. STEPHENSON. Alas, no.

Mr. GOWDY. Do you agree with Irving Younger that the single best way to elicit the truth is through the power of cross-examination?

Mr. STEPHENSON. No, I don't think I agree with that.

Mr. GOWDY. Would you agree that we use it for things as simple as determining whether or not the light was red or green, and things as complex as whether or not there is a DNA match?

Mr. STEPHENSON. We certainly do use it for those purposes, absolutely.

Mr. GOWDY. And it is almost without limitation in the criminal context because it is so good at getting out the truth. We even make victims of domestic violence or child abuse come and testify in front of their punitive or alleged attacker because we believe in the power of confrontation, right?

Mr. STEPHENSON. Yes. But with an important qualification, if I may. Many of the people who have engaged seriously these issues

that you are raising about the value of cross-examination have drawn a distinction between different contexts and have emphasized the importance of the procedures that we use for getting at the truth being appropriately tailored to the context. So there are certain contexts where cross-examination, at least historically, has been thought to be extremely valuable for the reasons that you suggest, although I am not aware of systematic study that would corroborate that intuition. But in other contexts, we don't rely on that kind of adversarial cross-examination.

For example, when scientists are engaged not in necessarily science for regulation, but the process of academic science, they don't necessarily use oral adversarial cross-examination to get to the root of those scientific issues. That doesn't mean that they don't debate, often rigorously or passionately. But they don't necessarily use the form and trappings of a civil or criminal trial. Now, whether that is right or not, I am not certain.

But I guess what I would say is that whenever we need to find the right method to lead us to the truth, we need to be sensitive to the context. There are not very many systematic studies of the agency rulemaking process about what methods are best associated with that context.

The one with which I am most familiar was a study that my former boss, then-professor, now-Judge Steven Williams conducted of hybrid rulemaking in the 1970's. It didn't have a lot of data. He looked at a handful of cases. But his analysis led him to conclude that it wasn't very well-suited for that process. But I can't say that I know for sure.

Mr. GOWDY. Mr. Francisco, I wanted to ask you your thoughts on the power of cross-examination as a tool by which to get at the truth. But the red light prevents me from doing it. Hopefully you will have an opportunity to weigh in on that if you choose.

And I would recognize the gentleman from Michigan, Mr. Conyers.

Mr. CONYERS. Well I would ask unanimous consent the Chairman have an additional minute to pose that question—it is an important one—to Mr. Francisco.

Mr. GOWDY. I thank you, Mr. Conyers and Mr. Quigley. Mr. Francisco, your thoughts on the power of cross-examination as the best means by which to elucidate the truth?

Mr. FRANCISCO. Thank you, Mr. Chairman. I think it is an extraordinarily powerful tool. As Professor Stephenson explained, often in the administrative process you do have extensive records. But that kind of extensive paper record provides a very useful way for masking the flaws often underlying the science that underpin regulations. It is very easy for the stakeholders to submit extensive comments and suggest enormous numbers of flaws in the regulatory process and then have an agency just, almost as it is handing down a ruling from on high, give it the back of the hand and say, We have considered it, we disagree, here is the rule.

It is a lot different when you have got somebody sitting on the stand. And when somebody sitting on the stand knows that they are going to have to answer direct questions about the quality of their analysis, I can virtually guarantee you that the quality of that analysis on average is going to rise dramatically.

You need only compare the type of expert report and expert witnesses that you see in high stakes litigation to the types of regulatory impact analyses and cost-benefit analyses that we see that the agencies issue in conjunction with regulations. And the difference is night and day. So I think that cross-examination is very important in this context.

Mr. GOWDY. Thank you, Mr. Francisco. At this point I would recognize the gentleman from Michigan, Mr. Conyers.

Mr. CONYERS. Thank you, Chairman Gowdy.

Mr. Francisco, you have represented tobacco companies; isn't that correct?

Mr. FRANCISCO. Yes, Your Honor. Yes, Congressman.

Mr. CONYERS. And you have had an opportunity to challenge the rulemaking process yourself as a part of your job as counsel?

Mr. FRANCISCO. Yes, sir. One of my jobs is to advise companies in the rulemaking process.

Mr. CONYERS. So this is what Chairman Gowdy meant about "job creation." This is a great way to create jobs for lawyers, because I know Professor and Attorney Warren has been to court more than once on the rulemaking process because I am looking at the cases.

Mr. WARREN. Yes.

Mr. CONYERS. You said "yes." Okay. It is kind of curious to me that the two witnesses for this event are distinguished lawyers, one almost two generations in the practice of law and teaching, maybe one of the highest Ranking Members of his law firm. Do you have a particular title inside Kirkland?

Mr. WARREN. No, I really don't anymore. But you are right; I have been around a long time.

Mr. CONYERS. What was your title?

Mr. WARREN. Well, at various points in time I was a partner. I have been a partner of the firm since 1975. I am now sort of semi-retired.

Mr. CONYERS. Sure.

Mr. WARREN. So I no longer have that title.

Mr. CONYERS. Well, what I am trying to demonstrate here is that it is sort of curious to me that—we want to make this a more effective and fair way to come up with rules, and yet you are the one that said that anyone that says this is a simple, straight-forward, and quick way to do it—the way we are doing it—is just not true. Now, will you name me one person that ever said that?

Mr. WARREN. I am not sure I quite understand the question.

Mr. CONYERS. Well, the question is that you said that—this is your quote.

Mr. WARREN. Right.

Mr. CONYERS. I have got the stenographer here to help us out. Anyone that thinks that this is a simple, straight-forward, and quick way to deal with agency regulations, it is just not true, right?

Mr. WARREN. Yes.

Mr. CONYERS. Is that correct?

Mr. WARREN. Yes.

Mr. CONYERS. Okay. Now, will you tell me one person that ever made that allegation?

Mr. WARREN. Yeah. I think so. I mean——

Mr. CONYERS. Name him.

Mr. WARREN. Well, let me state the point.

Mr. CONYERS. No. No. Name who it is.

Mr. WARREN. Well, look at——

Mr. CONYERS. Name somebody.

Mr. WARREN. I am going to. Richard Pierce. And you look at the back end——

Mr. CONYERS. Richard Pierce said this?

Mr. WARREN. Yes. Let me read a quote that——

Mr. CONYERS. You don't have to read it. I just want his name. Okay. That is enough.

How many people in your firm, even though you are semi-retired—well, I will tell you, 1,500 people. Maybe it is more by now.

Mr. WARREN. That is about right.

Mr. CONYERS. Yeah. And you have offices all over the world?

Mr. WARREN. That is correct.

Mr. CONYERS. Right. How many people in your firm? Can I help you with that a little bit?

Mr. FRANCISCO. Yes, sir.

Mr. CONYERS. Two-and-a-half thousand lawyers working in Jones, right?

Mr. FRANCISCO. I think that is about right.

Mr. CONYERS. Yeah. And you have offices all over the world.

Mr. FRANCISCO. Yes, sir.

Mr. CONYERS. And you are here now telling us that because lawyers should have a chance, as the Chairman said, the right to confront, to cross-examine like they do in child abuse and molestation cases, they should have the same right in trying to determine agency rules. Do you agree with that?

Mr. FRANCISCO. I agree that the——

Mr. CONYERS. Do you agree with that?

Mr. FRANCISCO. I agree that the right to cross-examine witnesses——

Mr. CONYERS. Do you agree with that? Do you agree with that?

