# THE QUALITY OF REGULATORY ANALYSES

## HEARING

BEFORE THE

SUBCOMMITTEE ON REGULATORY REFORM AND PAPERWORK REDUCTION

OF THE

COMMITTEE ON SMALL BUSINESS
HOUSE OF REPRESENTATIVES

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# THE QUALITY OF REGULATORY ANALYSES

**THURSDAY, JUNE 8, 2000**

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON REGULATORY REFORM AND
PAPERWORK REDUCTION,
COMMITTEE ON SMALL BUSINESS,
*Washington, DC.*

The subcommittee met, pursuant to notice, at 10:48 a.m., in room 311, Cannon House Office Building, Hon. Sue W. Kelly, [chairwoman of the subcommittee] presiding.

Chairwoman KELLY. Good morning, ladies and gentlemen. I would like to thank you for attending this hearing of the Subcommittee on Regulatory Reform and Paperwork Reduction. This is the second hearing in a series of hearings being held at the full Committee level and in this Subcommittee concerning the reauthorization of the Paperwork Reduction Act and the effectiveness of other regulatory reform efforts currently in place.

Yesterday, we focused on the regulatory burdens imposed on small business and the regulatory relief efforts of the administration. Today, we will narrow our focus to discuss the quality of agency regulatory analyses. In order to explore this issue, we must discuss the adequacy of agency compliance with analytical requirements mandated by the Administrative Procedure Act, the Regulatory Flexibility Act, and various other executive orders meant to direct agencies in producing regulations whose benefits outweigh their costs and achieve their objectives in the lowest cost manner possible.

Witnesses will focus on whether these analyses provide agencies with sufficient information to properly assess the impact that the rules will have on the regulated community and the small business community in particular. Additionally, we will discuss any changes that are needed to ensure that agencies recognize these impacts, including whether Congress should obtain an independent assessment of these analyses in order to carry out its legislative functions. And while the subject may not be as entertaining as hearing Chuck D expound on the sale of music on the Internet, for small businesses affected by the ever-burgeoning mound of regulation and paperwork requirements, it is critical that this Subcommittee place this rather dry subject at the top of legislative priority.

Small business owners are very familiar with the burdens that Federal regulations place on them. Some studies have shown that for small employers, the cost of complying with Federal regulations is more than double what it costs their larger counterparts, and you do not need any study to reach that conclusion. Common sense

will say that if a regulation costs General Motors and a 500–employee manufacturer of a copper tubing company the same amount of money, the overall impact on General Motors is going to be significantly less on a per unit basis.

As a result, small business owners have historically been interested in regulatory reform efforts in Washington. Any mechanism that will help control the size of this burden is naturally appealing to the small business community. The APA, SBREFA, and several other executive orders are such mechanisms. But these efforts will manage the regulatory burden only if they are implemented fully and only if Congress keeps a watchful eye on their progress.

As the Committee whose goal it is to promote and protect the interests of small businesses, we have the obligation to discuss how well agencies are satisfied with and are satisfying these analytical requirements and to explore ways in which Congress can better understand these regulations that small business owners struggle to comply with on a daily basis.

There is yet another underutilized mechanism reducing the regulatory burden on small business, the Congressional Review Act. On March 29, 1996, the Small Business Regulatory Enforcement Fairness Act, or SBREFA, became law. Included with this legislation was a section that established a CRA, a formal tool by which Congress could review and prevent new regulations from taking effect without going through the normal legislative process. Used properly, this new oversight device could greatly enhance the regulatory process by ensuring that only those regulations which are truly in the public interest are allowed to go into effect.

Unfortunately, the Congressional Review Act does not appear as if it is being used effectively because it is not being used at all. Not a single resolution of disapproval under the Congressional Review Act has passed. The House has failed even to vote on one. Some have given up on its ability to halt regulations that do not have sufficient justifications that go beyond what Congress, or that create unintended consequences that require correction. But I believe that combined with oversight hearings, legislative efforts, and the submission of Congressional comments, CRA still has some hope.

Regardless of whether or not you believe CRA can be used, you must admit that Congress does not have enough information to undertake appropriate oversight of the powers delegated to agencies by Congress. The power delegated to these agencies enables them to issue rules and those rules may not meet the objectives or have the consequences that Congress expected when it enacted the legislation.

For example, when Congress enacted the Federal Motor Carrier Safety Act to create the Federal Motor Carrier Safety Administration, it certainly expected that the agency would enact rules to improve the safety of our highways through improved regulation of truckers. However, the most recent proposal from the FMCSA may have substantial unintended consequences for tour bus operators, independent route salesmen, and manufacturers. These consequences apparently were not considered when the FMCSA decided to treat all those individuals who drive professionally on the nation's road systems in an identical manner.

To help address this problem, I was joined by Chairman Jim Talent in introducing H.R. 3669, the Congressional Oversight and Audit of Agency Rulemaking Actions Act. We call it COAARAA. This office would focus solely on conducting independent regulatory assessments of regulations to help determine whether the agencies have complied with the law and executive orders. Unfortunately, Congress cannot obtain unbiased information from participants in the rulemaking because each participant, including the Federal agency, has a particular viewpoint and bias. A Congressional Office of Regulatory Analysis would help fill the information gap and assist members of Congress in determining whether action is warranted.

The purpose of COAARAA, then, is to ensure that Congress exercises its legislative powers in the most informed manner possible. Ultimately, this will lead to better regulatory analyses, most cost effective regulations, and most importantly, legislation tailored in a manner to address a narrow problem and not overly broad legislation likely to impose unnecessary burdens on small business. Only through active oversight can Congress ensure that the laws that it passes are properly implemented. This is a responsibility that Congress must take seriously, because as countless small business owners can attest to, not doing so can have dramatic implications.

We have joining us today an excellent panel who will discuss some of these issues. I would like to thank each one of them for participating with us today and I look forward to hearing their testimony. I thank you very much.

Now, I would like to turn to Mr. Pascrell for his opening statement. If anyone else has an opening statement, I am going to ask that it be submitted for the record so that we can move this hearing on. Mr. Pascrell?

Mr. PASCRELL. Thank you. I would like to start my opening statement by thanking my friend, the distinguished Chairwoman from New York, for setting up this hearing to discuss the issue of regulations and their impact on small businesses. In fact, we almost had a little preliminary yesterday at another hearing. I think this serves as a nice complement and more focused follow-up to the hearing that we had yesterday.

The issue we deal with today is one of the most critical issues for small businesses. The need to have rules that are clear, well thought out, and that realistically gauge economic impact, can be critical to the success of small businesses, which are the backbone of our economy. I relish this opportunity to examine the strides that have been made in this area so we can see how successful agencies have been in completing economic analysis that reflect the true cost of these regulations.

Both sides of the aisle have concerns with regulations and their burdens that they place on businesses, and indeed, if one was to look since 1980 at the number of acts and executive orders that have addressed the problem of bureaucracy and regulation and paperwork, particularly in the last seven or eight years, one of the questions that we all have sitting around here is whether these regulations, first of all, are being implemented and how would we know if they were, and second of all, what is the fallout and is that

more treacherous than the regulation which was supposed to correct some problem in the first place?

I do not think that there is any Democratic or Republican way to design a regulation. There is just the correct way, one that is thought out and is not a rush to judgment. It is a way that involves a comment period where the agencies not only take comments but they listen to the suggestions made and evaluate the validity of business concerns.

I personally believe, and this is only my take on this, that any regulation or rule which is the result of legislation that the Congress passes, that since the Congress is taking great pains to discuss this with those folks who are most impacted, and that is why we debate these issues, that when an agency gets that law and now has to implement it, that the rules and regulations should reflect discussions with the particular business. Many times, they do, and many times, they do not, and that is where we have major problems. If there is no one monitoring how these regulations are being implemented, let alone promulgated, I think we have serious problems and we need to address them.

A regulatory impact analysis, which was mandated by the administration, is crucial in making sure burdens are not excessive, and I believe some of those burdens are excessive. I believe some of those burdens do not reflect the spirit and intent of the original laws. They go beyond, and they are usually imposed by second- and third-level bureaucrats who have no appreciation whatsoever of what business folks have to go into day in and day out.

As the study we will look at shows, and as we know from the many complaints our offices receive about overly burdensome regulations, the Federal Government has to do a better job with its analysis to ensure the regulations designed are efficient while at the same time being effective. It would seem to me the only way we can do that is have a report to each Congress of what has happened in the previous Congress and how these are being implemented so that the Congress itself knows of what has been monitored and what has not. You can have all the executive orders by whatever President you wish. If they are not being implemented or if the implementation of those executive orders are worse than the previous situation, then we have created a real amount of chaos and I am sure we do not want to do that.

It is interesting to note that the two parties who compiled the report on both sides of the political spectrum joined together on their conclusions. It is much like our work on the Small Business Committee, which has been for the most part bipartisan. We try to steer away from the extremes. I think that is healthy.

I look forward to using this hearing to look at the Chairwoman's COAARAA legislation contained in H.R. 3669. Maybe what we learn here today can help us weigh the need for an office within the General Accounting Office to compile separate analysis of regulations to balance the job currently done by the Office of Management and Budget.

So I look forward to today's testimony and I thank the Chairwoman for her indulgence.

Chairwoman KELLY. Thank you very much, Mr. Pascrell.

I do want to say one thing before we begin. I look forward to the testimony, but I also thank all of you, every one in the audience and everyone who is on the panel, for waiting for us so patiently. We had no idea when we set the timing on this hearing that we would be caught in the involvement on the floor of the House. So I thank you very much, and with that, we will begin with the testimony.

We will start with you, Mr. Hahn, Mr. Robert Hahn from the AEI-Brookings Joint Center on Regulatory Studies. He is the Director and we are very happy to have him with us today.

**STATEMENT OF ROBERT W. HAHN, DIRECTOR, AEI-BROOKINGS JOINT CENTER ON REGULATORY STUDIES**

Mr. HAHN. Thank you, Chairwoman Kelly, Congressman Pascrell, and Congressman Moore. In listening to your remarks, I am reminded of a Woody Allen story which I will tell you briefly, where his father comes home from work one day and says to his wife, "You would not believe it. You would not believe it." And she goes, "Well, what is wrong?" And he goes, "I have been replaced by a machine." She goes, "Oh, that is terrible but you will go out and find another job." And his mother immediately went out to the department store and bought one of these machines. [Laughter.]

I basically think that the remarks that you made in many ways reflect more common sense than what I am about to tell you, but I want to fill in some of the details that I think are important in talking about regulatory reform, but let me start with a couple of formalities.

First, I am going to talk to you more, so I would ask that my formal remarks be placed in the record. They reflect not only my sentiments but those of Robert Litan, who is the Co-Director of the American Enterprise Institute-Brookings Joint Center for Regulatory Studies.

Chairwoman KELLY. We are glad to have the remarks and we will put them in the record. Thank you.

Mr. HAHN. Thank you. My sister once told my niece, who I am hoping to visit later this afternoon if this hearing ends at a reasonable hour, once told my niece what her Uncle Bobby did, and she told her that he was an egghead. She said, "Well, what do eggheads do?" "They think a lot." So the next time I went down to visit my niece, who is now five, she said, "Uncle Bobby, what is it that you really do?" And I said, "Well, I study regulation." And she goes, "What is regulation?" Remember, I am talking to a five-year-old now. And I said, "We sort of study how when you tell a person to do something, you tell them to do it in a nice way." She says, "Well, how about an example?" I said, "Well, if Mommy tells you to clean up your room, she does not say, 'Put this toy over in that corner and put that toy under your bed,' or whatever. She leaves it up to you how to do that." And she thought about it for a minute and she says, "That is great. Can we watch Winnie-the-Pooh now?"

This is a real problem with regulatory reform in the large, and I do not have to tell you that. One is, one conveying to people why it is important, that it can have an impact on each of our freedoms, it can have an impact on the size of the economy, the way we run our personal lives, the way we choose to engage with each other in

business. So it seems that the more things change, the more they remain the same.

I am sure you have heard the story and probably testimony from former Senator George McGovern about when he left this august body, in this case the Senate, he talks about how he tried to start an inn in New England and he said, "Gosh, if I only knew then what I know now about regulation, I would have done things a lot differently."

There has been a steady stream of legislation and executive orders related to regulatory reform which you, Congressman Pascrell and you, Chairwoman Kelly, both told us about in your introductory remarks. The reality is that not much has been done. That is the bad news. The good news is, I think if we as foot soldiers, I include you in that army, if you will, and myself and the other distinguished members of the panel, if we stay focused and we stay focused on the right thing, I think we can make some headway.

First, let me start by asking what is the nature of the problem, and we go into this in more detail in our formal remarks. Well, the nature of the problem is the Federal Government requires expenditures on the order of $200 billion a year, very, very, very roughly speaking. Those costs are imposed on the private sector, and to a lesser extent government bodies, to do things. We do not have a particularly good idea of what is being done.

Congressman Pascrell, you talked about you have a hunch that some things are being done that do not make sense. Well, let me give you one example based on a study that I did not do but my colleagues, Randy Lutter and Elizabeth Mader, are just releasing today at the Joint Center.

We have a lot of legislation regulating lead out there because lead is of concern for children's health, among other things. Did you know that the regulations that you were in charge of making the laws for and that EPA and HUD are in charge of implementing, those regulations require more stringent regulation of lead at hazardous waste sites than in the kid's back yard? There may be no kids at the hazardous waste site. Lots of kids play in their back yard. Do we have a problem? Maybe.

We could be doing a much better job of improving kids' health, saving kids' lives, and saving money if we simply took a careful look at the process. We could do a better job of facilitating entrepreneurship in small business, in large business, if we took a serious look at what the paperwork requirements do and what these silly regulations of which I just gave you one example. George McGovern, for all we know, might be in business in New England today promoting bed and breakfasts. We could do a much better job of making sure that regulations do not impose a drag on the economy.

Okay, how do we do this? How do we begin to think about improving the quality of regulation so that you and appointed civil servants can make better decisions? The short answer is it takes two things. One, you guys have got to step up to the plate. You have got to have guts. This is in short supply in this town. You have really got to have guts. And the second thing is it requires common sense, which you have already articulated in your opening remarks.

Let me say a little bit about what I think we know about the quality of regulatory analyses, and I have a few people in the audience who I would like to acknowledge who have helped me on this, some of whom have already left me, very wisely. Irene Chan, who did some seminal work on this last year, looking at what the government actually does in terms of their regulatory analyses, and my colleagues, Jason Burnett and Aaron Labor, and will be happy to field any tough questions from you. But I will give you the broad-brush view of what I think we know.

First of all, based on my earlier research, from an economist's point of view, many of the regulations that the Federal Government are implementing now are not likely to pass an economist's version of a benefit-cost test. I estimate that on the order of half the regulations, using the government's own analyses as data, would not pass a benefit-cost test. I find that rather disturbing. That is the first point.

The second point, which speaks, Chairwoman Kelly, to the substance of this discussion today, is the quality of the analyses themselves. Well, the quality of the analyses in my view is really poor. We looked at analyses, so-called regulatory impact analyses, over the last three years, between 1996 and 1999, all of them that we could find for major environmental health and safety regulations, and the bottom line is they do a bad job of even complying with their own guidelines. This is based on a Joint Center study, not funded by any particular business or whatever, just an independent study by economists.

What do we find? We find that of those rules that we reviewed carefully, and Irene and Jason can tell you more about this, only 28 percent of those rules presented information on net benefits, that is, benefits and costs and taking the difference. Well, if you are going to be making multi-million and in some cases multi-billion-dollar decisions, I think the American public deserves to know what is happening.

The second thing we found is that they quantified benefits and costs of alternatives for only a quarter of the regulations. Did you think of another way to clean up your room, Katie, or is this the only way to do it? Most of the time, these guys did not bother to look whether there were other ways to clean up the room, the hazardous waste site, or the dirt in the back yard. Duh, we have got a problem.

All right. What are we going to do about this problem? I am going to briefly go through some of my recommendations, some of which are based on the good work of your Committee. The first is, I think in the interest of accountability and transparency, you ought to put these regulatory impact analyses and their underlying supporting documents on the Internet. Hey, if Al Gore invented it, we might as well use it. Let us use the Internet to tell people what is happening about regulation, with all due deference to the Vice President—just a joke. And before a regulation—this is important—before a regulation is actually considered at OMB, we ought to put it on the Internet so it is available to eggheads like myself and also real people.

My second point, and this is a point which you might find astounding, but it is not, is that these regulatory impact analyses do

not summarize in any sort of standardized way what they actually do. What does that mean? I have to hire a group of some of the best graduate students to spend sometimes up to a week to figure out what these analyses are saying. Well, Congress people do not have a week to look at what is in these analyses, so we recommend that you write a clear executive summary when you do these regulatory impact analyses and you attach a table to tell people what you did and what you did not do.

Did you consider costs? Did you quantify them? Did you consider benefits? Did you quantify them? Did you consider alternatives? Did you try to quantify the impacts of those alternatives? What were the kinds of technical assumptions you made underlying these analyses to get your results?

Again, it is not rocket science, but this is not enough. As Congressman Pascrell pointed out, you have got to figure out whether you have the guts to enforce these things. I mean, there are executive orders on the books here and there are tons of beautiful laws in the Soviet Union, or the former Soviet Union, that make it look like everything is hunky-dory, but, in fact, everything is not always hunky-dory and sometimes you have to step up to the plate to do things that we believe are common sensical.

Our third recommendation, and this follows along the suggestions of the Chairwoman, is to create something like the Congressional Office of Regulatory Analysis. We think it would help make the regulatory process more transparent to the American people. It would help Congress in finding out what is actually happening down at the other end of Pennsylvania Avenue in terms of regulations and their impact.

If you want me to say more words about COAARAA, I will be happy to do it. Mr. Litan and I testified on this, as you know, previously. We are great supporters of these initiatives for the reasons we state in the paper.

Something else we believe is important, and it would require a little bit of stepping up to the plate, but again, it is common sense, is we believe that Congress should require agency heads to balance the costs and benefits of major regulations. I am not even saying at this point, though I believe the benefits should be at least equal to the cost and ideally greater, but I am saying at least there should be a statement that we balanced these things and this is how we thought about them, if you are making a big decision like the national ambient air quality standards.

And finally, and this is again where you can step up to the plate to make things happen, is we believe that Congress should require that all regulatory agencies adhere to established principles of economic analysis when undertaking a regulatory impact analysis. OMB has already articulated a beautiful set of guidelines. The Joint Center has convened a group of scholars that also talks about established principles. The question is, as Congressman Pascrell pointed out, when are we going to begin to think about implementing these things?

So in conclusion, as I said earlier, it is really going to take guts and common sense. It is very clear to me that the common sense is out there. I hope the political will is there, and I will be happy to entertain any questions after the panel or now. Thank you.

Chairwoman KELLY. Thank you very much, Mr. Hahn.

[Mr. Hahn's statement may be found in appendix.]

Chairwoman KELLY. Next, we go to Mr. Robert Murphy. Mr. Murphy is the General Counsel for the General Accounting Office and Mr. Murphy, COAARAA might land in your lap, so I am very much looking forward to your testimony.

**STATEMENT OF ROBERT P. MURPHY, GENERAL COUNSEL, GENERAL ACCOUNTING OFFICE; ACCOMPANIED BY CURTIS COPELAND, ASSISTANT DIRECTOR, GENERAL GOVERNMENT DIVISION, GENERAL ACCOUNTING OFFICE**

Mr. MURPHY. Thank you, Madam Chairwoman, Mr. Pascrell. I am pleased to be here today to talk about GAO reviews of the compliance by agencies with procedural and analytical requirements of rulemaking. One of the assistant directors at GAO, Curtis Copeland, who led many of these jobs, accompanies me at the table today. With your leave, I will briefly summarize my testimony and in particular talk about two reviews that we did of regulatory impact analyses and ask that the full text of my prepared remarks be incorporated in the record.

Our reviews were conducted in response to Congressional concern that agencies were not, as Mr. Pascrell pointed out earlier, considering the effects of their actions on regulated entities, nor had they worked to minimize those negative effects. The requirements we examined are contained in a number of statutes from the Administrative Procedures Act to the Unfunded Mandates Reform Act, as well as Executive Orders 12866 and 12612.

While they may not have been representative of all rulemakings, our work disclosed inadequate data, methodologies and assumptions, and disclosed noncompliance with the statutory requirements and executive orders. There were examples where, as a result of our work, agencies changed their practices and we helped ensure better adherence to applicable regulatory requirements.

On the other hand, sometimes our reviews did not disclose noncompliances but they provided the facts and the analysis to the Congress to understand what the agencies were up to in their rulemaking. Sometimes we discovered that the issues that concerned the regulated community were not really those of the agencies but were of the underlying statutes concerned, that the aspects of the regulations that were considered burdensome by the regulated community were actually required by the statute being implemented.

Some of our work on regulatory issues has clearly demonstrated the value of Congressional oversight of agency rulemaking. Congressional oversight can clarify issues left unclear in agencies' public statements about their rules and on occasion can directly result in changes to agencies' rules. The targets of that oversight can vary substantially, from the particular and sometimes highly technical elements of agencies' economic analyses used to support the rules to the general public participation requirements in the rulemaking process.

I would like to address, as I said earlier, two particular reviews by GAO. In the last 20 years, we have seen enormous growth in both the breadth and the number of Federal regulations. According to OMB, these regulations have improved public health, safety, and

environmental quality, but they come at a real cost. I do not think anybody estimates the annual cost of these regulations below hundreds of millions of dollars every year.

To control the costs of these regulations, administrations have issued executive orders, such as 12866, and Congress has enacted laws, including the Unfunded Mandates Reform Act of 1995. These orders and laws require Federal agencies to prepare and use economic analyses, also known as regulatory impact analyses, to assess the benefit and costs of proposed significant actions before promulgating those regulations. These analyses are intended to inform and improve the regulatory process by identifying the likely costs and benefits of feasible alternatives.

We were asked to describe the extent to which Federal agencies' economic analyses incorporate best practices and the agencies' actual use of these analyses in regulatory decision making. We included in our review all economically significant proposed and final rules issued between July 1996 and March 1997 that addressed environmental, health, and safety matters. As a result, GAO reviewed the economic analyses used in promulgating 20 regulations by five agencies, the Departments of Agriculture and Transportation, the Environmental Protection Agency, the Food and Drug Administration within the Department of Health and Human Services, and the Occupational Safety and Health Administration in the Department of Labor.

We found that five of the 20 analyses did not discuss alternatives to the proposed regulatory action, six did not assign dollar values to the benefits, one did not assign dollar values to the costs, all of which OMB recommended in its best practices guidelines. OMB guidance gives agencies flexibility to decide how thorough their economic analyses should be. At the same time, the guidance stresses the importance of disclosing the reasons for omissions, gaps or other limitations. Although GAO found many instances in which best practices were not followed in the analyses, the reason for not following was disclosed in only one case.

In addition, eight of the economic analyses did not include an executive summary that could help the Congress, decision makers, the public, and other users quickly identify key information addressed in the analyses. Finally, only one of the 20 analyses received an independent peer review.

I should say that this past March, OMB issued a revision to its best practice guidance for agencies and we found that, again, that guidance falls short of the recommendations that we have made for best practices, and incidentally, several of those that Mr. Hahn has touched upon today.

In another instance, we found that a Congressionally requested review of agency regulatory analysis actually resulted in a change to those rules. We reported last year on the scientific basis for the Food and Drug Administration's proposed rule on dietary supplements containing ephedrine alkaloids and the agency's adherence to statutory and executive regulatory analysis requirements. Although the number and type of adverse event reports that FDA received warranted the agency's consideration of steps to address safety issues, we were concerned about the strength of the informa-

tion FDA used to support two aspects of the proposed rule, the dosing level and the duration of use limits.

We concluded that FDA generally complied with the statutory and executive orders applicable to rulemaking, but the economic analysis that accompanied the rule did not reflect the full range of uncertainty associated with the proposed rule. The agency did not always disclose why certain key assumptions were made or the degree of uncertainty involved in those discussions. It also did not disclose that alternate assumptions would have had a dramatic effect on the agency's estimate of the benefits of the proposed actions.

We recommended that FDA obtain additional information to support conclusions regarding the specific elements in the proposed rule before proceeding to final rulemaking. We also recommended that FDA improve the transparency of its cost-benefit analysis in its final rule.

I am happy to say that in April of 2000, FDA announced that it was withdrawing certain portions of its proposed rule, "because of concerns regarding the agency's basis for proposing certain dietary ingredient level and a duration of use limit for these products." That was an example of where Congressional oversight had an immediate benefit to the public and to the government.

There are numerous other examples of GAO reviews in recent years that demonstrate that Congressional oversight can be effective in ensuring that agency rules are carefully developed and that agencies permit public participation in the rulemaking process.

Madam Chairwoman, this concludes my statement. I would be pleased to respond to any questions.

Chairwoman KELLY. Thank you very much, Mr. Murphy.

[Mr. Murphy's statement may be found in appendix.]

Chairwoman KELLY. Let us move on to Mr. David Addington. Mr. Addington is Senior Vice President of the American Trucking Associations. Mr. Addington, thank you very much for being here today.

## STATEMENT OF DAVID S. ADDINGTON, SENIOR VICE PRESIDENT, AMERICAN TRUCKING ASSOCIATIONS

Mr. ADDINGTON. Thank you, Madam Chairwoman. I have two documents I would like to ask your permission to have in the record, my full written statement submitted to the Committee and the document I transmitted to the staff yesterday, five pages entitled "Summary of the Federal Motor Carrier Safety Administration's Proposed Hours of Service Changes, Updated May 15, 2000."

Chairwoman KELLY. By all means, we will accept them into the record. Thank you.

Mr. ADDINGTON. Madam Chairwoman and members of the Subcommittee, we appreciate the invitation to discuss the Department of Transportation's failure to properly conduct the required analyses to determine the full impact of proposed rules to govern the hours that truck drivers may work. The hours of service scheme proposed by the Department's Federal Motor Carrier Safety Administration is disastrous for the trucking industry, for the safety of the traveling public, and for American consumers. The proposed regulations hit trucking companies hard and they hit small trucking companies hardest. I will describe the trucking industry, some

key problems with the Department's proposed rule, and the defective analyses on which the Department of Transportation, which I will call DOT, based its rule.

The American Trucking Associations, which I represent, is a national trade association for the trucking industry, with more than 2,500 motor carrier company members, large and small who operate in every State of the union. Trucking is vital to the nation's economy. Trucks move the majority of the freight that moves in America. Trucking accounts for more than 80 percent of the transportation revenue in the economy. Seventy percent of America's communities depend for freight service exclusively on trucks. So DOT regulations restricting what companies can do with trucks and drivers directly affects a huge segment of the American economy.

Although some trucking companies are multi-billion-dollar companies whose names you know, such as Mr. Moore's district has the Yellow Corporation, most of the trucking industry is small business. According to DOT, almost 50 percent of motor carriers have only one truck, and a full 95 percent of motor carriers, almost 395,000 of them, have 20 or fewer trucks.

ATA has long called for reform of the existing Depression-era hours of service rule. We ask for new rules based on three things, sound science, public safety, and needs of the American economy. ATA spent two years forging an industry-wide consensus on a proposal for new rules that would meet these requirements and our board of directors adopted that proposal in November of 1999. We filed the ATA proposal with the Department of Transportation in December 1999, but instead, the Department published on May 2, 2000, proposed regulations that are inconsistent in a number of ways with fatigue science and are so far removed from safer highways and economic reality that the ATA must strongly oppose the DOT proposal.

The Department's proposed rules fail the test of science, safety, and economics. On science, for example, the DOT proposal takes drivers whose jobs consist of five night shifts a week and requires them to switch over to sleeping on both weekend nights. But fatigue science would counsel against requiring them to switch their sleep/wake cycle over on both weekend nights.

On safety, the Department's proposal will put more trucks and more drivers on the road just to move the same amount of freight that trucks move today and it will force more of the trucks to operate during daylight hours when traffic congestion is at its peak. Regulations that put more of the trucks on the roads when most of the cars are also on the roads can hardly be characterized as a safety regulation.

On economics, shippers will face significant price increases for freight service. Trucking companies will face tough obstacles in trying to meet the payroll and turn a profit. And businesses and consumers will pay more for the goods they purchase. Congress should send DOT back to the drawing board on its proposed hours of service regulation.

With regard to economic analysis, the Federal law requires the Department of Transportation to conduct an initial regulatory flexibility analysis, or IRFA, when it published its proposed rule. The

Department failed miserably in its attempt to meet this legal requirement. The Department provided only a cursory and inaccurate examination of the economic effects of the proposed rules on the trucking industry. Moreover, it completely ignored the larger economic impacts of the proposed rules on the economy as a whole.

With regard to the trucking industry, the Department undercounted by 100,000 the number of small trucking businesses and that taints the Department's entire IRFA. The IRFA also estimates the economic impact of only one part of the proposed rule, the requirement that companies install in their trucks electronic onboard recorders to monitor the compliance of drivers with the Department's hours of service regulation, and DOT even got that part wrong because DOT underestimates the number of companies that must install the recorders to be in compliance with DOT's proposed rule.

In any event, the regulatory costs that DOT attempted to address are dwarfed by the additional costs that DOT ignored. The Department's regulations will force trucking companies to incur costs for the purchase of new trucks and hiring new drivers. While ATA has not yet completed its final economic analysis of the DOT proposal, our preliminary conclusion is that labor and equipment costs to the trucking industry will increase by approximately 20 to 30 percent.

More trucks moving the same amount of freight also requires additional mechanics to maintain the trucks and additional dock workers to handle getting the freight in and out of the trucks, more costs that DOT ignored. Also, DOT ignored the cost of realigning trucking terminal networks, which were principally designed to allow truck drivers to move efficiently between terminals within the driving hours allowed under the current rules but not under the proposed DOT rules.

The Department also ignored the bigger economic impact beyond the trucking industry. Shippers will pay more to move freight, including smaller manufacturers, wholesalers, and retailers who are the engine of the nation's economy. Many of those costs will, of course, be passed on to consumers in the form of higher prices for goods. The direct result of DOT's proposed rule is inflation, which is hardly what the American economy needs.

With regard specifically to small business, the Department of Transportation failed to meet the legal requirement to compare the economic effects of the proposed rules on small entities with other alternatives. The Department examined alternatives, but only alternatives for the entire trucking industry. The Department did not design or analyze alternatives solely with small companies in mind, nor did it consider the alternatives for minimizing the impact on small entities that the law requires DOT to consider. Thus, the Department failed to produce an initial regulatory flexibility analysis comparing the relative costs and benefits of alternatives as they pertain to small entities.

The Department also made a mistake in its proposal that calls into question the quality of the DOT economic analysis. When it published its proposed rule on May 2, 2000, the Department included the following sentence in the preamble to its rule, ''Therefore, the FMCSA, in compliance with the Regulatory Flexibility

Act, 5 U.S.C. 601–612, has considered the economic impact of these requirements on small entities and certifies that this rule would not have a significant economic impact on a substantial number of small entities."

Now, on May 26, just a few weeks later, the Department stated instead that, "The FMCSA does not know with certainty the full economic impact of the proposal and, therefore, withdraws its negative certification." The withdrawal of the notification is a notable change because the certification has exempted the proposed rule from the Regulatory Flexibility Act's requirements. The Department has explained that its certification was included by error, but the initial erroneous inclusion of the language raises doubts about whether the Department conducted a careful initial regulatory flexibility analysis in the first place. Of course, the practical question also arises of how anyone at DOT could possibly think that the proposed rule would not have a significant economic impact on a substantial number of small entities.

