

NLWJC - Kagan

Counsel - Box 027 - Folder 005

**Regulatory Reform-legal & other
analyses [3]**

MEMORANDUM

November 6, 1995

TO: Michael Fitzpatrick

FROM: Kathryn Fulton
Hunter Jones HJ

RE: H.R. 994 -- Summary of SEC Comments

This responds to your request for a summary of SEC staff comments made at the November 3, 1995 meeting with House Commerce Committee staff.

- As Ms. Katzen from the OMB stated in her comments, H.R. 994 would significantly compromise the independence of independent regulatory agencies. The bill would vest with the Administrator of the OMB, or any other officer designated by the President, final discretion to determine whether rules should be continued, modified, or terminated. Such vesting of authority outside the SEC is contrary to the independence that has been vital to the SEC's protection of securities investors and to the promotion of fair and efficient markets during the sixty years of its existence.
- The comprehensive review that H.R. 994 would require the SEC to undertake would be expensive and inefficient. As reported by the Government Reform and Oversight Committee, the bill would require agencies to solicit public comments on eleven sets of criteria and to prepare preliminary and final reports on the agency's conclusions and recommendations. As reported by the Judiciary Committee, the bill would further require that, if the agency decides not to terminate the rule, it must submit the rule to the public for further notice and comment under the Administrative Procedure Act.
- The comprehensive review that H.R. 994 would require the SEC to undertake would supplant the selective, careful review process that the SEC normally performs. As part of the ongoing evaluation of administrative functions, the SEC frequently reviews its rules in order to determine whether they should be terminated or modified.¹ Often, requests for termination or modification come from persons who believe they are adversely affected by the rules. This

¹ In addition, pursuant to the Regulatory Flexibility Act, the SEC has reviewed more than 400 of its rules since 1980.

responsiveness to the public serves two functions: it allows the SEC to govern more effectively, and it allows the agency to prioritize its regulatory actions in accordance with the greatest needs for change.

- Automatic termination of rules as to which an agency does not complete its sunset review would be hazardous to the SEC's regulatory program and to the financial markets. Because the securities statutes do not establish all of the relevant standards needed to govern securities market participants, the SEC must carry out much of its regulatory mandate through rules. Securities Exchange Act Rule 10b-5, for example, is one of the major antifraud rules; it serves as the basis for a large part of the SEC's enforcement efforts. In addition, Securities Exchange Act Rule 15c3-1, the net capital rule, is a complex and important rule designed to protect the liquidity of customer accounts at brokerage firms. Automatic termination of either of these rules would significantly undercut the stability of, and public confidence in, U.S. securities markets.
- The SEC is not well positioned to spend its limited resources on the review functions that H.R. 994 would mandate. The SEC does not yet have a budget for the current fiscal year. The Senate funding bill would decrease the SEC's budget by ten percent, while the House bill would maintain the SEC's budget at the level of fiscal year 1995. Although the SEC hopes to maintain its current level of funding for the next year, there will probably be no increase -- and there may be a decrease -- in the SEC budget. Given the severe limitations on the resources of the agency, spending the funds in a manner that is redundant and unnecessary would be wasteful for the federal government and its taxpayers.²

² The staff has not yet estimated the costs that H.R. 994 would impose on the SEC, but plans to prepare an estimate soon.

Comments of the Department of Energy on H.R. 994

Background

- DOE is a non-traditional regulatory agency that both regulates elements of the energy market (e.g., energy efficiency standards) and is regulated by other agencies with respect to its facilities and operations (e.g., environmental cleanup).
- The Department has approximately 2200 pages of regulations codified in the Code of Federal Regulations, and is committed to the elimination or reinvention of 75 percent of its existing regulations. Over 500 pages of the CFR were eliminated in Fiscal year 1995.
- In addition, the Department has traditionally regulated the activities of its contractors, facilities and operations through DOE orders and directives that arguably fall within the scope of H.R. 994. The Department has reduced the number of DOE orders from a base of 312 to 156 during Fiscal Year 1995 in accordance with the Secretary of Energy Performance Agreement with the President. Many of the remaining DOE orders regulate such important activities as the safe operation of DOE nuclear reactors.
- As part of its commitment to streamlining and improving its regulatory program, the Department of Energy has consistently solicited public input. In 1994, following public notice and a mailing to over 300 intergovernmental customers and stakeholders, the DOE received 14 public suggestions for eliminating or reinventing its regulations. All of the suggestions have been considered in the course of its current reinvention efforts.

H.R. 994 Provides No Additional Value at Substantial Cost

- DOE estimates conservatively that the incremental cost of the petition and lookback procedures contemplated by H.R. 994 would be \$ 6 million and 6 additional staff positions annually during a period of extreme fiscal constraints. The requirements contemplated for cost-benefit analysis and risk assessment for any "new" regulations, including those retained following a sunset review, would add significantly higher resource costs.
- In some cases, the bill contemplates cost-benefit analyses and risk assessments for regulations under review that would assume the absence of prior regulation. But 50 years following the Manhattan Project, it would make little sense to measure the cost/benefit or risk of nuclear safety regulation in a vacuum, instead of considering the incremental effects of revised regulations, as DOE currently does.

The bill would be counter-productive, because it would prevent DOE from concentrating its limited resources on eliminating or improving those rules that are particularly in need of reform or are outdated. It would require DOE to expend resources on review of other rules that might be found to be within the bill's definition of covered rules, but for which full-scale review and termination would not be appropriate, such as the rules for collecting from employees for indebtedness to the federal government, or for garnishing employee

salaries for child support and alimony.

Because the bill would require DOE to devote limited resources, including personnel, to the review of so many existing and new rules, it would lessen the ability of the agency to fulfill its existing rulemaking mandates from Congress, as well as other legislative priorities.

Many of the Department's Regulations Should Not be Subject to Sunset

- The Department has recently concluded an accelerated reduction in the number of its internal DOE orders, most of which involved issues of environment, safety, health and nuclear safety of DOE operations done through contractors. With respect to just one order, on the subject of radioactive waste management, approximately 1,500 comments were received, addressing 150 major issues. These are not issues that can be addressed easily within the timeframes of H.R. 994.
- One of the lessons we learned in collaboration with an independent regulatory body, the Defense Nuclear Facilities Safety Board, was the sensitivity of the phrase "sunset review." Indeed, at the specific request of the DNFSB, the Department has deleted the automatic sunset provisions it had proposed for nuclear safety directives. These regulations by their very nature should not be allowed to sunset if we are to avoid creating potential risks to public health and safety, and uncertainty by the regulated community.

H.R. 994 -- FDA COMMENTS

- Virtually all FDA regulations/guidance documents¹ would be subject to review because they cause a \$100 million annual effect on the economy, are significant, or are petitioned for review.
- The bill requires FDA to undertake a review of regulations that Congress has mandated (e.g., pursuant to the Nutrition Labeling and Education Act of 1990 and the Mammography Quality Standards Act).
- FDA has estimated that it will cost the agency approximately \$55,000,000 annually to make the required reviews.
- HR 994 requires FDA to devote the same effort in reviewing effective regulations and problematic regulations. The staggering workload imposed by the bill will force FDA to direct valuable and scarce resources into HR 994 reviews. FDA would have to shift resources from consumer protection programs and product review in order to complete the reviews.
- A sample of vital FDA programs that could be affected include:

Mammography Quality Standards - ensure high quality mammography (currently the most effective method for detecting breast cancer). Using the most conservative estimate, some 200 women's lives would be saved each year by these regulations.

Performance Standards for Radiation Emitting Products - ensure the safety of TV receivers, microwaves, x-ray machines, lasers etc.

Blood Product Standards - protect the blood supply from AIDS, hepatitis, and other infectious diseases.

Human Tissue Regulations - put a stop to a major public health threat by requiring proper donor testing and screening as well as the recall and destruction of dangerous and violative human banked tissue.

Vaccine Standards - ensure the safety and effectiveness of the vaccines administered to our children (e.g.,

¹ The expansive definition of "rule" makes informal guidance, interpretive statements, agency manuals, agency releases, or even individual letters potentially subject to sunset review.

poliovirus, measles, mumps, rubella, and smallpox vaccines).

Adverse Reaction Reporting for Drugs - improves the reporting to FDA of serious and life-threatening reactions to drugs and biologics.

GMP Regulations - ensure safety and quality of foods, drugs, biologics, and devices.

Pediatric Labeling for Drug Use Rule - allows for wider use in children of important drugs and requires the inclusion of information in drug labeling on specific hazards associated with the drug's use in children and any limitations on the pediatric indications.

Iron Toxicity Prevention Rule - requires label warning statements for products that supplement the dietary intake of iron to alert parents to the seriousness of accidental ingestion of excessive amounts of iron by small children and to warn them to keep these preparations out of reach. The regulations would also require unit-dose packaging for products that contain 30 mg. or more of iron per dosage unit. Despite child-resistant packaging, elemental iron used as a dietary supplement is the leading source of poison-related deaths in infants and toddlers.

Seafood Safety Rule - ensures the safe processing and importation of fish and fish products through the use of industry-chosen, risk-based controls in accordance with Hazard Analysis Critical Control Point (HACCP) principles. It is estimated that the final rule, which is broadly supported by the food industry and consumers, would prevent an estimated 33,000 illnesses each year from improperly processed seafood.

Nutrition Labeling and Education Rules - require nutrition labels on most food products sold in this country. These regulations have received broad public support for providing a much needed service to ordinary consumers, and are expected to contribute enormously to healthier diets and lowered incidence of diet-related disease in the coming years.

Lead in Food Cans Rule - prohibits the use of lead solder to close the seams of food cans. Even at low levels, the effects of lead exposure on pregnant women, infants, and children have raised genuine public health concerns. This rule removes one final source of lead exposure and levels the playing field for American

manufacturers all of whom have abandoned the lead soldering process.

Bottled Water Standards - ensure that bottled water is free from pesticides, heavy metals and other contaminants. These regulations have the strong support of the bottled water industry.

- The bill unfairly exempts all pro-business regulations.
- FDA has already taken a number of steps aimed at streamlining and reducing the burden of its regulations.
 - A January 1993 examination of FDA's rulemaking process resulted in new procedures for planning and tracking regulations and the revocation of 100 outstanding proposed regulations.
 - In January 1994, pursuant to the President's Executive Order on regulations review, FDA sought public comment on its individual program areas to seek public advice aimed at identifying outdated, burdensome, inefficient, or otherwise unsuitable or unnecessary regulations. This resulted in a comprehensive retrospective review of the agency blood regulations.
 - In March 1995, the President announced a series of regulatory reforms aimed at reducing the burden from FDA regulations. Most of these reforms are being accomplished through changes to FDA's regulations. One set of regulations, totaling 700 pages, will be eliminated entirely. Those reforms will save the drug and device industry an estimated \$500 million per year. Companion reforms for the food and veterinary industries are being prepared.
 - Following the President's March 1995 announcement, the agency conducted an intensive line-by-line review of agency regulations. As a result of the review, FDA recommended deleting or reinventing 81% of its rules that have a regulatory impact, including deleting entirely 11% of its rules guiding the marketing and production of regulated products. In October 1995, FDA published an NPRM, which proposed to eliminate 141 pages of the CFR.