Mr. FRANCISCO. Obviously, yes.

Mr. CONYERS. You said yes?

Mr. FRANCISCO. The right to cross-examine witnesses——

Mr. CONYERS. Do you agree with it?

Mr. WARREN. I think my testimony suggests that the right to confront evidence should be limited to those things that are central to the rulemaking, and I give examples of what I think that means, and I give examples within my experience where that has worked, worked well, and made the agency process more efficient.

Mr. CONYERS. Thank you. Mr. Chairman, can I have 1 additional minute?

Mr. GOWDY. Without objection.

Mr. CONYERS. Thank you, sir. Will you name me any agency of—creation of rulemaking for any agency that you think that the process that has been suggested by our distinguished Chairman would have been superior to the one that was used?

Mr. WARREN. Can I speak to that?

Mr. CONYERS. Yes.

Mr. WARREN. Yes.

Mr. CONYERS. Name it, then.

Mr. WARREN. Yes. I would say the Occupational Safety and Health Administration, the procedure employed in the benzene case which I argued——

Mr. CONYERS. The benzene case?

Mr. WARREN. The benzene case which is contained as an attachment to my testimony. The very fact that I was able to cross-examine, not everybody, not—and just the central scientific evidence enabled Justice Stevens in his opinion, which I invite you to read, to deal with the substance of what was at issue in a very thorough and thoughtful way. Without cross-examination, without my opportunity——

Mr. CONYERS. All right. So what you are saying is that this is a great way for lawyers to get into the act. Do you have any cases that—do you have one case you can name, not a list of them which I normally ask for, name me one case.

Mr. FRANCISCO. That would?

Mr. CONYERS. That this method would have been superior to the one that is being used now.

Mr. GOWDY. If you want to answer the question briefly, you can.

Mr. CONYERS. Well, just one sentence.

Mr. FRANCISCO. There is not a specific case that——

Mr. CONYERS. You don't have a case.

Mr. FRANCISCO. In general, I think that it is something that improves the decision-making process, which is why we use it——

Mr. CONYERS. I get your drift. Thank you very much, Mr. Chairman.

Mr. GOWDY. Thank you, Mr. Conyers.

I want to thank, again, the panel. For someone who had never looked at the Administrative Procedures Act until 5 months ago, I can't think of three better people to help on that. And I applaud your knowledge, your collegiality, and politeness toward one another and toward us, and thank you for your time and your expertise. It is a treasure to be able to have folks with this kind of acumen come and testify before the various Subcommittees of Congress.

So, without objection, all Members will have 5 legislative days to submit to the Chair additional written questions for the witnesses, which we will forward and ask the witnesses to respond to as promptly as they can so their answers may be made part of the record.

Without objection, all Members will have 5 legislative days to submit any additional materials for inclusion in the record.

With that, again, I thank the witnesses. The hearing is going to be adjourned in just a moment. I would personally like to come shake your hands and thank y'all for your testimony at the conclusion. I won't keep you too long. Hearing is adjourned.

[Whereupon, at 5:02 p.m., the Subcommittee was adjourned.]

APPENDIX

Material Submitted for the Hearing Record

Response to Post-Hearing Questions from Edward W. Warren, P.C., Kirkland & Ellis, LLP

Questions for Edward W. Warren

From Mr. Coble

1. At the Subcommittee hearing, you were asked to identify one person to support your statement, "To think of it [i.e., the administrative process today] as simple and straightforward and quick is just not true."

   a. You identified Richard Pierce in response to this question. Can you provide the quote from Richard Pierce that you offered to give at the hearing?

Response: The citation to the quote is found at note 41 to my testimony. Professor Pierce's point is that in the wake of *Vermont Yankee*, courts have effectively substituted APA Section 553's requirement of adequate reasoning (essentially the holdings of *State Farm* and *Overton Park*) for the pre-*Vermont Yankee* procedures, and that the net result is a very cumbersome agency process. The massive records—including literally hundreds of pages required to respond to public comments—has slowed rulemaking "to the point of near paralysis." Richard J. Pierce, Jr., *The Role of the Judiciary in Implementing an Agency Theory of Government*, 64 N.Y.U. L. REV. 1239, 1265 (1989). In short, the whole notion that today's rulemaking process is in any sense streamlined or ideal is simply wrong.

   b. Is Professor Stephenson's description of the notice-and-comment process as "heavily proceduralized" and "somewhat akin to a paper hearing" also supportive of your above-quoted statement?

Response: Professor Stephenson's description is consistent with Professor Pierce's point. My proposal would actually lead to a more effective and streamlined rulemaking process by adding procedures that would focus attention on the few issues that really matter in major rulemakings —especially in the case of health, safety, and environmental regulations issued by EPA, OSHA, NHTSA, and similar agencies.

2. In your written testimony you observe that "the APA was enacted in reaction to the perceived excesses of New Deal agencies," and that the "current rulemaking system, especially for major rules which matter most, is broken."

   a. How have you seen agencies commit excesses and abuse their power in the course of your career?

Response: There are many examples of agency rules in which the benefits are minimal and the costs are excessive. Professor Cass Sunstein, currently head of the Office of Information and Regulatory Affairs ("OIRA") within the White House, has acknowledged "characteristic pathologies of modern regulation—myopia, interest group pressure, draconian responses to sensationalist anecdotes, poor priority setting, and simple confusion." Richard H. Pildes & Cass R. Sunstein, *Reinventing the Regulatory State*, 62 U. CHI. L. REV. 1, 4 (1995). Stephen Breyer, before joining the Supreme Court, also recognized that agencies may regulate "risk … so small as to be virtually meaningless." STEPHEN BREYER, BREAKING THE VICIOUS CYCLE: TOWARD EFFECTIVE RISK REGULATION 10, 13 (1993). Professor Kip Viscusi has documented this point,

as have many others. *See, e.g.*, W. Kip Viscusi, *Regulating the Regulators*, 63 U. CHI. L. REV. 1423 (1996).

b. What are some of the worst examples of how the system is broken now?

Response: There are many examples to choose from. Let's start with two recent examples. The NHTSA acknowledged that its Roof Strength Rule has negative "net benefits," i.e., its costs exceed its benefits, but promulgated the rule anyway. *See* 74 Fed. Reg. 22,348, 22,377-78 (May 12, 2009). Even more troubling, EPA's Endangerment Rule in support of regulating CO2 emissions provides no cost-benefit analysis at all. *See* 74 Fed. Reg. 66,496 (Dec. 15, 2009). In my experience, such agency overreaching is common, especially in the case of health, safety, and environmental rules. All three of the decided cases cited in my testimony—EPA's failure to suspend auto emission standards, OSHA's benzene rule, and EPA's asbestos rule under TSCA—are examples of agencies relying on shaky science and unsupportable projections or failing to consider risk tradeoffs.

Other examples, focusing only on my personal experience as a practitioner, include EPA's asbestos in schools rule, *see* 52 Fed. Reg. 41,846 (Oct. 30, 1987), which was promulgated despite the fact that removing asbestos poses more risk to removal workers and school personnel than does leaving it in place. I litigated and lost a case challenging those regulations because of the deference paid to an agency's scientific findings—findings which I had no opportunity to cross-examine. *See Safe Bldgs. Alliance v. EPA*, 846 F.2d 79 (D.C. 1988). Under the proposal I have outlined, things would have been different.