Lastly, while the Department of Transportation admits it does not know the full economic impact of its proposals, even after DOT has looked at various changes to hours of service rules for 20 years, it expects ATA and others to provide this information to DOT within the 90-day period that DOT allowed for comments on the proposed rule. We have asked for an additional 90 days so that we can effectively survey our trucking company members, large and small, and analyze and report the resulting economic data, but the Department has not granted our request.

When the trucking industry, the law enforcement community, the manufacturing industry, the Teamsters, the AFL–CIO all agree that more time is needed to analyze the economic impact of the proposed rule, one would expect the Secretary of Transportation to grant the additional 90 days, but that request has not been granted.

Madam Chairwoman, the Subcommittee asked only that I address the trucking hours of service issues and we appreciate having that opportunity, but I would be remiss if I did not draw the Subcommittee's attention that this rule is only one front of the current three-front regulatory war that this administration is conducting on the trucking industry. The rules on the other two fronts, OSHA's proposed rule on ergonomics and EPA's proposed rule on diesel engine and fuel standards, also are based on faulty economic analyses.

On all three fronts, hours of service, ergonomics, and diesel, the rulemaking process is not driven by the science, it is not driven by health and safety, it is not driven by economics, and it is not driven by the law. It is driven by the desires of the heads of those agencies to issue final rules before the administration leaves office in January 2001. The interests of the public in these rulemakings should not be subordinated to that artificial deadline. The agencies will still be here with qualified people at the helm to make decisions after next January. Let us take our time and get it right.

Thank you, Madam Chairwoman.

Chairwoman KELLY. Thank you very much, Mr. Addington.

[Mr. Addington's statement may be found in appendix.]

Chairwoman KELLY. Next, we are going to hear from Mr. Sal Ricciardi. Mr. Ricciardi, you are here in actually a double capacity, are you not? You are the President of Purity Wholesale Grocers, but also you are the President of the Pharmaceutical Distributors Association, and we appreciate your taking the time to be with us here today and look forward to your testimony.

**STATEMENT OF SAL RICCIARDI, PRESIDENT, PURITY WHOLESALE GROCERS, INC., AND PRESIDENT, PHARMACEUTICAL DISTRIBUTORS ASSOCIATION**

Mr. RICCIARDI. Thank you, Madam Chairwoman and members of the Subcommittee. Thank you for allowing me to speak to you today. I feel like I am really getting my money's worth because I am a member of his organization and I agree with everything he just said.

Mr. ADDINGTON. Thank you.

Mr. RICCIARDI. I request that the text of my prepared statement be placed into the record.

My name is Sal Ricciardi and I am President of Purity Wholesale Grocers of Boca Raton, Florida. I am speaking today for Supreme Distributors, a division of Purity that distributes prescription drugs and on behalf of the Pharmaceutical Distributors Association, PDA, a trade association of ten Rx drug distributors. Most importantly, I am informally representing approximately 4,000 small businesses which are licensed to distribute prescription drugs for human and animal use according to Food and Drug Administration estimates. That is an estimate the Food and Drug Administration made. And there are many thousand customers across America.

As I explained in detail in my written statement, these 4,000 small businesses will be economically devastated and most will be forced to close their doors if an FDA rule issued to complete the implementation of a 1988 law known as the Prescription Drug Marketing Act is allowed to go into effect. The FDA rule establishes a "catch-22" type situation wherein smaller drug distributors are required to obtain a very detailed sales history for drug products going back to the first sale by the drug manufacturer before those products can legally be resold. However, neither the PDMA nor the FDA rule require either the drug manufacturer or the large national wholesalers who purchase the large majority of drug products directly from manufacturers to provide this sales history to the secondary distributors. I know this is a mouthful. However, allow me to explain a little further.

The result is that the rule will make it illegal for most wholesalers to resell prescription drugs and this will cause the loss of thousands of jobs, disrupt existing distribution channels for thousands of nursing homes, clinics, doctors' offices, and veterinary practices across the country, potentially putting patients and animals at risk and remove an important restraint on pharmaceutical prices by reducing marketplace competition.

To understand the real impact of the rule, we called the authorities in each State who license the distribution of prescription drugs. We found that more than 32,000 licenses had been issued to distribute Rx drugs. It is obvious from this figure that most distribu-

tors, including small companies like mine, distribute in multiple States.

Of particular interest to the Subcommittee is the fact that the FDA's analysis of the effect of this rule on small business was 100 percent wrong. The FDA's analysis published in the Federal Register concluded that the majority of the estimated 4,000 small distributors will not be affected by this rule. In fact, they will all be seriously affected by the rule and most will be driven out of business. The FDA's analysis did not calculate the number of jobs that would be lost, the economic loss to the owners of the business that would be wiped out, the likely increased cost to pharmaceutical end users because of the elimination of existing supply channels, and a decrease in competition and the very real potential physical threat to patients whose supply of life-saving and life-enhancing drugs would be disrupted.

I believe that these impacts are more than large enough to qualify this regulation as a major rule and that the FDA should be required to perform the proper analysis before the rule is reimposed. I would also like to note that for about the past 12 years during which the drug distribution has been operating under FDA interim policy guidance, which does not require tracing sales history of products back to the manufacturers, there have been no significant quality or safety problems.

In conclusion, I would draw the Subcommittee's attention to H.R. 4301, a bipartisan bill that would make small but vital technical corrections to the statute. This bill would allow the 4,000 small distributors to continue to serve their customers and provide vital price restraining competition while preserving the current safety and integrity of our national pharmaceutical distribution system.

I thank you for your attention and will be happy to answer any questions you might have.

Chairwoman KELLY. Thank you very much, Mr. Ricciardi.

[Mr. Ricciardi's statement may be found in appendix.]

Chairwoman KELLY. Next, we would like to hear from Ms. Wallman, and thank you for being so patient, Ms. Wallman. Kathleen Wallman is President and CEO of Wallman Strategic Consulting, LLC. Thank you very much for being with us.

## STATEMENT OF KATHLEEN M.H. WALLMAN, PRESIDENT AND CHIEF EXECUTIVE OFFICER, WALLMAN STRATEGIC CONSULTING, LLC

Ms. WALLMAN. Thank you and good morning, Chairwoman Kelly and Congressman Pascrell. Thank you for the opportunity to participate in today's hearing.

My statement addresses the experience of a particular kind of small business, rural telephone companies, and offers some observations about regulatory impact analyses conducted by the independent Federal regulatory agency that regulates them, the FCC. My observations are based on my work with these companies in different capacities. I have worked on these issues most recently as an advisor to small companies and their Washington representatives and previously as chief of the Federal Communication Commission's Common Carrier Bureau and at the White House as Dep-

uty Assistant to the President for Economic Policy at the National Economic Council.

Rural telephone companies have a vital role in ensuring that all Americans, no matter where they live, have access to telecom networks. The special challenges that these companies face in serving remote and sparsely populated parts of our country are well documented in the policy literature and in FCC proceedings. Congress expressly recognized these small rural telephone companies as a category unto themselves in the Telecommunications Act of 1996. Most rural telephone companies fit easily into the category of small business and do not have resources devoted exclusively to monitoring Federal regulatory matters or mounting advocacy efforts in FCC proceedings.

This is why the Regulatory Flexibility Act passed in 1980 and amended by the Small Business Regulatory Enforcement Fairness Act in 1996 is potentially such an important tool in ensuring that Federal rules are adopted with an adequate awareness of the impact that the new rules or rule changes will have on small companies, such as rural telephone companies. The question is, how well is it working?

My own view that it is starting to work in some ways but that its implementation can be improved. There are inherent difficulties in trying to implement regulations that affect rural telephone companies in a way that is sensitive to the burdens that new regulations impose. One difficulty is the inescapable complexity of common carrier regulation. Today's common carrier regulation is the result of decades of Federal and State legislative and regulatory action. There is some hope that this area will become less complex as competition diminishes the need for regulation, but that is unlikely to happen very quickly. A topic for another day would be what dramatic deregulatory and decomplexifying steps regulators and Congress could take.

Another inherent difficulty and irony is the fact that many of these complex regulations were adopted to help rural telephone companies and their customers. Universal service regulations, for example, impose burdens on small companies in order to assess how much support the company and its customers should receive. So in appraising the process, it is important to remember that some regulations impose a burden in order to help the regulated entity.

Another difficulty is presented by two realities about the rulemaking process at the FCC. First, there is the enormous workload of the FCC. The dedicated staff at the Commission is still working through the many assignments delegated to the agency by the 1996 Act. Under the pressure of a production schedule, it is not surprising that the agency has attracted some criticism about their execution of the statutory procedural requirements of the RFA.

The second reality is that there is a tension between expertise and objectivity. It is very difficult to expect the same internal experts who advise the Commissioners that a new rule is sound and ripe for adoption to be objective in criticizing and editing that rule because of its anticipated impact on one constituency, small regulated companies.

Another difficulty is that rural telephone companies are small. Some of them are very small. They do not have Washington offices of their own. They rely on membership associations and outside advisors. Even with such assistance, the resources needed to monitor what is going on and to advocate reasonable results in each of many pending proceedings spanning several of the FCC's operating bureaus simply are not available.

There is some reason to praise progress and there are still some opportunities for improvement. At least some rural advocates have noticed some improvement. For example, OPASTCO, one of the leading membership associations that covers small telephone issues, has noted that the FCC has been more willing to treat rural telephone companies as small businesses rather than as dominant incumbents that would not be entitled to the benefit of the RFA small business analysis.

But there remains room for more improvement and the question is what should be done. The answer might include legislation, but there are a few steps short of legislation that would help, in my view.

First, Congress should consider whether the FCC needs more focused resources to conduct better RFA analyses. Adding more people to the process is not the answer, but adjusting the mix to include the right people might help. Additional economists and rural analysts specifically dedicated to the RFA process, for example, would help.

Second, Congress should also consider whether there are process changes that could be implemented at the FCC that would address the tension between objectivity and expertise. The people most intimately familiar with the substance of a rulemaking may benefit from the perspective of others not so closely involved in doing the RFA analysis. There may be candidates already on the organizational chart at the FCC that could provide such assistance and perspective if given the right resources.

Third, Congress should consider encouraging the FCC to adopt mechanisms that will allow it to communicate directly and easily with rural telephone companies. The simplest, best way for the FCC to ensure that it understands and can properly assess the impact of a proposed rule on small telephone companies is this: Ask them. But it is not always so simple. There are hundreds of small telephone companies. Which one should they call?

The FCC could make this "just ask" approach easier by creating a standing task force or Federal advisory committee consisting of rural telephone companies' representatives and experts on rural economic development. This would put valuable expertise close at hand and it would increase the likelihood that the impact of new rules on rural telephone companies would be authentically considered at the beginning of the process and weighed appropriately throughout the process. That is the goal, after all.

In a real way, the success of the RFA must be measured by these substantive results, and even the most scrupulous adherence to the formalities of the RFA's procedures should not be viewed as a substitute.

My view is that it would be wise to pursue options such as these before creating another step in the regulatory review process, such

as by empowering GAO to undertake its own RFA-type review. The views of GAO no doubt would make a thoughtful contribution to the process, but one of the great problems of rural telephone companies is the damage to investment plans that uncertainty inflicts. Adding another possible review step might exacerbate that uncertainty.

Nevertheless, even without new legislation, Congress can have an important oversight role. Parties dissatisfied with the way the RFA has been conducted in a particular case can call to the Subcommittee's attention these deficiencies and provide the basis for oversight steps with resulting guidance to the agency for improvement.

I thank you very much, the Subcommittee, for your work in this area and thank you very much for the opportunity to testify.

Chairwoman KELLY. Thank you, Ms. Wallman.

[Ms. Wallman's statement may be found in appendix.]

Chairwoman KELLY. I appreciate the testimony of all of you today. It seems to me that we have a problem with regard to an enormous amount of rules and regulations that the agencies are promulgating. I think that all of this testimony and any of it is certainly helping us focus on how to resolve the problem and make it easier for all of us to do our business, our small businesses in the nation. I would like to ask some questions. I am just going to ask a few of my questions first and then go to Mr. Pascrell.

Mr. Murphy, I was really interested in some of your testimony. I found that you cited cases where the statute actually limited the agency's discretion in developing sound regulation. When it is your belief that clarification is necessary and that a law should be amended, how do you communicate that to Congress?

Mr. MURPHY. Well, in cases where we have been asked to look at, for instance, the Unfunded Mandates Reform Act or the Regulatory Flexibility Act and we have concluded that there were aspects of the Act that really were not accomplishing what we believe that the Congress intended by passing them in the first place, we include recommendations in our reports to the Congress suggesting that the Congress should consider whether amending those statutes might accomplish their purpose.

Chairwoman KELLY. And that is a written report that comes in?

Mr. MURPHY. Yes, ma'am.

Chairwoman KELLY. I am interested because I am also thinking that it might help us in Congress if you too considered the Internet. That might be helpful to us. Are they posted on the Internet?

Mr. MURPHY. All of our reports are on the Internet. In fact, our website gets some accolades. I think it includes not only all of our reports, but all of our testimonies will be there within a day of being given. Our legal opinions are posted there, also.

Chairwoman KELLY. Do you know how often a member will then take that information and use it to try to draft some sort of a legislative solution or a fix to the problem?

Mr. MURPHY. I have no way of knowing how often that occurs. We have anecdotal—I can remember occasions when that occurred, but we do not have any systematic way of measuring that.

Chairwoman KELLY. If you can already provide Congress with independent assessments of the regulatory costs and benefits, do you think that we could use COAARAA?

Mr. MURPHY. Well, in this sense, I think it would be important. The General Accounting Office, for example, is responding to statutory requirements for evaluations and requests from chairs and ranking minority members of Committees and Subcommittees, and so when a request comes in for GAO to take a look at a cost-benefit analysis, we do not have staff that can drop the work they are doing for other members and immediately jump on that. In order for the Congress to have information about a regulatory impact analysis quickly enough so that it can affect what the agency is actually accomplishing and perhaps decide whether to use the Congressional Review Act, which as you pointed out really has not been used at all, that information has to come in very quickly.

So a CORA approach would allow GAO, or if it were located someplace else, to establish a separate organization within GAO staffed—we would have to hire economists and experts in regulatory processes so that when the regulation hit the street and a Committee was interested and wanted us to take a look at it, we could look at it very, very quickly. Some of these regulations are in development for years and so in order to take a look at them and provide the information that Congress needs, we think that a separate organization either within GAO or in some other place is really critical.

Chairwoman KELLY. Do you think that the agencies, the sheer number of regulations that the agencies produce every year contributes to their inability to comply with all of the regulations, or is that too loaded a question?

Mr. MURPHY. I can only speculate, really. Every year, agencies must report to GAO, provide to GAO and to the Congress all of the rules which they are promulgating. I took a look at the numbers that came in just last year to GAO and saw that there were over 4,500 rules filed with GAO spread across a lot of agencies. Many of these agencies have substantial numbers that they are processing. I was looking at the Internal Revenue Service which filed almost 250 rules with us. The Environmental Protection Agency filed almost 750 rules with us, and that is just in the last 12 months.

Chairwoman KELLY. That number again is 4,000 and something, you said?

Mr. MURPHY. Last year, yes, ma'am.

Chairwoman KELLY. Last year, it was 4,000——

Mr. MURPHY. Four-thousand-five-hundred-and-thirty-four——

Chairwoman KELLY [continuing]. 534——

Mr. MURPHY [continuing]. Regulations that were filed at GAO in calendar year 1999.

Chairwoman KELLY. Well, it is no wonder that our small businesses are having some problems with keeping up with whatever is coming out there at them.

Mr. MURPHY. It is a big government.

Chairwoman KELLY. And a highly active group of agencies.

Mr. MURPHY. Yes, ma'am.

Chairwoman KELLY. It is not that anybody is doing something that we perhaps do not need, but we need to find out if there is a relief for some of this problem.

The other thing I would like to ask you is, when you look at rules and regulations, do you also look for overlap and redundancy?

Mr. MURPHY. I think that is always something that you look at. You look to see whether what the regulation is seeking to accomplish is already being accomplished in other ways. That would be a baseline that you would have to begin with.

Chairwoman KELLY. Within the single agency or across agency lines?

Mr. MURPHY. Well, we would have to be aware of whether it was being accomplished across agency lines. That would be a piece of information that agencies need. I am not sure as a legal matter that that would be important to an agency who was given the job of promulgating a regulation to implement a statute. The fact that another agency is already working in that area should be something that they take into account in drafting their regulations, but they are still going to have to implement their own regulations with respect to the statute.

Chairwoman KELLY. I am wondering, Mr. Hahn, I see you have your hand up here. If you want to jump in, feel free. Anyone on the panel is free to speak up here. These questions, I am just speaking with Mr. Murphy, but feel free, Mr. Hahn.

Mr. HAHN. The problem that Mr. Murphy and you are talking about is a fairly deep problem. Judge Breyer, before he became Supreme Court Associate Justice, wrote a book called Breaking the Vicious Circle, and one of the points that he made related to a point that Mr. Murphy was making, that you have all of these agencies trying to do good, if you will, on the basis of statutes and turning out tremendous numbers of regulations. We have no clue what is out there in terms of its impact. I can say that because I am viewed at this point as one of the grand old men in the field in terms of assessing the costs and benefits. We do not even have time to look at the minor regulations, and the agencies tell us they are simply too busy to do it, cranking out stuff for Congress.

And Judge Breyer notes in his book, one of the problems is each of these agencies, while they are trying to do good, they are trying to do good usually in a single policy area, like the environment, like consumer product safety, like FDA, whatever, and he calls this tunnel vision, and it is not an accident that that occurs. The question is, can we begin to develop overarching legislation to put a check on this?

COAARAA is one example of that. We could talk about other examples. I think COAARAA is really important. I think in earlier testimony I pointed out that we are not sure that GAO is the best place to put it. If I had my druthers, and perhaps it is because I am obsessed with regulation, I would set up an additional agency, which is not politically correct to do today, but I think regulation is an important enough area to do that. I think if you cannot do that, CBO is a more logical place to put it.

But the generic problem, to suggest that we really know, in direct response to your question, whether regulations are consistent

with each other and what is actually coming out of the pipeline, we only have a very dim idea of what is going on.

Chairwoman KELLY. I thank you very much, Mr. Hahn. We have considered some other alternatives as to the placement of putting the office, the COAARAA office. Currently, I have a lot of confidence in Mr. Murphy's group and I think a number of other people do because they are in a position where they already have a number of experts on staff. A separate bureaucracy right now may be a step overreaching.

The importance to me of trying to get COAARAA in place is simply that we have got, I think, to do something about the fact that we are getting 4,534 regulations a year thrown at us in all walks of business life and all walks of life, and I think people get very concerned that we have this huge bureaucracy. The only way that we can make it make sense is if we make it accountable.

So I think that in the right instances, I think GAO is the first place to do it, to start, and hopefully we will be able to have in the budget enough money for them to be able to hire people. We will get it started and we will at least begin the walk. As you know, in Washington, things begin slowly, and we want to take it one step at a time because we want to make sure if we are doing this, it is effective. That is the bottom line. We need to relieve the problem, and I am sure you understand and agree with that.

Mr. Hahn, as long as we are talking, I think the alternatives that are supplied often by the regulated community and the data is often readily available, but the agencies just ignore the alternatives and they pay no attention to the executive order mandate. I wonder, again, if you want to address that. Do you think that there is a way we can try to make something happen there? I am concerned because from your testimony, it seems to me that this is worse than I thought.

Mr. HAHN. Well, we did not know how bad it was until we actually did this fairly serious study, which is published on our website. How do you get the agencies to do it? Well, OMB issued guidelines. Several distinguished economists have said it is a good idea. Congressman Pascrell, this really relates to the point you made in the beginning about implementation. You and the other side of Pennsylvania Avenue have to have the political will to do this. You both can exercise it independently or you can work together, but you could do lots of very simple things.

You could say, if you do not make an honest attempt to look at alternatives, the regulation will not move forward, except in cases of emergency because people will yell at you and say, my gosh, what if there is this emergency regulation? But that is one way to do it. You simply write into law that a regulation is not going to move forward unless it passes the kind of checklist that we put at the end of our testimony. Did you consider cost? Did you consider benefits? Did you consider alternatives? Did you consult with important parties to this regulation, or whatever?

So you can do it. We are not talking rocket science here. The reason I am big on providing a summary statement at the beginning of a regulatory impact analysis and in clear English, a paragraph, what you did—we took a look at this regulation on truckers, for example, and we think it is going to have these costs, these benefits,

these groups will be advantaged, these groups will be disadvantaged—people are going to see that.

Right now, these documents are written in Greek. They are hard to dissect, purposely so in some cases. They do not want you to know that they are not considering alternatives. There are five people at OMB who know this. I know this. Jason Burnett knows this. But most of the rest of the world does not know or does not care. And if we can get this information out there in summary form so people can use it, see in some cases how regulations are well designed and in other cases they are very poorly designed, I think we can make a lot of progress.

The key, as Congressman Pascrell points out, is what hooks do you put in either legislation or what executive orders do you impose and what enforcement guidelines are there. If there is no enforcement, we can just forget it.

Chairwoman KELLY. So, Mr. Hahn, if I understand you correctly—let me rephrase this. What is so difficult about having some of these alternative things, do you think?

Mr. HAHN. Nothing. It is political will. My shorthand language for that is guts. If a President wanted to spend some political capital on this, he or she could do so. If the Congress was oriented in this direction, and I think this is a bipartisan issue in a lot of ways——

Chairwoman KELLY. It definitely is.

Mr. HAHN [continuing]. I just do not think it is on the radar screen of lots of people because it does not have a high political payoff, even though it is potentially big bucks in the large for the economy, these 4,500 regulations that Mr. Murphy talks about.

But I think a starting point that is just not going to be controversial at all is to say, let us force these regulations before they move forward, force the analysts who are doing these analyses to fill out a little summary and write a paragraph in English that a layperson can understand with a high school education. I think that is a starting point, because then you are going to see the kinds of results that have emerged from our fairly exhaustive analysis, which took a summer to do.

You can see it very quickly.

Chairwoman KELLY. Mr. Hahn, can you explain why in approximately 60 percent of the rules that you studied, the benefit numbers in the Federal Register were inconsistent with the IRA?

Mr. HAHN. With the RIA?

Chairwoman KELLY. Excuse me, the RIA?

Mr. HAHN. I would ask Jason to answer that.

Chairwoman KELLY. Come forward and identify yourself, please.

Mr. BURNETT. I am Jason Burnett. I work at the AEI-Brookings Joint Center. I think that there are probably two reasons for that. First of all, the RIA is created for the proposed rule and there are some changes in the final rule and some changes both in the analysis as well as the rule itself. That would explain some of the inconsistencies.

The second reason may be that incompetency on the behalf of agencies. We found several cases where agencies use an inconsistent discount rate or dollar year within a single document and there's no good explanation for that.

Chairwoman KELLY. Do you think there are two sets of benefit numbers being calculated?

Mr. BURNETT. Two separate?

Chairwoman KELLY. Yes, several sets?

Mr. HAHN. Let me take this question, Jason. Jason is not used to being on the record. We simply do not know. I mean, we do not have the data. As he pointed out, the inconsistencies are there, but I do not think we know.

Chairwoman KELLY. Okay. Thank you very much.

I wanted to ask Mr. Ricciardi, Mr. Ricciardi, you have asked for a stay of action, and I really appreciate your testimony. I think both you and Mr. Addington offer good examples of just what the problem is with regard to these agencies promulgating rules that they perhaps have not looked at the total effect of. Can you just quickly tell me where that stay of action is?

Mr. RICCIARDI. The stay has been granted. Originally, the regulation was to take place December of this year and the stay was granted until October of the year 2001. But if I can equate it to our business and the businesses that I represent, I feel like a prisoner on death row who has been stayed, and the reason I say that is our attempts to bring our message to the FDA, in correspondence that the FDA has made, they do not seem to want to move on the regulation.

I am relatively new at this process, Madam Chairman, and I am learning as I go. One of the suggestions I could make to any agency is for representatives of those agencies, prior to regulation, is to come and visit with the companies that they are regulating. I have had a couple meetings and correspondence with the FDA, and in every correspondence that I have had, I have suggested that they come and visit our organization, and to this date, they have not.

Chairwoman KELLY. Thank you. We have just been called for a vote, and I am thinking I would like to hold this open. What I am going to do is I am going to hold the hearing open.

I am going to allow Mr. Pascrell to question at this time. We can stay for at least the second bell.

Mr. PASCRELL. Thank you, Madam Chairman.

Mr. Hahn, you held up the regulatory impact summary. Are you saying that nothing like that exists at this point?

Mr. HAHN. Nothing to my knowledge.

Mr. PASCRELL. So this is a two-sheet form here which you are recommending.

Mr. HAHN. Right. It could be a one-sheet form. It does not really matter.

Mr. PASCRELL. But how are records kept, then, by those rule makers? I mean, this seems to be a very simple form to the point you made it that way. This is like rule and regulation making disclosure. I want to know who makes these things. The folks out there have a right to know who makes the rules and where the regulations are coming from, and if these folks are hiding behind the screen of employment, behind their jobs, then there is something wrong. I mean, talk about cooking the books. If we are not disclosing the purpose of the rule, the cost and the benefit, it seems to me we are not doing anything.

Mr. HAHN. They are disclosing. They are just disclosing sometimes in 100 to 1,000 pages and I would prefer it in one or two pages for people who do not have an infinite amount of time to read this wonderfully written prose, so-called regulatory impact analysis.

Mr. PASCRELL. If we lay this out, I think the political will will be there, and some of these things do not need another bill passage. These things can be done internally, so that if the administration, whatever that administration looks like in the future or is now, that administration can basically send out some orders to indicate that this is what we would like to happen so we keep track of what is going on if we want to do that. Now, we may not want to know what is going on. We may not want to. We may simply want a headline that these are the rules of the FDA, these are the rules, et cetera, et cetera, but we do not care down the road what is going to happen, what the results were going to be.

I was interested, Mr. Murphy, how many of those 4,500 rules or regulations that you talked about were promulgated by the INS, God bless them?

Mr. MURPHY. Well, I think I can tell you, Mr. Pascrell. Sixteen.

Mr. PASCRELL. That is pretty conservative.

Mr. MURPHY. I have to say that we do an audit comparing the Federal Register to what is filed at GAO and we find annually several hundred that are not filed at GAO, largely through oversight. And also, there are a lot of regulations that are not filed because the agencies contend they are not regulations. For instance, the Tongass Forest management plan, which took ten years to develop, the agency says it is not a regulation and so they are not——

Mr. PASCRELL. The agency determines itself whether it defines such and such as a regulation?

Mr. MURPHY. Yes. We have been unable to get OMB to take leadership to clarify that over the last four years.

Mr. PASCRELL. This is government in absentia. There is no two ways about it. It seems to me there is very little difference between Red China and what you are doing in subverting the will of the people. That is why we have a legislative branch of government, why we have an administrative branch of government, in terms of checks and balances but even to find public disclosure. I find that obscene, if I can choose that word, since every other word has been used. I find it obscene, the methodology of how most of these rules and regulations are coming to the fore.

Let me ask, if the agencies are subverting—we have the idea in our minds that the end goal is who is the President and what does the Congress look like. Second-level, third-level management in these agencies remain the same, and we do this on the State level when I was a State legislator. We are forgetting this. They are going along the merry path writing these rules and regulations and I am sure it is not all cavalier, but that is the impression I am getting.

Mr. Ricciardi, who benefits, to use your example, from the definition, the shrinking definition of who can sell pharmaceutical products? Who is benefitting from that rule, from that——

Mr. RICCIARDI. From that new regulation?

Mr. PASCRELL. Yes.

Mr. RICCIARDI. The manufacturers, and they will increase drug prices.

Mr. PASCRELL. So the pharmaceutical companies are.

Mr. RICCIARDI. That is correct.

Mr. PASCRELL. Can you explain for the record, very briefly, how they do that?

Mr. RICCIARDI. There is multiple pricing throughout the country at any given point in time, and as long as there is more than one drug for a particular illness, such as to treat prostate, there is open market trading of pricing on drugs and we as a company and the 4,000 companies that are out there find opportunities to keep the prices down and buy throughout the country. By eliminating us as part of the open market system, the manufacturers will then be able to dictate their price and will be able to charge higher prices to the wholesaler, ultimately the consumer.

Mr. PASCRELL. And this came out of a 1988 law?

Mr. RICCIARDI. Yes.

Mr. PASCRELL. And we are just getting to the promulgation of this thing at this particular point, and 4,000 companies are going to be affected.

Let me just conclude by saying this. The more I get into this, the more animated I become in spirit. If we are to compete on a worldwide basis, and indeed if we are going to compete within our own borders, we need to make sure that we are not shrinking the possibilities of competition.

It would seem to me that many of our companies that have to deal with environmental rules and regulations have good records on the environment, but how can our companies compete with the Chinese rules and regulations in the final analysis? We have found the downside of our trade with Mexico when our companies just cannot compete. We have to spend thousands and thousands of dollars to meet these rules and regulations while these characters, many of them American corporations producing down in Mexico, have a cakewalk.

So we talk out of both sides of our mouths and I want this to continue. I do not think we can continue today, but I think there is a lot more here than meets the eye and I really appreciate all of your testimony.

Chairwoman KELLY. I am going to recess the Committee for approximately ten minutes while we go to the floor and vote and come back. Mr. Pascrell, thank you, and I will also hold the hearing open so that you can submit written questions if you would like. Thank you.

[Recess.]

Chairwoman KELLY. Thank you for waiting for the vote. I apologize. It took a bit longer than we expected.

I want to go back and ask a couple more questions. I think Mr. Pascrell is coming back, but even if not, there are a couple more questions that I would like to ask.

Ms. Wallman, do you think the FCC adequately estimates the costs and benefits of the proposed regulation of small telephone companies?

Ms. WALLMAN. I think that there are ways in which they could do a much better job. The analogy that comes to mind, what I was

thinking about, what I would do if I had a magic wand goes back to 1993 when the FCC started hiring a lot of economists. Before that time, the economic analysis review was done at the end of the process. There was a chief economist who had no staff and he would look it over at the end and make sure it did not commit any mortal sins, but by that time, the decision was really made and it was made by people in other disciplines who did the best job that they could figuring out what the right answer was based on comments in the record.

In 1993 and 1994, the FCC started hiring a lot of economists and they started sprinkling them throughout all the bureaus and it really effected a transformation in the way that the rules were conceived and developed and written because at every stage, not just at the end, you had the influence of economists saying not just what do you think is the right answer but what is the empirical case for this being the right answer or the best answer.

And so I think that really this is a question of management focus and really changing the mission definition, the hearts and minds of the people actually writing the rules and sprinkling throughout the agency people who are adept at either knowing on their own or being able to draw from people who are in the small telephony business what the real impact will be on a day-to-day basis.

So there is room for improvement, and if I had a magic wand, what I would do is sprinkle that expertise throughout the agency so that it would be there at the beginning, middle, and end of the process, not just at the end looking back at what has already been done.

Chairwoman KELLY. Thank you. I think that is a very interesting and good answer that could be utilized by other agencies, as well. Should the FCC, do you think, establish a separate office? Would that help, a separate office to perform the reg flex analyses?

Ms. WALLMAN. I think that they probably have enough boxes on the organizational chart that there may be some candidates there already. My experience there was in 1994 and 1995, so I am sure things have changed since then, but my understanding now is that in addition to having the bureau with substantive expertise and actually writing the rule involved, they do get comment from other groups. But the pen is held by the people in the substantive bureau. It may be that the folks who have stayed up all night actually writing a substantive regulation would benefit from stronger input from the general counsel's office and from the business opportunity office.

So establishing an additional box, my inclination is generally against creating new units, but I think there are talented people there whose talents could be supplemented with the right resources so that they could improve the way that they do the analyses.