United States
CONSUMER PRODUCT SAFETY COMMISSION
Washington, D.C. 20207

MEMORANDUM

DATE: November 6, 1995

TO : Mike Fitzpatrick
FROM : Eric Rubel, CPSC General Counsel
SUBJECT: Comments on Hyde Amendment to H.R. 994

This memorandum is in response to your request for an assessment of the impact the Hyde amendment to H.R. 994 would have on CPSC. This supplements my comments on H.R. 994 to the Commerce Committee staff, dated October 30, 1995.¹

IMPACT OF THE HYDE AMENDMENT

The Hyde Amendment makes several changes to H.R. 994. Most significantly, it removes the "automatic" termination of rules. However, this would not alter the result that many (perhaps most) of CPSC's important and successful safety rules could be eliminated. With or without the Hyde Amendment, H.R. 994 would waste valuable resources and threaten public health and safety.

Section 5 of the bill, as amended, would still force agencies to reconsider each rule as if it were being issued for the first time. As we see it, a rule that has been effective might well be unable to continue under these criteria. For example, to issue a safety rule under the Consumer Product Safety Act ("CPSA"), the Commission must find, among other things, that the rule is "reasonably necessary to eliminate or reduce an unreasonable risk of injury" associated with a consumer product. 15 U.S.C. § 2058(f)(3)(A). If a rule has achieved its objective, by greatly reducing deaths and injuries, the risk is no longer unreasonable and the Commission might not be able to re-issue the rule. The CPSA does not allow the Commission to conduct "hypothetical rulemaking" -- to ask if there were no rule, and if a product's safety feature were removed, would the risk be unreasonable. Yet that is the inquiry that would be necessary under H.R. 994 with or without the Hyde Amendment.

¹ This memorandum reflects the views of CPSC staff, and has not been reviewed by the Commissioners.

The Commission's 1993 safety standard making disposable cigarette lighters child-resistant provides a specific example. As required by the CPSA, the Commission found that the rule was reasonably necessary to eliminate or reduce an unreasonable risk of injury associated with disposable cigarette lighters. The Commission found that the rule would provide net benefits of approximately \$115 million per year and between 80 and 105 lives saved annually. Industry supported the rule because it preempts inconsistent state laws and provides a level playing field among competing companies.

However, assume that the Commission "reviewed" the cigarette lighter rule and found that, because manufacturers and importers were complying with the rule, burn injuries and deaths involving cigarette lighters had been greatly reduced. The Commission would not likely be able to find that the risk was still "unreasonable." Therefore, the rule would have to be terminated under H.R. 994 or the Hyde Amendment. Gone would be the requirement that disposable cigarette lighters be child-resistant, as well as preemption and certainty for industry. The deaths and injuries might return, and CPSC could then issue the regulation again. In short, we would be taking one step forward two steps back. And, to what end?

We believe that the other fundamental points made in our October 30, 1995, statement for the House Commerce Committee staff concerning H.R. 994 would also apply to the bill as amended by Congressman Hyde. It would require highly theoretical and expensive cost-benefit analysis even for rules adopted initially with cost-benefit analysis (see pp. 6-8 of CPSC Statement on H.R. 994). Because the Hyde Amendment diminishes the OIRA Administrator's role only with respect to petitions, the bill as amended would still remove a great deal of discretion for rule reviews from agencies, and threaten the independence of independent agencies like CPSC (see pp. 8-9 and 12-14 of CPSC Statement).

Coverage of the bill remains unworkably broad under the Hyde Amendment. If anything, the amended bill would bury agencies in even more paperwork because of the added APA procedures in section 8. In order to continue, modify, or terminate a rule, an agency would have to issue a sunset review notice (§ 8(a)), a preliminary report on sunset reviews (§ 8(b)), and a final report (§ 8(c)). In addition, under the Hyde amendment, the agency must conduct a full rulemaking proceeding (§ 8(d)). Most significantly, as amended, the bill would still undermine consumers' health and safety by leading to the elimination of many successful rules.

COST OF H.R. 994 AND THE HYDE AMENDMENT

CPSC is a small agency operating with a staff of only 487 employees and a budget of only \$40 million -- half the size it was in 1979 in inflation adjusted dollars. Without any additional funds appropriated for agencies to meet these requirements, the mandate to review virtually all of our rules would require CPSC to shift its entire regulatory program from

addressing emerging hazards (which we do through both mandatory and voluntary standards) to simply reviewing existing rules.

We anticipate that evaluating and re-proposing (or terminating) existing CPSC regulations under either the Hyde amendment or H.R. 994 would annually require approximately 120 FTEs and contract expenditures of approximately \$1 to \$1.5 million. However, for 1996, CPSC has available only \$136,000 for contract expenditures for hazard assessment and reduction. This alone demonstrates that with or without the Hyde Amendment, H.R. 994 would impose an extreme burden on CPSC that would severely impede its safety mission.

**CPSC Staff Comments on
Hyde Amendment to H.R. 994¹**

This paper supplements the Consumer Product Safety Commission's ("CPSC") comments on H.R. 994 to the Commerce Committee staff, dated October 30, 1995.

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OCT 30 1995

STATEMENT OF ERIC A. RUBEL, GENERAL COUNSEL
THE U.S. CONSUMER PRODUCT SAFETY COMMISSION
TO THE STAFF OF THE
U.S. HOUSE COMMITTEE ON COMMERCE
CONCERNING REGULATORY SUNSET AND REVIEW¹

This briefing paper addresses the implications of H.R. 994, the Regulatory Sunset and Review Act of 1995. While my specific comments refer to provisions of the Clinger substitute, most of the points in this paper also apply to the previous version of H.R. 994 and to other lookback and sunset legislation generally. An addendum to this briefing paper elaborates on the specific provisions of the Clinger substitute that we find most objectionable.

CPSC's mission is to protect Americans and their families from unreasonable risks of death and injury from the 15,000 different types of consumer products within its jurisdiction. The Commission does this with a streamlined staff of 487 employees, roughly half the size it was during the 1970s, and with a budget that is about half of what it was in 1979, when adjusted for inflation. Our small size makes efficient operation essential. Therefore, we must be particularly wary of rigid requirements that yield few benefits, while wasting vital resources and distracting the Commission from its important safety mission. Unfortunately, H.R. 994 is such a measure.

When Richard J. Pierce recently accepted an award from the ABA's Administrative Law and Regulatory Practice Section, he made

¹ The views expressed in this paper do not necessarily reflect those of Commissioner Mary Gall.

several remarks about the current regulatory reform debate that I believe aptly describe H.R. 994. Noting that "the current debate is taking place in a manner that is so completely divorced from reality that it is likely to produce terrible results," Professor Pierce stated:

"In particular, the problem cannot be addressed by demonizing agencies, imposing on agencies absurdly expensive procedural mandates that would never pass a cost-benefit test, and demanding that courts perform tasks for which they are totally unsuited."

CPSC strongly supports the essential goals underlying regulatory reform -- providing efficient, cost-effective and scientifically sound government action. Indeed, these principles already control CPSC's regulatory safety efforts. CPSC is statutorily required to perform cost-benefit analyses for almost all of its safety rules; all of its actions must have a sound factual and scientific basis; and the Commission regularly relies on risk-based decision making in setting its priorities.

However, this lookback and sunset legislation actually contradicts the basic goals of regulatory reform. Both the underlying concept of the bill and the specific approach taken in the Clinger substitute guarantee less efficient and more costly government that would likely reduce health and safety. The bill is grossly overbroad, sets out unworkable procedures and impossible deadlines, and elevates unproductive paperwork to a high art. The result could well be automatic termination of many

successful rules that save lives and reduce injuries. Fundamentally, the bill is built on a foundation of false assumptions.

A. FALSE ASSUMPTION 1: Once a Problem is Fixed, Repeal the Regulation.

Underlying this and other lookback and sunset legislation is the false premise that once a safety hazard is reduced, the regulation is no longer needed. However, the very reason for the improvements in safety is likely the regulation. And, once the regulation is eliminated, the hazard may be resurrected, requiring another regulation. This approach commits agencies to an endless pattern of regulating, relaxing, and re-regulating. Moving one step forward and two steps back could prove costly in both resources and lives.

Example: Refrigerator Safety Act

The Commission's regulations under the Refrigerator Safety Act provide one potential example of this senseless dance. This law was enacted in the 1950s to correct the tragic problem of children being trapped and killed while playing inside discarded refrigerators. At that time, 30 to 40 children a year died this way. The Act directed agency adoption of requirements to enable refrigerator doors to open easily from the inside.

As a result, there is currently little, if any, risk of children becoming trapped and killed inside refrigerators. However, this lack of casualties hardly indicates that there is no ongoing need for, or benefit from, the regulation. In fact,

the opposite is likely true: the hazard is virtually non-existent because the rule continues to be effective. Yet, as discussed below, determining the regulation's costs and benefits would be a highly theoretical and complex exercise, seeking to measure deaths and injuries that would have occurred but for the rule.

Ongoing enforcement of the rule costs CPSC nothing, because industry uniformly complies with the rule. And we have yet to hear a complaint from industry about the rule. Indeed, Whirlpool recently cited development of the technology to open refrigerators from the inside as one of the corporation's proudest achievements. But, would it be possible or worth the expenditure of resources to estimate how many children would die if the rule were lifted?

CPSC's refrigerator regulation is a simple, non-controversial rule. But because the scope of this bill under section 4 is enormous, it opens every rule to potential review. Even rules with minor economic impact and generally recognized (though not necessarily quantified) safety benefits could terminate. The \$100 million monetary threshold is just one factor for determining which rules are covered. The two executive orders referred to in section 4(b) provide a whole host of additional and often vague criteria. Most importantly, the petition procedure in section 4(c) provides virtually unlimited opportunity to re-open rules. The low threshold for petitions -- they must be granted unless it would be "unreasonable" to conduct

a review -- and the paltry \$20 processing fee ensure a flood of petitions (see § 4(c)(1) and (2)(C)). A petition might be filed by a single fringe manufacturer who, for example, wants to produce a refrigerator without the safety feature to lower production costs. ✓

Moreover, the bill is even flawed in how it would apply the \$100 million monetary threshold. The bill looks not only at the ongoing costs of a rule, but at whether in the past it "has resulted" in a \$100 million annual effect on the economy (§ 4(b)(1), as amended). Why should a rule be subject to review because years ago it had high compliance costs, when today those costs may be marginal? ✓

Example: Poison Prevention Packaging Act

Other life-saving rules could be threatened as well. For example, under the Poison Prevention Packaging Act, the Commission issues rules requiring child-resistant packaging for hazardous household products like over-the-counter drugs, drain cleaners, and turpentine. These safety caps and packages have prevented hundreds of deaths of children who could otherwise accidentally ingest potentially poisonous substances around the home. For aspirin and oral prescription drugs alone, there were up to 700 fewer such accidental child deaths from the early 1970s (when child-resistant packaging was first required for these items) through 1991. Yet, the bill would open such poison prevention rules to review and possible termination.

The combination of the number of rules open to review

(potentially every one) and the short deadlines for review virtually guarantees that some rules will terminate simply because we run out of time. It is then -- when, for example, we see more children suffocate in refrigerators or poison themselves with a jar of aspirin left unattended -- that we may rediscover the need for our rules.