Numerous NHTSA CAFE rules, *see, e.g.*, 75 Fed. Reg. 25,324 (May 7, 2010), also demonstrate that the system is broken. CAFE standards have almost no positive effect in reducing fuel consumption while adding auto safety risks (downsizing cars and trucks) and impairing the competitiveness of the U.S. auto industry. *See, e.g.*, Hal J. Singer & Robert W. Crandall, *Don't Drink the CAFE Kool-Aid*, WALL ST. J., Sept. 3, 2007, *available at* http://www.brookings.edu/opinions/2007/0906business_crandall.aspx; ROBERT W. CRANDALL *ET AL.*, REGULATING THE AUTOMOBILE (1986).

Likewise, EPA's revision of the ozone ambient air quality standard both in 1997, *see Area Designations for 1997 Ground-level Ozone Standards*, http://www.epa.gov/glo/designations/1997standards/regs.htm#2 (listing "all regulatory actions related to the 1997 8-hour ozone standard"), and currently, *see* National Ambient Air Quality Standards for Ozone, 75 Fed. Reg. 2,938 (Jan. 19, 2010), are examples of a broken system. Indeed, even the White House has recognized that such regulation is not cost-justified. *See* Deborah Solomon & Tennille Tracy, *Obama Asks EPA to Pull Ozone Rule*, WALL ST. J., Sept. 3, 2011, *available at* http://online.wsj.com/article/SB10001424053111904716604576546422160891728.html. I litigated a challenge to the ozone standards and lost in the Supreme Court, *see Whitman v. American Trucking Assns., Inc.*, 531 U.S. 457 (2001), because the Court

concluded that costs were irrelevant under the Clean Air Act, *see id.* at 471 ("The [statute] unambiguously bars cost considerations from the NAAQS-setting process ....").

3. You suggest that the presiding officer should be required to make a written decision with respect to each and every contested question presented by regulated parties or interested persons. Would this kind of record help courts significantly when they review agency decisions?

Response: Yes, this requirement would focus the court on the evidence that really matters—separating the wheat from the chaff. In my experience, most of today's massive rulemaking records consist almost entirely of chaff. The evidence that really matters often gets lost. My proposal would provide focus for the agency, OIRA, and reviewing courts. The net result would be better regulations, more focused records for judicial review of major rules, and a shorter—not longer—process from start to finish.

4. You testify that the party in control of a particular piece of evidence should have the burden of proof as to that piece of evidence. Is it too much to ask that an agency should bear the burden of showing that the few key facts or scientific studies it is relying on to make a major rule are reliable and amount to "substantial evidence" supporting the proposed rule?

Response: No, it is not too much to ask. That is, of course, the essence of my proposal. Courts have asked and should always ask for agencies to bear the burden of putting forward reliable scientific evidence and to support all assumptions and projections from the available evidence. *See Indus. Union Dep't, AFL-CIO v. Am. Petroleum Inst.*, 448 U.S. 607, 653 (1980) ("[T]he burden was on the Agency to show, on the basis of substantial evidence, that it is at least more likely than not that long-term exposure to 10 ppm of benzene presents a significant risk of material health impairment."); *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1214 (5th Cir. 1991) ("The burden remains on the EPA, however, to justify that the products it bans present an unreasonable risk, no matter how regulated."); *Int'l Harvester v. Ruckelshaus*, 478 F.2d 615, 632 (D.C. Cir. 1973) ("EPA's burden of proof"). Whether viewed from the standpoint of substantial evidence or arbitrary and capricious review, agency decisions that rely on weak scientific and technical evidence or unsupported assumptions should fail judicial review. My proposal is aimed at improving—through carefully limited cross-examination—those regulations that fail this test. Stated another way, major agency rules that fail to provide proven benefits exceeding costs would not pass muster.

From Mr. Cohen

5. Professor Stephenson states that "there is no systematic evidence demonstrating that adversarial oral cross-examination is the most effective tool for making sound scientific or policy judgments on general issues of the sort addressed in most rulemakings."

   Can you point to any such evidence?

Response: Our entire system of justice, including our Constitution, is based on the demonstrated premise that cross-examination is the greatest engine of truth-seeking available. I have given in my testimony examples from three major health, safety, and environmental rules where cross examination was allowed and proved very effective. We need look no further than the other form of regulation—namely, tort litigation—to see how essential and effective cross-examination of scientific and technical evidence can be. This point has been recognized time and time again by the Supreme Court in *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993), and subsequent cases regarding the central role played by scientific testimony and cross-examination.

6. Is there any need to address witness demeanor in the context of formal rulemaking?

Response: Demeanor is really not the point of my proposal, although I can imagine instances in which demeanor could matter if the witness's testimony is not credible. Rather than demeanor, my proposal focuses primarily on the substance of the evidence on which the agency relies and contrary scientific evidence that the agency often ignores. As in any other setting, forcing expert witnesses to defend their results and to explore its strengths and weaknesses, including any assumptions or projections that the witness or the agency has made, is the best way to arrive at the truth and to genuinely serve the public interest. In short, oral testimony and cross-examination in rulemaking, just as in the tort context, is the best means of probing the strength or weakness of studies, risk assessments, and similar evidence or projections.

7. Would formal rulemaking, as Professor Stephenson notes, generate a greater role for attorneys in the rulemaking process?

Response: Attorneys already play key roles in major rulemakings and subsequent judicial review. The role of attorneys in major rulemakings would change in certain respects under my proposal but I do not think their role would expand. Indeed, by focusing on the really important evidence—again separating the wheat from the chaff—rulemakings and judicial review would likely become more streamlined and, therefore, the role of attorneys (measured in billable hours) would be reduced.

8. What is your response to Professor Stephenson's contention that even minor FDA labeling rules subject to formal rulemaking can result in a process that can take close to a decade?

Response: Under my proposal that would not occur because cross-examination would be carefully limited using the methods the best federal judges employ in focusing cross-examination in major tort cases.

9. What is your response to Professor Stephenson's assertion that "slowing down the rulemaking process does not necessarily privilege non-regulation, but rather privileges the status quo"?

Response: I disagree that my proposal would slow down the rulemaking process. I also disagree that it favors the status quo. Most examples of deregulation would not qualify as major rules. The current examples of deregulation recently touted by OIRA head Cass Sunstein exemplify that point. *See* Cass Sunstein, *Washington Is Eliminating Red Tape*, WALL ST. J., Aug. 23, 2011,

available at
http://online.wsj.com/article/SB10001424053111903596904576518652783101190.html.

10. Where an Administration or an agency wants to scale back unnecessary or overly burdensome regulations, should that process be subject to formal rulemaking?

Response: No, not unless it qualifies as a major rule.

11. Professor Stephenson states that the case law is "replete with examples of judges getting basic statistical, scientific, or economic concepts badly wrong."

    What is your response?

Response: Of course judges can make mistakes but, again, *Daubert* and progeny show that, on balance, review of scientific evidence by judges and even juries improves the decision-making process. That is especially the case for heath, safety, and environmental rules, most of which are judicially reviewed by the D.C. Circuit. The judges on that Circuit are experts in administrative law and are uniquely adept as judges of scientific and technical evidence and testimony.