Chairwoman KELLY. When the EPA and the OSHA issue some significant proposal, they are required by law to put together groups that are basically focus groups of the businesses, people who are affected by the proposed rulemaking and by the proposed rule. Do you think that that would be an option for the FCC? It might slow the process, but do you think that might be worth it?

Ms. WALLMAN. I think it would be a great idea. I had an opportunity to see how some of those EPA-type groups work when I was

at the White House and I thought they were really quite helpful. And hearing the presentation live was very helpful. The FCC gets written comments. I should say that in many cases, I know some decision makers in the Commission will bring people in. Sometimes they will bring them in and sort of stage a debate so that they can make sure they are not persuaded by the last voice they have heard. They have people come in and they actually go back and forth and try to hear the debate live. But I think opportunities like that, like what EPA does, like what OMB does in some cases, could be a real illumination of the process at the FCC.

Chairwoman KELLY. Thank you. I really appreciate your testimony here today. I think you have added a lot because of your perspective.

I want to go to you, Mr. Addington. Yesterday at the full Committee hearing, we had John Spotila, the Administrator of OIRA and he commended the FMCSA for their regulatory streamlining efforts, and I asked him then if the FMCSA had developed too many resources to streamlining and not enough resources to complete regulatory analysis, given the trucking and bus industry's complaints about the hours of service rule, and he replied, and I am quoting, that DOT would be considering all of the comments and that the comment period has not yet closed. He implied my question was jumping the gun.

How do you respond to his suggestion? My question really is based a question that I am jumping from earlier that I asked, basically, and that is do you think that we should wait for the comment period to close before——

Mr. ADDINGTON. No, ma'am. As I told you in my testimony, the American Trucking Associations has worked before years because we want——

Chairwoman KELLY. Can you pull the microphone closer to your mouth? Thank you.

Mr. ADDINGTON. The American Trucking Associations, as I said in my testimony, has been seeking hours of service reform. The rules we have now on the books come from 1937, I believe it is. They last had any significant amendment in 1962 and they are out of date and they need work, and we agree with the government on that.

We were, frankly, surprised when they issued the proposal that they issued because we had expected it to be somewhat in the ballpark so that you could hope in the normal rulemaking process to improve things, to get the data out there and fix it. We also expected, frankly, that the Regulatory Flexibility Act, all the other requirements would be complied with in such a way that, frankly, they would have a better product. We think it is so bad that we need to stop and start over.

One thing I will say in their defense in this process is what is now the Federal Motor Carrier Safety Administration has been through the bureaucratic equivalent of the seven circles of hell in the last year. At the beginning of 1999, they were known as the Office of Motor Carriers in the Federal Highway Administration. Then Congress passed as part of the Appropriation Act, because Congress was not satisfied with the performance of that office as part of the Federal Highway Administration, a prohibition on the

Transportation Department's appropriations bill for the fiscal year 2000 that said the Secretary of Transportation cannot delegate his trucking authority to that office as long as that office stays in the Federal Highway Administration.

So the Transportation Department had to figure out, okay, what do we do with it? They established a new office in the Office of the Secretary of Transportation known as the Office of Motor Carrier Safety, moved the bureaucratic boxes around, pushed people, different people in charge, lots of paperwork for delegations of authority and all that.

It was not there more than a few months, I believe, at the most, because we, and we considered this a good thing, the trucking industry fought for this, creation of the Federal Motor Carrier Safety Administration as a separate modal in administration of the Department. That took effect January 1.

So all the boxes over there are moving back and forth. The people are moving back and forth. People are spending their time trying to figure out, which appropriations accounts do I charge for what? They are in all this while they are trying to produce these rules. So that may account for some of the reason that people did not quite get the thorough job that the law requires done to put together the regulatory package. That is not necessarily an excuse, and certainly is not to us. We will fight in the rulemaking and we will fight in the courts later, if necessary, because it is the government's responsibility to govern properly, but it may explain why they had as much trouble as they had trying to put together a regulatory package.

Chairwoman KELLY. Well, I also sit on the Transportation Committee and I was in on those hearings and I know why Congress did what it did and I know it has been a problem perhaps to make sure that you are getting the right letterhead at the top of the stationery, but on the other hand, we want to make sure that we are able to have an office that is a responsible office. That was why it was moved around a little bit, but——

Mr. ADDINGTON. And we supported what Congress did. We think that is great.

Chairwoman KELLY. Oh, I know you did. I know you were there, and there were many people from the industry that testified. But I am very saddened to see this regulation coming out and I am concerned that I believe there was just a sloppy initial reg flex analysis on this. You evidently feel that they just probably did not have the right information or enough careful information in order to put the rule together before they wrote the rule.

I am not going to ask that in the form of a question because I do not want to put you on the spot, but I want to ask another question and that is, do you think that this proposal should be withdrawn and reissued after the DOT and the FMCSA do another analysis under the Regulatory Flexibility Act?

Mr. ADDINGTON. Yes, ma'am. I think it ought to be withdrawn and done properly under the current laws, and that will be part of the comments that we will file with the Department. It is to their advantage, as well, because there is no point in all of us putting this massive energy in this to end up litigating this in court because they have not complied with the applicable laws.

Chairwoman KELLY. All right. Thank you very much. I will not only—I am glad we have that in our record, but I will see that we manage to get the record transmitted to the other Committee, as well.

I want to go back now just to discuss COAARAA, since it is dear to my heart. This question is really for Mr. Hahn and Mr. Murphy. Some people feel that Congress has oversight at any point in the process and that currently through hearings, Congress can better understand agency rulemakings and analyses and that COAARAA is not needed. I would like very much to hear both of you discuss how you feel that COAARAA would be useful. We can start with you, Mr. Hahn, or whichever. Mr. Murphy.

Mr. HAHN. I testified on this, and I am happy to refer you to that, and I think you know more about this subject than I do, but let me suggest that I think COAARAA is useful for at least three reasons, and the relevant analogy here, as you know, has to do with OMB, when we had a budget process without CBO. I think it is much improved by having the two organizations compete with each other and they provide an independent check on each other. So that is one good reason. You have an independent check on the analysis of the executive branch.

A second is a lot of what OMB does is not always open to the public, and I think COAARAA would make the process more transparent and improve the process and in so doing it will give you better ideas for improving your laws and the regulators better ideas for improving regulations. So it is really that simple to me.

Chairwoman KELLY. Thank you very much, Mr. Hahn. Mr. Murphy?

Mr. MURPHY. Madam Chairwoman, I was thinking that maybe one way to respond would be to ask Curtis Copeland to talk about some actual examples where we have been able to look at economic models or look at the highly technical details of the regulation process, something that really would be more difficult for a Committee or a Subcommittee to do in the course of the hearing format or the hearing model, and because we have been able to get into those—in fact, we have a number underway at the moment with respect to EPA regulations—we have been able to get the kinds of information that would be useful to the Congress, that otherwise would be very difficult to come up with, through a more CORA-type model.

Chairwoman KELLY. Mr. Copeland, would you like to identify yourself, and yes, by all means, we would be glad to hear from you.

Mr. COPELAND. Sure. I am Curtis Copeland. I am an Assistant Director within the General Government Division at GAO and we do a lot of the cross-cutting work that looks at agencies' compliance with these analytical and procedural requirements.

The rules that we have looked at over the course of the last few years in many cases are highly technical. For example, we are looking at one now, a rule that EPA issued last year that drops the threshold for reporting of lead and lead compounds under the Toxic Release Inventory Program from 25,000 pounds to ten pounds, and EPA said that this rule would not have a significant economic impact on small businesses and so we have been asked to look at that certification statement.

It is extraordinarily difficult to plow into an economic analysis that has six different chapters and is about 300 or 400 pages in length. So it is something that requires a great deal of effort just to get comfortable with what the agency is describing, much less trying to get into the particulars as to what alternatives they might could have considered.

Last year, we looked at a rule that FDA issued on the dietary supplements containing ephedrine alkaloids and the science behind that and the adverse event reports that are being reported to FDA, and after a great deal of review, looking at more than 1,000 of these adverse event reports, we determined that only 13 of them really constituted the basis of the rule. And so it took a long time, though, to determine that those 13 were the critical ones that FDA relied on, and so we suggested that EPA get better data in order to support the rulemaking and FDA agreed with us and in February of this year withdrew the rule.

Chairwoman KELLY. Good. Thank you very much for saying that. I think that is part of the problem. It is almost impossible for our staffs here, if we wanted to look at a rule before it was actually finalized, it is almost impossible for our staffs to, under the workload that they carry, to examine all of this. And also, it is a problem with regard to their expertise. So I think it is always important that we try to do something.

I think that the whole point of what I am trying to do with COAARAA, what I am hoping to do with COAARAA is to raise the quality of the analyses and ask the agencies to be more careful, as you have just pointed out, in terms of not only looking within themselves but also transmitting that information to those people who are going to be affected by the rule or regulation.

I think that we have identified in this hearing that there is a problem and we are following your model, Mr. Hahn. We are identifying the problem, we are analyzing the problem, and I think the answer for us perhaps is to start with passing COAARAA.

I really thank you very much. I think that it is really wonderful that you were willing to sit through as lengthy a process as this has been. I did not expect it to be that when we set this meeting for ten o'clock in the morning, but I thank all of you for being here and I thank you very much for your testimony. You may be hearing from some of the other members of the Committee simply because there is so much going on on the Hill today, markups and so forth, that that is why some people could not be here.

With that, I am going to adjourn. Thank you very much. [Whereupon, at 1:00 p.m., the Subcommittee was adjourned.]

**House Committee on Small Business**
**Subcommittee on Regulatory Reform and Paperwork Reduction**

"The Quality of Regulatory Analyses"

June 8, 2000

Opening Statement of Rep. Sue Kelly
U.S. House of Representatives

Good morning, ladies and gentlemen. I would like to thank you for attending this hearing of the Subcommittee on Regulatory Reform and Paperwork Reduction. This is the second hearing in a series of hearings being held at the Full Committee level and in this subcommittee concerning the reauthorization of the Paperwork Reduction Act and the effectiveness of other regulatory reform efforts currently in place. Yesterday we focused on the regulatory burdens imposed on small business and the regulatory relief efforts of the Administration.

Today we will narrow our focus to discuss the quality of agency regulatory analyses. In order to explore this issue we must discuss the adequacy of agency compliance with analytical requirements mandated by the Administrative Procedure Act, the Regulatory Flexibility Act, and various executive orders meant to direct agencies in producing regulations whose benefits outweigh their costs and achieve their objectives in the lowest cost manner possible. Witnesses will focus on whether these analyses provide agencies with sufficient information to properly assess the impact that the rules will have on the regulated community and the small business community in particular. Additionally,

we will discuss any changes that are needed to ensure that agencies recognize these impacts, including whether Congress should obtain an independent assessment of these analyses in order to carry out its legislative functions. And while the subject may not be as entertaining as hearing Chuck D expound on the sale of music on the Internet, for small businesses afflicted by the ever-burgeoning mound of regulation and paperwork requirements, it is critical that the Committee and this Subcommittee place this rather dry subject at the top of its legislative priority.

Small business owners are very familiar with the burdens that Federal regulations place on them. Some studies have shown that for small employers, the cost of complying with Federal regulations is more than double what it costs their larger counterparts. And you do not need any study to reach that conclusion. Commonsense will say that if a regulation costs General Motors and a 500 employee manufacturer of copper tubing the same amount of money, the overall impact on General Motors will be significantly less on a per unit basis. As a result, small business owners have historically been interested in regulatory reform efforts in Washington. Any mechanism that will help control the size of this burden is naturally appealing to the small business community. The APA, SBREFA, and several executive orders are such mechanisms. But these efforts will manage the regulatory burden only if they are implemented fully and only if Congress keeps a watchful eye on their

progress. As the committee whose goal it is to promote and protect the interests of small business, we have an obligation to discuss how well agencies are satisfying these analytical requirements and to explore ways in which Congress can better understand these regulations that small business owners struggle to comply with on a daily basis.

There is yet another underutilized mechanism to reducing the regulatory burden on small business, The Congressional Review Act. On March 29, 1996, the Small Business Regulatory Enforcement Fairness Act (SBREFA) became law. Included within this legislation was a section that established CRA, a formal tool by which Congress could review and prevent new regulations from taking effect without going through the normal legislative process. Used properly, this new oversight device could greatly enhance the regulatory process by ensuring that only those regulations which are truly in the public interest are allowed to go into effect.

Unfortunately, the Congressional Review Act does not appear as if it is being used effectively because it is not being used at all. Not a single resolution of disapproval under the Congressional Review Act has passed. The House has failed even to vote on one. Some have given up on its ability to halt regulations that do not have sufficient justifications, that go beyond what Congress, or that create unintended consequences that require correction. . But I believe that combined with oversight hearings, legislative efforts, and the

submission of Congressional comments, CRA still has some hope.

Regardless of whether or not you believe CRA can be used, you must admit that Congress does not have enough information to undertake appropriate oversight of the powers delegated to agencies by Congress. The power delegated to these agencies enables them to issue rules and those rules may not meet the objectives or have the consequences that Congress expected when it enacted the legislation. For example, when Congress enacted the Federal Motor Carrier Safety Act to create the Federal Motor Carrier Safety Administration, it certainly expected that the agency would enact rules to improve the safety of our highways through improved regulation of truckers. However, the most recent proposal from the FMCSA may have substantial unintended consequences for tour bus operators, independent route salesman, and manufacturers. These consequences apparently were not considered when the FMCSA decided to treat all those individuals who drive professionally on the nations road systems in an identical manner. To help address this problem I was joined by Chairman Jim Talent in introducing H.R. 3669, the "Congressional Oversight and Audit of Agency Rulemakings Actions Act." This office would focus solely on conducting independent regulatory assessments of regulations to help determine whether the agencies have complied with the law and executive orders. Unfortunately, Congress cannot obtain this unbiased information from the participants in the rulemaking because each participant, including the federal agency, has a particular

viewpoint and bias.

A Congressional Office of Regulatory Analysis would help fill this information gap and assist Members of Congress in determining whether action is warranted. The purpose of CORA then is to ensure that Congress exercises its legislative powers in the most informed manner possible. Ultimately, this will lead to better regulatory analyses, more cost-effective regulations, and, most importantly, legislation tailored in a manner to address a narrow problem and not overly broad legislation likely to impose unnecessary burdens on small business. Only through active oversight can Congress ensure that the laws that it passes are properly implemented. This is a responsibility that Congress must take seriously, because as countless small business owners can attest to, not doing so can have dramatic implications.

We have joining us today an excellent panel who will discuss some of these issues. I would like to thank each of them for being with us today and I look forward to hearing their testimony. Thank you..

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# Improving Regulation: Start with the Analysis and Work from There

Testimony before the
Subcommittee on Regulatory Reform
and Paperwork Reduction
House Committee on Small Business

Robert W. Hahn and Robert E. Litan

Testimony 00-1

June 2000

Robert W. Hahn and Robert E. Litan are directors of the AEI-Brookings Joint Center for Regulatory Studies. A copy of this testimony can be obtained from the Joint Center's web site: www.aei.brookings.org. The authors would like to thank Jason Burnett, Irene Chan, Sarah Holden, Beth Mader, Petrea Moyle, and Paul Tetlock for contributing to the research upon which this testimony is based. They would also like to thank Randall Lutter for helpful comments. The views expressed here represent those of the authors and do not necessarily reflect those of the institutions with which they are affiliated.

# JOINT CENTER

In response to growing concerns about understanding the impact of regulation on consumers, business, and government, the American Enterprise Institute and the Brookings Institution have established the AEI-Brookings Joint Center for Regulatory Studies. The primary purpose of the center is to hold lawmakers and regulators more accountable by providing thoughtful, objective analysis of existing regulatory programs and new regulatory proposals. The Joint Center builds on AEI's an impressive body of work over the past three decades that has evaluated the economic impact of regulation and offered constructive suggestions for implementing reforms to enhance productivity and consumer welfare. The views in Joint Center publications are those of the authors and do not necessarily reflect the views of the staff, council of academic advisers, or fellows.

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**Executive Summary**

This testimony reviews research from the Joint Center on regulatory impact analyses and provides five recommendations for improving the regulatory process. These recommendations include: making regulatory impact analyses publicly available on the Internet; providing a regulatory impact summary table for each regulatory impact analysis that includes information on costs, benefits, technical information, and whether the regulation is likely to pass a benefit-cost test; establishing an agency or office outside the executive branch to assess independently existing and proposed federal rules; requiring that the head of a regulatory agency balance the benefits and costs of a proposed regulation; and requiring that all regulatory agencies adhere to established principles of economic analysis when doing a regulatory impact analysis.

**Improving Regulation: Start with the Analysis and Work from There**

Robert W. Hahn and Robert E. Litan

1. Introduction

We are pleased to appear before this subcommittee to provide our views on improving regulation and the regulatory process. We have studied and written about regulatory institutions for over two decades. Two years ago, we helped organize a cooperative effort between the American Enterprise Institute and the Brookings Institution to study regulation. The result was the AEI-Brookings Joint Center for Regulatory Studies.[1]

A primary objective of the center is to hold lawmakers and regulators more accountable by providing thoughtful, objective analysis of existing regulatory programs and new regulatory proposals. The Joint Center has been in the forefront of outlining principles for improving regulation, enhancing economic welfare, and promoting regulatory accountability.[2]

You have expressed interest in the adequacy of agency compliance with analytical and reporting requirements aimed at providing economic analysis of regulations and ensuring that such analysis is publicly available. The requirements include executive orders, such as President Clinton's Executive Order 12866, which stipulates various analytical requirements and outlines how those requirements shall be enforced; and laws, such as the Administrative Procedures Act, which requires agencies to make the process and results of such an analysis public.

In addition, you have asked for suggestions on changes needed to ensure that agencies comply with economic analysis requirements, particularly those related to assessing the impacts of regulations on the regulated community. An example of one such change is the creation of a congressional agency that would independently assess the quality of regulations.

Our testimony proceeds in three parts. First, we provide a brief overview of regulation and offer a slightly different definition of the problem from that given by the subcommittee. Second, we present some results from research undertaken at the Joint

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[1] All publications of the Joint Center can be found at www.aei.brookings.org.
[2] *See* Arrow et al. (1996).

Center, which reviews the implications of economic impact analyses of regulation performed by the federal government. Third, we offer some suggestions for reforming regulation to improve both the quality of analysis and the quality of regulatory decisionmaking.

2. Regulation and Oversight

Although regulations often have no direct fiscal impact, they pose real costs to consumers as well as businesses. Regulations aimed at protecting health, safety, and the environment alone cost over $200 billion annually—about two-thirds as much as outlays for federal, nondefense discretionary programs.[3] Yet, the economic impacts of federal regulation receive much less scrutiny than the budget.[4]

To encourage the development of more effective and efficient regulations, Presidents Reagan, Bush, and Clinton have directed agencies to perform analyses on major regulations that show whether a regulation's benefits are likely to exceed the costs, and whether alternatives to that regulation can achieve the same goal for less money. They also have attempted to increase agency accountability for decisions by requiring that the President's Office of Management and Budget review all major regulations. More recently, Congress embraced regulatory reform and inserted accountability provisions and analytical requirements into laws such as the Safe Drinking Water Act Amendments of 1996, the Small Business Enforcement and Fairness Act of 1996, and the Unfunded Mandates Reform Act of 1995.[5]

The most prominent and far-reaching of these regulatory reform efforts are President Reagan's Executive Order 12,291 and President Clinton's Executive Order 12,286. Both require agencies to prepare a Regulatory Impact Analysis ("RIA") for all major federal regulations.[6] Agencies have prepared RIAs for almost twenty years in

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[3] See Arrow et al. (1996); OMB (1999). All dollar figures are presented as constant 1999 dollars, adjusted by using the consumer price index.

[4] See Joint Economic Committee Study (1998).

[5] Some examples of accountability mechanisms include regulatory oversight, peer review, judicial review, sunset provisions, regulatory budgets, and requirements to provide better information to Congress. Analytical requirements include mandates to balance costs and benefits, consider risk-risk tradeoffs, and evaluate the cost-effectiveness of different regulatory alternatives. See Hahn (2000).

[6] President Reagan coined the term *regulatory impact analysis* in Executive Order 12,291, *see* 3 C.F.R. 128 (1981). President Bush also used Executive Order 12,291. President Clinton's Executive Order 12866 changed the term *regulatory impact analysis* to *assessment, see* 3 C.F.R. 638 (1993). Executive Order 12866 maintains most of Reagan's requirements but places greater emphasis on distributional concerns.

accordance with the executive orders and guidelines for economic analysis provided by the President's Office of Management and Budget ("OMB").[7]

The subcommittee is particularly interested in focusing on the impact of regulations on the regulated community and small business.[8] While we believe it is important to consider such impacts, particularly when they are significant, *we would urge the committee to focus its efforts on having an agency do a good benefit-cost analysis of a regulation, as economists typically define it.*[9] That analysis would include an evaluation of an agency's preferred option along with relevant alternatives. As we shall argue below, such good analyses tend to be the exception rather than the rule. When done well, such analyses can help provide a general measure of the social impact of regulations. In contrast, measures of industry-specific impacts, while important, do not adequately address whether the overall benefits of a regulation are likely to exceed the costs. In addition, it is often difficult to develop reliable measures of industry-specific impacts of a regulation.

3. What Do the Government's Economic Analyses of Regulations Tell Us?

The Joint Center has been engaged in conducting a systematic review of regulatory impact analysis since its inception. We wish to focus on three different efforts: one provides a comprehensive assessment of the costs and benefits of federal regulatory activities; a second examines the extent to which the costs and benefits of regulations are reported in the *Federal Register*; and a third assesses the quality of regulatory impact analyses.[10]

To assess net benefits of final regulations between 1981 and mid-1996 the Joint Center reviewed 168 regulations. On the basis of the government's own numbers, these

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Executive Order 12866 also directs agencies to show that the benefits of the regulation "justify" the costs, whereas Reagan's executive order required agencies to show that the benefits of the regulation "outweigh" the costs. *See* Exec. Order No. 12,291, 3 C.F.R. 128 (1981–1993); Exec. Order No. 12866, 3 C.F.R. 638 (1993–2000), *reprinted in* 5 U.S.C. § 601 (1994).

[7] See OMB (1996).

[8] Examples include estimates of the impact on employment in a specific industry or the impact on plant closures.

[9] See Arrow et al. (1996); see OMB (1996).

[10] See Hahn (1999a), Hahn (1999b), and Hahn et al. (2000).

regulations are estimated to yield net benefits of close to $2 trillion.[11] The analysis also shows that the government can significantly increase the net benefits of regulation. Less than half of final regulations pass a neutral economist's benefit-cost test. Net benefits could increase by approximately $300 billion if agencies rejected such regulations. Net benefits could also increase if agencies replace existing regulations with more efficient alternatives, or if agencies substantially improve regulatory programs. While one could argue with the particular interpretation of the numbers provided in this study, we feel comfortable saying that a significant fraction of the government's final regulations would not pass an economist's benefit-cost test using the government's own numbers. That suggests that the executive orders requiring a careful weighing of costs and benefits have not been taken very seriously.[12]

A second strand of research examined how the government used the *Federal Register* to convey important information on the impacts of regulation. The *Federal Register* was selected because it is a key repository of information on regulation within the government.

Joint Center researchers examined seventy-two final rules promulgated by regulatory agencies from 1996 through February 10, 1998, that were subject to review by the OMB. Each rule was scored on pertinent information related to alternatives considered, costs, cost savings, benefits, and other essential economic information.[13] Two important conclusions emerge from that analysis. First, *Federal Register* notices that present regulatory analysis currently exhibit a great deal of variation in the kind of information that is presented.[14] Second, with some key changes in the requirements for including and presenting information, the content of those notices could be improved dramatically.

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[11] The net benefits estimate does not include two rules on stratospheric ozone that, according to the Environmental Protection Agency, have net benefits in the trillions of dollars. Those rules would have a large impact on the overall estimate of net benefits (taking the government numbers as given), but not on the fraction of rules that pass a benefit-cost test.

[12] An alternative interpretation is that those numbers were carefully weighed and then dismissed for other reasons, for example, because they left out important aspects of the problem.

[13] Once each *Federal Register* notice was reviewed, the data were entered into a database. Each notice was then reviewed a second time to check for accuracy.

[14] For example, there was little consideration of alternatives. For all seventy-two rules, thirty-one (43 percent) considered alternatives; only nineteen (26 percent) discussed specific alternatives; and eight (11 percent) quantified them.

Further insight into the extent to which the government's analyses of regulations provide an adequate basis for decisionmaking can be found in a Joint Center study of regulatory impact analyses.[15] That study provides the most comprehensive evaluation of the quality of recent economic analyses that agencies conduct before finalizing major regulations.

We construct a new dataset that includes analyses of forty-eight major health, safety, and environmental regulations from mid-1996 to mid-1999. That dataset provides detailed information on a variety of issues, including an agency's treatment of benefits, costs, net benefits, discounting, and uncertainty. We use that dataset to assess the quality of recent economic analyses and to determine the extent to which they are consistent with President Clinton's Executive Order 12866 and the benefit-cost guidelines issued by the OMB.

We find that economic analyses prepared by regulatory agencies typically do not provide enough information to make decisions that will maximize the efficiency or effectiveness of a rule. The study of regulatory impact analyses shows that agencies only quantified net benefits —the dollar value of expected benefits minus expected costs—for 29 percent of the forty-eight rules, even though the executive order directs agencies to show that the benefits of a regulation "justify" the costs. The agencies also did not adequately evaluate alternatives to the proposed regulation, another element of the Executive Order. Agencies failed to discuss alternatives for 27 percent of the rules and quantified the costs and benefits of alternatives for only 31 percent. In addition, the agencies often failed to present the results of their analysis clearly. Agencies provided executive summaries for only 56 percent of the rules.

Taken together, those studies illustrate four key points. First, many major regulations are not likely to pass a standard benefit-cost test using the government's own numbers. Second, the quality of analyses is generally poor, though there is a great deal of variation in quality. Third, the analyses are not readily accessible to the general public. Finally, useful summaries of the analyses are not readily available to the general public.

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[15] See Hahn et al. (2000).

4. Recommendations for Improving Regulation

A complete discussion of improving regulation is beyond the scope of this testimony.[16] Here, we wish to focus on a few key policies that will either promote economic welfare (broadly understood) or promote greater regulatory accountability. We believe the subsequent recommendations are modest in the sense that they could be implemented with bipartisan support. We also believe that proposals that are viewed as more far-reaching, such as requiring that a regulation pass a broadly defined benefit-cost test, are unlikely to be implemented in the near future because the political support will not be there.

We begin from the presumption that neither Congress nor the next administration (whether Democratic or Republican) is likely to put regulatory reform or regulatory improvement at the top of its political agenda.

Recommendation 1: Congress should require that agencies make each regulatory impact analysis and supporting documents available on the Internet before a proposed or final regulation can be considered in the regulatory review process.

Discussion: If the RIA is expected to inform the decision process, the analysis must precede the decisions themselves. Making such analyses widely available is an important first step in holding lawmakers and regulators more accountable for proposed and final regulations. Some agencies, such as the Department of Health and Human Services and, increasingly, the Environmental Protection Agency, are moving in that direction by eventually putting the regulatory impact analysis on the Internet. Requiring that an analysis and supporting documents be made available on the Internet before the regulatory review process starts at OMB provides an agency with an additional incentive to make it available to the public.

Recommendation 2: Each regulatory impact analysis should include an executive summary with a standardized regulatory impact summary table that contains information on costs, benefits, technical information, and whether the regulation is likely to pass a benefit-cost test based on the best estimate of quantifiable benefits and costs.

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[16] See, e.g., Breyer (1993), Breyer (1984), and Litan et al. (1983).

Discussion: The executive summary, regulatory impact summary table, and the requirement of standardization would all promote greater regulatory accountability. The standardization and summary will make it easier for the public, interest groups, and academics to obtain information on the government's views of the benefits and costs of regulation.

The information identified in the regulatory impact summary table is similar to that required by Executive Order 12866, the Unfunded Mandates Reform Act, and the Regulatory Flexibility Act. Congress should simply consider passing an amendment requiring that the information be summarized and produced in the form suggested here. The cost would be trivial, and the benefits could be potentially quite large.

We present an example of a regulatory impact summary table in table 1. That information should be standardized across agencies to enable Congress and stakeholders to make comparisons when setting regulatory priorities.

Recommendation 3: Congress should create a congressional office of regulatory analysis (CORA) (e.g., within CBO) or a separate agency outside of the executive branch to assess independently existing and proposed federal rules.

Discussion: CORA is sound for three reasons. First, because it is likely to serve as an independent check on the analysis done in the executive branch by OMB and the agencies. Second, it will help to make the regulatory process more transparent. Third, Congress can use the independent analysis to help improve regulation and the regulatory process.

OMB's Office of Regulatory and Information Affairs (OIRA) faces inherent limits in the scope of its review of individual regulatory proposals. OIRA is headed by a political appointee chosen by the same administration that appoints the heads of the regulatory agencies. There is likely, therefore, to be some implicit understanding that the head of OIRA is not to press the agencies excessively hard because he or she is on the same team as the agency heads. Even if the head of OIRA were given authority to challenge regulations, the basis for those challenges is rarely made public; and the scope of those challenges is likely to be limited. The constraints on the OMB are manifested in its annual report, in which it has, so far, simply accepted the benefits and cost estimates compiled by the agencies instead of providing any of its own assessments. CORA would

not face those constraints but instead would be able to provide its independent analysis, much as CBO has done in the budget arena.

CORA could help Congress implement its recent legislation, such as the Small Business Regulatory Enforcement Fairness Act. CORA could also aid Congress in periodically assessing the need to modify its own regulatory statutes. As it is now, if and when Congress chooses to do so, it will have to rely on the agency's own estimates of the impacts of a rule and on any other data that interested parties may or may not have submitted in the rulemaking record. Significantly, Congress now has no *credible, independent source of information* upon which to base such decisions. That is analogous to the pre-CBO Congress, which had to make budget and appropriations decisions based solely on the information developed by the executive branch.

Recommendation 4: Congress should require agencies to balance the benefits and costs of major regulations.

Discussion: While the Reagan and Clinton Executive Orders have encouraged agencies to consider the benefits and costs of regulations, executive orders do not have the authority of statutes. Executive orders are difficult to enforce in part because they are not judicially reviewable, and agencies cannot be sued for noncompliance. Congress should therefore require agencies by statute to comply with requirements similar to those in the executive orders and in the OMB's implementation guidance for the executive orders. Although some statutes already require agencies to balance the benefits and costs of regulation, these statutes apply to only a small number of major regulations and agencies often do not comply with the requirement. Other statutes either do not require benefit-cost analysis or actually restrict its use. The Clean Air Act, for example, precludes the consideration of costs for certain regulatory decisions. A congressional requirement to balance benefits and costs will increase the transparency of the regulatory process by forcing agencies to provide high-quality analyses that the courts could review in the event of significant controversy.[17]

[17] If a balancing requirement is seen as problematic, then Congress should consider passing an amendment that does not preclude agency heads from explicitly considering costs and benefits in regulatory decision making.

Recommendation 5: Congress should require that all regulatory agencies adhere to established principles of economic analysis when undertaking a regulatory impact analysis.

Discussion: It is clear from a careful review of regulatory impact analysis that agencies are currently not taking the guidelines imposed by the executive branch very seriously in carrying out regulatory analyses. To add political weight to those guidelines, Congress should consider adopting the kinds of principles contained in the OMB guidelines. It should also consider requiring that an agency, such as OMB, enforce those guidelines. It, too, could help to enforce those guidelines by holding hearings. An obvious question is how far Congress would be willing to go in providing methods for enforcement. One possible mechanism that deserves consideration is not allowing agencies to move forward on regulations unless an oversight agency, such as OMB, determines that the guidelines are met.