B. FALSE ASSUMPTION 2: Two Cost-Benefit Analyses are Better than One.

This bill relies on another assumption that several other regulatory proposals accept: more analysis is always better. Even if an agency conducted a cost-benefit analysis when it issued a rule, it must conduct another analysis under this bill (see § 5(a)).

Yet the passage of time creates several analytical dilemmas. A rule may have had significant initial costs but now have only slight costs. Which time period is used to calculate costs and benefits? Industry has likely changed in the years following the regulation. Are some changes (and associated costs) due to the regulation or are they only incidental? Or do we turn back the clock and assess the regulation as if it had never been issued? How is an agency to determine whether particular fringe players in an industry are likely to disregard a safety measure once a regulation is revoked, thereby decreasing costs, but also decreasing the benefits of reduced deaths and injuries. And, in any event, why are we rewarding this kind of behavior?

Example: Child-Resistant Disposable Cigarette Lighters

CPSC's 1993 safety standard making disposable cigarette lighters child-resistant illustrates the fallacy of the assumption that cost-benefit analysis should be piled on top of cost-benefit analysis. To satisfy existing statutory requirements, the Commission conducted a cost-benefit analysis for the child-resistant lighter rule which showed potential net benefits (taking into account the costs) of approximately \$115 million per year, and between 80 and 105 lives saved annually. The analysis was based largely on data up through 1992.

Under the bill, CPSC would have to re-analyze the costs and benefits of the rule. And to what end? If industry or others believed that the cost-benefit data used to support the rule were incorrect, they could have commented on the proposed rule or challenged the final rule in court when CPSC issued it in 1993. It would be pointless now to revisit the earlier data.

A review of ongoing costs and benefits, rather than those in the past, would pose other problems. If a rule reduced the hazards it was intended to address, the original risk may no longer exist and the rule might be considered to have no ongoing benefits. Assume that several years from now CPSC's review shows that the lighter rule has greatly reduced the number of people injured and killed in fires started by children playing with lighters. How could the agency definitively show that the injuries and deaths would return if the rule was revoked?

Similarly, all refrigerators now manufactured allow children

to escape from inside. Since the risk has been virtually eliminated, arguably only costs and no ongoing benefits remain. Considered this way, successful rules -- those that achieve their goals -- are the prime candidates for termination. Or at best, they would require very expensive regression analysis to demonstrate their effectiveness.

Moreover, the bill makes the odd assumption that more recent regulations are in greater need of review. It generally provides an accelerated three year period for review of rules that take effect after the bill's enactment (see § 7(a)(2)(A)). The agency will have just finished issuing the rule when the time arrives to review it. What is the point of beginning the sunset process for rules whose sun has just risen? This could also have the perverse result of placing on the fast track for review the very regulations that comply with the cost benefit requirements of other regulatory reform legislation. Such a waste of scarce resources defies logic.

. C. FALSE ASSUMPTION 3: Agencies are Incapable of Revising Rules to Adapt to Technological, Economic or Other Changes.

The bill assumes that in the absence of a statutory requirement, agencies will never review or amend existing rules. The truth is that agencies can, and we do, make common sense changes to rules to respond to changing circumstances. Where agencies fail to do so, sharper Congressional oversight or focused legislative changes -- not a blanket approach to reform

that puts all rules at risk -- is the appropriate solution.

For example, earlier this year, after assessing the need for regulatory change, CPSC revised the adult test under which child-resistant packaging is evaluated. These changes, supported by industry, make it easier for adults to use the protective packaging properly without sacrificing its child resistance. Adults who found child-resistant packaging difficult to use -- and therefore left the caps off or did not close them properly -- will be more likely to use them. The increased use of such improved packaging will save additional lives. The revisions respond to an aging population and technological advances that make the new caps possible.

The Commission also issues exemptions, frequently in response to petitions, when a rule is no longer necessary for a particular product. A regulation the Commission issued last year exempting video games from regulations covering fire and shock hazards for electrical toys is just one example. At industry's request, the Commission examined the regulation and found that video games present only a small risk of electrical injury to children. The exemption relieves manufacturers of testing, recordkeeping, and labeling costs.

D. FALSE ASSUMPTION 4: Terminating Rules is Good for Business.

The bill creates considerable momentum to terminate rules. In fact, the thrust seems to be more toward eliminating the maximum number of rules in the minimum amount of time, rather

than establishing a careful review of the most significant rules. This "cut and run" approach ignores the fact that rules not only provide safety for consumers, but also certainty for industry. What will be the effect when rules clarifying industry's obligations are eliminated, but the underlying statutes demanding industry's compliance remain?

The breadth of the bill exacerbates this problem. The bill's sweep includes agency guidance documents and interpretations, and even documents describing agency procedures and practices (see § 13(4)(A)). These "rules" are often intended to inform the regulated community of the agency's interpretation of statutory requirements. Getting rid of such "rules" will not change the agency's interpretation; it will only leave industry in the dark on the agency's thinking.

Example: Toy Labeling Under the Child Safety Protection Act

Earlier this year, CPSC issued regulations implementing the Child Safety Protection Act, which requires labeling of certain toys to warn of potential choking hazards. The law was enacted last year at the urging of industry to preempt different state labeling requirements. Congress specifically directed CPSC to adopt implementing regulations without complying with the cost-benefit requirements applicable to other CPSC rulemaking. The toy safety regulations explain CPSC's interpretation of the Act's requirements. Absent the rule, industry would still have to label toys according to the statute -- without the practical guidance the rules provide. It is difficult to see how providing

less information benefits anyone.

Nor is industry necessarily served by eliminating substantive rules. For example, the lighter industry was among the many advocates for CPSC's child-resistant cigarette lighter standard. The industry wanted a uniform mandatory standard so that it would not be subjected to varying state laws or a voluntary standard that would pose a competitive disadvantage to reputable manufacturers that chose to comply. The level playing field that such regulations provide offers consumers protection from unsafe products while ensuring fair competition for manufacturers.

The bill requires agencies to solicit comments on a laundry list of issues, including whether revoking the rule would "create an unfair advantage to those who are not in compliance with it" (§ 8(a)(3)(G)). Thus, the bill's drafters recognize that it would be unfair to give a competitive advantage to companies that choose to disregard safety measures. But, agencies would be unable to preserve rules that fail rigid cost-benefit tests even if their repeal would provide an unfair advantage to unscrupulous companies.

Example: Small Parts Regulation

The potential problems that wholesale termination of rules would create is increased for long-standing rules upon which industry has come to rely. One of the Commission's most important rules prohibits toys and other products for children under age 3 from having small parts that pose a choking hazard.

The rule is responsible for a significant reduction in choking incidents. Before the regulation, the Commission had approximately 12 reports annually of children under age 3 dying when they choked on small parts from these products. Now virtually no such deaths are reported. Although a relatively simple rule, its impact is pervasive since it applies to virtually all items intended for children under three years of age. This means that nearly every manufacturer of every juvenile product for children of this age group relies on CPSC's small parts regulation -- not to mention the parents of these children. Yet, the bill would cast the future of this rule in doubt.

In a very odd provision, the Clinger substitute increases uncertainty even further by allowing a "non-agency party" to pick and choose which terminated rules would apply (§ 11(a)(2)). This creates a "through the looking glass" world where no one knows which rules apply to whom, a nightmare for agencies and regulated industries alike.

E. FALSE ASSUMPTION 5: OIRA Can and Should Control
Regulatory Review.

The Clinger substitute differs from the previous version of H.R. 994 in the tremendous authority it gives to the Administrator of the Office of Information and Regulatory Affairs ("OIRA") of the Office of Management and Budget ("OMB"). The Administrator is responsible for determining which rules are "covered rules" (§ 4(a) and (b)); which petitions will be accepted (§ 4(c)); and which Congressional requests for review

will be accepted (§ 4(d)). After making these initial decisions, the Administrator must inventory all existing rules and issue a list of those to be reviewed (§ 6(a)(1)(A)); group the significant and related rules to determine their termination dates (§ 6(a)(2) and (3)); provide guidance to agencies conducting the reviews (§ 6(a)(4)); and review and evaluate each preliminary and final report that agencies develop (§ 6(a)(5)). The Administrator also determines whether to accept the agency's recommendation for each rule the agency reviews (§ 6(c)) and whether to extend the termination date for any covered rules (§ 7(b)).

The time periods dictated for the OIRA Administrator's actions are so short that they would require either a colossal staff or superhuman efforts. The Administrator has only 90 days to decide petitions, with a 30 day extension possible (§ 4(c)(4)); 30 days to designate a Congressional request for review (§ 4(d)(1)); and a mere 6 months to inventory all existing rules and decide which are covered (§ 6(a)(1)(A)). Moreover, the Administrator is required to update the list of rules for review annually (§ 6(a)(1)(B)).

The bill assumes that OIRA has the expertise to make decisions that involve the substance of often complex regulations. When the Administrator receives a petition for review of a highly technical regulation, how will he or she be able to determine whether it is reasonable to review the regulation? The likely result is that most petitions will be

accepted. And if the Administrator is overwhelmed, as is likely, the petition could be deemed granted when the Administrator has not acted within 120 days (§ 4(c)(5)). The tremendous paperwork burden would then shift to the agencies which must review the flood of rules brought in by petitioners in addition to other regulations already scheduled. ✓

The bill gives the Administrator significant authority to prioritize the review of rules. It provides a list of criteria for the Administrator to consider, but these really give little guidance (see § 6(a)(2)(B)). Some of the criteria seem to drive the Administrator to questionable priorities. For example, while other regulatory reform bills are encouraging rules that provide greater flexibility for industry compliance, this one demands quicker review for rules issued under statutory provisions that give the agency greater discretion (see § 6(a)(2)(B)(v)). Yet, such statutory provisions are precisely those that allow the agency to issue flexible rules.

As an independent agency, the extensive role the bill gives the Administrator is particularly troubling to CPSC. Through OIRA, the bill would greatly expand OMB's influence on independent agencies. This politicizes the ongoing process of regulatory review, and fundamentally changes the independent status of agencies like CPSC. ✓

Conclusion

We believe that the premises underlying this and other lookback and sunset legislation are ill-conceived. The presumptions that rules are obsolete when they have achieved results, that more analysis is always better, and that terminating rules necessarily helps industry, are seriously flawed. These faulty assumptions drive a process that elevates paperwork over safety, and quick elimination of rules over thoughtful consideration. Contrary to the legitimate goals of regulatory reform, this approach denies agencies the ability to define appropriate priorities, wastes resources on unnecessary reviews, and virtually ensures that measures responsible for saving consumers' lives will be eliminated. In short, the approach in H.R. 994 and similar bills would sacrifice public safety through added bureaucracy and red tape.

The specific flaws of the Clinger substitute are too numerous to fully identify in this paper. We have discussed only the most important ones. The bill's provisions only exacerbate the general problems we have identified, taking a shaky concept and making it completely unworkable.

H.R. 994 is an excellent example of the regulatory approach which Philip K. Howard denounced in his book, The Death of Common Sense. He said, "[r]ules have replaced thinking. Process has replaced responsibility." As a result, "[g]overnment accomplishes almost nothing." H.R. 994 should be rejected.