12. On page 8 of your written testimony, you stated that major rules "call for the greatest expenditure of private sector resources," and therefore recommended that more formal rulemaking procedures be used in their promulgation. However, the Congressional Research Service reported earlier this year that most of the 100 major rules issued last year were considered "major" for reasons other than compliance costs. (See CRS Report R41651.) These rules were major because they involved more than $100 million in annual transfers of federal funds (e.g., grants, food stamps, Medicare reimbursements); consumer spending (e.g., pursuant to setting migratory bird seasons); recovered fees (e.g., for passport applications and nuclear power plant inspections); and regulatory benefits (with costs expected to be less than $100 million). Do you believe that these types of "major" rules should be subject to formal rulemaking procedures, or only those that impose $100 million in annual compliance costs?

Response: My experience is with health, safety, and environmental rules which, in my experience, almost invariably qualify as major rules. But as you note from my testimony, major rules as a class "call for the greatest expenditure of private sector resources," and hence presumptively should be treated the same way. In my judgment, major rules as defined by the various Executive Orders and reviewed by OIRA constitutes a workable rule-of-thumb for identifying those rules that should be subjected to the enhanced procedures set forth in my testimony.

13. H.R. 1432, the "Creating Sunshine, Participation, and Accountability for Our Nation Act," would require formal rulemaking procedures for any rule issued pursuant to the Patient Protection and Affordable Care Act (P.L. 111-148). Do you support enactment of this legislation?

Response: I would support enhanced procedures along the lines of my proposal for any rule issued pursuant to the Patient Protection and Affordable Care Act that qualifies as a major rule.

14. On page 8 of your written testimony, you described the OIRA review process as "a closed process" that addresses agency compliance issues in a "non-transparent manner." However, Executive Order 12866 contains numerous transparency requirements on rulemaking agencies and OIRA. For example, agencies are required to make available to the public all information on a rule's costs and benefits, and to identify for the public the substantive changes made at the suggestion or recommendation of OIRA. OIRA posts on its website when rules are submitted and cleared, the participants in all meetings about rules under review, and return letters describing why rules are sent back to the agencies for reconsideration. Documents in OIRA's and the agencies' rulemaking dockets provide other details about the review process. How, then, is this a "closed" or "non-transparent" process?

Response: The OIRA process has improved over the years but it is still a process that relies primarily on a dialogue between agency staffers and OIRA officers. That process does not lead to a probing, in-depth review of scientific and technical evidence. My proposal is intended to fill that gap.

15. On page 10 of your written testimony, you quoted Professor Richard Pierce as saying that the open-ended requirement of adequate reasoning was "delaying the policymaking process to the point of near paralysis." You therefore concluded that the current rulemaking system, particularly for major rules, was broken, and suggested (among other things) that agencies use more formal rulemaking procedures for major rules. However, virtually every administrative law scholar for the past 70 years has said that the use of formal rulemaking procedures would lead to even more paralysis. Why, then, do you believe otherwise-- that formal rulemaking would remedy the current situation?

Response: My testimony cites decisions by the leading administrative law jurists of the pre-*Vermont Yankee* era—Justice Frankfurter, Judge Friendly, and Judge Leventhal. Each was a leading administrative law teacher and scholar. *See, e.g.*, Felix Frankfurter, *The Task of Administrative Law*, 75 U. PA. L. REV. 614 (1927); FELIX FRANKFURTER & J. FORRESTER DAVISON, CASES AND OTHER MATERIALS ON ADMINISTRATIVE LAW (1932); Henry J. Friendly, *The Federal Administrative Agencies: The Need for Better Definition of Standards*, 75 HARV. L. REV. 863 (1962); Henry J. Friendly, *Some Kind of Hearing*, 123 U. PA. L. REV. 1267 (1975); Harold Leventhal, *Principled Fairness and Regulatory Urgency*, 25 CASE W. RES. L. REV. 66 (1974-1975). Leading judges of that era, both liberal and conservative, were experienced as practitioners and well-understood the value of cross-examination and careful evaluation of agency reasoning. *See, e.g.*, *Walter Holm & Co. v. Hardin*, 449 F.2d 1009, 1016 (D.C. Cir. 1971) (Leventhal, J.) ("[T]he oral hearing may be legislative in type, although fairness may require an opportunity for cross-examination on the crucial issues."); *Ethyl Corp. v. EPA*, 541 F.2d 1, 36 (D.C. Cir. 1976) (Bazelon, J.) ("There is no inconsistency between the deferential standard of review and the requirement that the reviewing court involve itself in even the most complex evidentiary matters; rather, the two indicia of arbitrary and capricious review stand in careful balance."); *Indus. Union Dept. v. Hodgson*, 499 F.2d 467, 469 (D.C. Cir. 1974) (McGowan J.) ("Congress—with no apparent awareness of anomaly—has explicitly combined an informal agency procedure with a standard of review traditionally conceived of as suited to formal adjudication or rulemaking.") (citations omitted). It is primarily from that perspective, echoing the wisdom of the pre-*Vermont Yankee* era, that I have testified before the Subcommittee and outlined my proposal for improving the rulemaking process for major rules.

Response to Post-Hearing Questions from Noel J. Francisco, Esq., Jones Day LLP

QUESTIONS FOR NOEL FRANCISCO

CCAL Subcommittee Hearing: "Formal Rulemaking and Judicial Review"
May 31, 2011

1. **You acknowledge that Congress on occasion "passes a broad and open-ended law, leaving it to an Executive Branch administrative agency to 'fill in the gaps' through administrative regulation." When agencies exercise that power and the courts accord deference to such agencies, you note that we risk "concentrating all three powers of government in the Executive Branch alone."**

   Isn't the source of this problem Congress itself, through over-delegation of legislative authority, lack of specificity with respect to such delegation, or insufficient oversight of agencies? Would additional procedures solve the problem as you have articulated it?

   The problem I attempted to identify involves all three branches of our federal government: (1) Congress passes broad and open-ended laws; (2) the Executive Branch often interprets those laws expansively; and (3) the Judicial Branch defers to both (a) Congress's original delegation, and (b) the Executive Branch's interpretation. There are different ways to solve this problem. The one I attempted to elaborate upon in my testimony would have the judiciary engage in more rigorous review of the Executive Branch's interpretations. This, in my view, will address both (1) and (2), since it will encourage Congress to pass laws with greater specificity and discourage the Executive Branch from engaging in overly expansive interpretations.

2. **When you were with the Bush Administration, did you advocate expanded use of formal rulemaking?**

   During President George W. Bush's Administration, I had the honor of serving in the Office of Counsel to the President and in the Department of Justice's Office of Legal Counsel. I do not recall having had an opportunity to address the issue of formal rulemaking during that time.

3. **What accounted for the fact that the infamous peanut butter formal rulemaking took nearly a decade to reach a conclusion?**

   I, unfortunately, am not sufficiently familiar with the details of the peanut butter formal rulemaking to comment on the many different factors that could have contributed to the length of time it took to reach a conclusion in that matter.

4. **If there are, as you allege, so many benefits of formal rulemaking, why hasn't it been used more often?**

   There are several reasons why formal rulemaking has not been used more often. For example, while the Administrative Procedure Act provides procedures for formal and informal rulemaking, formal procedures only apply when the agency's authorizing statute explicitly requires them. *See United States v. Florida East Coast Ry. Co.*, 410 U.S. 224

(1973). Congress, however, rarely requires formal rulemaking. In addition, agencies generally prefer informal procedures as they accord agencies greater latitude by (a) allowing agencies to enact rules through less cumbersome procedures, and (b) subjecting their decisions to a lower standard of judicial review. There are likely additional reasons as well.