If Congress and the White House are serious about regulatory reform, they must cooperate to enforce the regulatory impact analysis requirement. Successful enforcement requires high-level political support, statutory language requiring all agencies to adhere to established principles of economic analysis, and rigorous review of agency analyses by an independent entity. If lawmakers are willing to exert the political muscle, real reform could be achieved.

**Table 1**

| Regulatory Impact Summary | |
|---|---|
| **I. BACKGROUND ON RULE AND AGENCY** | |
| AGENCY AND DEPARTMENT/OFFICE NAME | |
| CONTACT PERSON | TELEPHONE NUMBER |
| TITLE OF THE RULE | |
| RIN NUMBER | DOCKET NUMBER |
| TYPE OF RULEMAKING (FINAL/INTERIM/PROPOSED/NOTICE) | TYPE OF RULE (REGULATORY/BUDGET IMPACT) |
| STATUTORY AUTHORITY FOR THE RULE | RULEMAKING IMPETUS |
| BRIEF DESCRIPTION OF THE RULE | |
| **II. OVERALL IMPACT** | |
| 1. Will the rule have an impact on the economy of $100 million or more? | ☐ Yes ☐ No |
| 2. Best estimate of the present value of quantifiable benefits of the rule. | $_____ |
| 3. Best estimate of the present value of quantifiable costs of the rule.[18] | $_____ |
| 4. Do the quantifiable benefits outweigh the quantifiable costs? | ☐ Yes ☐ No |
| 5. Report the dollar year of costs and benefits. _____ | |
| 6. Report the discount rate used in the calculations for costs and benefits. _____ If more than one discount rate was used in calculations, please explain why. _____ | |
| 7. Discuss level of confidence in the benefit-cost estimates and key uncertainties. Include a range for costs and benefits. _____ | |
| 8. Identify benefits or costs that were not quantified. _____ | |

[18] Costs are defined as costs minus cost savings.

## III. COSTS AND BENEFITS

**Estimated Incremental Costs**

1. Costs and breakdown of quantifiable costs by type.

| | Annual | Years in Which Costs Occur | Present Value |
|---|---|---|---|
| Total Costs | _____ | _____ | _____ |
| Compliance Costs | _____ | _____ | _____ |
| Administrative Costs | _____ | _____ | _____ |
| Federal Budget Costs | _____ | _____ | _____ |
| Local/State Budget Costs | _____ | _____ | _____ |
| Other Costs | _____ | _____ | _____ |

Notes: _____

2. Give a brief description of who will bear the costs. _____

**Estimated Incremental Benefits**

1. Benefits and breakdown of quantifiable benefits by type.

| | Annual | Years in Which Benefits Occur | Present Value |
|---|---|---|---|
| Total Benefits | _____ | _____ | _____ |
| Health Benefits | _____ | _____ | _____ |
| Pollution Benefits | _____ | _____ | _____ |
| Other Benefits | _____ | _____ | _____ |

Notes: _____

2. Give a brief description of who will benefit. _____

## IV. ALTERNATIVES TO THE REGULATION

1. List and briefly describe the alternatives to the rule that were considered and why they were rejected, including a summary of costs and benefits of those alternatives. If no alternatives were considered, explain why not.

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# Assessing the Quality of Regulatory Impact Analyses

**Robert W. Hahn, Jason K. Burnett, Yee-Ho I. Chan, Elizabeth A. Mader, and Petrea R. Moyle**

Working Paper 00-1

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**Executive Summary**

This study provides the most comprehensive evaluation of the quality of recent economic analyses that agencies conduct before finalizing major regulations. We construct a new dataset that includes analyses of forty-eight major health, safety, and environmental regulations from mid-1996 to mid-1999. This dataset provides detailed information on a variety of issues, including an agency's treatment of benefits, costs, net benefits, discounting, and uncertainty.

We use this dataset to assess the quality of recent economic analyses and to determine the extent to which they are consistent with President Clinton's Executive Order 12866 and the benefit-cost guidelines issued by the Office of Management and Budget (OMB).

We find that economic analyses prepared by regulatory agencies typically do not provide enough information to make decisions that will maximize the efficiency or effectiveness of a rule. Agencies quantified net benefits for only 29 percent of the rules. Agencies failed to discuss alternatives in 27 percent of the rules and quantified costs and benefits of alternatives in only 31 percent of the rules. Our findings strongly suggest that agencies generally failed to comply with the executive order and adhere to the OMB guidelines. We offer specific suggestions for improving the quality of analysis and the transparency of the regulatory process, including writing clear executive summaries, making analyses available on the Internet, providing more careful consideration of alternatives to a regulation, and estimating net benefits of a regulation when data on costs and benefits are provided.

# Assessing the Quality of Regulatory Impact Analyses

**Robert W. Hahn, Jason K. Burnett, Yee-Ho I. Chan, Elizabeth A. Mader, and Petrea R. Moyle**

## 1. Introduction

The impact of federal regulation has increased dramatically over the past thirty years. The cost of federal environmental, health, and safety regulation is currently on the order of $200 billion annually.[1] To put that in perspective, the total nondefense domestic discretionary spending budget was just 50 percent greater.[2] Yet, the economic impacts of federal regulation receive much less scrutiny than discretionary programs in the budget.

Recognizing that better economic analysis can potentially improve regulatory outcomes, Presidents Reagan, Bush, and Clinton ordered agencies to provide a regulatory impact analysis (RIA) for all economically significant proposed rules.[3] Done well, those analyses can help agencies identify regulatory alternatives that are more effective and enhance economic efficiency. The analyses can also hold regulators and lawmakers more accountable for their actions. The Office of Management and Budget (OMB) has been assigned the task of reviewing draft regulations to ensure that they are consistent with executive orders. As part of the process, OMB reviews draft RIAs produced by the agency. Several scholars have noted, however, that the quality of such analyses varies across a wide range.[4]

This study provides the most comprehensive, systematic evaluation of the quality of economic analysis that agencies conduct on the basis of a new dataset of almost all major health, safety, and environmental regulations from mid-1996 to mid-1999.[5] The

[1] See Arrow (1996) and OMB (1999a).

[2] See Joint Economic Committee Study (1999). All dollars figures are presented as constant 1999 dollars, adjusted by using the consumer price index.

[3] Executive Order 12866 uses the term assessment in place of regulatory impact analysis, the term used in Reagan's Executive Order 12291 (Reagan, 1981) and still used by many agencies to refer to the economic analysis agencies complete before proposing or finalizing major rules. The agencies publish the results of their economic analysis in the RIA and in the *Federal Register* notice. When we refer to the economic analysis, we are referring to the analysis in either or both sources. According to Executive Order 12866, an agency must produce an economic analysis if the rule is expected to "have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities." We use the terms *rule* and *regulation* interchangeably.

[4] See, for example, Hahn (1996) and Morgenstern (1997).

[5] The dataset includes regulations from April 1996 through July 1999.

study also provides detailed information on a variety of issues, including agencies' treatment of benefits, costs, net benefits, discounting, and uncertainty.[6]

The study was undertaken as the first phase of the Joint Center Regulatory Improvement Project. The primary aim of this project is to enhance regulatory accountability and transparency by making information about regulations more readily available on the Internet. The project has two objectives: first, to provide information on the quality of recent regulatory impact analyses; and second, to provide information to interested parties on specific regulatory analyses.[7] Both this paper and the database used for this analysis can be viewed and downloaded from the Joint Center web site at www.aei.brookings.org.[8]

An appreciation of the kind and quality of information contained in the agencies' economic analyses can help provide insights into how the regulatory analyses could be improved and how summaries of regulatory analyses could help inform interested parties.[9] We score each economic analysis in a variety of dimensions. We then aggregate this information from many regulations into a regulatory scorecard. The scorecard provides an overview of different kinds of information contained in the agencies' economic analyses.

We find that economic analyses prepared by regulatory agencies typically do not provide enough information to make decisions that will maximize the efficiency or effectiveness of a rule. While a sound analytical justification may exist for failing to comply with the guidelines in specific instances, our findings strongly suggest that agencies generally failed to comply with the executive order and adhere to the OMB (1996) guidelines.[10]

Agencies frequently fail to report the net benefits of a rule or give adequate consideration to alternatives. Net benefits are defined as the dollar value of benefits

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[6] The approach is similar to that contained in Hahn (1999a) and Hahn (1999b) but provides more details.

[7] In addition to assessing the quality of analysis, the Joint Center Regulatory Improvement Project will provide interested parties with information and links that will make it easier to understand and investigate the impacts of specific regulations.

[8] The database includes links to the full text of the rules, the RIA when available, and the data used in this paper. See the website for more information.

[9] We have opted for measures of quality that are, arguably, objective, in the sense that others could reproduce our results–if not exactly, then at least approximately. While such measures are informative, they are far from complete. It is quite possible, for example, for a regulatory analysis to score well on the dimensions identified below but be done very poorly. We address that issue later.

[10] The term executive order refers to President Clinton's Executive Order 12866 (Clinton, 1993).

minus costs. That value is an important indicator of the extent to which a regulation is likely to enhance economic efficiency. Agencies quantified net benefits for only 29 percent of the rules. Agencies failed to discuss alternatives in 27 percent of the rules and quantified costs and benefits of alternatives in only 31 percent of the rules. We offer specific suggestions for improving the quality of analysis and the transparency of the regulatory process, including writing clear executive summaries, making analyses available on the Internet, providing more careful consideration of alternatives to a regulation, and estimating net benefits of a regulation when data on costs and benefits are provided.

Section 2 of the paper reviews our methodology. Results are presented in section 3. Finally, section 4 reviews the key conclusions and offers policy recommendations.

## 2. Methodology

Many studies have assessed the quality of agencies' economic analyses.[11] By focusing on an individual or a small group of analyses, scholars have provided a detailed assessment of the strength and weaknesses of particular analyses. This case study approach allows researchers to question key assumptions and assess the appropriateness and application of models used in particular analyses. In this study, we choose to assess the quality of many economic analyses using a different approach that takes the government's numbers and categorization as given. Such an approach has the benefit of being more reproducible than a critique by experts. At the same time, that approach cannot address some critical issues related to quality, such as identifying sources of bias in the estimates or the correct framing of the problem.

This paper will examine the extent to which agencies' economic analyses issued from mid-1996 through mid-1999 meet the government's own standards for analysis. Those standards are discussed in two places: Executive Order 12866, in which President Clinton redefined the nature of the regulatory analysis function OMB performs, and in the OMB guidelines, which specify best practices for implementing the executive order.[12]

[11] For a review of several economic analyses, see General Accounting Office (1984), EPA (1986), Fraas (1991), and Morgenstern (1997). Smith (1984) provides a review of the regulatory oversight process.

[12] Section (F)(7)(d) of the executive order requires the OMB to provide agencies guidance in writing economic analyses. The OMB convened an interagency group to describe the best practices for preparing

The executive order requires agencies to include the following information in their analysis: a statement of the potential need for the proposal, an examination of alternative approaches, an assessment of benefits and costs, the rationale for choosing the regulatory action, and a statement of statutory authority.[13]

This study focuses on the extent to which agencies quantify benefits and costs and assess alternatives, two key requirements of the executive order. The order states that agencies shall provide "an assessment, including the underlying analysis," of benefits and costs expected from a regulation and, "to the extent feasible" provide a quantification of those benefits and costs.[14] The OMB guidelines further direct agencies to express benefits and costs in monetary terms "to the fullest extent possible."[15] To quantify agency compliance with the executive order, this study measures the extent to which agencies have quantified and monetized the impacts of regulations.[16]

One of the primary purposes of the requirement to quantify the benefits and costs is to assist the agency in selecting among regulatory alternatives. The executive order states that "agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating."[17] The order requires economic analyses to provide sufficient information to demonstrate that the agency is selecting the regulatory approach that maximizes net benefits, unless prohibited by statute.[18] The language in the order is vague and requires interpretation. While several interpretations are possible, this paper uses an economic interpretation, the specifics of which the OMB guidelines set forth.[19] This study measures the extent to which agencies have met this

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economic analyses. The results of that effort were presented in a paper in January 1996. This paper will be referred to as the OMB (1996) guidelines.

[13] The Unfunded Mandates Reform Act of 1995, which applies to many of the rules considered here, also requires an economic analysis that includes a quantification of impacts and consideration of alternatives.

[14] See Clinton (1993).

[15] See OMB (1996). The OMB guidelines discuss principles for putting an explicit value on benefits that are difficult to monetize, such as environmental amenities.

[16] Both the executive order and the OMB guidelines note that it is not always possible or desirable to monetize all benefits and costs.

[17] See Clinton (1993).

[18] The executive order states that "agencies should select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributional impacts; and equity), unless a statute requires another regulatory approach."

[19] The OMB guidelines describe specific steps to comply with this mandate including the choice of alternatives to analyze. Agencies are urged to define carefully the proper baseline, discuss uncertainty and bias in estimates, and carefully describe key assumptions used in developing estimates of benefits and costs (OMB, 1996).

requirement of the executive order by assessing cost and benefits of different alternatives.[20]

To examine the extent to which an analysis met the requirements of the executive order, we developed an evaluation worksheet that is summarized in table 1. The scorer determined whether an agency evaluated costs, benefits, net benefits, and alternatives to a rule by reading each *Federal Register* notice and RIA from the database.[21] If an analysis scores well using our criteria, it does not follow that it is necessarily of high quality; however, if several analyses score poorly, that raises cause for concern–particularly if key economic variables are not assessed, such as the net benefits of a regulation.

Objective criteria, such as determining whether an agency used a consistent dollar year or discount rate, ensured that the results could be replicated. In addition, researchers peer-reviewed all judgments made in filling out the worksheet. The analysts resolved disagreements and established clear guidelines, which are presented in the online database. Given the complexity of many of the analyses, some errors are likely.[22]

Another problem arises in establishing consistent criteria by which to evaluate agency compliance. Defining what was meant by "discussed alternatives" was relatively easy; an agency simply must mention the existence of alternative regulatory approaches. This criterion was designed to be a very low hurdle that would meet the minimum requirements of the executive order.[23]

It is less clear how to evaluate whether an agency presented a "reasonable range of alternatives." While we feel this measure contains some useful information, we recognize that it is more subjective and have not included it in the analysis presented here. For completeness, we have decided to include all categories in the database.[24]

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[20] While agencies may present reasons not to quantify and monetize benefits and costs, and not consider alternatives for individual regulations, we believe they should be able to meet those requirements of the executive order for a majority of regulations. We recognize that there may be cases where it is very difficult to quantify benefits and costs and that a qualitative measure may be of value. Some of those cases appear in the OMB guidelines.

[21] When a discrepancy existed between the numbers presented in the *Federal Register* and the RIA, we used the *Federal Register* number because it is the official publication for agency documents. In addition, agencies incorporate OMB's comments into the *Federal Register* notice but do not always update the RIA.

[22] Suggestions should be submitted on the AEI-Brookings website at www.aei.brookings.org.

[23] In EPA's "Federal Test Procedure Revisions" rule, for example, the agency did not discuss alternatives, except to claim the option selected "is the most cost-effective alternative currently available" and to refer the reader to a discussion elsewhere. In this case, the rule was scored as considering alternatives.

[24] Researchers using this database should consult the definitions for an explanation of the criteria used for scoring purposes.

The database contains almost all economically significant non-transfer rules finalized between April 1996 and July 1999.[25] We excluded transfer rules because they tend to focus explicitly on the transfer of wealth to specific groups, whereas nontransfer rules tend to focus on achieving regulatory objectives such as cleaner air.[26] We examined the nontransfer rules because they tend to be the focus of serious economic analysis and are most relevant for applying the benefit-cost requirements of the executive order and the OMB guidelines.

We included only economically significant rules in the database for two reasons. First, economically significant rules typically have annual costs or benefits in excess of $100 million per year. These rules therefore have the largest impact on society and should receive greater scrutiny by agencies.[27] Second, with a few exceptions, all economically significant rules have an economic analysis.

Three agencies have finalized more than five rules in the database: the Department of Transportation (DOT), the Environmental Protection Agency (EPA), and the Department of Health and Human Services (HHS). We presented the results from those agencies separately but grouped results from the remaining rules together, simply because no other single agency finalized enough rules for summary statistics to be meaningful.[28]

### 3. Results

This section describes the aggregate results of our study of agencies' economic analyses. In general, we find that most economic analyses do not meet the intent of the executive order or the OMB guidelines, and a significant percentage are in clear violation

[25] We obtained from OMB a list of all the rules that OMB reviewed in the past four years (OMB, 1999b). From that list, we eliminated all transfer rules and rules without an economic analysis. We then selected the economically significant rules that were finalized between the beginning of April 1996 and the end of July 1999. The criteria we used for including a rule in our database are similar to OMB's criteria for major "Environmental" and "Other Social" rules (OMB, 1999a). In several cases, an agency finalized an economically significant rule but did not produce an economic analysis because Congress prohibited funding the analysis. See, for example, the Corporate Average Fuel Economy Standards. We excluded those rules from in our database because no analysis was available.

[26] In practice, a transfer rule is designed to move resources from the federal government coffers to designated segments of the population. A nontransfer rule is typically aimed at addressing a market failure. According to OMB (2000), "a transfer occurs when wealth or income is redistributed without any direct change in aggregate social welfare."

[27] Presidents Reagan and Clinton recognized the importance of careful analysis of economically significant rules when they issued Executive Orders 12291 and 12866, respectively.

of the order. The analyses are often of low quality, though considerable variation exists. They frequently do not provide the kind of information needed to select the best regulatory alternative or to show that a regulation should be implemented.

We present information on a variety of categories, including benefits, costs, a comparison of benefits and costs, alternatives, and the clarity of presentation for forty-eight rules. We then conclude with a discussion of our analytical conclusions.

*Costs*

Agencies always define some categories of costs and usually quantify some part of those costs. Ninety-five percent of the economic analyses quantified some costs, and 90 percent of economic analyses monetized some costs.[29] Figure 1 provides an overview of the information agencies presented on monetized costs. The three agencies that finalized the majority of the rules in our database (DOT, EPA, and HHS) monetized costs in over 80 percent of their respective rules. The other agencies monetized costs for only about one-half of the rules. The agencies monetized all stated costs in only 63 percent of the rules.

Those statistics need to be interpreted with care. Some agencies noted, for example, that regulations have costs in addition to direct compliance costs and administrative costs. It would be misleading to suggest lower quality analysis from those agencies simply because they noted some of the indirect costs of regulations but did not attempt to quantify the costs. In fact, the acknowledgement of indirect costs is often an indication of a more thorough analysis on the part of agencies.

Figure 1 shows that agencies presented a best estimate of monetized costs far more often than they presented a range. Over two-thirds of the regulations gave a best estimate of costs, while only one-fourth presented a range of cost estimates. Only 13 percent of the regulations presented both a best estimate and a range of costs.

An improved understanding of the impact of regulatory costs on different groups allows policymakers to address distributional concerns more effectively. We considered whether an economic analysis identified costs to the following groups: producers,

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[28] The other agencies include the Department of Commerce (DOC), the Department of Energy (DOE), the Department of Labor (DOL), and the Department of Agriculture (USDA).

[29] "Monetize" means that an agency put a dollar value on at least some part of the relevant category, such as costs or benefits.

nonfederal governments, and the federal government.[30] Almost all economic analyses (94 percent) note that a regulation will impose compliance costs on producers. A third identify costs to nonfederal governments, while about one-quarter of the regulations identify federal budgetary costs.

Regulations impose costs on those groups in many ways. Agencies routinely note and quantify some of these costs. Over two-thirds of the analyses note that the regulation will have administrative costs.[31] In contrast, the agencies rarely discuss and never quantify the macroeconomic impacts of regulations in their economic analyses.

*Benefits*

Almost all of the regulations (96 percent) had stated benefits. The two rules that do not explicitly address benefits were designed to reduce the costs of existing regulations.[32] Of those rules with benefits, about 70 percent described benefits in quantitative terms, as either a range or a best estimate. Only 17 percent of the rules presented both a best estimate and a range of those quantitative benefits.

Figure 2 provides information on the extent to which agencies monetized any benefits. Agencies converted benefits into dollar equivalents less than one-half of the time. Rarely did agencies give best estimates and ranges for monetized benefits. DOT and EPA are the only agencies that monetize benefits at least one-half of the time. DOT presented monetized benefits for two-thirds of the rules, while HHS only monetized benefits one-third of the time.

Often agencies quantify and monetize only some of the stated benefits. Agencies quantified all stated benefits for 54 percent of the rules and monetized all benefits in only 28 percent of the rules. We were not able to determine the extent to which agencies quantified and monetized the most significant benefits, precisely because agencies did not quantify those benefits. Agencies monetized certain categories of benefits more frequently than others. For example, 83 percent of the rules for which agencies identify safety benefits presented monetized estimates of those benefits; 54 percent of the rules

[30] Although those categories are useful, it is not a simple matter to estimate the ultimate impact of costs on consumers and workers. Indeed the data presented generally do not permit an assessment of the impact of regulations on consumers, workers, and owners of capital.

[31] The Paperwork Reduction Act requires agencies to estimate the paperwork burden of regulations.

[32] In addition to benefits and costs, agencies include cost savings as a category of regulatory impacts. The difference between cost-savings and benefits is more a matter of semantics than economics, but we

for which agencies identify health benefits monetized those benefits, and only 11 percent of rules for which agencies identify benefits from pollution reductions monetized those benefits.[33]

*Comparing Costs and Benefits*

This subsection addresses a variety of issues related to the aggregation of costs and benefits, including net benefit calculations, the reporting of costs and benefits, and the use of discounting.

Figure 3 presents information on the extent to which agencies present information on net benefits, a key indicator of the economic efficiency of a rule. Only 28 percent of the rules presented information on net benefits. Of those, about one-third presented best estimates, and the other two-thirds presented a range. Only two rules presented both a range and best estimate of net benefits.[34] Of the three agencies that promulgated more than five rules, HHS and EPA presented net benefits most often, while DOT never presented net benefits.

For several rules, agencies provided enough information to calculate net benefits but did not do so. Of the rules with monetized costs and benefits, agencies presented net benefits only 56 percent of the time. It is not clear why agencies did not calculate net benefits more often when all that is required is to subtract one estimate from another. One possibility is that agencies do not feel that the cost or benefit estimates are reasonable.[35] Thus, taking the difference between the two might not provide a meaningful estimate of net benefits.

Another possibility is that agencies may be reluctant to present net benefit estimates if those estimates are negative. In our database, thirty-one rules provided estimates of costs and benefits sufficient to calculate net benefits. Of those, about one-half had benefits and costs savings that exceeded the costs.

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disaggregated cost savings and benefits according to an agency's own categorization. Often a cost saving regulation would make an existing regulation less burdensome.

[33] Most of the monetized benefits from pollution reduction are due to lower morbidity and mortality. We included pollution reduction benefits as a separate category because a substantial fraction of the rules in our database (44 percent) are expected to reduce pollution.

[34] These rules are EPA's "Findings of Significant Contribution and Rulemaking for Certain States in the Ozone Transport Assessment Group Region for Purposes of Reducing Transport of Ozone" and DOE's "Energy Conservation Program for Consumer Products; Conservation Standards for Room Air Conditioners."

[35] DOT does not present net benefits if it believes the benefit or cost numbers are not sufficiently robust (DOT 1999).

We divided those thirty-one rules into the twelve where the agency presented net benefits and the nineteen where the agency did not. In the first group, where the agency presented net benefits, three-quarters pass a benefit-cost test. In the second group, only one-third pass the same test. The results provide some support for the view that agencies present net benefits numbers more often when those numbers will support their regulation.

Some differences existed in the extent to which agencies monetized all identified costs and benefits. Agencies monetized all costs for 60 percent of the rules in the database, monetized all benefits for 49 percent of the rules, and monetized all costs and benefits for only 19 percent of the rules. The finding that agencies tend to monetize costs more frequently than benefits is consistent with previous studies.[36]

Sometimes agencies present cost-effectiveness numbers, either in addition to or instead of information on net benefits. The agency calculates cost-effectiveness by dividing monetized costs by some nonmonetary quantitative measure of benefits.[37] A cost-effectiveness calculation allows the agency to provide information on the effectiveness of a regulation relative to alternative regulatory approaches without assigning a monetary value to quantified benefits.

Figure 4 describes how often agencies presented cost-effectiveness estimates for rules that did not supply information on net benefits. We focus on those rules because cost-effectiveness calculations may be especially useful if benefits are difficult to monetize or agencies are reluctant to monetize benefits. Over one-third of the rules in the database that did not present an estimate of net benefits did present an estimate of cost-effectiveness. That means, however, that just less than two-thirds did not. That is, about half (48 percent) of the forty-eight rules examined here presented no direct measures of net benefits or indirect measures based on cost-effectiveness. Only 6 percent of the forty-eight rules presented both an estimate of net benefits and an estimate of cost-effectiveness.[38]

Figure 4 also reveals a variation in the extent to which different agencies present cost-effectiveness information. EPA presented cost-effectiveness information for about

[36] See Hahn (1999a).

[37] Cost-effectiveness is a more useful measure when there is only one expected benefit from the rule. If the agency expects several benefits, it is not immediately obvious how they should be summed to generate the denominator for the cost-effectiveness calculation.

half of the rules for which it did not present net benefit numbers. DOT is the only other agency that provided any information on cost-effectiveness for rules in which net benefit information was not supplied. EPA usually presented cost-effectiveness in terms of cost per ton of pollution abated, while DOT used variations on cost per life saved or "equivalent life saved."[39] By presenting cost-effectiveness numbers, EPA avoided the task of assigning a dollar value to the pollution abated, and DOT avoided the politically charged task of assigning a value to extending a life.

Often, agencies do not appropriately present the results from cost-effectiveness calculations. When a single regulation reduces several types of pollution, EPA often grouped all pollutants together in its calculation of cost-effectiveness.[40] Depending on the composition of pollutants reduced by the rule, that approach will either exaggerate or understate the costs relative to a net benefit calculation. At other times, EPA calculated the cost-effectiveness of reducing a single pollutant while ignoring the other benefits of the regulation.[41] Such an approach overstates the true cost that should be attributed to each ton abated.

An important issue in comparing benefits and costs is the choice of a discount rate. Future benefits and costs are converted into an equivalent value in present terms by using a discount rate. Almost three-fourths of the analyses used a consistent discount rate for costs and benefits, a generally accepted practice; but about one-fourth did not. Of those using a single discount rate, 86 percent used the rate of 7 percent specified in the OMB guidelines, 14 percent used a discount rate less than 7 percent and only one used a discount rate greater than 7 percent.[42]

*Discussion of Alternatives*

Executive Order 12866 and the OMB guidelines direct agencies to ensure that the regulatory alternative chosen maximizes net benefits.[43] Unfortunately, agencies did not

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[38] This estimate could either be a best estimate and/or a range.

[39] In DOT's "Federal Motor Vehicle Safety Standards; Child Restraint Anchorage Systems, Child Restraint Systems," for example, the agency used "equivalent life saved," which included injuries.

[40] This aggregation may be more useful when a weighted average is used. For example, DOT provides cost-effectiveness estimates for several of its regulations after combining injuries and deaths by employing a weighting system.

[41] EPA did not include direct hydrocarbon and particulate matter reductions in its calculation of cost-effectiveness of $NO_x$ emission reduction in its rule titled "Emission Standards for Locomotives and Locomotive Engines."

[42] HHS's rule, "Medical Devices: CGMP Quality Systems Regulation" used a discount rate of 10 percent.

[43] See Clinton (1993) and OMB (1996).

provide much analysis of alternatives, even when they were able to conduct a quantitative analysis of their preferred option.[44]

Figure 5 shows the extent to which different agencies analyzed alternatives. While agencies discussed alternatives for over two-thirds of the rules, they quantified the costs and benefits of alternatives for only a quarter. The three agencies with more than five rules in our database (DOT, EPA, and HHS) quantified benefits and costs of alternatives between 20 percent and 35 percent of the time. None of the other agencies quantified benefits and costs of alternatives for any of their rules. Only two rules out of forty-eight calculated incremental net benefits of the alternatives.[45] Such incomplete consideration of alternatives makes it difficult to judge whether alternatives would actually be superior to an agency's preferred policy, even using an agency's own assessment.

*Clarity of Presentation*

Clarity afforded by a uniform format helps agencies ensure that they are using consistent assumptions and are presenting consistent results. In fact, less than a quarter of the rules were consistent in even the most fundamental assumptions and results, such as the discount rate chosen, benefits and costs.[46] Less than 60 percent of the rules provided completely consistent benefit numbers in the *Federal Register* and the RIA. While such inconsistencies may reflect new information used in the analysis, no attempt was made to explain them.

Improving the clarity of presentation in RIAs would assist stakeholders in understanding the impact of regulations and help agencies ensure that they are using consistent assumptions and presenting consistent results.

*General Results*

The agencies' economic analyses generally do not provide an adequate basis to make decisions on the net benefits of a proposed rule or its alternatives. Agencies

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[44] For 35 percent of the rules, agencies presented estimates of benefits and costs for the chosen alternative but failed to present estimates of benefits and costs for other alternatives. If agencies are able to quantify costs and benefits for the chosen alternative, it is highly likely that they would also be able to quantify benefits and costs of relevant alternatives because doing so would not require significant new information or modeling techniques.

[45] Both are EPA rules: "Findings of Significant Contribution and Rulemaking for Certain States in the Ozone Transport Assessment Group Region for Purposes of Reducing Transport of Ozone" and the "Regional Haze Rule."

[46] Only ten out of forty-eight rules used a consistent dollar year, a consistent discount rate and a consistent estimate of benefits and costs.

quantified benefits and costs in 71 percent and 85 percent of the rules, respectively; yet, net benefits were quantified for only 29 percent of the rules. Agencies failed to discuss alternatives in 27 percent of the rules and quantified benefits and costs of alternatives in only 31 percent of the rules. The absence of information on net benefit measures suggests strongly that agencies have largely ignored the intent of the executive order and the OMB guidelines.

RIAs are not transparent, in part, because they lack a consistent format for presentation. At a minimum, it would be useful to have an executive summary. An executive summary, which can be used to summarize the key results of an analysis, is found in only about one-half of the RIAs. Only fourteen regulations (29 percent) used an executive summary to present tables of qualitative or quantitative estimates of benefits and/or costs. While other RIAs had such information, it was not as readily available.[47]

RIAs do not have a consistent format, and the presentation of key results is often unclear. Specific economic information is often buried within technical discussion of the health or environmental impacts.[48] It often takes hours to find a specific piece of information in an RIA. While the *Federal Register* has often been criticized for poor presentation, it is easier to navigate and presents information in a more uniform, accessible format than RIAs.[49]

**4. Recommendations and Conclusions**

An agency's formal economic analysis of a regulation, such as that contained in an RIA, should be viewed as the starting point for serious policy analysis rather than an end point. We believe the government should provide its assessment of the benefits and costs of proposed regulations in a complete and transparent manner. The majority of the economic analyses we reviewed did not do so and thus failed to adhere to the OMB guidelines or the executive order.

Even if benefits and costs of a proposed regulation are presented in a clear, succinct fashion, a deeper issue that needs to be addressed is related to quality. While our

[47] Several of the thirty-four regulations without summary tables in the executive summary did present their results in an accessible format.

[48] Often rules describe basic economic concepts such as discounting and nonmarket valuation. While they may be essential for an understanding of the analysis, a lengthy discussion of techniques detracts from and obscures the issues and assumptions that are unique to an individual analysis. Instead, the agencies should simply refer to OMB guidelines that address those more general concerns.

worksheet did not directly measure the quality of the underlying analysis because doing so would require knowledge of specific technical issues, we have reason to be very concerned. First, as noted above, many key pieces of information were simply unavailable and, in some cases, were inconsistent within an RIA. Second, many RIAs did not present information in a clear manner. Third, case studies by scholars suggest that some economic analyses are of high analytical quality, but many suffer deep shortcomings.[50] It is clear the quality issue cannot simply be handled by enforcing guidelines, though that could certainly make the results more transparent.