**CPSC STAFF ADDENDUM TO STATEMENT ON H.R. 994,
AS REPORTED BY THE COMMITTEE
ON GOVERNMENT REFORM AND OVERSIGHT**

I. Intent.

The evident purpose of this legislation is to require periodic reviews of existing regulations with an eye towards modifying or eliminating them. The probable intended effect of this review is to eliminate many regulations and to reduce the scope or specificity of others. The role of the Administrator of the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget (OMB) in this review process is dramatically expanded by the legislation.

II.. Sections 3 and 7(a)(1) provide that all existing covered rules terminate on the 4, 5, 6, or 7 year anniversaries of the date of the enactment of the legislation, depending on how the OIRA Administrator assigns them.

- A. The term "rule" is defined (Section 13(4)(a)) so broadly that it will include many interpretative and guidance rules, dramatically increasing the workload of agencies and of the Administrator of OIRA.
- B. The term rule is also expanded by the characterization that a set of rules designated in the Code of Federal Regulations as a part consists of one rule for purposes of review under the new legislation (Section 13(4)(B)). This characterization of a rule could be very burdensome in some cases. For example, Part 1500 of Title 16 of the Code of Federal Regulations concerns Consumer Product Safety Commission regulations under the Federal Hazardous Substances Act and occupies 84 single-spaced, small print pages. Reviewing such a wide-ranging and detailed set of regulations as if they were a single rule will be burdensome.
- C. "Covered rules" are defined by Section 4.
 - 1. Annual effect on the economy of \$100 million or more (Section 4(b)(1)). Since an entire part of the Code of Federal Regulations is treated as a single rule, many groups of rules may well meet this monetary threshold.
 - 2. Major rules as defined by two Reagan Administration Executive Orders.
 - a. Major rule as defined by Executive Order 12291, as of the first date that that Executive Order went into effect. (Section 4(b)(2)). Such a definition excludes interpretations that were developed during the period of time (approximately 12 years) that Executive Order 12291 was in effect.

- b. A rule issued pursuant to a significant regulatory action, as defined by Executive Order 12866 (Section 4(b)(3)), also as of the first date that that Executive Order went into effect. Any interpretations of that Executive Order would be excluded by such a definition.
 - c. The term "major rule" in Executive Order 12291 and "significant regulatory action" in Executive Order 12866 are ambiguous. This ambiguity was not too burdensome in the case of the two executive orders because they applied only to new rules, but this legislation applies to a great number of previously issued rules, to which the criteria of the executive orders will have to be applied.
3. A rule designated as a covered rule by the OIRA Administrator.
- a. Such designation may be in response to a petition filed pursuant to Section 4(c). There are a number of problems associated with this petition procedure.
 - i. The burden is on the OIRA Administrator to find that the rule is not a covered rule. If petitioners do not bear the burden of proving that a rule is a covered rule, there is virtually no reason not to file petitions.
 - ii. The universe of people able to file petitions is vast: the only requirement is that the person be adversely affected and there is no explicit requirement that that allegation be included in the petition itself.
 - iii. If the petition is defective the OIRA Administrator is required to advise the petitioner about how to formulate a petition that does meet the requirements. Rather than go into the "petitioner education business," the OIRA Administrator is likely simply to grant the petition and list the rule as a covered rule.
 - iv. The \$20 filing fee is extremely low and will not even begin to cover the costs of deciding on the petition, let alone conducting the review.
 - v. The OIRA Administrator is required to "take into account" the number and nature of other petitions received on the same rule. But the legislation is silent on

how the OIRA Administrator is supposed to take them into account. If there have been a lot of petitions that have been denied, should the Administrator regard the latest as just one more candidate for the "round file?" Or is the fact that a lot of petitions have been filed supposed to influence the OIRA Administrator to believe that "where there's smoke, there's fire," and grant the latest version?

- vi. The petition procedure applies only to rules that are not significant rules: presumably one cannot petition to have a significant rule reviewed "out of turn." This raises the question of just what significance a "significant" rule has.
- b. Petitions may be deemed granted if not acted upon within 120 days. (Section 4(c)(4) and (5)). There are a number of problems with this section.
- i. Since the burden is on the OIRA Administrator to affirmatively come up with reasons to deny the petition within 120 days, the tendency will be simply to grant the vast majority of petitions. Such a mass of petitions could overwhelm both the agencies and the OIRA Administrator as they start coming up for sunset review in 4 to 7 years. The true concept of a covered rule is apt to be lost.
 - ii. The legislation subjects the delay in acting on a petition to review by "a court," without specifying which court it is to be. This will almost invariably lead to inconsistent decisions around the country in interpreting this provision.
- c. Action by or within a Congressional Committee can trigger review by the OIRA Administrator to determine whether a rule is a covered rule (Section 4(d)(1) and (2)). There are some problems, or at least anomalies, associated with this subsection.
- i. The Committee can act in one of three ways: (1) by a majority of the Members; (2) by a majority of the Committee's majority party members; or (3) by a majority of the Committee's minority party members. This is a strange way to enable a Committee to act: if a

majority of either the majority or minority party members can request such a designation, why would a Committee chairman ever put such a request on the agenda?

- ii. Although the Administrator is authorized to deny the Congressional request, the legislation states no criteria by which the Administrator is supposed to assess it. In addition, the Congressional request route to review is limited to rules that are not significant. It is more likely that Congressional committees will want the agencies reviewing significant rules out of turn than rules that are not significant.
 - iii. Explicitly enabling Congressional committees to act separately to trigger substantive action within the Executive Branch runs a subtle but real risk of "balkanizing" the agencies, with each agency responsible to its own committee constituency. Committees are often not representative of the Congress as a whole and may drive action in a direction different from that of the entire Congress. Congress should not saddle future Administration with the burden of constantly reviewing substantive rules in response to congressional committee requests.
- d. Section 7(a)(3) provides for expedited review for rules that become covered rules by either petition or congressional committee request.
- i. Part of the point of having covered rules is to review those rules that have the greatest impact first. By giving review priority to those rules that become covered rules because of petitions or congressional request, which must not be significant rules, those priorities can be bypassed rather easily and new priorities given to "insignificant" rules. If rules become covered rules by reason of petitions or congressional requests, they should be "put in line" with the other rules and not be allowed to jump to the head of the line.
 - ii. Moving rules that become covered rules to the head of the line for review defeats the elaborate review for prioritization of regulation review called for in Section 6(a)(1)(B).

III. Criteria for Review.

- A. Each regulation undergoing sunset review must be reviewed as if it was a notice of proposed rulemaking (Section 5(a) and (b)).
- B. Cost/benefit analyses, risk analysis and risk assessments must be performed for all regulations undergoing sunset review (Section 5(a)).
- C. While a periodic review even of widely accepted regulations is not necessarily a bad thing, such a review could be much more efficient if it followed these lines for consumer product safety rules.
 - 1. Begin with a search of staff records concerning accidents involving such products, complaints received about such products and the regulations, followed by a Federal Register notice soliciting comments
 - 2. After evaluating the comments, the decision could be made whether to proceed with a full-scale review, including a cost-benefit analysis, or whether, as will probably be most often the case, to simply continue the regulation without modification.
 - 3. A resource-intensive, full-fledged "de novo" review of the regulation, in the absence of significant complaints about or problems with the rule, would be a waste of resources and would probably not even be supported by the industries producing the regulated products.

IV. All of the time periods set forth in the bill are unreasonably short.

- A. Section 6(b)(1) contemplates that the review process will begin 2 1/2 years before the regulation is terminated.
- B. Since the statute also contemplates that the review will be just as extensive as if the existing rule was a notice of proposed rulemaking, it should be noted that many rules, especially in the environmental area, take longer than 2 1/2 years to promulgate. Either the review will have to be shorter than the time ordinarily taken to actually promulgate new regulations, or more time than 2 1/2 years is going to have to be allocated for sunset review.
- C. The legislation provides that a new rule comes up for "sunset review" within three years after it takes effect (Section 7(a)(2)). If an agency has just finished the process of promulgating a regulation and making it effective, what is the point of making them begin the process all over again? If the objective of this legislation is sunseting regulations that have outlived their usefulness, what is the point of beginning the sunset process for rules for which the "sun has just

risen?" There will, after all, be little or no record beyond that which the agency has just developed in deciding to promulgate the regulation.

- D. If H.R. 994 is itself "sunsetting" after 10 years, the timing of review will become quite complicated after the first three years. Should agencies schedule regulations for review in years in which the act mandating and authorizing such review will, by its own terms, have expired?
- V. Under some circumstances even a terminated rule can be resurrected (Section 11(a)(2)).
- A. The ability of a party in an agency proceeding or court action to give legal effect to an otherwise terminated rule could lead to big problems. What happens if there are multiple non-governmental parties to an agency proceeding or court action and some of them want legal effect given to the terminated rule and others do not?
- B. There is another problem that will occur if regulations are terminated because of failure to get them reviewed and approved through the new process, but the underlying act remains in effect. In such a case, the regulated industries would have to "obey the law," without the benefit of the (now sunsetted) interpretive regulations. Such a result could lead to more arbitrary enforcement of the law, since the interpretive regulations will no longer exist.
- VI. The Administrator of OIRA plays a crucial role in this review process: if this legislation became law the Administrator would be one of the most powerful persons in the government, second only to the President in the area of domestic policy. This authority is particularly troubling for independent agencies like the CPSC.
- A. The Administrator of OIRA is allowed to give advice to agencies on the "front end" of the review process (Section 6(a)(4) and 6(b)(1)(B)).
- B. The Administrator of OIRA has great discretion in assigning to the agencies the rules to be reviewed for termination (Section 6(a)(1), (2) and (3)).
- C. The Administrator of OIRA is also the person who reviews the report produced by the agency at the end of the sunset review process (Section 6(a)(5)). The Administrator has the authority to substitute his or her judgment for that of the head of the agency as to what changes should be made to a regulation that has been the subject of a sunset review (Section 6(a)(5)(C), 6(c) and (d)).
- D. The Administrator of OIRA's concurrence is required to consider regulations out of their normal turn. (Section 7(o)).

- E. The Agency Regulatory Review Officers that the legislation directs be appointed report not only to the agency head, but also to the Administrator of OIRA (Section 9). This bifurcation of reporting responsibility between both the agency head and the Administrator of OIRA puts the Agency Regulatory Review Officers in an almost impossible position, since the Administrator of OIRA has explicit authority to overrule the agency heads on decisions of regulatory modification and termination. "No man can serve two masters."
- F. The great power and discretion granted to the Administrator of OIRA and the ability of the Administrator of OIRA to substitute his or her judgement for that of the agency head is the single biggest feature of this legislation. Under the previous Reagan Administration Executive Orders, the only power that the Administrator of OIRA had was to determine that a particular rule was not consistent with the President's regulatory agenda. Regulations could be and were issued even without that determination (e.g., the September 1991 issuance of the Municipal Solid Waste Landfill regulations). This legislation is a huge grant of authority to the Administrator of OIRA. OIRA will have to grow significantly in order to carry out this function, and will become a general regulatory clearinghouse (or bottleneck) for regulations undergoing sunset review.
- G. In some cases, the review ordinarily exercised by the Administrator of OIRA can be assigned to "another officer designated by the President" (Section 6(c) and (d)).
1. All of the observations about the authority that the OIRA Administrator has also apply to officials receiving such ad hoc appointments.
 2. The accountability of an official appointed under an ad hoc arrangement for review of a specific rule is likely to be limited.
 3. There is little guarantee that officials appointed for such specific purposes and under such ad hoc arrangements will have the breadth of understanding and experience necessary to reach balanced and informed judgments about particular regulations.
 4. The appointment of other such officers may require Senate confirmation because of the appointments clause of the Constitution (Art. II, Section 2, clause 2).
- H. The resources assigned to the Office of Information and Regulatory Affairs are going to have to grow exponentially to keep up with the flood of regulatory review work that will occur if this legislation becomes law. Note particularly

that the Administrator of OIRA is required to review both preliminary and final regulatory review reports that agencies submit (Section 6(a)(5)).