5. **You allege that courts "[o]ver time" have shifted "strongly toward deference and away from rigorous judicial review." What accounts for this apparent shift?**

It is difficult to surmise why courts trend in certain directions over time, as such trends often reflect a combination of factors. But, particularly in the area of administrative law, it is entirely appropriate to revisit rules in light of experience—and, if necessary, to revise them. For example, shortly after the Subcommittee's hearing, Justice Scalia, who authored the Supreme Court's decision in *Auer v. Robbins*, 519 U.S. 452 (1997), which approved of a very deferential standard of review for agency interpretations of their own regulations, wrote that he has "become increasingly doubtful of its validity." *Talk America, Inc. v. Michigan Bell Telephone Co.*, __ S. Ct. __, Nos. 10-313, 10-329, 2011 WL2224429, at *11 (June 9, 2011) (Scalia, J., concurring).

6. **In your written and oral testimony, you indicated that you believe that formal rulemaking is a better method of getting at "the truth" than informal rulemaking. However, the Administrative Conference of the United States recommended that Congress should not require procedures beyond informal rulemaking, and should never require trial-type procedures for resolving questions of policy or fact. (ACUS Recommendation 72-5, Procedures for the Adoption of Rules of General Applicability, 38 Federal Register 19782, 1972.) Why do you disagree with the Administrative Conference on this point?**

As noted during my testimony, I believe that the ability to cross-examine witnesses has many benefits. First, it is a powerful means of identifying the strengths and weaknesses in a factual argument. Perhaps more importantly, it encourages more rigorous analysis, because potential witnesses will know that their conclusions will be subject to more careful scrutiny and agencies will know that their reasoning process will be on public display. In addition, the "substantial evidence" standard of judicial review, which applies to rules promulgated through formal procedures but not informal procedures, in my view, may strike a better balance between judicial deference and judicial review than does the "arbitrary and capricious" standard.

7. **Your written statement describes formal rulemaking as "more rigorous and transparent than informal rulemaking." However, with the advent of electronic dockets at regulations.gov and other transparency mechanisms, the public has access to all of an agency's informal rulemaking underlying data, cost-benefit analyses, public comments, changes made at OMB's suggestion or recommendation, and a host of other materials. In contrast, formal rulemaking would only provide access to these kinds of materials to a much smaller "public" (lawyers), and certain rulemaking requirements (e.g., analyses under the Regulatory Flexibility Act and the Unfunded Mandates Reform Act) would no longer be applicable because they**

apply only when the agency is required to publish a notice of proposed rulemaking. Therefore, with regard to the general public, why do you believe that formal rulemaking would be more transparent than informal rulemaking?

Certain aspects of formal rulemaking procedures provide for greater "transparency" in the sense that they provide a more robust mechanism for understanding and analyzing the factual underpinnings of an agency's policies. In particular, only formal rulemaking allows for the direct testing of an agency's evidentiary support in a public forum through cross-examination. However, given that formal rulemaking procedures have been rarely used, it is possible, as this question presupposes, that such procedures may warrant modification in order to take advantage of technological developments.

8. **H.R. 1432, the "Creating Sunshine, Participation, and Accountability for Our Nation Act," would require formal rulemaking procedures for any rule issued pursuant to the Patient Protection and Affordable Care Act (P.L. 111-148). Do you support enactment of this legislation?**

I believe that there are advantages to adopting certain aspects of formal rulemaking, most notably the greater transparency and more rigorous standard of review that accompany these procedures. As reflected in my testimony, there are different ways to realize such benefits. I defer to the Subcommittee on how best to balance the various competing concerns.

9. **It seems that the public's trust in government, or at least in the federal government, is as low as it has ever been. You testify that "rigorous and transparent adherence to administrative processes serve to enhance the democratic legitimacy of regulations." What are the most important reasons we need to make sure that agency rules have democratic legitimacy?**

Unlike the President and Members of Congress, agency secretaries, deputy secretaries, assistant secretaries, and other political and career agency officials do not stand for election. Thus, they are not directly subject to democratic checks. Increased transparency and adherence to process, however, in combination with the democratic checks that exist on the President and Members of Congress, can allow the public to have meaningful input on the rules and regulations promulgated by agencies. This is important because the rules and regulations promulgated by agencies often have as much impact upon the lives and livelihoods of the American citizenry as do laws duly enacted by Congress and signed by the President.

10. **Employers need to know how an agency will apply a regulation, so they can have the confidence to take steps that will create jobs. Ambiguous regulations foster uncertainty and discourage private enterprise. How in your experience does the standard of review given by the Supreme Court in *Seminole Rock*, and re-affirmed in *Auer*, give agencies the incentive to make ambiguous regulations?**

Justice Scalia, the author of the Supreme Court's opinion in *Auer*, well summarized the potential problems with *Auer* in his recent concurring opinion in *Talk America Inc. v.*

Michigan Bell Telephone Co., __ S. Ct. __, Nos. 10-313, 10-329, 2011 WL2224429, at *11 (June 9, 2011), in which he stated that he has "become increasingly doubtful of [*Auer*'s] validity." Justice Scalia explained:

> Deferring to an agency's interpretation of a statute does not encourage Congress, out of a desire to expand its power, to enact vague statutes; the vagueness effectively cedes power to the Executive. By contrast, deferring to an agency's interpretation of its own rule encourages the agency to enact vague rules which give it the power, in future adjudications, to do what it pleases. This frustrates the notice and predictability purposes of rulemaking, and promotes arbitrary government. The seeming inappropriateness of *Auer* deference is especially evident in cases such as these, involving an agency that has repeatedly been rebuked in its attempts to expand the statute beyond its text, and has repeatedly sought new means to the same ends.

Id. For further discussion of this issue, I would recommend the article relied upon by Justice Scalia in his *Talk America* concurrence. *See* John F. Manning, *Constitutional Structure and Judicial Deference to Agency Interpretations of Agency Rules*, 96 Colum. L. Rev. 612 (1996).

11. The *Baltimore Gas & Electric* standard of review gives agencies the incentive to dress their decisions up in scientific and technical terminology, to discourage courts from looking too closely at the evidence. What can Congress do to prevent agencies from abusing this standard?

As I discussed during my testimony, one possibility that some commentators have suggested would be to streamline the applicable standards of deference. Under this approach, *Skidmore* deference would apply to agency interpretations unless Congress has explicitly delegated lawmaking authority, in which case *Chevron* deference would apply. Accordingly, the other standards currently employed by courts, such as *Auer* and *BGE*, would be eliminated as unnecessary.

12. *Skidmore* was decided in 1944, and the APA was adopted in 1946. You describe in your testimony how over the years "courts have become increasingly deferential to agency interpretations of the law." What would be some of the benefits to restoring more effective, thorough standards of judicial review than courts currently employ?

As I discussed during my testimony, perhaps the largest benefit is that effective judicial review prevents an undue concentration of power in a single branch of government. The purpose of judicial review of agency action, after all, is not to increase judicial power, but to ensure that Congress has an appropriate role in the policymaking process. In addition, if agencies understand that their decisions will be subject to more significant review, they will have greater incentives to undertake more rigorous analysis when promulgating those rules in the first place.

13. You note that under *Chevron* "some courts have held that courts should defer to an agency's determination of whether it has regulatory jurisdiction in the first place." How do you think a court should approach this question?