A complete discussion of options for improving regulatory analysis and the regulatory process is beyond the scope of this paper.[51] However, there are a variety of recommendations that flow naturally from this analysis. They include:

- requiring an agency to calculate net benefits when it can estimate benefits and costs; and asking that agency to note the limitations of those estimates;
- requiring an agency to present both best estimates and ranges for benefits, costs, and net benefits; or, alternatively, asking an agency to justify why that cannot be done;
- requiring an agency to quantify any benefits or costs that it is unable or unwilling to monetize; or, alternatively, asking that agency to justify why that cannot be done;
- requiring an agency to expand its consideration of alternatives;
- requiring a clear executive summary that summarizes what is known about the likely benefits and costs of the regulation in a clear format;
- requiring RIAs to have a consistent format so that it is easier to obtain information from different RIAs and compare them;
- requiring that an RIA be posted on the Internet so that such analyses are more easily obtained by interested parties; and
- requiring OMB to provide clearer guidance on how cost-effectiveness numbers should be presented and calculated to avoid some of the current problems.

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[49] See Hahn (1999b).
[50] See, for example, Hahn (1996), Morgenstern (1997), and Lutter (1999).

A critical challenge is to get agencies to adhere to such standards. It is fairly clear that President Clinton, working with OMB, has not been successful in implementing such reforms, probably due to a lack of interest and willingness to spend political capital.[52] We believe that such reforms are likely to be worthwhile, not necessarily because the analysis itself will improve dramatically, but rather because they will at least make the regulatory process more transparent.

Congress could pass a bill that incorporates our suggestions. It could also create an agency outside the executive branch to report on how such guidelines are being implemented and to review regulations. We recognize the lack of political enthusiasm for making the process more transparent. At the same time, the issue could have some bipartisan appeal because it would arguably hold regulators more accountable for their policies.

Making the regulatory process more transparent is likely to have two benefits. First, it will give interested parties greater access to the key part of the regulatory process used to support a decision. Second, it will make it more likely that scholars will engage in independent regulatory analysis that could lead to improvements in both the regulatory process and regulatory outcomes.

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[51] See, for example, Breyer (1993), Noll (1999), and Pildes and Sunstein (1996).

[52] While the Clinton administration may deserve some blame, we believe that the problem is also relevant to earlier Republican administrations. The analyses contained in Hahn (1999) and Morgenstern (1997) would suggest that economic analyses of regulations by agencies were not necessarily better during the Bush and Reagan administrations. Indeed, it may be that most presidents would be unwilling to spend the necessary capital to improve the quality of analysis.

Table 1

**Economic Analysis Scorecard**[a]

**General Information**

Regulation Name:_____

Agency and Department:_____ Date:_____

RIN#: _____ Status: final interim-final page

Economically Significant: yes no page Transfer Rule: yes no page

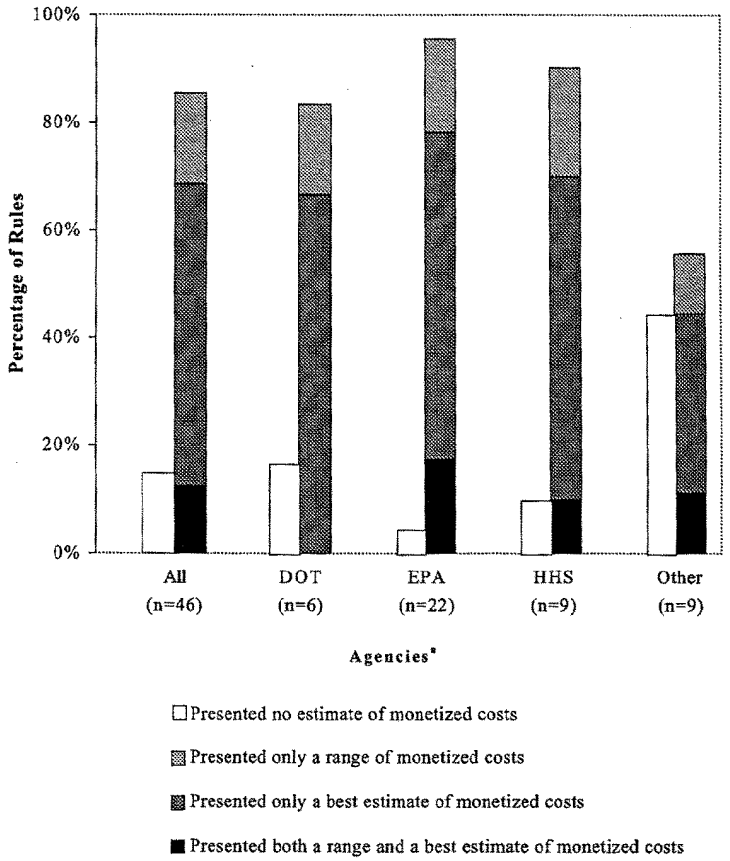
| | Score | page | Notes |
|---|---|---|---|
| 1. Identified Discount Rate | | | |
| 2. Used a Consistent Discount Rate | | | |
| 3. Identified Baseline for Costs | | | |
| 4. Identified Baseline for Benefits | | | |
| 5. Used Consistent Baseline for Costs and Benefits | | | |
| 6. Identified Dollar Year | | | |
| 7. Used Consistent Dollar Year | | | |
| 8. Performed Sensitivity Analysis | | | |
| 9. Gave Executive Summary | | | |
| 10. RIA is Available on the Internet | | | |
| 11. The RIA was Peer-Reviewed | | | |
| 12. Presented Best Estimate of Net Benefits | | | |
| 13. Presented Range of Net Benefits | | | |
| 14. Presented Best Estimate of Cost-Effectiveness | | | |
| 15. Presented Range of Cost-Effectiveness | | | |
| 16. Discussed Alternatives | | | |
| 17. Quantified Costs and Benefits of Alternatives | | | |
| 18. Quantified Incremental Net Benefits of Alternatives | | | |

**Costs**

| | Agency States Exist | | Agency Quantified | | Agency Monetized | |
|---|---|---|---|---|---|---|
| | Score | page | Score | page | Score | page |
| 1. Private Sector Producer Compliance Costs | | | | | | |
| 2. Federal Budgetary Costs | | | | | | |
| 3. Local and/or State Government Costs | | | | | | |
| 4. Other Costs | | | | | | |
| 5. Presented Range of Cost Estimates | | | | | | |
| 6. Presented Best Estimate of Costs | | | | | | |
| 7. Presented Consistent Cost Figures Between RIA and *Federal Register* | | | | | | |

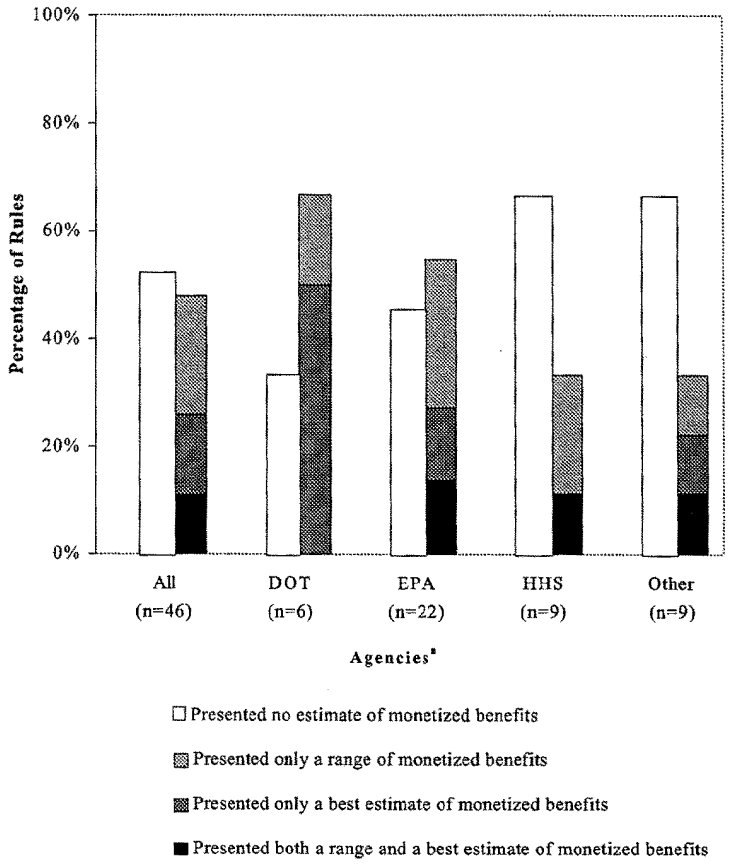
[a] See www.aei.brookings.org for a complete copy of this scorecard, including the factors analyzed for an agency's treatment of cost savings, benefits, uncertainty and bias.

**Figure 1: Agency Analysis of Monetized Costs**



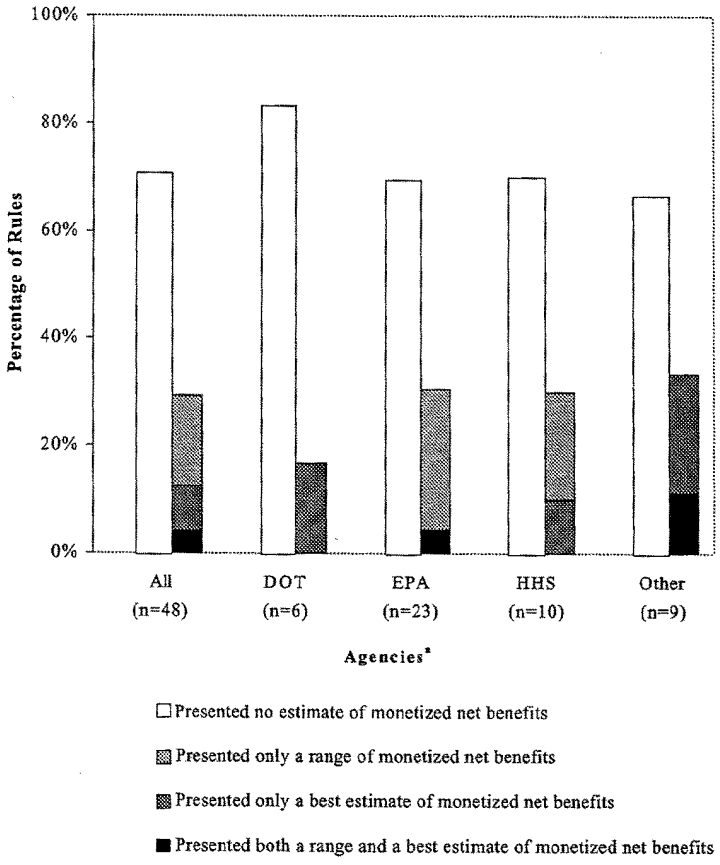

[a] DOT - Department of Transportation. EPA - Environmental Protection Agency. HHS - Health and Human Services. DOC - Department of Commerce. DOE - Department of Energy. DOL - Department of Labor. USDA - Department of Agriculture. The category "Other" includes DOC, DOE, DOL, and USDA.

**Figure 2: Agency Analysis of Monetized Benefits**




[a] DOT - Department of Transportation. EPA - Environmental Protection Agency. HHS - Health and Human Services. DOC - Department of Commerce. DOE - Department of Energy. DOL - Department of Labor. USDA - Department of Agriculture. The category "Other" includes DOC, DOE, DOL, and USDA. In two rules the agencies do not expect any benefits. These rules are excluded from this analysis.

**Figure 3: Agency Analysis of Monetized Net Benefits**




[a] DOT - Department of Transportation. EPA - Environmental Protection Agency. HHS - Health and Human Services. DOC - Department of Commerce. DOE - Department of Energy. DOL - Department of Labor. USDA - Department of Agriculture. The category "Other" includes DOC, DOE, DOL, and USDA.

**Figure 4: Agency Analysis of Cost-Effectiveness**

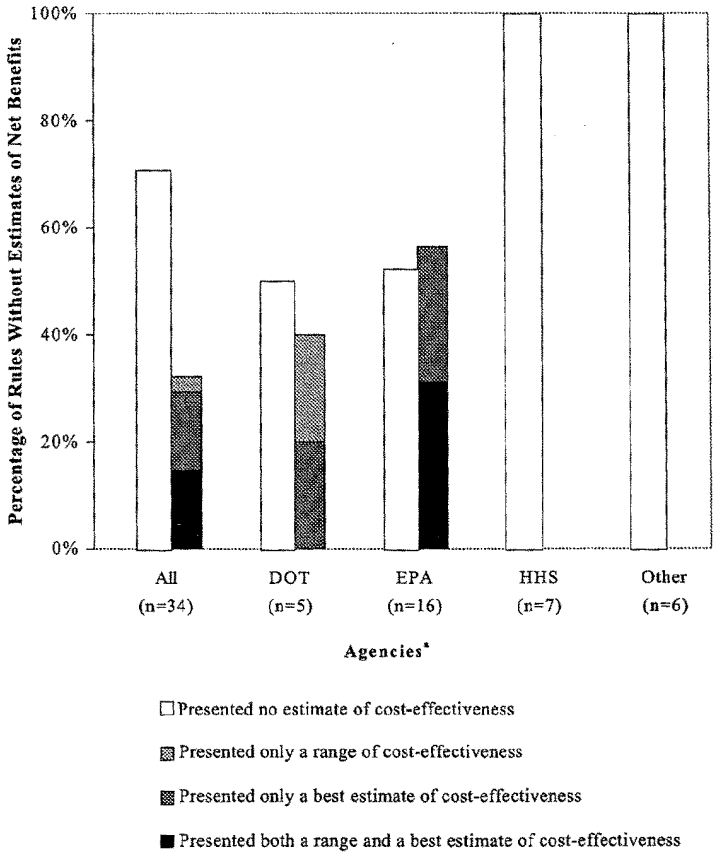



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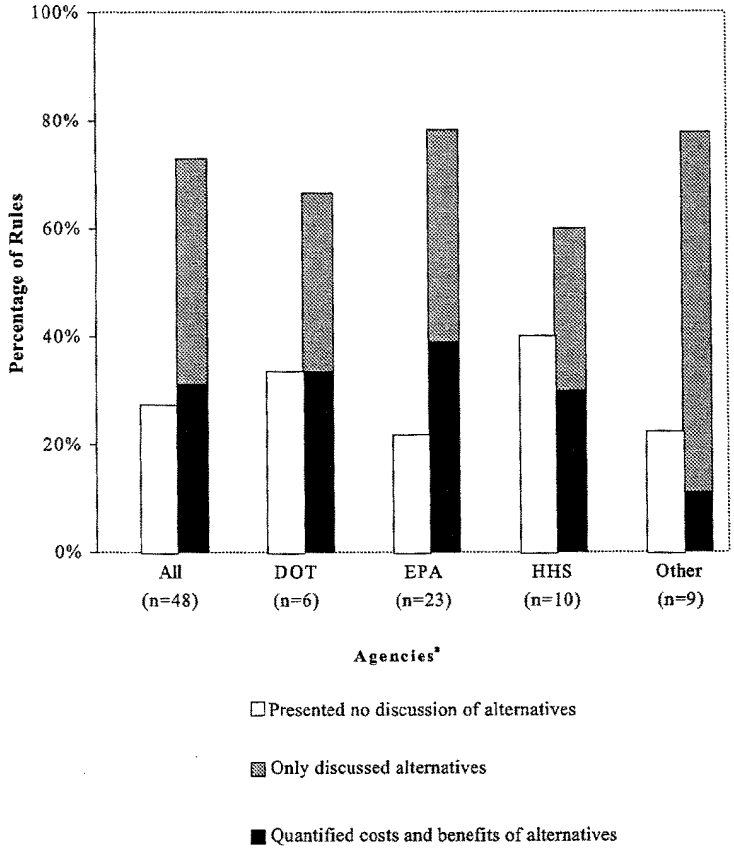
**Figure 5: Agency Analysis of Alternatives**




[a] DOT - Department of Transportation. EPA - Environmental Protection Agency. HHS - Health and Human Services. DOC - Department of Commerce. DOE - Department of Energy. DOL - Department of Labor. USDA - Department of Agriculture. The category "Other" includes DOC, DOE, DOL, and USDA.

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Testimony

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# REGULATORY REFORM

# Procedural and Analytical Requirements in Federal Rulemaking

Statement of Robert P. Murphy, General Counsel

GAO/T-GGD/OGC-00-157

Statement

# Regulatory Reform: Procedural and Analytical Requirements in Federal Rulemaking

I am pleased to be here today to discuss our reviews of agency compliance with a number of procedural and analytical requirements in federal rulemaking. The reviews were conducted in response to congressional concerns that agencies had not adequately considered the effects of their actions on regulated entities or worked to minimize any negative effects. The requirements that we examined are contained in a number of statutes and executive orders governing the rulemaking process, including the Administrative Procedures Act, the Regulatory Flexibility Act, the Unfunded Mandates Reform Act, and Executive Orders 12866 and 12612.

In brief, our congressionally-requested evaluations have produced a mixed result. While they may not have been representative of all rulemakings, in some cases our work disclosed inadequate data, methodologies, or assumptions, and in other disclosed noncompliance with statutory requirements or executive orders. There are examples in which our reviews have helped ensure better adherence to applicable regulatory requirements. On the other hand, sometimes our reviews did not disclose a failure to comply with rulemaking requirements, but provided Congress with factual detail and a better understanding of the agencies' procedures and decision making. In others cases, our reviews established that the agencies were acting within allowable discretion to determine that certain requirements were inapplicable, and in others, that the requirements themselves were narrowly tailored and had little effect on rulemaking. We also found cases where regulations that were considered burdensome by the regulated community were required by the statute being implemented.

## Congressional Oversight Can Address Some Regulatory Concerns

Some of our work on regulatory issues has clearly demonstrated the value of congressional oversight of agency rulemaking. Congressional oversight can clarify issues left unclear in agencies' public statements about their rules and, on occasion, can directly result in changes to agencies' rules. The targets of that oversight can vary substantially—from the particular (and sometimes highly technical) elements of agencies' economic analyses used to support the rules, to the general public participation requirements in the rulemaking process.

### Reviews Indicate Some Agency Economic Analyses Need Improvement

A great deal of congressional attention and concern has recently been focused on the economic analyses that agencies prepare in support of their regulatory actions. Under Executive Order 12866, issued by President Clinton in September 1993, covered agencies are required to submit their "significant" rules to the Office of Management and Budget (OMB) before publishing them in the Federal Register. Agencies are also required to prepare a detailed economic analysis for any regulatory actions that are "economically significant" (e.g., have an annual effect on the economy of

$100 million or more).[1] According to the executive order, the analyses should include an assessment of the costs and benefits anticipated from the action as well as the costs and benefits of "potentially effective and reasonably feasible alternatives to the planned regulation." The order also states that, in choosing among alternatives, an agency should select those approaches that maximize net benefits and "base its decisions on the best reasonably obtainable scientific, technical, economic, and other information concerning the need for, and consequences of, the intended regulation."

In January 1996, OMB issued "best practices" guidance on preparing cost-benefit analyses under the order. The guidance gives agencies substantial flexibility regarding how the analyses should be prepared, but also indicates that the analyses should contain certain basic elements and should be "transparent"—disclosing how the study was conducted, what assumptions were used, and the implications of plausible alternative assumptions.

At the request of Members of Congress, we have examined agencies' economic analyses both in our reviews of selected federal rules issued by multiple agencies and in the context of particular regulatory actions. In one of our reviews, we reported that some of the 20 economic analyses from 5 agencies that we reviewed did not incorporate all of the best practices set forth in OMB's guidance.[2] Five of the analyses did not discuss alternatives to the proposed regulatory action, and, in many cases, it was not clear why the agencies used certain assumptions. Also, five of the analyses did not discuss uncertainty associated with the agencies' estimates of benefits and/or costs, and did not document the agencies' reasons for not doing so. We recommended that OMB's best practices guidance be amended to provide that economic analyses should (1) address all of the best practices or state the agency's reason for not doing so, (2) contain an executive summary, and (3) undergo an appropriate level of internal or external peer review by independent experts.

## Oversight of Analyses Can Result in Changes to Rules

In some cases, our congressionally-requested reviews of agencies' regulatory analyses have resulted in changes to the associated rules. For example, we reported last year on the scientific basis for the Food and Drug Administration's (FDA) proposed rule on dietary supplements

[1]Similar economic analysis requirements had previously been in place under Executive Order 12291, issued by President Reagan in 1981.

[2]Regulatory Reform: Agencies Could Improve Development, Documentation, and Clarity of Regulatory Economic Analyses (GAO/RCED-98-142, May 26, 1998).

containing ephedrine alkaloids and the agency's adherence to statutory and executive order regulatory analysis requirements.[3] Although the number and type of adverse event reports that FDA received warranted the agency's consideration of steps to address safety issues, we expressed concerns about the strength of some of the information FDA used to support two aspects of the proposed rule—the dosing level and duration of use limits. We concluded that FDA generally complied with the statutory and executive order requirements applicable to the rulemaking, but the economic analysis that accompanied the rule did not reflect the full range of uncertainty associated with the proposed rule. The agency did not always disclose why certain key assumptions were made or the degree of uncertainty involved in those assumptions. It also did not disclose that alternative assumptions would have had a dramatic effect on the agency's estimate of the benefits of the proposed actions. We recommended that FDA obtain additional information to support conclusions regarding the specific elements in the proposed rule before proceeding to final rulemaking. We also recommended that FDA improve the transparency of its cost-benefit analysis in its final rule. In April 2000, FDA announced that it was withdrawing certain portions of its proposed rule "because of concerns regarding the agency's basis for proposing a certain dietary ingredient level and a duration of use limit for these products."[4]

In a review that we released earlier this year, we reported on the Federal Emergency Management Agency's (FEMA) plans to revise its regulations pertaining to public assistance insurance requirements.[5] Although the rule was economically significant, FEMA had not conducted an analysis of the expected costs and benefits of the draft regulation before submitting it to OMB for its review, and had not prepared a comprehensive analysis of other alternatives. In response to our preliminary discussions with FEMA about these issues, FEMA entered into a contract with a management consulting firm to conduct a cost-benefit analysis and to examine and assess alternative approaches. FEMA also began additional analysis of the impact of its draft regulations on small entities in response to OMB's concerns about FEMA's compliance with the Regulatory Flexibility Act. Finally, FEMA decided to issue an advance notice of proposed rulemaking before issuing the proposed rule.

[3]Dietary Supplements: Uncertainties in Analyses Underlying FDA's Proposed Rule on Ephedrine Alkaloids (GAO/HEHS/GGD-99-90, July 2, 1999).

[4]Federal Register, Vol. 65, No. 64 (Apr. 3, 2000), p. 17474.

[5]Disaster Assistance: Issues Related to the Development of FEMA's Insurance Requirements (GAO/GGD/OGC-00-62, Feb. 25, 2000).

In some cases, we are asked to review and comment on agencies' rulemaking approaches without specific reference to Executive Order 12866. For example, in response to a requirement in the Balanced Budget Act of 1997, we issued a report in February 1998 evaluating a Health Care Financing Administration (HCFA) proposed rule describing revisions to fee schedules used to pay physicians in the Medicare program.[6] We concluded that the methodology that HCFA used to develop the fee schedules was generally acceptable, but needed some modifications. In June 1998, HCFA published its revised proposal, and published its final rule in November 1998. Several Members of Congress then asked us to monitor and report on HCFA's new methodology. In a report issued last year, we concluded that the new methodology was an acceptable approach, and that it responded to several concerns we had with the agency's original approach.[7] Nevertheless, we said that certain questions about the data and methodology needed to be addressed before full implementation. We recommended that the Administrator of HCFA take several actions to address our concerns.

## Oversight of Analyses Can Clarify Agencies' Actions, Answer Questions

Some of our reviews of agencies' specific regulatory analyses have clarified how the associated rules were developed or answered other questions posed by congressional requesters, but did not conclude that the agencies actions were deficient. These kinds of information-gathering efforts are often crucial to ensure that Congress and the public understand how regulations are developed, and the strength of the data, methodology, and assumptions that underlie the rules. For example, in January 1998, we reported on our review of the Environmental Protection Agency's (EPA) final rule that limited sulfur dioxide emissions from the Navajo Generating Station by approximately 90 percent.[8] Specifically, we discussed the effect of changes between the proposed and final rule on emissions reductions and associated costs, how the agency determined the expected level of visibility improvements, and how the agency estimated the monetary value of those improvements.

In January 1999, we explained why there were significant differences between EPA's and the industry's cost estimates of EPA's proposed

[6] Medicare: HCFA Can Improve Methods for Revising Physician Practice Expense Payments (GAO/HEHS-98-79, Feb. 27, 1998).

[7] Medicare Physician Payments: Need to Refine Practice Expense Values During Transition and Long Term (GAO/HEHS-99-30, Feb. 24, 1999).

[8] Air Pollution: Estimated Benefits and Costs of the Navajo Generating Station's Emissions Limits (GAO/RCED-98-28, Jan. 27, 1998).

pretreatment standards for industrial laundries.[9] We also discussed how EPA estimated the benefits of the proposed rule, uncertainties associated with the accuracy of its estimates, and how EPA's analysis supported the agency's belief that it had chosen the least costly, most cost-effective, or least burdensome regulatory alternative.

## Agency Explanations for Use of the APA's "Good Cause" Exception Were Sometimes Unclear

The most long-standing and broadly applicable federal rulemaking requirements are in the Administrative Procedure Act (APA) of 1946. Among other things, the APA generally requires that agencies publish a notice of proposed rulemaking (NPRM) in the Federal Register. After giving "interested persons" an opportunity to comment on the proposed rule, and after considering the public comments, the agency may then publish the final rule. However, the APA says that the notice and comment procedures generally do not apply when an agency finds, for "good cause," that those procedures are "impracticable, unnecessary, or contrary to the public interest."[10] When agencies use the good cause exception, the act requires that they explicitly say so and provide a rationale for the exception's use when the rule is published in the Federal Register.

In August 1998, we reported that about half of the 4,658 final regulatory actions published in the Federal Register during 1997 were issued without NPRMs.[11] Although most of the final actions without NPRMs appeared to involve administrative or technical issues with limited applicability, some were significant actions, and 11 were economically significant. Some of the explanations that the agencies offered in the preambles to their rules for using the good cause exception were not clear. For example, in several cases, the preambles said that an NPRM was "impracticable" because of statutory or other deadlines that had already passed by the time the rules were issued. In other cases, the agencies asserted in the preambles that notice and comment would delay rules that were, in some general way, in the "public interest." For example, in one such case, the agency said it was using the good cause exception because the rule would "facilitate tourist and business travel to and from Slovenia," and therefore delaying the rule to allow for public comments "would be contrary to the public interest." In another case, the agency said that soliciting public comments on the

[9] Water Pollution: Proposed Pretreatment Standards for Industrial Laundries (GAO/RCED-99-42R, Jan. 20, 1999).

[10] The APA also provides exceptions to the NPRM requirement for certain categories of regulatory action (e.g., rules dealing with military or foreign affairs). It also says the notice and comment procedures do not apply to interpretive rules; general statements of policy; or rules of agency organization, procedure, or practice.

[11] Federal Rulemaking: Agencies Often Published Final Actions Without Proposed Rules (GAO/GGD-98-126, Aug. 31, 1998).

rule was "contrary to the public interest" because the rule authorized a "new and creative method of financing the development of public housing."

When agencies publish final rules without NPRMs, the public's ability to participate in the rulemaking process is limited. Also, several of the regulatory reform requirements that Congress has enacted during the past 20 years use as their trigger the publication of an NPRM. Therefore, it is important that agencies clearly explain why notice and comment procedures are not followed. We recommended in our report that OMB notify executive departments and agencies that (1) their explanations in the preambles to their rules should clearly explain why notice and comment was impracticable, unnecessary, or not in the public interest, and (2) that OMB would, as part of its review of significant final rules, focus on those explanations.

## Inconsistent Compliance With Congressional Review Act Requirements

We have also had an effect on agencies' rulemaking actions as a result of our responsibilities under the Congressional Review Act (CRA). For example, under the CRA, before a final rule can become effective it must be filed with the Congress and GAO. However, in 1998, we reported that several hundred final rules had been published in the Federal Register but had not been submitted to us. We then worked with the agencies and OMB to correct the situation, and now virtually all of the rules that should have been submitted are being filed.

A related problem has been determining whether certain documents constitute "rules" that must be submitted in accordance with the CRA. For example, in one case, EPA claimed that its interim guidance for investigating complaints under title VI of the Civil Rights Act of 1964 was not a "rule," and therefore did not have to be submitted to the Congress and GAO before it could become effective. We concluded that the document was a rule because it clearly affected the rights of nonagency parties, and therefore had to be submitted pursuant to the CRA's requirements.

Another problem related to the CRA has been the failure of some agencies to delay the effective dates of their major rules for 60 days as required by section 801(a)(3)(A) of the Act. Agencies were not budgeting enough time into their regulatory timetable to allow for the delay and were misinterpreting the "good cause" exception to the 60-day delay period found in section 808(2) of the Act. We again worked with the agencies and, as a result, agencies have been much less likely to erroneously avoid the required 60-day delay.

## Some Rulemaking Requirements Are Unspecific or Apply to Few Rules

In each of the examples that I have cited, we were able to compare the agencies' rulemaking actions to statutory or executive order requirements and determine whether the agencies' actions satisfied the requirements. However, some of the concerns that have been expressed about agencies' compliance with rulemaking requirements appear traceable to the requirements themselves. Some are not specific, giving the agencies broad discretion to determine whether the mandated actions are applicable to their rules. Other requirements apply to few rules and/or require little new analysis for the rules to which they are applicable.

### Regulatory Flexibility Requirements Need Clarification

The Regulatory Flexibility Act (RFA) of 1980, enacted in response to concerns about the effect that federal regulations can have on small entities, is an example of a broadly-based rulemaking requirement. Under the RFA, an agency must prepare an initial regulatory flexibility analysis at the time proposed rules are issued unless the head of the agency determines that the proposed rule would not have a "significant economic impact upon a substantial number of small entities." The act also requires agencies to ensure that small entities have an opportunity to participate in the rulemaking process, and requires the Chief Counsel of the Small Business Administration's (SBA) Office of Advocacy to monitor agencies' compliance with the Act. The RFA was amended in 1996 by the Small Business Regulatory Enforcement Fairness Act to, among other things, require that EPA and the Occupational Safety and Health Administration convene advocacy review panels before publishing an initial regulatory flexibility analysis.

We have reported on the implementation of the RFA on several occasions in the past, and a recurring theme in our reports is the varying interpretation of the RFA's requirements by federal agencies. For example, in 1991, we reported that each of the four federal agencies that we reviewed had a different interpretation of key RFA provisions.[12] The report pointed out that the RFA provided neither a mechanism to enforce compliance with the act nor guidance on implementing it. We recommended that Congress consider amending the RFA to require that SBA develop criteria for whether and how federal agencies should conduct RFA analyses.

In 1994 we examined the 12 SBA annual reports on agencies' RFA compliance that had been issued since 1980.[13] The reports indicated that

[12] Regulatory Flexibility Act: Inherent Weaknesses May Limit Its Usefulness for Small Governments (GAO/HRD-91-16, Jan. 11, 1991).