- VII. Miscellaneous comment. Section 5(b): This "conflict resolution" section turns in on itself by postulating an irreconcilable conflict between "such applicable" requirements and some other law, and proceeds to fail to resolve it when it states that the agency should review the regulation as if it were issuing a new regulation. Such a direction simply does not adequately resolve an irreconcilable conflict.

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U.S. House of Representatives
Committee on Commerce
 Room 2125, Rayburn House Office Building
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JAMES E. SENDERIAN, CHIEF OF STAFF

Guests for H.R. 994 Staff Briefing

2123 Rayburn, 9:30a.m.
 November 3, 1995

- OMB: Sally Katzen, Administrator, Office of Information and Regulatory Affairs
- CPSC: Eric Rubel, Agency General Counsel (301/504-0980)
- NRC: Martin Malsch, Deputy General Counsel
- DOE: Eric Fygi, Deputy General Counsel & Romey Diaz, General Counsel's Office
- DOT: Neil Eisner, General Counsel's Office (366-4723)
- FTC: Maryann Kane, Office of Congressional Relations (326-2195)
- EPA: Lynn Ross, Office of Congressional Affairs *Gary Guzy 260-7960*
- SEC: *Kate Fulton 202-942-~~8014~~ 0014*
- FDA: Diane Thompson (301/443-3793) sent a representative

DRAFT

March 1, 1996
(House Floor)

H.R. 994 - Small Business Growth and Administrative
Accountability Act of 1996
(Chapman (D) TX and 48 cosponsors)

The Administration supports judicial review of agencies' regulatory flexibility analyses. The Administration, however, has concerns about a one year statute of limitations where a shorter period of review for the final agency action is provided by law. Moreover, the statute of limitations should begin after the publication date of the regulation, not the effective date.

The Administration also supports the concept of legislative branch accountability for regulations, and for that reason, has endorsed a limited period of review by the Congress of rules before they take effect. The Administration, however, opposes extending this review period from the 45 days provided in the Senate passed bill (S. 219) to 60 days in this legislation.

The Administration is committed to administrative review of existing regulations and to eliminating those that are outdated, ineffective, or unduly burdensome. The substitute amendment to H.R. 994, however, does not provide an effective or workable means of achieving this goal. The Administration strongly opposes the substitute amendment to H.R. 994 because, among other things:

- The scope is overly broad. The bill's definition of "major rule" and "covered rule" encompasses virtually every rule in the existing Code of Federal Regulations, many of which are non-controversial, insignificant, or otherwise do not warrant review.
- The review process is overly prescriptive and burdensome. Agencies will be tied in knots while trying to comply with the bill's burdensome and elaborate review procedures. H.R. 994 prescribes detailed requirements for each step, including initial designation of rules, review and analysis, solicitation and consideration of public comments, as well as full rulemaking proceedings. These procedures would have

to be followed even where the agency's analysis indicates that the rule should be continued without change. There is, in addition, a petition process that would force agencies to devote resources to reviewing less significant rules before more significant rules.

- Excessive litigation would result. The bill would create numerous new opportunities for judicial review, thus introducing additional delay, cost, and uncertainty.
- Agency resources would be drained. Administration experience with review of existing regulations has shown that such a review, when thoroughly done, is very time consuming and expensive. Under this bill, these costs would be imposed on agencies, for potentially every regulation in the Code of Federal Regulations, at a time when many agencies are experiencing large budget reductions.

On the basis of these objections, if the substitute amendment to H.R. 994 were presented to the President, the Director of the Office of Management and Budget and the Secretaries of Education, Energy, Health and Human Services, Labor, Transportation, the Treasury, and Veterans Affairs, and the Administrator of the Environmental Protection Agency would recommend that it be vetoed.

* * * * *

THE WHITE HOUSE

WASHINGTON

March 5, 1996

MEMORANDUM FOR MEMBERS OF CONGRESS

FROM:

JOHN HILLEY *JH*
ASSISTANT TO THE PRESIDENT AND
DIRECTOR OF LEGISLATIVE AFFAIRS

SUBJECT:

H.R. 994, THE SMALL BUSINESS GROWTH AND
ADMINISTRATIVE ACCOUNTABILITY ACT OF 1996

Enclosed for your information are materials to assist Members during the House of Representatives's consideration of H.R. 994, the Small Business Growth and Administrative Accountability Act of 1996. Included is a briefing paper on the impacts of Title II of H.R. 994, an assessment of the Clinger/Hyde substitute to H.R. 994, and the Statement of the Administration's Policy on H.R. 994. I hope you find this information useful during the upcoming debate.

Please do not hesitate to contact the Office of Legislative Affairs if you have any questions or require further assistance.

BACKGROUND ON IMPACTS OF H.R. 994, TITLE II THE HYDE/CLINGER SUBSTITUTE

March 5, 1996

OVERVIEW

Under Title II of the Hyde/Clinger Substitute to H.R. 994, virtually every rule in the Code of Federal Regulations (C.F.R.) would be subject to review, whether or not the rule was controversial or a review made sense. Careful and thorough reviews of existing rules would be at huge expense to the agencies, diverting increasingly scarce resources from other critical activities such as protecting health, safety, and the environment. Furthermore, the bill's petition process would force agencies to review less significant rules before major rules which may be more worthy of review.

SUMMARY OF H.R. 994, TITLE II

- o Existing rules would be reviewed to determine whether they should be continued, modified, or repealed. If the detailed multi-step process for a rule is not completed by a certain deadline, the rule could be suspended.
- o Covered rules include: (1) major rules having an annual effect on the economy of \$100 million or more; (2) rules designated by petition or Congressional request; and (3) any group of rules that form a part of the C.F.R. Virtually all rules and related materials would meet one of these tests and qualify for review.
- o Covered rules would have to be reviewed within 4-9 years. New significant rules must be reviewed within 7 years of their effective date.
- o Agency decisions to continue, consolidate or modify existing rules as well as OMB decisions to deny petitions would be subject to judicial review.

EFFECTS OF THE LEGISLATION

As a consequence of the burdensome procedures in this title, several serious problems would result from enactment of this provision:

- (1) Limited agency resources would be diverted to expensive and unnecessary reviews and away from higher priority activities;
- (2) Burdensome procedures would waste the taxpayers' money, create a costly new bureaucracy, and spawn excessive litigation;
- (3) Sensible rules that protect the public could be struck from the books.

BILL EXPENDS EFFORT ON RULES THAT DO NOT NEED REVIEW

Many existing rules are not controversial and do not need to be subjected to a formal review. However, under Title II of the Hyde/Clinger Substitute to H.R. 994, such reviews would have to be conducted anyway, squandering limited agency resources. For example:

- o Phase-out of lead in gasoline.

One of the greatest environmental successes has been the reduction of air emissions due to the phase-out of lead in gasoline. Exposure to lead in childhood can impair brain functions and perceptions. Since promulgation of the rule by EPA, lead emissions have dropped 98% since 1970 and the level of lead in the blood of children has dropped dramatically.

- o Refrigerator safety latches.

Since the 1950s, the Consumer Product Safety Commission (CPSC) has required safety latches that permit refrigerators to be opened from the inside to prevent children from becoming fatally trapped inside discarded refrigerators. As a result, there is currently little risk of children becoming trapped inside refrigerators, although prior to the adoption of this rule 30-40 children a year died in this manner.

- o Seat belts.

Lap and shoulder belts in passenger cars have been required since 1968 and in light trucks a few years later. Seat belts are widely accepted by the public and the industry and have had a great safety impact. For example, DOT estimates that 9,175 lives were saved in 1994 because of seat belt usage.

- o Nutrition labeling.

Nutrition labels now appear on most food products and have broad public support. Use of labels by consumers is expected to contribute substantially to healthier diets and lower incidence of disease.

- o Guidance documents.

H.R. 994 requires the review of agency guidance and other documents that are often intended to provide useful information to the public. Examples of guidance documents that would not make sense to put through an elaborate or costly review include: FDA documents for small business about clinical test procedures, manufacturing processes, and scientific protocols; and EPA documents showing business how they can save money through voluntary, energy efficiency measures.

THIS BILL CREATES BUREAUCRACY AND WASTES TAXPAYERS' MONEY

- o Numerous reviews would be required.

Because of the exhaustive language in the definition of a major rule, just about every rule that exists currently could be subject to review. In addition, H.R. 994 allows each "part" of the C.F.R. (an enumerated group of rules on a related subject) to be reviewed as a single rule, with the result that almost every "part" of the C.F.R. would qualify as a major rule under the \$100 million threshold test. **Since there are approximately 9,300 parts to the C.F.R., the government could have to perform hundreds of reviews a year to meet even the bill's longest deadline (9 years).**

- o Special interest petitioning would drive decision-making.

In addition to the scheduled review of major rules, any interested party can petition to have a rule reviewed. Because these rules must be reviewed before major rules on the agency's review schedule, this process permits private parties to dictate agency priorities.

- o The potential costs of all the reviews are potentially huge.

The CBO assumed that agencies would only have to review 50 regulations a year at \$75,000 a regulation for a total cost of \$4 million. However, preliminary agency projections from eight agencies (DOE, USDA, HHS, DOL, DOI, EPA, Education and the Treasury) using mid-range estimates of costs indicate that the review of rules under Title II would require **over 2,000 Federal employees with total costs exceeding \$400 million a year.** If guidance documents and other agency documents are included, hundreds of additional workers and hundreds of millions of dollars in additional costs would be required.

- o Thorough reviews of major rules can be resource intensive.

For example, the Department of Commerce (DOC) recently concluded a re-write of the Export Administration's Regulations (EAR). The new requirements will greatly streamline the export process. **However, review of this single rule took three years and cost DOC \$1.75 million.** In another case, the Department of Labor undertook a careful and comprehensive review of coal mine ventilation regulations. **The publication of the revised final rule took several years to complete and cost \$5.2 million.**

- o H.R. 994 creates opportunities for costly and burdensome litigation.

The bill creates numerous opportunities for judicial review of agency decisions to continue, consolidate, or modify rules as well as OMB decisions to deny petitions.

THE BILL COULD ROLLBACK RULES THAT SERVE THE PUBLIC

Title II of the Hyde/Clinger Substitute to H.R. 994 would require an immense number of rules to be reviewed in a comparatively short period of time with an enormous cost relative to agency resources. If all of the deadlines are not met, it could result in suspension of the rule.