Chevron is based on the principle that when Congress delegates to an agency the power to promulgate rules implementing a statute, this delegation carries with it the power to resolve ambiguity in the statute in a reasonable manner. However, the question is considerably different where the ambiguity involves whether or not Congress intended to confer regulatory jurisdiction in the first place – or, put another way, whether Congress has actually delegated power over the subject matter to the agency. In such circumstances, in my view, courts should rigorously analyze an agency's assertion of regulatory jurisdiction in the first instance to ensure that it is consistent with congressional intent.

RESPONSE TO POST-HEARING QUESTIONS FROM MATTHEW C. STEPHENSON, PROFESSOR, HARVARD LAW SCHOOL

Matthew C. Stephenson

Testimony to the House Judiciary Committee's Subcommittee on Courts, Commercial and Administrative Law

Answers to Members' Additional Questions for the Record in Connection with the May 31, 2001 Hearing on "Formal Rulemaking and Judicial Review: Protecting Jobs and the Economy with Greater Regulatory Transparency and Responsibility"

June 24, 2011

1. **In your prepared statement, you indicate that there is "disturbing evidence that judges' personal policy preferences play a greater role than they should in evaluating agency regulations." Could you please expand upon what this evidence consists of?**

The evidence that judges' policy preferences influence their evaluation of legal challenges to agency regulations consists primarily of studies finding that there are systematic differences in the voting patterns of judges appointed by Republican presidents and judges appointed by Democratic presidents. (The finding is actually a bit more subtle: It seems, from the weight of the evidence, that judicial *panels* in which a majority of the judges are Democratic appointees behave differently from panels in which a majority of the judges are Republican appointees. Moreover, ideologically homogeneous panels – those in which all the judges were appointed by presidents from one of the two parties – behave differently than panels that contain at least one "minority" judge, appointed by a president of a different party.) Some of these studies look for correlations between judicial votes between judicial partisan affiliation and the substance of judicial rulings (for example, treating a finding in favor of an environmental advocacy group as a "liberal" outcome and a finding in favor of an industry group as a "conservative" outcome) and typically find a correlation between the political ideology of the President who appointed a given judge and the liberalism or conservatism of that judge's subsequent votes.

Taken together, this body of evidence suggests that there are real and significant differences in how Democratic and Republican appointees vote in cases involving review of agency regulations, and that these differences seem to track what we might think of as a stereotypical difference between "liberal" and "conservative" political ideologies or regulatory philosophies.

It is important not to overstate or distort what these studies actually show. The evidence does *not* support the proposition that judges are "ideologues," or that they are unconstrained by law. The evidence does not show that Democratic and Republican appointees *always* vote differently, nor does it show that Democratic judges always take a stereotypically "liberal" position while Republican judges always take a stereotypically conservative position. Often judges of different political backgrounds agree – indeed, they agree more often than they disagree. Moreover, there is a great deal of

heterogeneity among judges, even among judges who were all appointed by the same President.

Nonetheless, the evidence does seem to support the proposition that judges' political ideologies influence their disposition of cases involving review of agency regulations. Perhaps this is inevitable to some degree: Many of the prevailing standards of review in administrative law call for an inquiry into the "reasonableness" of an agency's decision, and it is not all that surprising that one's assessment of reasonableness may be influenced by one's own views of sound policy. Yet the consistent evidence that judges' political ideology influences their decisions – even in contexts where the law would seem to leave little room for discretionary policy judgments – may be cause for concern.

A number of the studies showing the affect of partisan affiliation on case decisions in the administrative law context are cited and summarized in the following book chapter: Matthew C. Stephenson, "Statutory Interpretation by Agencies," in *Research Handbook on Public Choice and Public Law* (Daniel A. Farber & Anne Joseph O'Connell, eds. 2010), pp. 306-307.

2. **You note in your prepared statement that "very few statutes use the precise 'on the record after opportunity for an agency hearing' language" that would trigger formal rulemaking requirements. Although Congress clearly has the power to require formal rulemaking in any statute pertaining to agency rulemaking, why has this power been so rarely invoked?**

The reason seems to be that by the late 1970s, or at least by the early 1980s, a broad bipartisan consensus had emerged that the formal rulemaking process was not well-suited to the sorts of complex regulatory decisions that make up the bulk of agency rulemaking activity. In those few instances where Congress had mandated full-blown formal rulemaking, the results were bad enough – and Congress got enough complaints from constituents and the executive branch – that the requirements were often scaled back or dropped entirely.

The most prominent example of this is the Food and Drug Administration's food labeling rules. As was noted in the hearing, the FDA used to be required to use a formal rulemaking process to make or alter food labeling rules. The result was an absurd degree of inefficiency, exemplified by the famous "peanut butter case," in which the FDA's decision to increase the minimum peanut content in products sold as "peanut butter" from 87% to 90% took nine years in the administrative process, plus two additional years in litigation, and a retrospective analysis revealed that the extensive oral hearings had added almost nothing of value to the decision-making process. In 1990, Congress enacted the Nutrition Labeling and Education Act, which eliminated the formal rulemaking requirement for FDA food labeling rules (with a small number of specific exemptions). This seems to have been a direct response by Congress to the bad experience with formal rulemaking.

A second reason that Congress may have been reluctant to impose formal rulemaking requirements is that such requirements might not seem necessary in light of the gradual but dramatic expansion of the procedural requirements associated with the nominally "informal" notice-and-comment process. That process already provides for extensive opportunities for participation in the agency decision-making process and criticism of agency proposals. So there has not been a perceived need for more proceduralization of the rulemaking process in most regulatory policy areas.

3. Last week, President Obama announced his plan to scale back or eliminate hundreds of federal regulations that would save American businesses billions of dollars in unnecessary costs. What impact would formal rulemaking have on this effort?

Because the process for repealing or amending a regulation is also a "rulemaking" under the Administrative Procedure Act (APA) (see § 551(5) of the APA), virtually all of these proposals for scaling back or eliminating costly regulations would need to go through the rulemaking process. If formal rulemaking were required for these changes, then the process would take considerably longer, and in many cases agencies might not be able to proceed with these cost-saving rulemakings, simply because they lack the time and resources to conduct formal rulemakings on all these mattes.

4. Our colleagues on the other side of the aisle appear to argue that formal rulemaking provides an opportunity for facts to be proven more rigorously and promotes more transparency with regard to agency decision-making. What is your response?

Respectfully, I do not think that this claim is correct, for two related reasons. First, the notice-and-comment rulemaking process already provides extensive procedural safeguards that ensure both a considerable degree of transparency and ample opportunity for challenging agency factual assertions. I am not aware of any systematic evidence that notice-and-comment procedures are inadequate in this regard. Of course, one can always find cases where one disagrees with the agency's conclusions, and in such cases it is always possible (and tempting) to assert that if only there had been more (or different) procedures, the outcome would have been different (and better). But I'm not aware of any credible evidence that there are significant problems with the notice-and-comment system with respect either to transparency or to the accuracy of agency factual conclusions.