[13] Regulatory Flexibility Act: Status of Agencies' Compliance (GAO/GGD-94-105, Apr. 27, 1994).

agencies' compliance with the RFA varied widely from one agency to another, and that some agencies' compliance varied over time. We noted that the RFA does not expressly authorize SBA to interpret key provisions of the statute, and does not require SBA to develop criteria for agencies to follow in reviewing their rules. As a result, different rulemaking agencies were interpreting the statute differently. We said that if Congress wanted to strengthen the implementation of the RFA it should consider amending the act to provide SBA with clearer authority and responsibility to interpret the RFA's provisions and require SBA to develop criteria on whether and how agencies should conduct RFA analyses.

We essentially repeated this recommendation in our 1998 report on the implementation of the small business advocacy review panel requirements, noting that Congress should provide SBA or another entity with interpretive authority and responsibility.[14] We said that the lack of clarity regarding whether EPA should have convened review panels for its two proposed rules on ozone and particulate matter was traceable to the lack of agreed-upon government criteria for whether a rule has a "significant economic impact on a substantial number of small entities" under the RFA. Similarly, we concluded in our 1999 report on the review requirements in section 610 of the RFA that the agencies we reviewed differed in their in their interpretation of those review requirements.[15] We said that if Congress was concerned about these varying interpretations it might wish to consider clarifying those provisions.

## Federalism Executive Order Had Little Effect on Rulemaking

Executive Order 12612 on "Federalism," issued by President Reagan in 1987, also gave federal agencies broad discretion to determine its applicability. The executive order required the head of each federal agency to designate an official to be responsible for determining which proposed policies (including regulations) had "sufficient federalism implications" to warrant preparation of a federalism assessment. If the designated official determined that such an assessment was required, it had to accompany any proposed or final rule submitted to OMB for review.

We examined the preambles of more than 11,000 final rules that federal agencies issued between April 1996 and December 1998 to determine how often they mentioned the executive order and how often the agencies

[14] Regulatory Reform: Implementation of the Small Business Advocacy Review Panel Requirements (GAO/GGD-98-36, Mar. 18, 1998).

[15] Regulatory Flexibility Act: Agencies' Interpretations of Review Requirements Vary (GAO/GGD-99-55, Apr. 2, 1999).

indicated that they had prepared a federalism assessment.[16] Our work indicated that Executive Order 12612 had relatively little visible effect on federal agencies' rulemaking actions during this time frame. The preambles to only 5 of the more than 11,000 rules indicated that the agencies had conducted a federalism assessment.

Most of these rules were technical or administrative in nature, but 117 were economically significant rules. However, the agencies prepared a federalism assessment for only one of these economically significant rules. The lack of assessments for these rules is particularly surprising given that the agencies had previously indicated that 37 of the rules would affect state and local governments, and said that 21 of them would preempt state and local laws in the event of a conflict.

Federal agencies had broad discretion under Executive Order 12612 to determine whether a proposed policy has "sufficient" federalism implications to warrant the preparation of a federalism assessment. Some agencies have clearly used that discretion, to establish an extremely high threshold. For example, in order for an EPA rule to require a federalism assessment, the agency's guidance said that the rule must, among other things, have an "institutional" effect on the states (not just a financial effect), and affect all or most of the states in a direct, causal manner. Under these standards, an EPA regulation that has a substantial financial effect on all states, but does not affect the "institutional" role of the states, would not require a federalism assessment.

Executive Order 12612 was revoked by President Clinton's Executive Order 13132 on "Federalism," which was issued August 4, 1999, and took effect on November 2, 1999. Like the old executive order, the new order provides agencies with substantial flexibility to determine which of their actions have "federalism implications" and, therefore, when they should prepare a "federalism summary impact statement."

## UMRA Had Little Effect on Rulemaking

The Unfunded Mandates Reform Act (UMRA) is another example of a regulatory requirement that has had little effect on agency rulemaking. For example, title II of UMRA generally requires covered federal agencies to prepare written statements containing specific information for any rule for which a proposed rule was published that includes a federal mandate that may result in the expenditure of $100 million or more in any 1 year by state, local, and tribal governments, in the aggregate, or the private sector.

[16] Federalism: Previous Initiatives Have Had Little Effect on Agency Rulemaking (GAO/T-GGD-99-31, June 30, 1999).

The statute defined a "mandate" as not including conditions imposed as part of a voluntary federal program or as a condition of federal assistance.

We examined the implementation of title II of UMRA during its first 2 years and concluded that it appeared to have only limited direct impact on agencies' rulemaking actions.[17] Most of the economically significant rules promulgated during that period were not subject to the act's requirements for a variety of reasons (e.g., no proposed rule, or the mandates were a condition of federal assistance or part of a voluntary program). There were only two rules without an UMRA written statement that we believed should have had one (EPA's proposed national ambient air quality standards for ozone and particulate matter), but even in those rules we believed that the agency had satisfied the substantive UMRA written statement requirements. Also, title II contains exemptions that allowed agencies not to take certain actions if they determined that they were duplicative or not "reasonably feasible." The title also required agencies to take certain actions that they already were required to take or had completed or that were already under way.

## Agencies Sometimes Have Little Rulemaking Discretion

In some cases, concerns expressed by regulated entities about burdensome regulations are traceable to the statutes underlying the regulations, rather than a failure of the agency to comply with rulemaking requirements. For example, in November and December 1996, we reported what officials from 15 private sector companies said were the federal regulations that were most problematic for their businesses.[18] Our reports also listed responses from the 19 federal agencies that issued the regulations underlying the 125 company concerns. In about one-quarter of the cases, the agencies indicated that the companies' concerns were, at least in part, attributable to statutory requirements underlying their regulations.

We analyzed the particular statutes in question and, in a January 1999 report, concluded that the statutes underlying about half of the concerns gave the rulemaking agencies no discretion in establishing the regulatory requirements at issue; the statutes underlying most of the other concerns gave the agencies only some discretion.[19] In cases where the underlying

[17] Unfunded Mandates: Reform Act Has Had Little Effect on Agencies' Rulemaking Actions (GAO/GGD-98-30, Feb. 4, 1998).

[18] Regulatory Burden: Measurement Challenges and Concerns Raised by Selected Companies (GAO/GGD-97-2, Nov. 18, 1996); and Regulatory Burden (GAO/GGD-97-26R, Dec. 11, 1996).

[19] Regulatory Burden: Some Agencies' Claims Regarding Lack of Rulemaking Discretion Have Merit (GAO/GGD-99-20, Jan. 8, 1999).

statute is the source of regulatory burden, regulatory reform initiatives focused on the agencies (e.g., cost-benefit analysis requirements) are unlikely to have much direct effect on the burden that those agencies impose.

## Congress Needs Assistance to Perform Regulatory Oversight

In summary, Madam Chairwoman, oversight alone of the regulatory process cannot, as we have learned, change agency behavior where the underlying statutes and executive orders do not clearly compel desired policies, procedures, or results. On the other hand, the examples of agency regulations that we have reviewed also demonstrate that congressional oversight can be an effective approach to ensure that agencies' rules are carefully developed and permit participation by the public in the rulemaking process. The examples also illustrate the difficulties involved in that endeavor. Agencies' rules are often highly technical, and the data, methodologies, scientific studies, and economic analyses that agencies use to develop those rules are frequently voluminous and extremely difficult to understand. The subject matter involved in these rules ranges from the health effects of environmental and occupational contaminants to the rates at which physicians are paid in the Medicare program. Therefore, it is not surprising that there are proposals to establish an independent source of analysis to evaluate agencies' development of significant regulations.

Although Congress could, theoretically, ask the agencies themselves to provide the information they need for oversight, the agencies are hardly an unbiased source of information about their own rules. Although OMB reviews every significant rule covered by Executive Order 12866 and has a wealth of expertise on rulemaking issues, its primary mission is to support the policies and goals of the President. As we said last year in our analysis of OMB's reports on the costs and benefits of all federal rules, OMB cannot realistically be expected to alter or dispute the administration's own estimates of regulatory costs and benefits in a report to Congress.[20]

Therefore, if Congress wants an independent assessment of regulatory costs and benefits, it should consider assigning that responsibility to an organization outside of the executive branch. As the examples that I previously cited illustrate, Congress has, on an occasional basis, requested that we perform that function. Legislation that was recently passed by the Senate, and other proposals introduced by you, Madam Chairwoman, and others in the House, would regularize that analytic responsibility. While

[20] Regulatory Accounting: Analysis of OMB's Reports on the Costs and Benefits of Federal Regulation (GAO/GGD-99-59, Apr. 20, 1999).

we stand ready to assist Congress in carrying out its oversight responsibility, our ability to successfully do so will depend on (1) the scope of the analysis contemplated, (2) the number of requests that we receive, (3) the time allotted to perform the reviews, and (4) the resources that we are given to accomplish the tasks involved. These subjects are not strictly the focus of this hearing, but we would be happy to meet with Members and staff of the Subcommittee to discuss this possible legislation.

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Madam Chairwoman, this completes my prepared statement. I would be pleased to answer any questions.

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PRINTED ON RECYCLED PAPER

**Statement by David S. Addington**
**Senior Vice President for Law and Regulatory Affairs**
**of the American Trucking Associations, Inc.**

**Before the Subcommittee on Regulatory Reform and Paperwork Reduction**
**of the Committee on Small Business**
**of the House of Representatives**

**on the Government's Justification for Proposed Rules**
**to Govern Trucking Hours of Service**

**June 8, 2000**

Madam Chairwoman and Members of the Subcommittee:

We appreciate the invitation to discuss the Department of Transportation's failure to properly conduct the required analyses to determine the full impact of proposed rules to govern the hours that truck drivers may work.

The hours-of-service scheme proposed by the Department's Federal Motor Carrier Safety Administration (FMCSA) is disastrous -- for the trucking industry, for the safety of the traveling public, and for American consumers. The proposed regulations hit trucking companies hard, and hit small trucking companies hardest.

I will describe the trucking industry, some key problems with the Department's proposed rule, and the defective analyses on which the Department of Transportation (DOT) based its rule.

## ATA and the Trucking Industry

The American Trucking Associations, Inc. (ATA) is the national trade association for the trucking industry, with more than 2500 motor carrier company members -- large and small -- who operate in every State in the Union.

Trucking is vital to the Nation's economy. Trucks move the majority of the freight that moves in America. Trucking accounts for more than 80% of the transportation revenue in the economy. Seventy percent of America's communities depend for freight service exclusively on trucks. So, DOT regulations restricting what companies can do with trucks and drivers directly affects a huge segment of the American economy.

Although some trucking companies are multi-billion dollar companies whose names you know, most of the trucking industry is small business. According to DOT, almost 50% of motor carriers have only one truck, and a full 95% of motor carriers, almost 395,000 of them, have 20 or fewer trucks.[1]

## ATA Objective: Rules Based on Sound Science, Public Safety, & Needs of Economy

ATA has long called for reform of the existing Depression-era hours-of-service rules. We asked for new rules based on three things: sound

[1] Docket Item FMCSA 1997-2350-954, Preliminary Regulatory Evaluation, page 60, paragraph 3.

science, public safety, and the needs of the American economy. ATA spent two years forging an industry-wide consensus on a proposal for new rules that would meet these requirements.

We filed the ATA proposal with the Department of Transportation in December 1999.[2] But instead, the Department published on May 2, 2000 proposed regulations that are inconsistent in a number of ways with fatigue science, and are so far removed from safer highways and economic reality, that ATA must strongly oppose them.

Failure of Department of Transportation's Rules

The Department's proposed rule fails the tests of science, safety, and economics.

On science, for example, the DOT proposal takes drivers whose job consists of 5 night-shifts a week and requires them to switch over to sleeping on both weekend nights. But fatigue science would counsel against requiring them to switch their sleep/wake cycle over on both weekend nights.

On safety, the Department's proposal will put more trucks and more drivers on the road, just to move the same amount of freight that trucks move today. And it will force more of those trucks to operate during daylight hours, when traffic congestion is at its peak. Regulations that

[2] Docket Item FMCSA 1999-2350-921.

put more of the trucks on the roads when most of the cars are also on the road, can hardly be characterized as "safety regulations."

On economics, shippers will face significant price increases for freight service, trucking companies will face tough obstacles in trying to meet the payroll and turn a profit, and businesses and consumers will pay more for the goods they purchase.

Congress should send the Department of Transportation back to the drawing board on its proposed regulations.

Department of Transportation's Flawed Economic Analysis

Federal law required the Department of Transportation to conduct an initial regulatory flexibility analysis, or I-R-F-A, when it published its proposed rule.[3] The Department failed miserably in its attempt to meet this legal requirement.[4] The Department provided only a cursory and inaccurate examination of the economic effects of its proposed rules on the trucking industry. Moreover, it completely ignored the larger economic impacts of the proposed rules on the economy as a whole.

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[3] Section 603(a) of Title 5 of the U.S. Code states in part: "Whenever an agency is required . . . to publish general notice of proposed rulemaking for any proposed rule . . . the agency shall prepare and make available for public comment an initial regulatory flexibility analysis. Such analysis shall describe the impact of the proposed rule on small entities. The initial regulatory flexibility analysis or a summary shall be published in the Federal Register at the time of the publication of general notice of proposed rulemaking for the rule."

[4] The Department of Transportation's discussion of the Regulatory Flexibility requirements appears at 65 *Fed. Reg.* 25595-25596 (May 2, 2000). The DOT initial regulatory flexibility analysis is Docket Item FMCSA 1997-2350-954.

With regard to the trucking industry, the Department undercounted by 100,000 the number of small trucking businesses, which taints the Department's entire I-R-F-A.[5]

The I-R-F-A also estimates the economic impact of only one part of the proposed rule -- the requirement that companies install in their trucks electronic on-board recorders to monitor the compliance of drivers with the Department's hours-of-service regulations. And DOT even has that part wrong, because DOT underestimates the number of companies that must install the recorders to be in compliance with the proposed rules.[6]

In any event, the recorder costs that DOT attempted to address are dwarfed by the additional costs that DOT ignored. The Department's regulations will force trucking companies to incur costs for the purchase of new trucks and hiring new drivers. While ATA has not yet completed its final economic analysis of the DOT proposal, our preliminary

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[5] See DOT's figures on small trucking businesses in its Preliminary Regulatory Evaluation (PRE) (Page 60, paragraph 3)(395,000 motor carriers have 20 or fewer trucks) and DOT's figures on small trucking businesses in its Regulatory Flexibility Analysis (RFA) (page RFA-2, paragraph 4)(250,000 motor carriers own 6 or fewer trucks). DOT Docket Item FMCSA 1997-2350-954. Using the industry average revenue per power unit of $133,000 per truck (*Motor Carrier Financial & Operating Statistics Annual Report: 1998 Data*, ATA, Inc. from DOT data), and the Small Business Administration standard of $18.5 million or less in revenue to be considered a small business, it is plain that the DOT PRE and initial RFA substantially understate the number of trucking small businesses. The DOT should consider, under SBA standards, that a trucking company with 138 or fewer trucks, is likely to be a small business.

[6] DOT assumed for purposes of its economic analysis that only trucks used by drivers dedicated to long-haul and regional driving would have electronic on-board recorders (EOBRs) installed. DOT Preliminary Regulatory Analysis, page 59, DOT Docket Item FMCSA 1997-2350-954. However, FMCSA failed to recognize that other types of drivers would at times be required to operate in long-haul or regional mode and that, therefore, the trucks in which these other drivers operate would also need EOBRs, requiring additional installation expenditures of which DOT did not take account.

conclusion is that labor and equipment costs to the trucking industry will increase by approximately 20 to 30 percent. More trucks moving the same freight also requires additional mechanics to maintain trucks and additional dock workers to handle getting freight in and out of trucks -- more costs that DOT ignored. Also, DOT ignored the cost of realigning trucking terminal networks, which were principally designed to allow truck drivers to move efficiently between terminals within the driving hours allowed under current rules, but not under the DOT proposed rules.

The Department also ignored the bigger economic impact beyond the trucking industry. Shippers will pay more to move freight, including those smaller manufacturers, wholesalers and retailers who are the engine of the Nation's economy. Many of those costs will, of course, be passed on to consumers in the form of higher prices for goods. The direct result of DOT's proposed rule is inflation -- hardly what the American economy needs.

The Department of Transportation failed to meet the legal requirement to compare the economic effects of its proposed rules on small entities with other alternatives.[7] The Department examined

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[7] Section 603(c) of Title 5 states in part: "Each initial regulatory flexibility analysis required under this section shall also contain a description of any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities. Consistent with the stated objectives of applicable statutes, the analysis shall discuss significant alternatives such as--(1) establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or

alternatives, but only alternatives for the entire trucking industry. The Department did not design or analyze alternatives solely with small companies in mind, nor did it consider the alternatives for minimizing the impact on small entities that the law requires DOT to consider. Thus, the Department failed to produce an initial regulatory flexibility analysis comparing the relative costs and benefits of alternatives as they pertain to small entities.

Department of Transportation's Certification of No Significant Impact on Small Business

The Department made a mistake that calls into question the quality of the DOT economic analysis. When it published its proposed rule on May 2, 2000, the Department included the following sentence in the preamble to the rule: "Therefore, the FMCSA, in compliance with the Regulatory Flexibility Act (5 U.S.C. 601-612), has considered the economic impacts of these requirements on small entities and certifies that this rule would not have a significant economic impact on a substantial number of small entities."[8]

On May 26th, the Department stated instead that "the FMCSA does not know with certainty the full economic impact of the proposal and

simplification of compliance and reporting requirements under the rule for such small entities; (3) the use of performance rather than design standards; and (4) an exemption from coverage of the rule, or any part thereof, for such small entities."

[8] 65 *Fed. Reg.* 25596 (May 2, 2000).

therefore withdraws its negative certification."[9] The withdrawal of the certification is a notable change, because the certification had exempted the proposed rule from the Regulatory Flexibility Act's requirements.[10]

The Department's explanation was that the certification had been included by error. But the initial erroneous inclusion of language raises doubts about whether the Department conducted a careful initial regulatory flexibility analysis in the first place. Of course, the practical question also arises of how anyone at DOT could possibly think that the proposed rule would not have a significant economic impact on a substantial number of small entities.

Labor and Industry Are United on the Need for More Time to Analyze

Lastly, while the Department admits that it does not know the full economic impact of its proposal -- even after DOT has looked at various changes to hours-of-service rules for 20 years -- it expects ATA and others to provide this information to DOT within the 90 day period that DOT allowed for comments on the proposed rule.

We have asked the Department for an additional 90 days, so that we can effectively survey our trucking company members -- large and small

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[9] 65 *Fed. Reg.* 34903 (May 26, 2000).

[10] Section 605 of Title 5 provides in part: "Sections 603 and 604 of this title shall not apply to any proposed or final rule if the head of the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities."

-- and analyze and report the resulting economic data,[11] but the Department has not granted our request. Many other organizations whose members are affected by the proposed rules have made the same request, such as the Commercial Vehicle Safety Alliance that represents the safety enforcement community,[12] the National Association of Manufacturers,[13] the International Brotherhood of Teamsters,[14] and the Transportation Trades Department of the AFL-CIO.[15]

When the trucking industry, the law enforcement community, the manufacturing industry, the Teamsters, and the AFL-CIO all agree that more time is needed to analyze the economic impact of the proposed rule, one would expect the Secretary of Transportation to grant the additional 90 days. But that request has not been granted.

## Conclusion

Madam Chairwoman, the Subcommittee asked only that I address the trucking hours-of-service issue, and I am pleased that we had that opportunity. But I would be remiss if I did not draw to your attention that this rule is only one front of the current three-front regulatory war that the Administration is waging on the trucking industry. The rules on

[11] Docket Item FMCSA 1997-2350-1102.

[12] Docket Item FMCSA 1997-2350-1102.

[13] Docket Item FMCSA 1997-2350-1213.

[14] Docket Item FMCSA 1997-2350-1272.

the other two fronts -- OSHA's proposed rule on ergonomics and EPA's proposed rule on diesel engine and fuel standards -- also are based on faulty economic analyses.

On all three fronts -- hours of service, ergonomics, and diesel -- the rulemaking process isn't driven by the science, isn't driven by health and safety, isn't driven by economics, and isn't driven by the law. It is driven by the desires of the heads of those agencies to issue final rules before the Administration leaves office in January 2001. The interests of the public in these rulemakings should not be subordinated to that artificial deadline. The agencies will still be here, with qualified people at the helm to make decisions, after next January. Let's take our time and get it right.

We appreciate the opportunity to appear before you and would be pleased to answer questions.

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[15] Docket Item FMCSA 1999-2350-1441.

# United States of America

## Before the

## Subcommittee on Regulatory Reform and Paperwork Reduction

## of the

## Committee on Small Business

## United States of House of Representatives

Sal Ricciardi

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President
Pharmaceutical Distributors Association

June 8, 2000

I am Sal Ricciardi, President of Purity Wholesale Grocers, Inc. of Boca Raton, Florida. I am speaking today for Supreme Distributors, a Purity division that is a wholesale distributor of prescription drugs, and on behalf of the Pharmaceutical Distributors Association, a trade association of ten such distributors. But most importantly, I am informally representing the approximately 4,000 state licensed prescription drug distributors across the United States who are, by any definition, small businesses, many of whom are our customers, and who are threatened with economic ruin by a final Rule of the U.S. Food and Drug Administration (64 Fed. Reg. 67720, Dec. 3, 1999) that has now been stayed for ten months (65 Fed. Reg. 25639, May 3, 2000). Most distributors operate in more than one state and we have recently conducted a telephone survey of state licensing authorities which found that over 32,000 wholesale distribution licenses have been issued. These small businesses compete, by pricing and service, to distribute pharmaceuticals to many thousands of other small state licensed businesses, such as doctors, medical groups, clinics, nursing homes, and veterinarians, all of whom would be forced to find alternative sources of affordable service and supply.

**The Prescription Drug Marketing Act**

The final FDA regulations that I am going to describe implement the Prescription Drug Marketing Act ("PDMA"), which was enacted in 1988 to ensure the safety and efficacy of prescription drugs that are distributed in the U.S. The law has been quite

successful, including the provisions relating to state licensure of all prescription drug wholesalers and wholesale distribution of prescription drugs. Distribution has been governed by paperwork requirements set forth in an "interim" FDA policy Guidance in place for about the last 12 years. Despite the positive experience under this Guidance, FDA in December 1999 finalized regulations, proposed over six years earlier, which changed the agency's interpretation of the law relative to wholesale drug distribution and created a "Catch-22" type situation in the paperwork requirement which will make it impossible for most licensed drug distributors to buy and distribute prescription drugs.

PDMA is unusual because it puts paperwork burdens on small businesses – and specifically exempts large businesses from those burdens. PDMA requires all prescription drug wholesalers who are not "authorized distributors," *i.e.*, those that are not major wholesalers who have an ongoing relationship with and purchase products directly from drug manufacturers, to provide their customers with a detailed sales history of the drug product before it can be resold. After the law was enacted in 1988, the FDA provided interim Guidance requiring wholesalers who do not purchase product directly from a manufacturer on an ongoing basis to trace the sales history of that product back to the "authorized distributor" and to provide that history to their customer.

FDA's 1988 Guidance appeared to recognize some of the business realities of wholesale distribution and the potential impact PDMA's requirement would have on smaller wholesalers. First, FDA made the sales history requirement only go back to the last "authorized distributor," *i.e.*, the last distributor not required by law to provide a sales history. Second, an authorized distributor was defined as any company that had an "ongoing relationship" consisting of two transactions in two years with a

manufacturer. This meant that many smaller distributors were deemed to be authorized under the FDA Guidance because they were occasionally able to buy directly from manufacturers. Drug manufacturers have been reducing the number of authorized distributors for the last several years, and the FDA's Rule would accelerate this trend by requiring written contracts, thus letting manufacturers determine who is "authorized," regardless of the actual volume or number of sales to a wholesaler.

Prescription drug distribution in the U.S. is dominated by five major full line prescription drug wholesalers, the largest of which is McKesson. Next in size are another seventy or so regional wholesalers. Almost all drug sales by manufacturers go first to the big five or the regional distributors. There are also secondary wholesalers like my company that actively seek out prices lower than average wholesale – through "deals," sales before price increases and overstock. Finally, there are the 4,000 small wholesaler businesses that buy from other wholesalers (the big five, the seventy and the secondaries) and distribute to small pharmacies, physicians, dentists, veterinarians, nursing homes, and small clinics. These small businesses exist because service is still meaningful to their customers and because the large wholesalers do not, have not, and will not seek to penetrate down to that level.

**FDA Creates a "Catch 22" Requirement**

Although this system has worked well for the last twelve years, the FDA in its Rule changed its interpretation of the law to require that wholesalers trace the sales history of the product all the way back to the manufacturer and deleted the option of

going back to the "authorized distributor." This seemingly small change has huge consequences because, as I said earlier, when Congress enacted this law, "authorized distributors" -- the big distributors – were exempted from the requirement to provide a sales history. For the last twelve years, small distributors have been able to provide sales history information back to the authorized distributor. Now they must do so back to the manufacturer. But they cannot reasonably obtain sales information back to the first sale by the manufacturer because the big authorized distributors are not required by PDMA to provide this sales history information to subsequent sellers.

FDA's response to this "Catch-22" is that the Agency urges "authorized distributors" voluntarily to provide sales history information. See 64 Fed. Reg. at 67747. Don't hold your breath. The cost of segregating and tracking the huge volumes of products in the manner now required of small companies by PDMA would be prohibitive for the large national distributors even if they desired to provide this information to their customers voluntarily. It requires tracking every lot by purchase date and with their volume of purchases and sales, it would necessitate a monumental change in their business practices. But without this very detailed sales history, secondary wholesalers and those 4,000 smaller wholesalers cannot legally buy and resell these prescription drugs purchased through the big distributors.

**FDA's Impact Analysis on Small Business Is Seriously Deficient**

We are here before this Subcommittee because the FDA's analysis of the impact of the Rule on small business was seriously deficient. Indeed, small business distributors were simply overlooked by FDA.

The FDA's Small Business Analysis of the Rule published in the Federal Register on December 3, 1999 (see 64 Fed. Reg. at 67753) concluded that "the majority" of the estimated 4,000 distributors "will not be affected by the rule." The reason for this is that FDA never looked to see what its 1988 Guidance required and how the Guidance worked and compared that practice to its Rule. Had FDA done so, it would have found a devastating impact on small business. The one comment made in 1994 against the rule was brushed aside by FDA. In fact, if FDA had bothered to look, it would have found that virtually all small distributors could be forced out of business if the FDA Rule goes into effect, destroying thousands of small, family run businesses and displacing countless employees. The FDA analysis also failed to make any assessment of the potential health and safety risk to patients, whose access to life saving drugs may well be seriously disrupted if an important segment of the national distribution system for prescription drugs is literally wiped out.

The end result of the FDA Rule, if it were to go back into effect, is that an estimated 4,000 distributors who are small businesses will be economically crippled or driven out of business entirely. Their employees will lose their jobs and their owners will lose their investments along with years of hard work and service that has created the customer goodwill that makes their businesses valuable. The 4,000 small distributors

occupy a niche in the market which large distributors either cannot or chose for economic reasons not to fill. They are particularly important in rural areas and to other customer categories with relatively low volumes. It is not at all clear that alternative sources of supply for these providers would be available on a timely basis or at a reasonable cost.

Secondary source wholesalers also play an important role in restraining drug prices. By purchasing in advance of price increases, buying products from large full line distributors who are temporarily overstocked in a particular product and need to free up warehouse space, or taking advantage of regional product promotions, secondary wholesales seek to obtain product at prices lower than the average price at which a manufacturer sells to a large national distributor. These lower priced goods are sold to retailers and to other wholesalers, providing an important source of competition and a restraining influence on drug prices. Eliminating this segment of the market would tend to increase prices, costing consumers and taxpayers more money. The FDA did not provide any estimate of the increased costs which might well occur if competition in the wholesale pharmaceutical marketplace was significantly reduced.

**A Legislative Solution is Needed**

By failing to perform a proper impact analysis of the Rule, the FDA has painted itself into a corner. While the agency has, however reluctantly, responded to our Association's petition (copy attached) and to heavy Congressional pressure – including, thankfully, from Chairman Talent of the full committee – and agreed to stay and reopen

the final Rule and consider additional comments, the prospects for a fundamental revision in the Rule that would mitigate the disastrous impact on small businesses appear small. The FDA has clearly indicated in letters to Members of Congress and elsewhere that it believes that its flexibility to interpret the law and revise the Rule is very limited – despite twelve years of success under its prior interpretation. The only solution is to enact corrective legislation in this Congress. While the final Rule has been stayed until October 1, 2001, the FDA has not provided for the grandfathering of product inventory, and distributors will have to sell existing stocks and cease to order replacement product well before that date. Thus, the impact on the national drug distribution system will be felt many months before October 1, 2001.

I strongly commend to the attention of the Chair and the Members of the Subcommittee H.R. 4301, a bipartisan bill that would fix the problems in the FDA's Rule relative to drug distribution. I would hope that Members of the Small Business Committee would become familiar with the substance of this bill and take the lead in cosponsoring and enacting this technical corrective legislation that will substantially reduce paperwork burdens on state licensed pharmaceutical distributors.

ranging from 3 to 8 years on which the various body system listings would no longer be effective unless extended by the Secretary of Health and Human Services or revised and promulgated again. Effective March 31, 1995, the authority to issue regulations was transferred to the Commissioner of Social Security by section 102 of Public Law 103–296, the Social Security Independence and Program Improvements Act of 1994.

In this final rule, we are extending the dates on which several body system listings will no longer be effective to July 2, 2001. These body systems are:

Cardiovascular System (4.00 and 104.00).
Digestive System (5.00 and 105.00).
Genito-Urinary System (6.00 and 106.00).

We last extended the dates on which these body system listings would no longer be effective in final rules published as follows:

June 5, 1997 (62 FR 30746): Digestive System and Genito-Urinary System.
January 30, 1998 (63 FR 4570): Cardiovascular System.

We believe that the requirements in these listings are still valid for our program purposes. Specifically, if we find that an individual has an impairment that meets or is medically equivalent in severity to an impairment in the Listings or functionally equivalent to the Listings in SSI claims based on disability filed by individuals under age 18 and also meets the statutory duration requirement, we will find that the individual is disabled at the third step of the sequential evaluation process. We are extending these dates because we do not expect to develop revised listings criteria for these body systems by the expiration dates currently shown in the regulations. However, we are reviewing the listings and we plan to publish proposed and final rules over the course of the next two years.

**Regulatory Procedures**

*Justification for Final Rule*

Pursuant to section 702(a)(5) of the Social Security Act, 42 U.S.C. 902(a)(5), as amended by section 102 of Public Law 103–296, SSA follows the Administrative Procedure Act (APA) rulemaking procedures specified in 5 U.S.C. 553 in the development of its regulations. The APA provides exceptions to its notice and public comment procedures when an agency finds there is good cause for dispensing with such procedures on the basis that they are impracticable, unnecessary, or contrary to the public interest. We have determined that, under 5 U.S.C. 553(b)(B), good cause exists for dispensing with the notice and public comment procedures in this case. Good cause exists because this regulation only extends the date on which these body system listings will no longer be effective. It makes no substantive changes to those listings. The current regulations expressly provide that listings may be extended, as well as revised and promulgated again. Therefore, opportunity for prior comment is unnecessary, and we are issuing this regulation as a final rule.

In addition, we find good cause for dispensing with the 30-day delay in the effective date of a substantive rule provided by 5 U.S.C. 553(d). As explained above, we are not making any substantive changes in these body system listings. However, without an extension of the expiration dates for these listings, we will lack regulatory guidelines for assessing impairments in these body systems at the third step of the sequential evaluation process after the current expiration dates of these listings. In order to ensure that we continue to have regulatory criteria for assessing impairments under these listings, we find that it is in the public interest to make this rule effective upon publication.