Accordingly, the bill is likely to result in a rollback of existing rules that are important to the public health and safety. Examples of some valuable rules that could be threatened follow:

- o Blood supply standards.

These FDA regulations protect the nation's blood supply from infectious diseases. Examples include AIDS and hepatitis.

- o Clean Water Act effluent guidelines.

The Clean Water Act requires national minimum performance standards, or effluent standards, for over 50 industrial categories. These guidelines result in the removal of over four billion pounds of pollution from industrial discharges each day, including over one billion pounds of toxics per year.

- o Toxic Releases.

Under the Emergency Planning and Community Right-to-Know Act of 1986 and the Pollution Prevention Act of 1990, manufacturing facilities are required to provide information to the public about releases of toxic chemicals into the environment. This information is gathered into EPA's Toxic Release Inventory (TRI) database. Since 1988, national toxic releases have declined by 42.7%.

- o Child-resistant cigarette lighters.

CPSC has issued a safety rule establishing requirements to make disposable cigarette lighters child-resistant. Fires started by children under the age of five cause an average of 150 deaths, 1,100 injuries, and nearly \$70 million in property damage.

- o "Brown lung" disease.

In 1978 OSHA issued a standard to protect textile workers from "brown lung" -- a crippling and sometimes fatal disease. By 1985 the prevalence of the disease has declined from 40,000 cases to 900 cases, or less than 1% of textile workers.

- o Mammography quality standards.

These regulations ensure high quality mammography, currently the most effective method for detecting breast cancer. According to the most conservative estimate, 200 lives a year could be saved by these regulations.

- o Mine explosions and fires

Ventilation standards issued by the Mine Safety and Health Administration for underground coal mines prevent the accumulation of methane and coal dust-fuel for explosions and fires. In the 25 years before passage of the Coal Mine Health and Safety Act of 1969, 901 miners were killed in explosions. In the 25 years after the Act was passed, explosions claimed only 133 miners.

ASSESSMENT OF THE CLINGER/HYDE SUBSTITUTE TO H.R. 994

March 5, 1995

The Substitute would force agencies to reopen virtually every rule on the books, as well as guidance, manuals, and other agency interpretive materials, and engage in elaborate and expensive review and rulemaking processes, even for rules that are non-controversial and that are effectively doing the job they were intended to do. The result will be to tie agencies in knots, drain increasingly scarce agency resources, and subject agencies and our already overburdened courts to a flurry of new lawsuits. The following assessment focuses on the provisions of the most serious concern:

- **Overly Broad Scope.** The Substitute defines as "covered rules" (sec. 204(a); 205(a)(3)(B)) for purposes of review: (1) major rules (\$100 million annual effect, major increase in prices, or significant adverse effects); (2) rules designated in response to petitions or congressional requests; and (3) related rules ("necessary for a comprehensive review"). This definition encompasses virtually every rule on the books. Even more troubling is that to the extent that the definition of major rule is intended to have any limits, those limits are vitiated by the Substitute's extraordinarily broad definition of "rule" (sec. 214(6)), which includes guidance documents, policy statements, and other interpretive materials and which establishes that "each set of rules designated in the CFR as a part shall be treated as one rule."
- **Burdensome Petition Process.** The Substitute creates a petition process (sec. 203(c)) through which private parties can request that agencies review "non-major" rules. The petition process is problematic for several reasons:
 - First, the threshold for review is too low -- the OIRA Administrator (who would have to review all petitions) must grant the petition and designate the rule for review unless "it would not be in the public interest" to do so.
 - Second, the bill provides for extremely tight deadlines for OMB's response (30 days to tell non-compliant petitioners how to rewrite their petitions, 90 days to respond to petitions on the merits, 30 days for congressional requests). Failure to respond by the deadline as well as any denials of petitions would lead to litigation that would drain OMB

resources.

-- Finally, the requirement that a rule reviewed as a result of a petition (by definition a non-major rule) must be reviewed within 4 years gives less significant rules priority over major rules that are more worthy of review.

- Burdensome and Unreasonable Review Procedures. The Substitute requires that all existing major rules must be reviewed within 5-9 years. New significant rules promulgated after enactment must be reviewed within 7 years of their effective date. Rules subject to review as a result of petitions or congressional requests must also be reviewed within 4 years (sec. 206). These deadlines may be impossible to meet considering the workload involved. It will be both exceedingly difficult and expensive for agencies to conduct the many complex and detailed assessments and to comply with the multiple procedural steps that will be required
- Arbitrary and Dangerous Suspension Procedure. Permitting courts to suspend rules (sec. 211(d)(3)) if an agency fails to complete review by the deadline is unreasonably harsh and dangerous -- important health and safety rules would be erased from the code for no other reason than a deadline was missed. This is contrary to reasoned rulemaking and the public interest.
- Arbitrary Restriction on Future Regulatory Improvements. The Substitute will make it extremely difficult for an agency to conduct "a comprehensive review and significant revision" of a rule more frequently than every 7 years (sec. 206(b)). This could seriously undermine continuing efforts to streamline and reform rules.
- Overly Burdensome and Prescriptive Review Requirements. The Substitute establishes a rigid and complex set of procedural steps that agencies and OMB must follow in conducting the reviews (sec. 205). It is a classic "one-size-fits-all" approach that would result in enormous unproductive make-work. In addition, the Substitute requires that agencies follow detailed and specific formats in issuing notices and reports as part of the review (sec. 207).

More importantly, even for rules the agency decides to continue without change (and there are many that are non-controversial and widely accepted rules where change is unwarranted), it must still publish a notice of proposed rulemaking and complete a full rulemaking. This is an especially unproductive drain on resources.

- Loss of Agency Discretion to OIRA. The Substitute creates numerous new responsibilities and powers for the Administrator of OIRA which OIRA does not have the resources, FTEs, or, in some cases, the expertise to carry out. Of particular concern to agencies are provisions giving OIRA authority to: (1) grant

petitions (sec. 204(c)); (2) determine whether particular existing rules should be reviewed in 5, 6, 7, 8, or 9 years (sec. 205(a)); and (3) veto agency decisions whether rules should be continued unchanged, modified, or consolidated with other rules (sec. 208(c)).

- **Excessive Litigation.** The Substitute creates numerous new opportunities for judicial review of agency decisions to continue, modify, or consolidate rules as well as OIRA's decisions to deny petitions for review or alleged delay in responding to petitions (sec. 211). This provision will subject agencies to an endless stream of costly court cases, further burdening our already overstretched court system and delaying the implementation of real regulatory reform.
- **Enormous Drain on Dwindling Agency Resources.** Under the Substitute, agencies would have to: (1) continuously conduct multi-step, burdensome reviews of almost all their rules; (2) regularly complete the full rulemaking process, even for those non-controversial or widely accepted rules that should be retained without change; (3) continue to handle everyday responsibilities responding to new legislation and new problems; and (4) respond to increasing litigation. All this while agency resources are not meeting current demand.



March 1, 1996
(House)

STATEMENT OF ADMINISTRATION POLICY

(THIS STATEMENT HAS BEEN COORDINATED BY OMB WITH THE CONCERNED AGENCIES.)

H.R. 994 - Small Business Growth and Administrative
Accountability Act of 1996
(The Clinger/Hyde substitute)

The Administration supports judicial review of agencies' regulatory flexibility analyses. The Administration, however, has concerns about a one-year statute of limitations where a shorter period of review for the final agency action is provided by law. Moreover, the statute of limitations should begin after the publication date of the regulation, not the effective date.

The Administration also supports the concept of legislative branch accountability for regulations and, for that reason, has endorsed a limited period of review by the Congress of rules before they take effect. The Administration, however, opposes extending this review period from the 45 days provided in the Senate-passed bill (S. 219) to 60 days in this legislation, and objects to its retroactive application.

The Administration is committed to administrative review of existing regulations and to eliminating those that are outdated, ineffective, or unduly burdensome. The substitute amendment to H.R. 994, however, does not provide an effective or workable means of achieving this goal. The Administration strongly opposes the administrative review provisions in H.R. 994 because, among other things:

- The scope is overly broad. The bill's definition of "major rule" and "covered rule" encompasses virtually every rule in the existing Code of Federal Regulations, many of which are non-controversial, insignificant, or otherwise do not warrant review, as well as guidance and other policy documents.
- The review process is overly prescriptive and burdensome. Agencies will be tied in knots while trying to comply with the bill's burdensome and elaborate review procedures. H.R. 994 prescribes detailed requirements for each step, including initial designation of rules, review and analysis, solicitation and consideration of public comments, as well as full rulemaking proceedings. These procedures would have to be followed even when the agency's analysis indicates that the rule should be continued without change. There is, in addition, a petition process that would force agencies to

devote resources to reviewing less significant rules before more significant rules.

- Excessive litigation would result. The bill would create numerous new opportunities for judicial review, thus introducing additional delay, cost, and uncertainty.
- Agency resources would be drained. Administration experience with review of existing regulations has shown that such a review, when thoroughly done, is very time-consuming and expensive. Under this bill, these costs would be imposed on agencies for potentially every regulation in the Code of Federal Regulations, at a time when many agencies are experiencing large budget reductions.
- Important health and safety rules could be suspended. The bill would allow courts to suspend regulations if rulemakings are not completed by a set date. Given the tremendous number of rulemakings that agencies will have to conduct under this bill, important health and safety rules, as well as rules that provide important economic benefits, could be suspended.

On the basis of these objections, if the substitute amendment to H.R. 994 were presented to the President with the provisions regarding administrative review of existing regulations, the Director of the Office of Management and Budget and the Secretaries of Agriculture, Education, Energy, Health and Human Services, the Interior, Labor, Transportation, the Treasury, and Veterans Affairs, and the Administrator of the Environmental Protection Agency and would recommend that it be vetoed.

* * * * *

Environmental Stands Alienate Some Backers Of the GOP's Agenda

Presidential, Congressional Races May See Backlash Because of 'Wedge Issue'

One Antidote: Visit the Zoo

By DENNIS FARNEY and TIMOTHY NOAH
Staff Reporters of THE WALL STREET JOURNAL

COLORADO SPRINGS, Colo. — Andrea Oberschlake, who admires Newt Gingrich's "guts" and winces at the sound of Bill Clinton's name, is Republican to the core. But one thing deeply troubles her about her party: In her view, it's anti-environment.

"Why even have a government if you can't have a planet to practice government on?" asks the 27-year-old medical-assistant trainee.

Computer consultant Ron Stone, also 27 and just as Republican, couldn't agree more. Environmental protection is "a good function of government," he insists. Even as the GOP Congress curbs environmental spending, he argues for increased spending. "Runoff from mines is producing fish with three eyes out here!" he says with some hyperbole.

Republicans don't come more granite-solid than the party faithful who gathered here recently for a Lamar Alexander presidential-campaign rally. Colorado Springs is Republican the way Chicago is Democratic; it's instinctive, bred in the bone. But there is a fault line running through the granite over the environmental issue. The environment will be one of the concerns at the forefront of GOP primaries today in Colorado and New England as well as in Florida and Oregon next Tuesday.