The second reason that formal rulemaking procedures will probably contribute much to the quality of the agency decision-making process is that formal rulemaking procedures are not all that well-suited to complex policy decisions that require balancing a broad array of competing interests. Formal rulemaking procedures are modeled after the procedures used for judicial trials. They imagine a highly adversarial process focused figuring out whether particular facts are true or not, and where much will turn on the credibility of witnesses' accounts of a particular event. The archetypical sort of dispute that hearings like this are designed to address is whether a particular defendant broke a

particular existing law. But most rulemakings are more like legislative acts than adjudicative acts. They're not about finding someone "guilty" or "liable," but about designing the best policy to response to some complex social problem. The procedures that are appropriate therefore look more like the procedures a legislative body would use, rather than those that a court would use. (In this regard, it is worth observing that the U.S. Congress does not subject its Members, or their staffs, to cross-examination by lawyers representing opposing interests. Thinking about the reasons why Congress does not do this – even though it could – may be helpful in revealing important qualifications to sweeping statements about the virtues of adversarial, lawyer-dominated cross-examination, which in turn might clarify why so many commentators view these procedures as inappropriate for the rulemaking as well.)

One final, related point: Much of the concern about the agency regulatory process seems to focus on agency use of scientific evidence. However, there is very little evidence that agencies are making scientific errors of the sort that cross-examination, or the other trappings of the formal rulemaking process, are likely to correct. Most of the disputed scientific questions at issue in agency regulations are issues of interpretation or extrapolation from inevitably imperfect data or theories. Moreover, the quasi-judicial formal rulemaking process seems particularly ill-suited for rigorous evaluation of these complex scientific questions. It is true that courts must often assess scientific evidence as well, and we do use cross-examination of expert witnesses in that context. But countless observers have argued persuasively that the courts in fact do quite a bad job handling this sort of complex scientific evidence, precisely because trial-type adversarial procedures are not very well-adapted to those sorts of issues.

5. You note in your prepared statement that the "effect of imposing more stringent hard look review would be to make it more difficult and costly for agencies to adopt new rules." Who would bear these additional costs?

The costs would be borne (directly) by the agencies themselves, which would have to devote additional time and resources to each rulemaking proceeding.

The costs would also be borne (indirectly) by those members of the public who would benefit from the delayed or forgone agency's action.

6. Should judicial review be available to determine whether an agency has complied with the Information Quality Act?

My instinct is no. The Information Quality Act already provides an administrative mechanism whereby parties can seek to ensure that agencies are in compliance with the regulations on information quality. There is no evidence that these administrative mechanisms are inadequate. Indeed, I am not even aware of any individual cases in which these administrative mechanisms have failed to correct a clear violation of the relevant regulations. (There have been a few lawsuits making such allegations, but the assertions in those cases, so far as I can tell, seem fairly weak.) All judicial review would add, in this context, is additional cost to the agency, which in turn gives outside parties a

weapon that they can use to deter agencies from publishing controversial information. In other words, judicial review under the IQA would facilitate the equivalent of "nuisance suits" in the private civil litigation context, where even meritless claims are used to extort concessions from a target anxious to avoid litigation costs.

Though this is a bit beyond your question, I think it may also be worth pointing out that a potential problem with the IQA is its asymmetrical effect in the rulemaking process. If an agency wants to rely on its own studies or reports as the factual basis for a rule, those studies presumably must comply with the standards for quality and reliability laid out in the regulations promulgated pursuant to the IQA. The studies included in comments submitted by outside parties, however, do not need to meet these quality standards – even though these comments often make factual assertions that would not meet the relevant IQA guidelines. If Congress is committed to retaining the IQA, one might consider remedying this asymmetry by amending the IQA and/or the APA to make clear that an agency need not take into account public comments that rely on data or studies (including studies of a regulation's likely economic impact) if those studies would not conform to the IQA guidelines that would apply to government information on the same topic.

7. Mr. Francisco contends that courts "[o]ver time" have shifted "strongly toward deference and away from rigorous judicial review." Do you agree that such a shift has occurred?

Respectfully, I do not agree. It is certainly true that the federal courts are generally deferential to agency conclusions of fact, law, and policy. This has been true for some time. But the claim that the level of deference is high is distinct from the claim that the level of deference has been increasing. There is no solid evidence to support the latter claim, and indeed there are some suggestive indicators that the claim is incorrect.

This is most evident with respect to judicial review of questions of law. Prior to the 1980s, judicial review of agency legal interpretations, though deferential, applied a multi-factor balancing test. Often the courts would reject an agency's proposed construction of a statute if the reviewing court concluded that, all things considered, deference would not be appropriate. The Supreme Court's seminal decision in *Chevron v. Natural Resources Defense Council* prompted a move toward a more categorical and deferential approach to judicial review of agency statutory interpretations. But in 2001, the Court decided *United States v. Mead Corporation*, which suggested significant limits to *Chevron*'s scope, and provoked a flurry of cases in the lower courts exploring these limits. Thus for the last ten years the movement in the doctrine seems to have been *away* from deference and toward (somewhat) more rigorous judicial review – precisely the opposite of Mr. Francisco's claim. (Indeed, I was somewhat surprised that Mr. Francisco's prepared statement did not even mention the *Mead* decision in his discussion of judicial deference to agency legal interpretations, despite the fact that *Mead* is probably the most important administrative law decision of the past decade.) More generally, the few studies that try to measure judicial deference over time have not found clear trends in one direction or another over the past several decades. Rather, the pattern seems to be more random, or

perhaps cyclical, with judicial deference sometimes increasing and sometimes decreasing. (My own contribution to this literature, now perhaps somewhat out of date, is Matthew C. Stephenson, "Mixed Signals: Reconsidering the Political Economy of Judicial Deference to Administrative Agencies," *Administrative Law Review* 56(3): 657-738 (2003).)

On "hard look" judicial review of agency factual and policy conclusions, the evidence is even murkier, but I am not aware of anything that would support the assertion that judicial deference has increased sharply over the past decade or so. Certainly it is not hard to find prominent cases in which the courts have invalidated agency decisions as arbitrary and capricious, or as unsupported by substantial evidence. Judicial reversal rates alone cannot tell us all that much, because agencies are likely to change their behavior in response to the anticipated behavior of the courts. Nonetheless, the "rigor" of judicial review on questions of fact and policy does not seem to have changed all that much.

Perhaps Mr. Francisco's claim was about a much longer-term trend. If his point was that courts (especially the D.C. Circuit) engaged in more rigorous judicial review in the 1960s and 1970s, but that since the mid-1980s the courts have generally adopted a more deferential approach, then I would largely agree. But if the claim is about a more recent trend toward increased judicial deference, then I would have to respectfully disagree that there is any reliable evidence supporting that assertion, and the limited evidence that does exist suggests that, if anything, the opposite is true.

8. **Would formal rulemaking inhibit or even largely foreclose significant public participation by individuals and noncommercial interests? Would it enable commercial interests to play a greater role – because of the attendant litigation expenses – than it affords individuals or noncommercial interests? Is it possible that formal rulemaking could be construed to be less democratic than informal rulemaking, which essentially provides a more level playing ground?**

I think I might disagree slightly with the suggestion, in the last part of your question, that informal rulemaking provides a "level playing ground." There is plenty of evidence that commercial interests are much better and representing their interests in this process than are other constituencies. (See, e.g., Jason Yackee & Susan Webb Yackee, "A Bias Toward Business?: Assessing Interest Group Influence on U.S. Bureaucracy," *Journal of Politics* 78: 128-139 (2006).)