*Executive Order 12866*

We have consulted with the Office of Management and Budget (OMB) and determined that this final rule does not meet the criteria for a significant regulatory action under Executive Order 12866. Thus, it was not subject to OMB review. We have also determined that this final rule meets the plain language requirement of Executive Order 12866 and the President's memorandum of June 1, 1998 (63 FR 31885).

*Regulatory Flexibility Act*

We certify that this final regulation will not have a significant economic impact on a substantial number of small entities. Therefore, a regulatory flexibility analysis as provided in the Regulatory Flexibility Act, as amended, is not required.

*Paperwork Reduction Act*

This final regulation imposes no reporting/recordkeeping requirements necessitating clearance by OMB.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security-Disability Insurance; 96.002, Social Security-Retirement Insurance; 96.004, Social Security-Survivors Insurance; 96.006, Supplemental Security Income)

**List of Subjects in 20 CFR Part 404**

Administrative practice and procedure, Blind, Disability benefits, Old-Age, Survivors and Disability Insurance, Reporting and recordkeeping requirements, Social Security.

Dated: November 24, 1999.

**Kenneth S. Apfel,**

*Commissioner of Social Security.*

For the reasons set forth in the preamble, part 404, subpart P, chapter III of title 20 of the Code of Federal Regulations is amended as set forth below.

## PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950- )

### Subpart P—[Amended]

1. The authority citation for subpart P of part 404 continues to read as follows:

**Authority:** Secs. 202, 205(a), (b), and (d)–(h), 216(i), 221(a) and (i), 222(c), 223, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 402, 405(a), (b), and (d)–(h), 416(i), 421(a) and (i), 422(c), 423, 425, and 902(a)(5)); sec. 211(b), Pub. L. 104–193, 110 Stat. 2105, 2189.

2. Appendix 1 to subpart P of part 404 is amended by revising items 5, 6, and 7 of the introductory text before Part A to read as follows:

**Appendix 1 to Subpart P—Listing of Impairments**

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5. Cardiovascular System (4.00 and 104.00): July 2, 2001.
6. Digestive System (5.00 and 105.00): July 2, 2001.
7. Genito-Urinary System (6.00 and 106.00): July 2, 2001.

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[FR Doc. 99–31322 Filed 12–2–99; 8:45 am]

BILLING CODE 4191–02–P

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Parts 203 and 205

[Docket Nos. 92N–0297 and 88N–0256]

RIN 0910–AA08

### Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing a final

requirements relating to facilities, security, storage, and recordkeeping.

The agency declines to adopt the exclusions recommended by the comment. The term radioactive drugs, as defined under 21 CFR 310.3(n), encompasses both radioactive and nonradioactive drug products. Radioactive drugs include drug products derived from by-product materials from nuclear reactors (i.e., radionuclide generators), cyclotron-produced products (i.e., Ga-67 Citrate, Tl-201 Chloride, and In-111 Oxide), and positron emission tomography products (e.g., Rubidium-82 and fludeoxyglucose). Nonradioactive reagent kits are also radioactive drugs and are compounded with radioactive substances by radiopharmacies or hospitals to make the final drug product.

As the comment points out, most radioactive drugs have a limited shelf-life which requires that they be distributed in a different manner than many prescription drugs. In addition, certain Federal and various State requirements for shipping, storage, handling, and recordkeeping apply to radioactive drugs. However, as discussed previously in conjunction with medical gases and the comments on bulk drugs, PDMA applies to all prescription drugs. Therefore, unless there is a clear indication in PDMA or its legislative history that Congress did not intend for PDMA to apply to a specific class of drugs, the agency does not believe that it is appropriate to exempt the class from PDMA requirements and restrictions. Except for the factors mentioned above, there is no indication in PDMA or its legislative history that Congress intended that radioactive drugs be treated differently than other types of prescription drug products. The agency does not believe that these factors, by themselves, indicate a clear congressional intent to exempt radioactive drugs from PDMA or to exclude radioactive drugs from specific PDMA requirements.

*H. Wholesale Distribution*

1. Section 203.50(a) and (a)(6)

Proposed § 203.50(a) and (a)(6) stated: * * * Before the completion of any wholesale distribution by a wholesale distributor of a prescription drug for which the seller is not an authorized distributor of record to another wholesale distributor or retail pharmacy, the seller shall provide to the purchaser a statement identifying each prior sale, purchase, or trade of such drug. This identifying statement shall include: * * * The business name and address of all parties to each prior transaction involving the drug, starting with the manufacturer * * *.

88. One comment objected to § 203.50(a) and (a)(6) because it would require an unauthorized distributor to provide information about all prior sales, purchases, or trades of the drug, starting with the manufacturer, even in cases where the seller from whom the distributor received the drug was an authorized distributor of record and did not provide any pedigree for the drug. The comment stated that "the proposed regulation would make it impossible, as a practical matter, for authorized distributors to sell into the [prescription] specialty market without providing a pedigree," which was not intended by Congress. The comment recommended revising the proposed rule to require that the drug origin statement (i.e., the "pedigree") only go back to the last authorized distributor of record.

The agency declines to revise the proposal in the manner suggested by the comment. Section 503(e)(1)(A) of the act requires that, prior to completion of a wholesale distribution of a prescription drug by a person who is not the manufacturer or an authorized distributor of the drug, a statement must be provided to the recipient identifying each prior sale, purchase, or trade of the drug, including the date of the transaction and the names and addresses of all parties to the transaction. There is no indication in PDMA that Congress intended that the statement include only those sales, purchases, or trades since the drug was last handled by an authorized distributor. Thus, an unauthorized distributor is required to provide a full drug origin statement in accordance with PDMA and the final rule whether or not it has purchased a prescription drug from an authorized distributor of record. Although the agency encourages authorized distributors to provide a drug origin statement to unauthorized distributors, they are not required to do so under PDMA or the final rule.

89. In the preamble to the proposal (59 FR 11842 at 11856 and 11857), the agency discussed at length its views on the use of coding that represents required information on the drug origin statement. The agency stated that, since the enactment of PDMA, FDA's position has been that the use of coded statements on the drug origin statement that make information unintelligible to purchasers without the intervention of a third party to decipher the code (e.g., "this shipment of drugs came from unauthorized distributor RS47GS2273") does not provide purchasers with the information that Congress intended that they receive. Moreover, the PDA, which amended section 503(e)(1) of the act to require, among other things, that the drug pedigree contain the "names and addresses of all parties to the transaction," made clear that product source codes may not be used on the drug pedigree as a substitute for required information.

One comment supported the agency's position on the use of coding. The comment stated that the practice of using codes places a large burden on distributors and recommended that the agency go a step further and revise the proposed regulations to prohibit the use of product source codes on drug origin statements.

The agency believes that its position against the use of product source codes as a substitute for the name and address of buyers or sellers in drug origin statements was adequately addressed in the preamble to the proposal and restated here. Accordingly, the agency declines to codify a prohibition on the use of such codes in the final regulation.

2. Section 203.50(b)

The agency has added § 203.50(b) to clarify that the drug origin statement is subject to the revised record retention requirements of § 203.60(d) and must be retained by all wholesale distributors involved in the distribution of the drug product, whether authorized or unauthorized, for 3 years. The agency is providing this clarification in response to numerous inquiries that it has received since the proposed rule was published.

3. Section 203.50(c)

Proposed § 203.50(c) stated: "Each manufacturer shall maintain at the corporate offices a current written list of all authorized distributors of record." Proposed § 203.50(c)(3) stated: "Each manufacturer shall make its list of authorized distributors of record available on request to the public for inspection or copying. A manufacturer may impose reasonable copying charges for such requests from members of the public."

90. One comment recommended that the list of distributors could be maintained at any company site and could be made available via electronic media or within 24 hours to other sites.

The rule does not require company records to be kept at every company site. As long as a company can produce the required information for review and copying by FDA or other Federal, State, or local law enforcement agencies at the site where they are requested within 2 business days, the company may maintain its records at a central location.

91. Several comments objected to the proposed requirement that manufacturers must make their list of authorized distributors of record available to the public. The comments stated that this information is proprietary in nature and should be kept confidential. One comment stated that FDA has acknowledged that this information was considered proprietary in the past.

Other comments stated that providing such information is unduly burdensome on manufacturers. One comment recommended adding a "reasonable hours of inspection and reasonable copying charges" provision to the section. Another comment recommended revising the section to require only that industry respond to individual inquiries about whether a specific wholesaler is an authorized distributor of record.

The requirement that manufacturers maintain a current list of authorized distributors of record appears at section 503(e)(1)(B) of the act. In the legislative history, Congress stated that this list must be made available for public inspection. (See S. Rept. 100–303, p. 7.) Thus, the agency believes that denying public access to lists of authorized distributors maintained by manufacturers would contradict Congress' clearly expressed intent.

In addition, the agency disagrees that a manufacturer's list of authorized distributors constitutes proprietary or confidential information. No provision of PDMA or the act designates such information as proprietary, and the agency is unaware of other laws or regulations that designate such information as proprietary. Moreover, the agency has not previously stated that this information is proprietary. In fact, in a 1988 letter to regulated industry (see Letter from Daniel L. Michels, Director, Office of Compliance to Regulated Industry, Docket No. 88N–258L, August 1, 1988), the agency specifically requested that manufacturers make lists of authorized distributors available at reasonable charge to any requesting person.

Finally, the final rule permits manufacturers to impose reasonable copying charges for requests. Such charges could include clerical time used to create copies, copying costs, and mailing costs, if the requested copies are mailed. Therefore, except for costs associated with creating, updating, and maintaining the authorized distributors lists themselves (a cost that has been evaluated separately by the agency in the "Paperwork Reduction Act of 1995" section under § 203.50(d)), the cost to comply with revised § 203.50(d)(3) should be reimbursed.

4. Sales to Licensed Practitioners by Retail Pharmacies

In the preamble to the proposal (59 FR 11842 at 11858), the agency stated:

FDA believes that permitting the sale of small quantities of prescription drugs by retail pharmacies to licensed practitioners for office use without the requirement of a State wholesale distributor's license satisfies a legitimate need and is consistent with the intent of the statute. Accordingly, the agency has included language in proposed § 203.3(y) that would exclude the sale of minimal quantities of drugs by retail pharmacies to licensed practitioners for office use from the definition of "wholesale distribution."

In this context, sales of prescription drugs by a retail pharmacy to licensed practitioners for office use will be considered to be minimal if the total annual dollar volume of prescription drugs sold to licensed practitioners does not exceed 5 percent of the dollar volume of that retail pharmacy's annual prescription drug sales.

92. One comment supported the agency's decision to exclude minimal sales of prescription drugs by retail pharmacies from the definition of wholesale distribution and recommended that the 5 percent threshold be codified in the final regulation under § 203.3(y)(11).

The agency believes that its position on what constitutes a minimal amount of prescription drugs for the purposes of revised § 203.3(cc)(10) was adequately explained in the preamble to the proposal and need not be codified.

93. Another comment recommended that the 5 percent threshold be increased to 20 percent and should be based on annual, not monthly or weekly, sales of a retail pharmacy. According to the comment, the 5 percent threshold would disadvantage small, independent pharmacies because a large percentage of their sales is derived from supplying local practitioners with prescription drugs. The comment also said that the 5 percent threshold could be reached easily by a pharmacy that supplies expensive drugs, such as chemotherapy medications, to practitioners.

The distribution of prescription drugs to practitioners for office use constitutes wholesale distribution under section 503(e) of the act and proposed § 203.3(y) (i.e., distribution to other than a consumer or patient). The agency excluded the sale of minimal quantities of drugs by retail pharmacies to licensed practitioners for office use from the definition of wholesale distribution to meet the needs of licensed practitioners who may not purchase enough prescription drugs to go through a wholesale distributor and thus may not otherwise be able to easily obtain drugs for office use. Thus, the exemption was not created to confer a special benefit on retail pharmacies, but to meet the legitimate needs of licensed practitioners. The agency believes that the 20 percent threshold recommended by the comment is inconsistent with the purpose of the exemption and declines to follow the recommendation. The agency notes that a retail pharmacy is not precluded from making more than 5 percent of its annual sales to licensed practitioners. It must, however, obtain a State wholesale distributor license to do so.

*I. Request and Receipt Forms, Reports, and Records*

1. Section 203.60(e)(1)

Proposed § 203.60(e)(1) stated: "Any person required to create or maintain reports, lists, or other records under PDMA, PDA, or this part shall retain them for at least 3 years after the date of their creation."

94. One comment objected to the proposed requirement in § 203.60(e)(1), stating that it conflicts with the 2-year retention period requirement under § 205.50(f)(2). The comment said that changing the record retention time in the manner proposed would "require 44 states that adopted FDA's 2-year standard to enact legislative and/or regulatory changes in order to have licensing programs that meet the minimum federal requirements." The comment also said that changing to a 3-year record retention period would serve no apparent public health purpose, citing the agency's rationale behind the 2-year requirement in the preamble to the final rule on State wholesale licensing guidelines. The comment recommended that the proposed section should be revised to require record retention for 2 years for all records kept by prescription drug wholesalers under PDMA.

Section 205.50(f)(1) requires that inventories and records of transactions regarding the receipt and distribution or other disposition of prescription drugs be created and maintained. Section 205.50(f)(2) requires that such records be "made available" to authorized Federal, State, or local law enforcement agencies for a period of 2 years following the disposition of the drugs to which the record relates. Because the requirement under proposed § 203.60(e)(1) that records be retained for 3 years after the creation of the record would apply to records required by § 205.50(f)(1), the requirements could potentially be conflicting. This result

each of the first 3 years, the agency estimates that an additional 5 square feet of storage space per affected manufacturer and distributor will be needed to accommodate the record retention requirements. After the third year, each subsequent year's records can replace the most previous year's, indicating that no more than 15 square feet of storage space will be necessary. FDA estimates that up to approximately 2,500 manufacturers and distributors will be affected; therefore, average annual storage costs will amount to approximately $118,000 in year 1, $236,000 in year 2, and $354,000 in each year thereafter. Though retention of drug return memos is also required of hospitals and charities, the agency believes these costs are negligible. Some of these storage requirements were initiated by PDMA, but other storage requirements have been added by this regulation. The agency did not separate these storage costs for the purpose of this analysis.

*C. Small Business Analysis*

The agency has analyzed this rule in accordance with the Regulatory Flexibility Act to determine its effect on small entities.

1. Need for and Objectives of the Rule

As stated previously, PDMA was enacted by Congress to prevent the sale of subpotent, adulterated, counterfeit, or misbranded drugs. Through this regulation, the agency is establishing the procedures and requirements to implement PDMA. The final rule facilitates the goals of PDMA by establishing procedural and recordkeeping requirements for drug sample distribution that will help to prevent the diversion and sale of drug samples. In addition, the final rule establishes wholesale distribution requirements that will permit the distribution chain of prescription drugs to be traced, and will make unauthorized wholesale distributors more accountable.

2. Description and Estimate of the Number of Small Entities

According to the Small Business Administration (SBA), distributors of drugs, drug proprietaries, and druggists' sundries with 100 or fewer employees or manufacturers of pharmaceutical preparations with 750 or fewer employees are considered small entities. The U.S. Census does not disclose data on the number of drug manufacturing firms by employment size, but between 92 percent and 96 percent of drug manufacturing establishments, or approximately 650 establishments, are small under this definition.[12] Although the number of firms that are small would be less than the number of establishments mentioned above, FDA still concludes that the majority of pharmaceutical preparation manufacturing firms are small entities. In addition, the agency found that 94 percent of the distribution firms, or approximately 4,000 firms, are small.[13] However, as stated previously, the agency believes that the majority of these do not distribute samples, and thus will not be affected by the rule. According to SBA's definition, general medical and surgical hospitals, and the offices and clinics of dentists and doctors of medicine that are either not-for-profit or have $5 million or less in revenue are also considered small. Using this definition, FDA determined that approximately 96 percent of the hospitals (or approximately 4,000 hospitals)[14] and 99 percent of the offices and clinics (or approximately 268,000 offices and clinics)[15] are small. In addition, due to their nonprofit status, the agency assumes that the 3,112 charities expected to be affected by this rule (based on a portion of not-for-profit hospitals,[16] doctors' offices, and clinics[17]) would be considered small by SBA. As noted in the paperwork section of this regulation, FDA believes that approximately 12 importers will be affected by this rule, and assumes that the majority of them are small.

The agency notes that the great majority of the costs of this rule will be incurred by the manufacturers and distributors that distribute drug samples. The costs will not be evenly distributed, but directly related to the size of each company's sales force. According to Census data, less than 10 percent of the manufacturing companies in the pharmaceutical preparations industry have 90 percent of the industry's sales.[18] Likewise, approximately 1 percent of the firms distributing drugs, drug proprietaries, and druggists' sundries have 74 percent of the industry's sales.[19] Consequently, the largest firms will incur the majority of the drug sample-related costs of this regulation, and the smallest firms will incur relatively few of these costs. While some small reimporters will be affected by the reimportation restriction, this impact will be moderated because most also import non-U.S. drugs or other products. The cost impact on charities will be minimal.

3. Estimate of the Recordkeeping Burden

The majority of the costs of this regulation are derived from the paperwork requirements. The manufacturers, distributors, and charities involved in the sample distribution process are required to comply with the recordkeeping requirements specified earlier in this analysis. These individuals should already possess the necessary skills to establish written policies and procedures, complete forms and applications, and prepare the required documentation. The paperwork specified by this rule does not require any special professional training or skills to complete and would be of a type already being handled by regulatory affairs professionals who are employed by drug manufacturers and distributors.

4. Analysis of Alternatives

FDA could have implemented the rule as proposed, but instead, the agency took several steps to minimize the economic impact on small entities. Specifically, the agency reduced or eliminated several of the requirements under the proposed rule. Examples of this can be found under the requirements for sample inventory, lot or control numbers, sample unit identification, and sample record retention. Under the proposal, the inventory of drug samples held by sales representatives would be conducted by an executive other than the representative or the immediate supervisor. Comments emphasized the costliness of this requirement, indicating it was time consuming and entailed travel expenses to regional sales offices. In response to these comments, the final rule allows sales representatives and their supervisory personnel to conduct the inventory and reconciliation functions. Also, in response to comments on the proposal, FDA reduced the administrative burden

[12] "Drugs Industry Series," Table 4, pp. 28C to 12.

[13] "Establishment and Firm Size," *1992 Census of Wholesale Trade*, U.S. Department of Commerce, Economics and Statistics Administration, Bureau of the Census, Table 7, pp. 1 to 186.

[14] "Establishment and Firm Size," *1992 Census of Service Industries*, Table 4a and 4b, pp. 1 to 174 and pp. 1 to 184.

[15] "Establishment and Firm Size," *1992 Census of Service Industries*, Table 4a and 4b, pp. 1 to 171 and pp. 1 to 183.

[16] *The Statistical Abstract of the United States*, U.S. Department of Commerce, Bureau of the Census, 1996, No. 187, p. 127.

[17] "Establishment and Firm Size," *1992 Census of Service Industries*, Table 1b, pp. 1 to 51.

[18] "Concentration Ratios in Manufacturing," *1992 Census of Manufacturers*, U.S. Department of Commerce, Economics and Statistics Administration, Bureau of the Census, Table 3.

[19] "Establishment and Firm Size," *1992 Census of Wholesale Trade*, Tables 7 and 8, pp. 1 to 186 and pp. 1 to 218.

associated with the donation of prescription drug samples to charity. Furthermore, FDA found it unnecessarily burdensome to require that lot or control numbers appear on drug sample records, receipts, and reconciliation reports, as proposed. Therefore, the final rule adds flexibility by allowing the recording of lot or control numbers on other types of records. Also, in response to comments, the agency is allowing the use of adhesive stickers on retail units to designate a sample unit as a sample. The final rule reduces the drug sample record retention period, which was proposed as 3 years from the sample expiration date. The agency decided that retention of drug sample records for 3 years from the date of their creation is sufficient for recall facilitation and proper accountability over sample distribution.

The agency considered minimizing the impact of this rule by not requiring manufacturers and authorized distributors to verify with the State that the practitioner to whom samples are distributed is licensed or authorized by law to prescribe the drug product. However, under the final rule, this license verification requirement was added in response to comments. The cost of this requirement is estimated at approximately $3.2 million per year. The agency determined that this requirement is the only reliable way of proving that the practitioner requesting samples is actually licensed by a State to prescribe drugs. The agency does not believe that allowing a manufacturer to deem acceptable a license or authorization number on a request form without verifying its authenticity would offer any such assurance.

The agency considered eliminating the receipt requirement for representative-delivered samples. This would reduce the cost of the final regulation by approximately $22.6 million per year. However, although Congress did not expressly require a receipt for representative-delivered samples, FDA concluded that this requirement is necessary to help ensure effective enforcement, increased accountability and oversight of sample distribution, and to provide adequate safeguards against drug sample diversion.

5. Response to Comments

Several of the comments indicated that the initial economic analysis understated the impact of the proposed rule. FDA reevaluated and significantly increased the paperwork estimates to more accurately reflect industry's implementation of this final regulation. For example, the agency increased the estimated time for a manufacturer to conduct an annual inventory and complete a reconciliation report from 30 minutes to 40 hours per manufacturer. The agency also increased the amount of time estimated to generate a sample receipt from 1 minute to 3 and 5 minutes for distribution by mail and representative respectively, and the estimated time to investigate possible significant loss or theft of samples from 1 hour to 24 hours. In addition, the agency identified and estimated the burden associated with requirements other than recordkeeping that were not quantified under the proposed rule. For example, FDA allotted 2 hours for the development of each of the sample request and receipt forms. The annual printing costs associated with these forms have also been assessed. Storage costs have been added as necessitated by the paperwork requirements of this regulation.

*D. Conclusion*

FDA calculated both the incremental costs of this final rule and the costs initially imposed upon the enactment of PDMA, and determined that there are one-time costs of $318,000 for developing forms, and total annual costs of approximately $82 million. Approximately $39 million of these annual costs have been incurred by industry since the enactment of PDMA by Congress in 1988. An estimated additional $43 million per year will result from the new requirements in this regulation. This rule is not a significant regulatory action as defined by the Executive Order, and is therefore not subject to review under the Executive Order. This rule does not impose any mandates on State, local, or tribal governments, nor is it a significant regulatory action under the Unfunded Mandates Reform Act. Finally, the agency has analyzed this rule in accordance with the Regulatory Flexibility Act and provided each of the elements required for a final regulatory flexibility analysis.

**V. Executive Order 13132: Federalism**

FDA has analyzed this final rule in accordance with Executive Order 13132: Federalism. Executive Order 13132 requires Federal agencies to carefully examine actions to determine if they contain policies that have federalism implications or that preempt State law. As defined in the Order, "policies that have federalism implications" refers to regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

FDA is publishing this final rule to set forth agency policies and requirements and provide administrative procedures, information, and guidance for those sections of PDMA that are not related to State licensing of wholesale prescription drug distributors. Because enforcement of these sections of PDMA is a Federal responsibility, there should be little, if any, impact from this rule on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. In addition, this regulation does not preempt State law.

Accordingly, FDA has determined that this final rule does not contain policies that have federalism implications or that preempt State law.

**VI. Paperwork Reduction Act of 1995**

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

*Title*: Prescription Drug Marketing Act of 1987; Policies, Requirements, and Administrative Procedures.

*Description*: The final rule provides for the collection of information from establishments engaged in the reimportation and wholesale distribution of prescription drugs; the sale, purchase, or trade of (or offer to sell, purchase, or trade) prescription drugs by hospitals, health care entities, and charitable institutions; the distribution of prescription drug samples; and the wholesale distribution of prescription drugs.

*Description of Respondents*: Businesses, hospitals, health care entities, charitable institutions, and other for-profit and not-for-profit organizations; small businesses or organizations.

Although the March 1994 proposal provided a 60-day comment period under the Paperwork Reduction Act of 1980, and this final rule responds to the comments received, FDA is providing

Custodian states that the Primary Custodian will agree to exercise reasonable care, prudence, and diligence in performing the requirements of paragraphs (a)(1)(i)(A) and (B) of this section, or adhere to a higher standard of care.

(2) *Withdrawal of assets from eligible securities depository.* If a custody arrangement with an Eligible Securities Depository no longer meets the requirements of this section, the Fund's Foreign Assets must be withdrawn from the depository as soon as reasonably practicable.

(b) *Definitions.* The terms *Foreign Assets, Fund, Qualified Foreign Bank, Registered Canadian Fund,* and *U.S. Bank* have the same meanings as in § 270.17f–5. In addition:

(1) *Eligible Securities Depository* means a system for the central handling of securities as defined in § 270.17f–4 that:

(i) Acts as or operates a system for the central handling of securities or equivalent book-entries in the country where it is incorporated, or a transnational system for the central handling of securities or equivalent book-entries;

(ii) Is regulated by a foreign financial regulatory authority as defined under section 2(a)(50) of the Act (15 U.S.C. 80a–2(a)(50));

(iii) Holds assets for the custodian that participates in the system on behalf of the Fund under safekeeping conditions no less favorable than the conditions that apply to other participants;

(iv) Maintains records that identify the assets of each participant and segregate the system's own assets from the assets of participants;

(v) Provides periodic reports to its participants with respect to its safekeeping of assets, including notices of transfers to or from any participant's account; and

(vi) Is subject to periodic examination by regulatory authorities or independent accountants.

(2) *Primary Custodian* means a U.S. Bank or Qualified Foreign Bank that contracts directly with a Fund to provide custodial services related to maintaining the Fund's assets outside the United States.

**Note to § 270.17f–7:** When a Fund's (or its custodian's) custody arrangement with an Eligible Securities Depository involves one or more Eligible Foreign Custodians (as defined in § 270.17f–5) through which assets are maintained with the Eligible Securities Depository, § 270.17f–5 will govern the Fund's (or its custodian's) use of each Eligible Foreign Custodian, while § 270.17f–7 will govern an Eligible Foreign Custodian's use of the Eligible Securities Depository.

Dated: April 27, 2000.
By the Commission.

**Margaret H. McFarland,**

*Deputy Secretary.*

[FR Doc. 00–11000 Filed 5–2–00; 8:45 am]

BILLING CODE 8010–01–P

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Parts 203 and 205

**[Docket Nos. 92N–0297 and 88N–0258]**

**RIN 0905–AC81**

### Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures; Delay of Effective Date; Reopening of Administrative Record

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; delay of effective date; reopening of administrative record.

**SUMMARY:** The Food and Drug Administration (FDA) is delaying until October 1, 2001, the effective date and reopening the administrative record to receive additional comments regarding certain requirements of a final rule published in the **Federal Register** of December 3, 1999 (64 FR 67720). The other provisions of the final rule become effective on December 4, 2000. The final rule implements the Prescription Drug Marketing Act of 1987 (PDMA), as modified by the Prescription Drug Amendments of 1992 (PDA) and the FDA Modernization Act of 1997 (the Modernization Act). FDA is delaying the effective date for certain requirements relating to wholesale distribution of prescription drugs by distributors that are not authorized distributors of record. FDA is also delaying the effective date of another requirement that would prohibit blood centers functioning as "health care entities" to act as wholesale distributors of blood derivatives. The agency is taking this action to address numerous concerns about the provisions raised by affected parties.

**DATES:** The effective date for §§ 203.3(u) and 203.50, and the applicability of § 203(q) to wholesale distribution of blood derivatives by health care entities, added at 64 FR 67720, December 3, 1999, is delayed until October 1, 2001. The administrative record is reopened until July 3, 2000, to receive additional comments on these provisions.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Lee D. Korb, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

**SUPPLEMENTARY INFORMATION:**

## I. Background

PDMA (Public Law 100–293) was enacted on April 22, 1988, and was modified by the PDA (Public Law 102–353, 106 Stat. 941) on August 26, 1992. The PDMA as modified by the PDA amended sections 301, 303, 503, and 801 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 331, 333, 353, 381) to, among other things, establish requirements for the wholesale distribution of prescription drugs.

Section 503(e)(1)(A) of the act states that each person who is engaged in the wholesale distribution of a prescription drug who is not the manufacturer or an authorized distributor of record for the drug must, before each wholesale distribution of a drug, provide to the person receiving the drug a statement (in such form and containing such information as the Secretary may require) identifying each prior sale, purchase, or trade of the drug, including the date of the transaction and the names and addresses of all parties to the transaction. Section 503(e)(4)(A) of the act states that, for the purposes of section 503(e), the term "authorized distributors of record" means those distributors with whom a manufacturer has established an "ongoing relationship" to distribute the manufacturer's products.

On December 3, 1999, the agency published final regulations in part 203 (21 CFR part 203) implementing these and other provisions of PDMA (64 FR 67720). Section 203.50 requires that, before the completion of any wholesale distribution by a wholesale distributor of a prescription drug for which the seller is not an authorized distributor of record to another wholesale distributor or retail pharmacy, the seller must provide to the purchaser a statement identifying each prior sale, purchase, or trade of the drug. The identifying statement must include the proprietary and established name of the drug, its dosage, the container size, the number of containers, lot or control numbers of the drug being distributed, the business

name and address of all parties to each prior transaction involving the drug, starting with the manufacturer, and the date of each previous transaction. Section 203.3(b) defines "authorized distributor of record" as a distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's products. "Ongoing relationship" is defined in 203.3(u) to mean an association that exists when a manufacturer and a distributor enter into a written agreement under which the distributor is authorized to distribute the manufacturer's products for a period of time or for a number of shipments. If the distributor is not authorized to distribute a manufacturer's entire product line, the agreement must identify the specific drug products that the distributor is authorized to distribute.

Thus, the final rule requires unauthorized distributors (i.e., those distributors who do not have a written authorization agreement) to provide a drug origin statement to purchasers showing the entire prior sales history of the drug back to the first sale by the manufacturer. As discussed in the preamble to the final rule (64 FR 67720 at 67747), manufacturers and authorized distributors of record are not required to provide an identifying statement when selling a drug, although the agency encouraged them to do so voluntarily to permit unauthorized distributors to continue to be able to purchase products from them.[1]

The provisions in the final rule related to wholesale distribution of prescription drugs by unauthorized distributors (i.e., §§ 203.3(u) and 203.50) were adopted from the provisions in the proposed rule published in the **Federal Register** of March 14, 1994 (59 FR 11842), and are essentially the same as the proposed provisions, except the definition for "ongoing relationship" in the proposed rule was revised to eliminate certain requirements.[2] The agency received two comments on the proposed definition of ongoing relationship and one comment on proposed § 203.50, and responded in detail to those comments in the preamble to the final rule (see 64 FR 67720 at 67727, 67728, and 67747).

Section 503(c)(3)(A) of the act states that no person may sell, purchase, or trade, or offer to sell, purchase, or trade any drug that was purchased by a public or private hospital or other health care entity. Section 503(c)(3)(B) states several exceptions to section 503(c)(3)(A), none of which are relevant to this discussion. Section 503(c)(3) also states that "[f]or purposes of this paragraph, the term 'entity' does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law."

In the final rule of December 3, 1999, § 203.20 provides, with certain exceptions, that no person may sell, purchase, or trade, or offer to sell, purchase, or trade any prescription drug that was purchased by a public or private hospital or other health care entity or donated or supplied at a reduced price to a charitable organization. In § 203.3(q) of the final rule, "Health care entity" is defined as meaning any person that provides diagnostic, medical, surgical, or dental treatment, or chronic or rehabilitative care, but does not include any retail pharmacy or wholesale distributor. Under both the act and the final rule, a person could not simultaneously be a health care entity and a retail pharmacy or wholesale distributor. Thus, under the final rule, blood centers functioning as health care entities could not engage in wholesale distribution of prescription drugs, except for blood and blood components intended for transfusion, which are exempt from the PDMA under § 203.1 of the final rule. Blood and blood components include whole blood, red blood cells, platelets and cryoprecipitated antihemophilic factor which are prepared by blood banks who collect blood from donors and separate out the components using physical or mechanical means. Blood derivatives are derived from human blood, plasma, or serum through a chemical fractionation manufacturing process. Examples of blood derivative products include albumin, antihemophilic factor, immune globulin, and alpha-1 anti-tripsin. As discussed in the preamble to the final rule in response to comments (64 FR 67720 at 67725, 67726, and 67727), blood derivative products are not blood or blood components intended for transfusion and therefore could not be distributed by health care entities, including full service blood centers that function as health care entities, after the final rule goes into effect.