Tension in the GOP

To be sure, there are plenty of people here like Frances Mathews, a crusty 63-year-old retiree whose environmental philosophy is encapsulated by the bumper sticker her car once sported: "If You're Hungry and Out of Work, Eat an Environmentalist." But what is striking, says Bob Gardner, the local GOP county chairman, is "the tension in this community, even within the Republican Party" over the environmental issue.

That tension spells election-year trouble for the GOP. The environment is rapidly developing into a "wedge issue" that threatens Republican candidates.

"I think we should be honest and admit that our party hasn't done a very good job on the environment," says former Tennessee Gov. Alexander in an interview here. "We would have been better off identifying what we're for." Mr. Alexander is the only GOP presidential candidate to talk much about the environment, though Sen. Robert Dole has raised it

Steve Jardig, of the Democratic Senatorial Campaign Committee, heavily credits the environmental issue for January's Democratic victory in Oregon's special Senate election. And he says the issue is popping up in states as diverse as Idaho, Michigan and Georgia. Just yesterday, congressional Democrats and Environmental Protection Agency chief Carol Browner attacked a new, watered-down regulatory-overhaul proposal that Republicans may bring to the House floor today. Within hours, House GOP leaders were considering jettisoning a provision of the bill that environmentalists most oppose—requiring federal agencies to review all "major" regulations within five to nine years or risk court challenges nullifying them.

A Holy Cause

So the question is, can the Republican elephant paint itself green? More important, do Republicans even want to paint themselves green? Many of them came to Washington determined to roll back environmental and other regulations—to them, a holy cause. Furthermore, spokesman Gordon Hensley of the National Republican Senatorial Committee argues that the "war on the West" campaign theme that the GOP used so effectively against Clinton administration environmental policies in 1994 will resonate this fall as well.

So far, a majority of congressional Republicans seem loath to go beyond symbolic gestures.

A House Republican Conference memo warned GOP members in the fall that "the environmentalist lobby and their friends in the eco-terrorist underworld" are working to portray the GOP as "hostile to the survival of every cuddly critter roaming God's green earth." As antidotes, the memo suggested Republican members of Congress do such things as participate in tree-planting ceremonies, pick up highway litter and "become active in your local zoo." And do it fast — "before your opponents can label your efforts 'craven, election year gimmicks.'"

Most Republicans insist theirs is merely a "perceptual problem," according to GOP pollster Linda DiVall. They argue that their overriding purpose is common-sense reforms in such matters as the Superfund and clean-air programs.

The GOP Contract With America didn't even contain the word "environment." But the contract did have sweeping language calling for regulatory overhaul, which inevitably meant cutting environmental regulations. As a result, the House passed bills requiring extensive cost-benefit analysis of new environmental rules, compensation when regulations lower property values and a drastic reduction in

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TUESDAY, MARCH 5, 1996

THE WALL STREET JOURNAL.

Environment Stand Splits GOP

Continued From First Page

wetlands protection, among other things. They also attached to an Environmental Protection Agency spending bill a string of legislative riders blocking enforcement of various clean-air and clean-water rules.

Cutting EPA Funds

Almost all major Republican initiatives have run aground in the more moderate GOP Senate or been vetoed by Mr. Clinton. However, the continuing budget impasse has cut funds for the EPA by 14%. And the GOP majority persuaded the president to sign legislation with a rider that makes it easier for timber companies to cut trees in "old growth" areas of national forests.

Though GOP legislative results remain spotty, the entire legislative culture changed after the 1994 Republican sweep. Colorado Democratic Rep. David Skaggs, a staunch environmentalist, says he could scarcely believe his ears when one House appropriations subcommittee held its initial meeting under the GOP majority early last year. Ideas bandied around that day, he reported to his constituents, included transferring great tracts of national forest land to private landowners, opening the Arctic National Wildlife Refuge to oil exploration, ending all federal energy-conservation programs and terminating all land purchases for national parks, wilderness areas and wildlife refuges for five years.

In entertaining such ideas, drawn from testimony that day by such conservative think tanks as the Cato Institute, the Heritage Foundation and Citizens for a Sound Economy, the Republicans apparently frightened many voters. As Ms. DiVall summed it up in a December memo to industry: "Most disturbing is that 55% of all Republicans do not trust their party when it comes to protecting the environment."

Now some Republicans, including presidential candidates, are scrambling to reposition themselves.

Everglades Restoration

Here in Colorado, Mr. Alexander portrays himself as "a champion of the great American outdoors" — an artfully crafted phrase that seemed designed to appeal, not only to environmentalists, but also to National Rifle Association members and sportsmen's groups like Ducks Unlimited, which tries to preserve duck habitat. Kansas Sen. Dole, fighting for delegate-rich Florida, has proposed a \$200 million measure for Everglades restoration; it recently cleared both houses of Congress. (The Clinton administration has proposed spending more than twice that amount.)

The two other major GOP presidential contenders have shown little enthusiasm for the green agenda. Patrick Buchanan favors eliminating the Endangered Species Act and opening the Arctic National Wildlife Refuge for oil drilling. Steve Forbes backs construction of new nuclear power plants in the U.S. and questions federal measures to restrict greenhouse-gas emissions because they are based on "global-warming theory which is unproven."

But the GOP Senate appropriations committee is preparing to restore as much as \$5 billion to environmental and other high-priority domestic programs. And New York Republican Rep. Sherwood Boehlert, a strong supporter of the environment, says the number of GOP votes for legislation rolling back environmental laws is dwindling. He has hosted a series of "Green Eggs and Ham" breakfasts during the past year, bringing environmental lobbyists and moderate Republicans together in his office to munch bagels and plot ways to block anti-environmental measures.

House Speaker Gingrich, leader of the Republican revolution, himself displays streaks of green at times. A member of the Sierra Club from 1984 to 1990, he has been a supporter of the Endangered Species Act in the past. After a House committee passed a bill significantly narrowing that law, the speaker informed Chairman Don Young, an Alaska Republican, that he wouldn't permit the measure to go to the floor. Mr. Gingrich is now trying to broker a compromise. Just yesterday, he held a news conference with GOP lawmakers at Sterling Forest, a large tract in New Jersey and New York, touting efforts to protect this "environmentally sensitive watershed."

But Mr. Gingrich remains a scourge of the EPA and has called federal environmental policies in general "absurdly expensive" and likely to allocate money on

"emotional and public-relations grounds."

Despite some GOP moderation, the dominant mood among Republican legislators remains strongly anti-environmentalist, particularly in the House. Recently Rep. Helen Chenoweth, a Republican firebrand from Idaho, attacked Clinton administration environmental policy as "a government-sponsored religion" based upon "New Age mysticism, Native American folklore and primitive Earth worship."

Low Marks on Scorecard

When the League of Conservation Voters, the environmental movement's political arm, issued its scorecard for the past congressional session, it gave a record 135 legislators "zero" rankings. All but one were Republicans. The League of Conservation Voters hopes to raise and spend nearly \$2 million in House and Senate campaigns this fall. "The environment hadn't been a partisan issue, but the Republican leadership has made it one."

running attack ads, weighed in heavily on the side of Democrat Ron Wyden in Oregon's special Senate election. Mr. Wyden won by less than 20,000 votes; environmental groups claimed to have turned out as many as 50,000 votes for him. The Sierra Club also will pour money into fall races.

Oregon will again be an environmental battleground when its voters pick a successor to GOP Sen. Mark Hatfield, who is retiring. So will Colorado, where Republicans must defend the open seat of GOP Sen. Hank Brown, also retiring.

Here in Colorado, the environment—particularly the issue of urban sprawl—promises to be a top election issue. The battle lines between the two parties could scarcely be more sharply drawn.

One leading contender for the Colorado GOP Senate nomination is Rep. Wayne Allard, whose 1995 House votes drew a score of eight of a possible 100 from the League of Conservation Voters. Among other things, Mr. Allard supports a proposal that could turn about 270 million acres of Federal Bureau of Land Management land — an acreage more than two times the size of California — back to the states, at state option. Colorado Sen. Ben Nighthorse Campbell, a Democrat-turned-Republican, vows the proposal will pass "over my dead body."

The other leading GOP contender is state Attorney General Gale Norton, who

worked under the controversial James Watt—later to become President Reagan's Interior Secretary — at Denver's Mountain States Legal Foundation. The foundation, the legal spearhead of the "wise use" movement, challenges environmental regulations and champions the rights of Western landowners.

The two leading Democratic candidates, according to a recent poll, are attorney Tom Strickland, a former Sierra Club volunteer, and Denver Councilwoman Ramona Martinez. Mr. Strickland says he is running against "the most environmentally hostile Congress in a quarter-century." Ms. Martinez argued in a recent debate that "you can never go too far . . . to protect our environment."

Here in Colorado Springs, there is no doubt how Mr. Gardner, the El Paso County GOP chairman, will vote. But even he worries about uncontrolled development beyond the city limits. And he apologizes to a visitor for a still-healing open pit that scars the foothills below Pikes Peak. The pit is a leftover from gravel mining.

"Here I am, the leader of one of the most conservative Republican Party organizations in the country," he muses. "But I want to see that pit remediated."

WEDNESDAY, MARCH 6, 1996

Regulatory Overhaul Put Off in House

'Behind in the Debate on the Environment,' GOP Postpones Action

By John E. Yang
Washington Post Staff Writer

Mindful of their party's public image of being harsh on environmental issues, House Republican leaders postponed action yesterday on a measure intended to overhaul the federal regulatory system and ease the burden of red tape on small businesses.

Environmental Protection Agency Administrator Carol M. Browner, environmental groups and some moderate House Republicans had said the measure could restrict the government's ability to protect the environment by giving businesses new ways to challenge federal rules they do not like.

In addition, Senate Republicans began to voice concern about parts of the House bill that would have suspended challenged federal regulations if agencies did not carry out court-ordered reviews in a timely fashion.

Rather than ask House Republicans to vote for a provision that might be modified in the Senate, House leaders decided to wait until the Senate acted, which could come before the end of this week. House consideration of the bill was to have begun yesterday afternoon.

"We're behind in the debate on the environment," House Majority Whip Tom DeLay (R-Tex.) told a small group of reporters over lunch. "We don't want to put our members out there taking a vote one more time that the environmental extremists can twist, turn and misrepresent in campaign ads."

In addition, Rep. Sherwood L. Boehlert (R-N.Y.), a leading House GOP moderate, had indicated he would seek to scale back the bill's requirement for a review of all existing federal regulations. If that effort failed, he said, he would try to delete the entire provision.

DeLay said Boehlert, Government Reform Committee Chairman William F. Clinger Jr. (R-Pa.) and Rep. David McIntosh (R-Ind.), chairman of the Government Reform subcommittee on regulatory affairs, would meet to work out a compromise.

"If we can work something out that makes sense, it's better to do that than go have a fight on the floor," DeLay said.

House Speaker Newt Gingrich (R-Ga.) has taken an interest in trying to rehabilitate the House Republicans' image on environmental issues, damaged last year when they pressed legislation that would have restricted EPA's regulatory powers.

Last week, Gingrich made a rare floor speech in favor of an amend-

ment to spend \$120 million to provide environmental safeguards for the Florida Everglades. The provision, offered by freshman Rep. Mark Foley (R-Fla.), was approved on a 299-to-124 vote.