But your question is really about a comparison between formal and informal rulemaking. Here, I'm not aware of any evidence one way or the other, in part because there are so few areas where formal rulemaking is required we don't have a lot of data. But I am inclined to agree with your suggestion that greater proceduralization of the rulemaking process will give an advantage to those who can participate directly in the process, which in turn means that more procedural formalization will tend to advantage those who can afford to hire fancy Washington lawyers who are good at this sort of thing.

So I think it's fair to hypothesize that formal rulemaking might give commercial interests even more of an advantage over individuals (though, again, true "individuals" – those not affiliated with some larger organization – already have very little real influence on agency decision-making.)

In terms of whether formal rulemaking will advantage (organized) commercial interests over (organized) commercial interests, I'm not as certain. Overall, I think I would agree that commercial interests would probably have an advantage, given their greater access to resources and more direct stake in many agency regulatory decisions. But certain non-commercial organizations might also benefit (at least in the short term) from greater formalization of the rulemaking process. It's always worth recalling, after all, that in the late 1970s and early 1980s it was often the "public interest" organizations, like the Natural Resources Defense Council, that sought to impose or exploit formal procedures in order to slow down, stop, or modify agency rules. The handful of public interest groups that are large, well-financed, and sophisticated might do reasonably well in a more formalized rulemaking environment. By and large, these are the same organizations that already have a reasonable degree of influence in notice-and-comment rulemaking.

9. When non-industry interests do not participate in the rulemaking process, is it more difficult for administrative officials to ascertain their views on issues of fact, law, or policy?

Yes, it is more difficult, though it is not impossible for interested parties to convey their views outside of the context of the "official" comments submitted in rulemaking.

It's also worth noting that although I share the concern about the distributional effects of greater formalization, the problem isn't so much that formal procedures would exclude parties who would otherwise have participated in the notice-and-comment procedure. After all, the formal rulemaking procedures do not prohibit interested parties from submitting written comments. The problem is that procedural formalization creates an additional opportunity to attack the agency regulation, and this set of additional procedural "weapons" can be more easily utilized by some parties than by others.

10. Is public participation in agency decisionmaking highly sensitive to cost and delay?

I'm not sure I completely follow the question, but if I understand it correctly, you're asking whether increasing the costs and delays of the rulemaking process would reduce public participation in that process. Here, I'd say that although there may not be a big direct effect, there's an important – and easy to overlook – indirect effect.

The reason I don't think there would be a big direct effect is that making agency rulemakings more costly and time-consuming for the *agency* does not necessarily mean that participation becomes much more costly to the *public*. (Certain forms of participation may be prohibitively costly, of course. But if a member of the public would

have sent in a comment in a notice-and-comment proceeding, she can send in exactly the same comment in a formal rulemaking proceeding.) There's even a sense in which greater delay might increase public participation, insofar as dragging on the hearing process for years enables more potentially interested parties to jump in, though in my view that sort of increased "participation" has very little true value.

So I don't think public participation in rulemaking is highly sensitive to cost and delay in the way your question implies. But I do think that greater formalization of the rulemaking process would have a profound adverse effect on public participation through a more indirect channel. As I mentioned in my prepared remarks, one likely (and reasonably well-documented) consequence of imposing greater procedural costs to the rulemaking process is the tendency of agencies to make more of their important policy decisions outside of that process. That is, as rulemaking becomes more costly, agencies will make their "rules" through case-by-case administrative adjudications or through ostensibly non-binding "guidance" documents. These alternative procedural forms do not provide the same opportunities for broad public participation as the notice-and-comment rulemaking process does. So, although increasing the costs and delays associated with rulemaking might not reduce opportunities for public participation in the rulemaking process itself, such an increase in procedural costs would lead agencies to make policy using other mechanisms that do not involve as much public participation, leading to an overall decline in public participation in the agency policymaking process.

11. Why have most scholarly commentators emphatically rejected the imposition of cross-examination as part of rulemaking procedures?

As I mentioned in my prepared remarks and in answer to a previous question, the reason is basically threefold:

First, existing notice-and-comment procedures provide ample opportunity for critical analysis of agency proposals and factual assertions, such that additional procedures like cross-examination do not seem to be needed.

Second, as the cautionary example of the FDA's peanut butter rule should remind us, cross-examination (and the other features of formal rulemaking) can impose substantial costs, delays, and inefficiencies, leading to the "ossification" of agency rulemaking and giving agencies incentives to find other, less socially desirable ways to make policy (such as case-by-case adjudication).

Third, adversarial cross-examination procedures, though perhaps well-suited for the resolution of certain types of individualized controversies (such as whether a particular defendant is broke an existing law), it is not all that well-suited to the sorts of quasi-legislative policy decisions that are central in most agency rulemakings, nor are they very effective in illuminating the interpretation of complex scientific data (which is perhaps why adversarial cross-examination, though used in judicial trials, is typically used neither by legislative nor scientific bodies).

I would like to emphasize here that the scholarly rejection of a formal cross-examination is broad and bipartisan. I fear, given the tenor of this hearing and some of the surrounding commentary, that this issue is in danger of developing a highly partisan cast, with Republican Members pushing for more formal rulemaking and Democratic Members opposing it. This would be unfortunate. I would respectfully suggest that before proceeding with any legislation in this area, majority Members canvass the views not only of the handful of D.C. lawyers who are pushing for more procedural formalization, but also of conservative Republican administrative law scholars (several of whom I would be happy to recommend) who would provide a very different perspective. I think the Committee would find that the opposition to mandating formal rulemaking is broad and bipartisan, and with good reason.

12. Under a less deferential judicial review standard, would agencies – in order to avoid judicial reversal – amass substantial records that could substantially slow down the rulemaking process and make it more cumbersome and expensive?

Yes, and there is substantial evidence that they already do this. The academic literature on this phenomenon – the so-called "ossification" of agency rulemaking – is extensive (though there are some who have questioned whether the effect under current law is as large as other scholars have claimed). Some of the scholarly books and articles documenting this phenomenon include: R. Shep Melnick, *Regulation and the Courts* (1983); Martin Shapiro, *Who Guards the Guardians? Judicial Control of Administration* (1988); Frank B. Cross, *Pragmatic Pathologies of Judicial Review of Administrative Rulemaking*, 78 N.C. L. REV. 1013 (2000); Thomas O. McGarity, *Some Thoughts on "Deossifying" the Rulemaking Process*, 41 DUKE L.J. 1385 (1992); Thomas O. McGarity, *The Courts and the Ossification of Rulemaking*, 75 TEX. L. REV. 525 (1997); Richard J. Pierce, Jr., *Seven Ways to Deossify Agency Rulemaking*, 47 ADMIN. L. REV. 59 (1995); Richard J. Pierce, Jr., *The Unintended Effects of Judicial Review of Agency Rules: How Federal Courts Have Contributed to the Electricity Crisis of the 1990s*, 43 ADMIN. L. REV. 7 (1991); Richard J. Pierce, Jr., *Judicial Review of Agency Actions in a Period of Diminishing Agency Resources*, 49 ADMIN. L. REV. 61 (1997).

13. Would a small business or community organization be able to provide sophisticated scientific of technical evidence in support of its position that could balance a large corporation's ability to flood the record with scientific studies that support its position?

Sometimes yes, but very often no.

14. Could well-financed interests be in a better position to control the factual conclusions of an agency proceeding than smaller organizations or even the agency itself?

Yes, that is often the case. This is true in the regulatory process in much the same way, and for much the same reason, that it is often true in the legislative and judicial process.

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