## II. Description and Rationale for a Partial Delay of the Effective Date of the Final Rule

### *A. Wholesale Distribution by Unauthorized Distributors*

Since publication of the final rule, the agency has received letters and petitions and has had other communications with industry, industry trade associations, and members of Congress objecting to the provisions in §§ 203.3(u) and 203.50. In early February 2000, the agency met with representatives from the wholesale industry and industry associations. The meeting participants discussed their concerns with both: (1) The requirement in § 203.3(u) that there be a written authorization agreement between a manufacturer and distributor for the distributor to be considered an authorized distributor of record under § 203.3(b), and (2) the requirement in § 203.50 that unauthorized distributors provide an identifying statement showing all prior sales going back to the manufacturer.

The meeting participants asserted that manufacturers are unwilling to enter into written authorization agreements with the majority of smaller wholesalers so that these wholesalers cannot become authorized distributors of record for the drugs they sell and, hence, must provide an identifying statement for these drugs. The meeting participants also said that smaller wholesalers cannot obtain an identifying statement showing all prior sales of the drugs they purchase for sale because a large portion of these drugs are purchased from authorized distributors who are not required to provide identifying statements and are unwilling to voluntarily provide them. The meeting participants asserted that authorized distributors will not voluntarily provide identifying statements when they sell drugs to unauthorized distributors because it would require them to change their warehouse and business procedures, which would entail additional effort and expense.

The meeting participants asserted that implementation of the final rule will prevent over 4,000 smaller, unauthorized distributors from distributing drugs to their customers and may put them out of business, at least with respect to their prescription drug wholesale business. They also asserted that because many of their customers are smaller retail outlets that are not served by larger distributors, implementation of the final rule may leave certain markets for prescription drugs, and ultimately consumers for prescription drugs, underserved.

[1] An unauthorized wholesale distributor that purchases a product from a manufacturer or authorized distributor of record without an identifying statement showing the prior sales of the drug could not provide an identifying statement to its purchasers and, therefore, could not conduct further wholesale transactions of the drug in compliance with § 203.50.

[2] The proposed rule defined "ongoing relationship" to require a written agreement and, in addition, the following two requirements that were eliminated in the final rule: (1) That a sale be completed under the written agreement and (2) that the distributor be listed on the manufacturer's list of authorized distributors.

In addition to the meeting discussed above and other informal communications that FDA has had with industry, industry associations, and Congress, FDA received a petition for stay of action requesting that the relevant provisions of the final rule be stayed until October 1, 2001. The agency also received a petition for reconsideration from the Small Business Administration (SBA) requesting that FDA reconsider the final rule and suspend its effective date based on the projected severe economic impact it would have on over 4,000 small businesses. The petitions argued that the requirement for a written agreement in § 203.3(u) is unreasonable because manufacturers are not willing to enter such agreements with the majority of smaller distributors. The petitions also asserted that authorized wholesalers are not now able and could not provide, at a reasonable cost, an identifying statement to their unauthorized distributor customers that meets the requirements of § 203.50 of the final rule. The SBA petition asserted that, if the effective date of the final rule is not stayed, drug products now in the inventory of wholesalers will have to be cleared and new orders will have to cease or be severely limited in order to comply with the final rule's December 4, 2000 effective date, with corresponding disruptions in the distribution of drugs possible by summer, 2000.

*B. Distribution of Blood Derivatives by Health Care Entities*

Since the time of the proposed rule, FDA has received 2 letters, one from a large blood center and the other from an association representing the blood center industry, and has held several meetings to discuss the implications of the regulations on blood centers that distribute blood derivative products and provide health care as a service to the hospitals and patients they serve. The blood center industry asserts that the regulations and, particularly the definition of "health care entity," will severely inhibit their ability to provide full service care to the detriment of client hospitals and the patients they serve, and may disrupt the distribution of these products to the public. The agency has also received a letter from a member of Congress on this issue. Although the agency was aware of this issue at the time the final rule was published, we believed that application of § 203.3(q) to blood centers would not result in a disruption in the distribution of blood derivative products. However, comments and information provided by representatives of the blood center industry have persuaded us that the final rule could disrupt the availability of blood derivative products to the public.

*C. Partial Delay of the Effective Date*

Based on the concerns expressed by industry, industry associations, and Congress about implementing §§ 203.3(u) and 203.50 by the December 4, 2000, effective date, the agency has decided to delay the effective date for those sections of the final rule until October 1, 2001. Additionally, the agency has decided to delay the applicability of § 203.3(q) to wholesale distribution of blood derivatives by health care entities, until October 1, 2001. All other provisions of the rule will become effective on December 4, 2000. This action should not be construed to indicate that FDA necessarily agrees with or has made decisions about the substantive arguments made in the petitions and other submissions related to implementation of §§ 203.3(u) and 203.50 or § 203.3(q), as it applies to wholesale distribution of blood derivatives by health care entities.

**III. Reopening of the Administrative Record**

The agency believes that providing additional time before these are to become effective is appropriate to permit the agency to obtain more information about the possible consequences of implementing these provisions, to further evaluate the issues involved, and to seek a legislative resolution to these issues, if necessary. Therefore, the agency is reopening the administrative record to receive additional comments on these provisions from interested individuals. Regarding §§ 203.3(u) and 203.50, the agency is especially interested in gaining further insight into the potential impact of the provisions on the wholesale distribution system generally, and on the ability of smaller pharmacies and other prescription drug retailers to obtain prescription drugs. In addition, the agency is seeking comments on the potential economic impact of the provisions on smaller wholesale distributors that are not authorized distributors of record. Regarding § 203.3(q), the agency also invites comment on the economic and public health impact of including full service blood centers under the definition of "health care entity," thereby prohibiting the wholesale distribution of blood derived products by such entities.

Interested persons may submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, written comments regarding this proposal by July 3, 2000. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

This action is being taken under FDA's authority under 21 CFR 10.35(a). The Commissioner of Food and Drugs finds that this delay of the effective date is in the public interest.

Dated: April 26, 2000.

**Margaret M. Dotzel,**

*Acting Associate Commissioner for Policy.*

[FR Doc. 00–10920 Filed 4–28–00; 12:34 pm]

BILLING CODE 4160–01–F

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 510**

**New Animal Drugs; Change of Sponsor's Name and Address**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor's name and address for Global Pharmaceutical Corp.

**DATES:** This rule is effective May 3, 2000.

**FOR FURTHER INFORMATION CONTACT:** Thomas J. McKay, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0213.

**SUPPLEMENTARY INFORMATION:** Global Pharmaceutical Corp., Castor and Kensington Aves., Philadelphia, PA 19124, has informed FDA of a change of sponsor's name and address to IMPAX Laboratories, Inc., 30831 Huntwood Ave., Hayward, CA 94544. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) to reflect the change of sponsor's name and address.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

Docket Nos. 92N-0927
88N-0258

BEFORE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

PETITION FOR STAY OF ACTION

BY THE

PHARMACEUTICAL DISTRIBUTORS ASSOCIATION

FINAL RULE CONCERNING POLICIES, REQUIREMENTS, AND

ADMINISTRATIVE PROCEDURES;

PRESCRIPTION DRUG MARKETING ACT

OF 1987; PRESCRIPTION DRUG AMENDMENTS OF 1992

March 29, 2000

The Pharmaceutical Distributors Association ("PDA"), a trade association of state-licensed wholesale distributors of prescription drugs, submits this petition pursuant to 21 C.F.R. § 10.35 to request the Commissioner of Food and Drugs to stay the December 4, 2000, effective date of those parts the final rule in Docket Nos. 92N-0297 and 88N-0258 which require a prescription drug pedigree to list all prior sales back to the manufacturer (21 C.F.R. § 203.50(a)(6)) and which require a written agreement to evidence an ongoing relationship between a wholesale distributor and a manufacturer (21 C.F.R. § 203.3(u)).

A. **Decision Involved**.

On December 3, 1999, the Food and Drug Administration ("FDA") published final rules implementing the Prescription Drug Marketing Act ("PDMA"), as amended. The final rule requires, for the first time since PDMA was passed in 1988, that prescription drug pedigrees include prior sale information back to the manufacturer even though authorized distributors are not required to provide pedigrees when they sell drugs to other distributors. 21 C.F.R. § 203.50(a)(6). In addition, these regulations, also for the first time, require a written agreement between a wholesaler and manufacturer to be in place as evidence of the ongoing relationship necessary to achieve authorized distributor status.

B. **Action Requested**.

The final rule was published December 3, 1999, and has an effective date of December 4, 2000. This petition requests that those portions of the regulation regarding the need for a written agreement as evidence of an ongoing relationship between a manufacturer and a distributor (21 C.F.R. § 203.3(u)) and those that require that the "identifying statement for sales by unauthorized distributors" identify "all parties to each prior transaction involving the drug, starting with the manufacturer" (21 C.F.R. § 203.50(a)(6)), be stayed until October 1, 2001, to provide PDA and its members time to achieve a legislative resolution to the

present controversy regarding these sections.[1] In granting such a stay, it is requested that FDA issue an interpretation of the stayed effective date for these provisions to state that only drugs **first** shipped by a manufacturer into interstate commerce after October 1, 2001 shall be required to bear information regarding prior sales back to the manufacturer.

During the time that the stay requested by this petition is in effect, it is requested that FDA announce that its 1988 guidance to industry, which is set forth in its August 1, 1988 letter "To Regulated Industry and Other Interested Persons," be deemed to be in effect with respect to these issues.

C. **Statement of Grounds**.

I. Since the Prescription Drug Marketing Act of 1987 was enacted, the wholesale drug distribution industry has operated in the main on the basis of the guidance provided to industry in FDA's letter of August 1, 1988. That letter interpreted PDMA to require that the statement identifying prior sales contain the following:

> 5. Statement identifying prior sales. FDA requests that the statement identifying prior sales of prescription drugs by unauthorized distributors be in writing, that it bear the title "Statement Identifying Prior Sales of Prescription Drugs by Unauthorized Distributors Required by the Prescription Drug Marketing Act," and that it include all necessary identifying information regarding all sales in the chain of distribution of the product, starting with the manufacturer or authorized distributor of record. FDA also requests that the identifying statement accompany all products purchased from an unauthorized distributor, even when they are resold. Identifying statements are not required to include information about sales completed before July 22, 1988. FDA requests that the identifying statement include the following information:

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[1] The initiation by PDA and its members of legislative oversight and discussions with respect to amendments to the PDMA should not in any way be construed as an admission by PDA or any of its members that FDA's final rule is lawful or that it properly interprets PDMA.

(a) The business name and address of the source from which the drug was purchased,

(b) The date of the sale, and

(c) The identity, strength, container size, number of containers, and lot number(s) of the drug. [Emphasis added.]

The final regulation published December 3, 1999 changes the 1988 FDA guidance to a regulation requiring the following:

§ 203.50(a) ***Identifying statement for sales by unauthorized distributors.*** Before the completion of any wholesale distribution by a wholesale distributor of a prescription drug for which the seller is not an authorized distributor of record to another wholesale distributor or retail pharmacy, the seller shall provide to the purchaser a statement identifying each prior sale, purchase, or trade of such drug. This identifying statement shall include:

(1) The proprietary and established name of the drug:

(2) Dosage;

(3) Container size;

(4) Number of containers;

(5) The drug's lot or control number(s);

(6) <u>The business name and address of all parties to each prior transaction involving the drug, starting with the manufacturer; and</u>

(7) <u>The date of each previous transaction.</u>

According to the FDA's own economic impact analysis, about 4,000 small business distributors will be directly affected by the regulation regarding statements identifying prior sales which is now scheduled to go into effect on December 4, 2000. Very few of these distributors purchase directly from manufacturers the pharmaceuticals that they then wholesale to others. Because PDMA does not require the full line wholesalers from whom other wholesalers purchase to provide prior sales history information, these "secondary" wholesaler distributors cannot continue to do business because to do so would violate the

regulation. They cannot pass on the required information about sales that occurred prior to the last authorized distributor of record selling the product because those authorized distributors of record do not provide this information to their customers.

Under the 1988 FDA guidance, this situation was avoided by FDA's interpretation that the prior sales information go back to "the manufacturer or last authorized distributor of record." This was a reasonable interpretation of PDMA and one which gave effect to both its requirement that prior sales history be provided by those wholesalers who are not authorized and that its provision that those who are authorized need not provide such information. The effect of the FDA's final rule will be to limit wholesalers who are not authorized to purchasing from manufacturers. Since many of these manufacturers will not do business with small wholesalers, the effect of the rule will be to drive thousands of small wholesalers out of business, disrupting the supply of prescription drugs to consumers and affecting prices.

II. In the final rule, FDA has defined "ongoing relationship" for purposes of determining whether one is an authorized distributor of record, in 21 C.F.R. § 203.3(u) as follows:

> Ongoing relationship means an association that exists when a manufacturer and a distributor enter into a written agreement under which the distributor is authorized to distribute the manufacturer's products for a period of time or for a number of shipments. If the distributor is not authorized to distribute a manufacturer's entire product line, the agreement must identify the specific drug products that the distributor is authorized to distribute.

This is a complete departure from FDA's 1988 guidance which stated:

> "Ongoing relationship," as used in the definition of "authorized distributors of record," may be interpreted to mean a continuing business relationship in which it is intended that the wholesale distributor engage in wholesale distribution of a manufacturer's prescription drug product or products. Evidence of such intent would include, but not be limited to, the existence of a written franchise, license, or other distribution agreement between the

> manufacturer and wholesale distributor; and the existence of ongoing sales by the manufacturer to the distributor, either directly or through a jointly agreed upon intermediary. The Agency would consider two transactions in any 24-month period to be evidence of a continuing relationship. [Emphasis added.]

Under the final regulation, prescription drug manufacturers will be able to control which of its customers are authorized and which are not. This means such manufacturers may determine which wholesalers are to be burdened by PDMA's requirement for a statement identifying prior sales and which are not. This is a power that cannot be delegated by Congress or by FDA to private companies.

It is the experience of PDA member companies that manufacturers decline to make wholesalers "authorized" for a variety of reasons. One such reason is that the wholesaler is too small to carry a full line of the manufacturers products. Another is that it is too small to maintain a required line of credit. Another reason is that the manufacturer already has adequate coverage in the area where the wholesaler is located. Each of these reasons work against small businesses and, with the change in the requirement for a statement identifying prior sales as described above, will cause many of these small businesses to go out of business because they will no longer have a source of supply.

III. PDA is a trade association of companies that are wholesalers of prescription drugs. These companies buy drugs directly from manufacturers, from full line wholesalers who are authorized distributors for manufacturers, and from wholesalers who are not authorized distributors of all the drugs they sell. PDA members in turn resell the drugs they buy to other wholesale distributors, to retail pharmacies, to health care entities and to physicians. These companies are sometimes called "secondary" wholesalers because the do not carry a full line of pharmaceuticals as do major wholesalers like McKesson. Like full line wholesalers, PDA members are licensed by each state in which they are authorized to do business and PDA member facilities are subject to inspection by FDA and state authorities. When these companies have two transactions in two years with a manufacturer, they are considered to have a continuing relationship

with such manufacturer and are "authorized distributors of record" in accordance with FDA's 1988 PDMA Guidance Information. If they cannot be considered to be authorized distributors of record, they provide a statement identifying prior sales to their customer, as required by PDMA.

It is important for PDA members to be able easily to determine from prior transactions whether they have achieved a continuing relationship that allows them to be an "authorized distributor of record." This is because written distribution contracts between manufacturers and wholesalers are the exception and not the rule in the pharmaceutical industry. Moreover, it is not by choice that PDA members are not contractually authorized by manufacturers to be their distributors. While manufacturers may do business with PDA members, they may not choose to make these companies contractually authorized distributors for reasons such as adequate existing relationships, credit requirements that smaller companies cannot meet, territorial distribution agreements, and the fact that smaller distributors may not wish to carry the manufacturer's full line of products. Because FDA's regulation has no standards, a manufacturer can determine, for any reason whatsoever, not to enter into a written agreement with a licensed distributor and cause that licensed distributor to be burdened by the requirement of a statement identifying prior sales.

Not being an authorized distributor of record puts PDA members at a competitive disadvantage in the wholesale marketplace. This is because of PDMA's extraordinary requirement that distributors who are not authorized must disclose to their customer, in the statement accompanying the sale, prior sales of that drug, including the source of the drugs they have sold. This requirement is extraordinary because it provides the wholesaler's customer the opportunity to deal directly with the wholesaler's source of supply the next time they wish to buy that drug or drugs.

Presently, when PDA members are required to provide a statement identifying prior sales, they do so back to the last authorized distributor in the chain of distribution, as they are permitted to do under

FDA's 1988 Guidance Information's contemporaneous interpretation of PDMA. This is as far back in the chain that they can go because authorized distributors of record are not required by PDMA to provide prior sales information to their customers and they do not do so. Under FDA's final rule, PDA member distributors who are not authorized are required to provide prior sales information back to the manufacturer even though FDA has acknowledged that authorized distributors are not required to provide that information to their customers. FDA's final rule has created an impossible situation for distributors who are not authorized, one which was avoided by FDA in its 1988 contemporaneous interpretation of PDMA. PDA members who buy from authorized distributors will not be able to comply with FDA's final rule and will now be shut out of doing business with those authorized distributors. If manufacturers refuse to sell to them as well, as many now do, they will be out of business entirely.

IV. Unless a stay is granted as requested herein, PDA members will suffer irreparable injury because they will no longer be able to purchase prescription drugs from the authorized distributors with which they have done business in the past. In addition, there is no guarantee that these companies, all of which are licensed wholesalers in the states where they do business, will be able to purchase these drugs directly from their manufacturers. Because of the effect of this regulation, these companies businesses will be severely disrupted and many will be forced out of business.

V. The legislative discussions initiated on these subjects by PDA are not frivolous and are being pursued in good faith. The issue presented by PDA to the Congress is a serious issue regarding the effect of FDA regulation on a significant number of businesses, most of them small businesses. FDA in its 1988 letter to industry interpreted PDMA in the same manner that PDA seeks to be the standard for going forward while these discussions take place.

VI. There is a substantial public policy in favor of small businesses. It is small businesses that will be most adversely impacted by the final rule unless the stay requested herein is granted. Moreover, there

is a substantial public policy against concentration in the wholesale prescription drug industry. That public policy as well will be advanced if the relief requested herein is granted.

VII. The stay requested herein and the resulting delay in the implementation of the portions of the final rule that are being discussed in the legislative arena is not outweighed by public health or other public interests. FDA and the prescription drug wholesales industry have operated under the guidance of FDA's 1988 letter for almost twelve years. Operating under that guidance as requested herein, until PDA's efforts to receive legislative relief is resolved, do not disserve the public interest.

D. **Conclusion**. There are no public health or other public interest considerations that would justify the disruption in the wholesale pharmaceutical distribution system that will occur if the provisions discussed above are stayed pending legislative discussions. The industry has operated since 1988 under the FDA guidance that has been changed in the final regulation without any public health explanation. The wholesale distributors that may be put out of their businesses by these provisions ought to be allowed to seek relief in Congress before the rules go into effect. Accordingly, we request the regulations noted above be stayed until October 1, 2001.

Respectfully submitted,

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*Statement of*

**KATHLEEN M.H. WALLMAN**
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*Before*

U.S. House of Representatives Committee on Small Business
Subcommittee on Regulatory Reform and Paperwork Reduction

June 8, 2000

**STATEMENT OF KATHLEEN M.H. WALLMAN**
**WALLMAN STRATEGIC CONSULTING, LLC**
**Before the U.S. House of Representatives Committee on Small Business**
**Subcommittee on Regulatory Reform and Paperwork Reduction**
**June 8, 2000**

Chairwoman Kelly and Members of the Subcommittee:

Thank you for the opportunity to participate in today's hearing addressing the quality of federal agency analyses concerning regulatory impacts on small businesses and whether Congress needs additional tools for sound oversight of the Executive Branch and independent agencies. It is an important subject. How agencies implement the laws Congress has enacted, whether the law's purposes are being fulfilled, and the costs and burdens that result, all indicate the effectiveness of our democratic processes.

My statement addresses the experience of a particular kind of small business -- rural telephone companies -- and offers some observations about regulatory impact analyses based on my work with them in different capacities. I have worked on these issues most recently as an adviser to small companies and their Washington representatives, and while in government as Chief of the FCC's Common Carrier Bureau and at the White House at the National Economic Council. With the expanding telecommunications industry and reforms enacted by the Congress in 1996, the regulatory environment, a great deal of which is shaped at the FCC, is of critical importance to both the companies involved and their customers. Circumstances over the past years have imposed significant challenges and strain upon rural telephone companies.

Rural telephone companies provide critical telecommunications services to their customers. Their role in bringing advanced telecommunications services to all Americans is vital. Provision and access to advanced telecommunications holds a pivotal

place in enhancing the quality of life in education, healthcare, and the overall economic well being of a region. Serving small towns and rural areas, many rural telephone companies are family owned, some cases for multiple generations. Most rural telephone companies fit easily into the category of small businesses and do not have resources devoted exclusively to federal regulatory matters.

The Regulatory Flexibility Act, passed in 1980 and amended by the Small Business Regulatory Enforcement Fairness Act in 1996, requires federal regulatory agencies to consider the impact of proposed regulations on small businesses and their customers, as well as to propose alternative rules for small companies. The RFA, as amended, was designed to change the culture of rulemaking, to assure that the interests of small businesses are considered at all stages in the rulemaking process in a substantive way. The question is how well is it working? My own view is that it is starting to work in some ways, that its implementation can be improved, and that some greater congressional involvement in oversight could be beneficial.

**Rural Telephone Companies, the Telecommunications Act of 1996, and the Federal Communications Commission**

There are inherent difficulties in trying to implement regulations that affect rural telephone companies in a way that is sensitive to the burdens that new regulations impose. One such difficulty is the inescapable complexity of common carrier regulation. Today's common carrier regulation is the result of decades of federal and state legislative and regulatory action. There are few people in the country who really and truly understand it. There is some hope that this area will become less complex as competition diminishes the need for regulation, but that is unlikely to happen very quickly. A topic

for another day would be to consider what dramatic deregulatory and "de-complexifying" steps regulators and Congress could take. But that is for another day.

Another inherent difficulty is the fact that many of these complex regulations were adopted, at least in principle. to help rural telephone companies and their customers. In assessing the impact of regulation on these small businesses, one thing that weighs on the plus side of the progress that has been made is that some of the additional regulations adopted that have an administrative impact on rural telephone companies actually benefit these businesses. One wants to criticize only very carefully a process that produced a useful result.

Another difficulty is the reality of the enormous workload of the FCC and the challenges that rural telephone companies, as small businesses, face in making their voices heard. In 1996, Congress enacted fundamental reforms in the regulation of telecommunications. The Telecommunications Act of 1996 established a national policy of competitive markets for telecommunications services, a dramatic change from the historic regulated monopoly environment. The law committed substantial responsibility to the FCC to implement a competitive environment in all markets, including local and interstate service. While embracing competitive markets, Congress also recognized that there were areas where investment in service would not otherwise be possible except for the various support mechanisms, commonly referred to as universal service, that had existed. The Congress instructed the FCC to reform and make explicit the universal service regime.

Congress recognized that many of the provisions of the 1996 law should not be applied, at least not initially, to rural telephone companies. Yet many of the provisions

are general, and leave to the FCC the responsibility to implement and structure how and to which entities the provisions would be applied. The law's direction of competition, and the steps necessary to implement this important goal, often conflict with the circumstances rural telephone companies face, where competition has been unevenly introduced, if at all. At the same time, provisions of the law, most significantly those encompassing universal service, were directed specifically to the needs of rural telephone companies and their customers.

The FCC is an agency of highly capable individuals, who take seriously the public trust committed to them. The energy and competence of those who work at the FCC reflect that which is envisioned of an expert independent agency. Regrettably, the agency has limited resources; there are not enough individuals to carry out its numerous responsibilities. This is one element that any examination of whether the necessary analysis is being fulfilled must include. In other words, Congress should consider whether the relatively straightforward remedy of additional, specifically targeted resources would help the agency do a better job of implementing regulatory analyses.

Under these circumstances, rural telephone companies have faced formidable challenges. The resources needed to monitor and advocate each pending proceeding, which during the FCC's initial implementation of the Act reached across each bureau of the agency, were far beyond the resources of most companies to do so individually. Virtually every proceeding affecting rural telephone companies, involved not only all other telephone companies, both local and long distance, but the range of interests constituting the entire telecommunications industry, whether it be manufacturers, cable operators, Internet Service Providers, television and radio stations, or satellite companies.

When rural telephone companies advocated, they competed with the largest of the Nation's corporations.

These factors, as well as the fact that many of the proceedings had statutory timeframes, tempered significantly the ability of rural telephone companies to have their views heard and considered. It is a problem not only of the agency being aware of an issue, but more importantly, having the rural telephone company interest saliently recognized and prominently considered throughout a rulemaking process. This is not always easy to achieve and sustain for the full range of issues that are of interest to rural telephone companies.

**Obtaining Substantive Advocacy**

Efforts taken to enhance opportunities for small business to participate actively in rulemaking proceedings are often viewed as having fallen victim to the breadth and range of interests involved in even the smallest of these rulemaking proceedings. It is a legitimate concern that the analysis the RFA requires of the agency has become more of a process than a substantive examination of the costs and benefits a particular rule has on small businesses. Yet, even here, the FCC must be credited with good faith and some real progress. The FCC's analyses are now acknowledging the status of rural telephone companies as small businesses; previously, there had been a more general treatment of rural telephone companies as incumbents, which are not necessarily small businesses.

It is, however, a problem of more than an agency not articulating adequately what small businesses are involved in a proceeding and taking steps to give these entities notice of an action. Even if the entities involved are enumerated, the goal should be for the agency to engage in a substantive examination of whether policies behind a particular

rule should be applicable to the small business, in light of the costs and burdens that will be imposed. Ideally, comprehension of the issues should be present before a rulemaking is initiated. The agency must be in a position to have sufficient information when it frames issues surrounding a proposed rule. It then becomes an easier task to assess the effect a rule will have, and make a decision as to whether it is worth the burdens and costs associated with it.

I am inclined to think that the goals of the RFA, as well as that of H.R. 3669, would more likely be met if the agency confronted the policies and the burdens, and made a determination, even if it is contrary to the interests of rural telephone companies. Congress' oversight role would be fulfilled by its examination of the balance that is chosen and can then determine if the law should be changed. Instead, what generally has evolved, is that the policies behind the rule are often weighed against the industry in general, and not particular entities such as rural telephone companies.

With substantive examination of the cost and burdens imposed on small businesses the goal, the question is one that in view of the limited resources of both small business in general, and to some degree the agencies themselves, how can the rulemaking process approach such substantive debate thereby enhancing the rulemaking process and better informing Congress what decisions are made and how.

There is a danger in searching for a solution that results in the rulemaking process being lengthened. It is important to consider that virtually all rulemakings of many agencies, but particularly those of the FCC, meet any minimum impact standard, and frequently cross-over to other proceedings. Any agency that is called upon to review a regulatory proceeding and the rules that are promulgated will face a challenge in terms of

its own resources, to keep abreast of what is transpiring. A more significant issue is whether the review will provide Congress, or the agency, a better insight into the issues that need to be addressed. The greatest challenge is not an agency deciding contrary to the advocacy of rural telephone companies, but not deliberating at all over the issues that are of concern. The goal is to assure not only that entities such as rural telephone companies have an opportunity to advocate their interest, but also that the agency starts with a comprehension of their concerns.

The short answer is to ask the entities most impacted. On some ongoing basis, the agency should advise representatives of particular interests, what actions are pending and the timing of the proceedings. While the Federal Advisory Committee Act provides a formal means, more flexible and less formal structures would serve more effectively. The goal of the agency would not be to obtain positions on an issue, but to communicate the substance and direction of its rulemaking so that interested entities can react and provide views.

The FCC has undertaken some efforts in this regard. Representatives from state, county and local governments meet on a regular basis at the FCC to discuss with the Commission staff pending proceedings and issues. The Rural Task Force has provided a useful forum for the productive exchange of ideas. Ultimately, such effort will engender a better comprehension of the interests and concerns from the start, thereby allowing the agency to comprehend and articulate the issues more effectively. This, in turn, will also allow opportunity for more substantive comments and debate.

The Subcommittee should be commended for its actions in this area. It is a difficult area, where the balance must instill enough accountability in an agency to carry

out Congress' intentions, yet not do so in such a degree that the rulemaking process is delayed or the significant debate that already pervades most rulemakings is undermined.

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Kathleen Wallman left the White House in November 1997 to start Wallman Strategic Consulting, LLC, providing strategic advice in the areas of video, voice and data communications, information technology and other infrastructure issues such as retail competition in electricity. She is also a principal of Critical Infrastructure Fund, L.P., which specializes in telecom and infrastructure investments, and serves as a director of Micromuse, Inc., a publicly traded network reliability software company, FolioTrade, LLC, a financial services company, and the Consumer Energy Council of America Research Foundation, which focuses on convergence issues, among others.

At the White House, Wallman served as Deputy Assistant to the President for Economic Policy and Counselor and Chief of Staff of the National Economic Council. In that capacity, she was responsible for mass media and domestic and international telecommunications issues including cable, broadcast, satellite, wireless and wireline matters and for coordinating policy decisions with Cabinet agencies. Wallman was a delegate to the China-U.S. Telecommunications Summit in China in October 1997, a keynote speaker at ComJapan in November 1997 and a keynote speaker or panelist at numerous U.S. industry conferences. Building upon her expertise in emerging competition in telecommunications, she was also responsible for coordinating the Administration's policy on introducing retail competition in the electricity industry. Prior to joining the National Economic Council, she served as Deputy Counsel to the President in the Office of the White House Counsel from November 1995 until January 1997.

Wallman began her government service in 1994 at the Federal Communications Commission as Deputy Chief of the Cable Services Bureau. From that position, she was promoted to serve as Chief of the Common Carrier Bureau in 1994-1995. Wallman was the senior staff authority on the country's telecommunications policy, including long distance and local competition, service to rural areas, and interconnection of wireless and wireline networks. Wallman came to the Commission from the Washington, D.C. law firm of Arnold & Porter, were she was a partner in the Legislative and Intellectual Property Practice Group, representing clients before Congress and Executive Branch agencies.

In January 1999, Wallman was appointed by FCC Chairman William Kennard to Chair the FCC's National Coordinating Committee, a federal advisory committee established to make recommendations to the FCC about how to ensure that federal, state and local law enforcement officials can communicate interoperably in spectrum dedicated to public safety use.

Wallman received her B.A. from the Catholic University of America where she was graduated in 1979 *summa cum laude*, Phi Beta Kappa. She earned a J.D. from Georgetown University Law Center, graduating in 1984 *magna cum laude*, and at the same time, a M.S. from Georgetown's Walsh School of Foreign Service, graduating with honors. She was a member of the Editorial Board of the *Georgetown Law Journal*. She served as a law clerk to Judge Pauline Newman of the U.S. Court of Appeals for the Federal Circuit and Judges Edward Tamm and Laurence Silberman of the U.S. Court of Appeals for the D.C. Circuit.