On Monday, Gingrich was in New Jersey to recognize the combined private, state and federal effort to preserve a 17,000-acre woodland known as the Sterling Forest.

Staff writer Helen Dewar contributed to this report.

THE WALL STREET JOURNAL.

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WEDNESDAY, MARCH 6, 1996

Gingrich Abandons GOP Bill to Revise Regulatory Process

By TIMOTHY NOAH

Staff Reporter of THE WALL STREET JOURNAL

WASHINGTON — House Speaker Newt Gingrich, responding to protests by environmental groups, abruptly withdrew Republicans' latest attempt to forge a compromise on regulatory revision.

Mr. Gingrich's action suggests the party's hopes are rapidly dwindling for passing even a watered-down bill to overhaul the regulatory system.

The newest measure, sponsored by Rep. Henry Hyde (R., Ill.) and William Clinger (R., Pa.), was scheduled to come to the House floor yesterday. But a section in the bill requiring agencies to review every "major" rule within five to nine years, or risk having it nullified by a federal court, stirred up so much opposition from environmental groups that Mr. Gingrich cancelled the vote and asked House Republicans to produce a less controversial version later this month.

Odds are that the two principal House members now assigned the task of working out a compromise bill — Rep. Sherwood Boehlert (R., N.Y.) and Rep. David McIntosh (R., Ind.) — won't succeed. Mr. Boehlert is the House GOP's leading environmental proponent; Mr. McIntosh, a top regulatory official in the Bush White House's competitiveness council, is among his party's fiercest regulatory critics.

Rep. McIntosh, a strong proponent of the regulatory-revision bill, said yesterday that withdrawing the bill was preferable to attempting a hasty compromise. It's "better to pass nothing than to pass a bad bill," he said.

Letter From Monsanto

But Rep. Boehlert said he believes agreement can be reached because Reps. Hyde and Clinger, who will also be in the negotiation, have made "constructive" suggestions to revise the bill. "Business interests don't want to dismantle a quarter-century of progress in environmental legislation that brings some certainty to the process," he said, citing a letter he received yesterday from Monsanto Co. opposing the provision that requires agencies to review regulations.

The National Association of Manufacturers, however, strongly supports the regulatory-review provision, as does House Majority Whip Tom DeLay (R., Texas). If Republican negotiators reach no agreement, House leaders will extract from the bill one or both of two relatively uncontroversial sections and bring these to the floor for a vote.

Impact on Small Business

One provision lets small businesses petition agencies to calculate the impact of new rules on them; the other grants Congress 60 days to reject new regulations before they take effect. The Senate is preparing to pass both provisions, possibly as early as this week.

Separately, Sen. Carl Levin (D., Mich.) has been negotiating with the Business Roundtable on language for a regulatory-revision bill. But at a White House meeting with Sen. Levin Friday, Chief of Staff Leon Panetta showed little enthusiasm for this effort. And an aide to Sen. Levin said the two sides haven't reached agreement.



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

July 10, 1995
(Senate)

STATEMENT OF ADMINISTRATION POLICY

(THIS STATEMENT HAS BEEN COORDINATED BY OMB WITH THE CONCERNED AGENCIES.)

S. 343 - Comprehensive Regulatory Reform Act of 1995

(Dole (R) KS and 29 cosponsors)

The Administration strongly supports the enactment of cost-benefit analysis and risk assessment legislation that would improve the regulatory system. S. 343, however, is not such a bill. Because the cumulative effect of its provisions would burden the regulatory system with additional paperwork, unnecessary costs, significant delay, and excessive litigation, the Secretaries of Labor, Agriculture, Health and Human Services, Housing and Urban Development, Transportation, the Treasury, and the Interior, the Administrator of the Environmental Protection Agency, and the Director of the Office of Management and Budget would recommend that the President veto S. 343 in its present form.

The Administration is particularly concerned that S. 343 could lead to:

- Unsound Regulatory Decisions. A regulatory reform bill should promote the development of more sensible regulations. S. 343, however, could require agencies to issue unsound regulations. It would force agencies to choose the least costly regulatory alternative available to them, even if spending a few more dollars would yield substantially greater benefits. It would also prevent agencies responsible for protecting public health, safety, or the environment from issuing regulations unless they can demonstrate a "significant" reduction in risk -- even if the benefits from a small reduction in risk exceed the costs. Both of these features would hinder, rather than promote, the development of cost-beneficial, cost-effective regulations. In addition, S. 343 could be construed to constitute a supermandate that would override existing statutory requirements indiscriminately.
- Excessive Litigation. While it is appropriate for courts to review final agency action to determine whether, taken as a whole, the action meets the requisite standards, S. 343 would increase opportunities for lawsuits and allow challenges to

agency action that is not yet final. Further, by needlessly altering numerous features of the Administrative Procedure Act, S. 343 could engender a substantial number of lawsuits concerning the meaning of changes to well-established law.

- A Backdoor Regulatory Moratorium. S. 343 would take effect immediately upon enactment, consequently leading to an unnecessary and time-consuming disruption of the rulemaking process. It would require proposed regulations that have already been through notice and comment, and are based on cost-benefit analysis, to begin the process all over again because of an agency's unknowing failure to follow one of the many new procedures in the bill.
- The Unproductive Use of Analytic Resources in Issuing New Rules. Since the mid-1970s, Presidents of both parties have selected \$100 million as the line of demarcation between that which warrants full-blown regulatory analysis and that which does not. Because cost-benefit and risk analyses can be costly and time-consuming, the Administration believes that \$100 million continues to be the appropriate threshold. S. 343, however, has as its threshold \$50 million --a decision that would require agencies to use their resources unproductively and that therefore cannot itself withstand cost-benefit scrutiny.
- Agencies Overwhelmed with Petitions and the Lapsing of Effective Regulations. S. 343 creates numerous, often highly-convoluted petition processes that, taken together, could create opportunities for special interests to tie up an agency in additional paperwork and, in the process, waste valuable resources. Several of these processes allow agencies inadequate time to conduct the required analyses and prepare the required responses to petitions; contain inadequate standards against which the adequacy of petitions can be judged; contain inadequate limitations on who may properly file petitions; and contain inadequate safeguards against an agency becoming overwhelmed by large numbers of petitions. These problems are exacerbated by provisions providing for the sunseting of regulations according to arbitrary deadlines, which could cause effective regulations to lapse without going through the notice and comment process.
- Inappropriate Use of Risk Assessment and Peer Review. S. 343's risk assessment and peer review provisions are overly broad in scope and would introduce unnecessary

delays into the regulatory process. They would inappropriately subject all health, safety, and environmental regulations to risk assessment and peer review, regardless of whether such regulations are designed to reduce risk or whether a risk assessment and a peer review would, from a scientific perspective, be useful or appropriate.

- Slowed Environmental Cleanups. S. 343 could needlessly slow ongoing and planned environmental cleanup activities, including those at military installations necessary to make the installations being made available for productive non-military use. It would also invite attempts to renegotiate cleanup agreements, thereby hampering enforcement efforts and increasing public and private transaction costs.
- A Less Accountable and Less Transparent Regulatory Process. Any regulatory reform bill should bring "sunshine" to the regulatory review process. Executive Order No. 12866, "Regulatory Planning and Review," provides both for centralized Executive branch review of proposed regulations and for the disclosure of communications concerning pending rulemakings between persons outside the Executive branch and centralized reviewers. S. 343, however, contains no such sunshine provision and could consequently remove accountability and transparency from the regulatory process.
- An Unduly Lengthy Congressional Layover. S. 343 includes a provision for a congressional layover of 60 days that goes beyond the provisions of S. 219, which provided for a 45-day layover. S. 219 passed the Senate by a vote of 100-0, with Administration support.
- Unrealistic, Unmanageable Studies. S. 343 would require a comprehensive study of and report on all risks to health, safety, and the environment addressed by all federal agencies. It would also require the President to produce annually a highly detailed estimate of and report on the costs, benefits, and effects of virtually all existing regulatory programs. Such studies would not only be unmanageable to conduct and costly to produce, but would require scientific and economic analytical techniques that go beyond the state of the art.
- Unnecessarily Hindered Enforcement of Regulations and Out of Court Settlements. S. 343 could create disincentives for regulated entities to bring potentially conflicting regulations to the appropriate agencies' attention. It could also make it

unnecessarily difficult for agencies to settle litigation out of court.

- Significant Changes in Substantive Law Without Proper Consideration. S. 343 goes beyond attempting to reform the regulatory process by making changes in substantive law -- altering, for example, the Delaney Clause and the Community Right-to-Know Act. Whether such changes are appropriate should be decided only after full hearings in the committees of jurisdiction and full debate on the merits.

The Administration is as concerned with the cumulative effect of S. 343 as with its particular features. The Administration remains committed, however, to improving the regulatory process, both administratively and through legislation.

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EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

ADMINISTRATOR
OFFICE OF
INFORMATION AND
REGULATORY AFFAIRS

JUN 23 1995

The Honorable Robert Dole
Majority Leader
United States Senate
Washington, D.C. 20510

Dear Mr. Leader:

We wish to provide the Administration's views on the June 21st discussion draft of S. 343, the "Comprehensive Regulatory Reform Act of 1995." The Administration is committed to seeing enacted into law a regulatory reform bill that will help produce more sensible regulations when they are needed. We recognize that improvements have been made to the draft bill since it was reported by the Judiciary Committee. Nonetheless, we continue to have serious concerns with S. 343, and I would recommend that the President veto it if it were presented to him in its current form. Some of our more important concerns include:

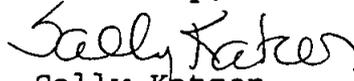
- Threshold. Because cost-benefit and risk analyses can be costly and time-consuming, the Administration believes that \$100 million is the appropriate threshold. S. 343, however, has as its threshold \$50 million -- a requirement that would cause agencies to use their resources unproductively and that therefore cannot itself withstand cost-benefit scrutiny.
- Risk Assessment/Peer Review. The Administration has concerns about the extent to which S. 343's risk assessment and peer review provisions are overly broad in scope and attempt to micromanage the process of assessing risks.
- Supermandate. We believe that Section 624, "Decisional Criteria," could be construed both to constitute a supermandate that would override existing statutory requirements indiscriminately and to require agencies to make unsound regulatory decisions.
- Judicial Review. We believe that the bill could invite substantial amounts of litigation that would neither improve the agency decisionmaking process nor lead to the production of more sensible regulations.
- Petition/Lookback Process. We remain concerned that these provisions could provide an opportunity for

special interests to tie up an agency in additional paperwork and drain valuable resources in the process. We are also concerned that they contain an arbitrary deadline as a trigger for sunseting regulations.

- Effective Date. S. 343 contains provisions that provide little, if any, time for transition. The Administration is concerned that an immediate effective date could result in unnecessary and time-consuming disruption of the rulemaking process, requiring regulations that have already been through notice and comment and subject to Executive Order No. 12866 review to begin the process all over again because of an unknowing failure to follow a particular procedure in the bill.
- Environmental Cleanups. The Administration is concerned that Section 628 of the bill could halt in their tracks hazardous waste cleanups now underway and postpone for substantial periods of time those about to begin.
- Regulatory Flexibility. S. 343 as originally introduced contained provisions for judicial review of Regulatory Flexibility Act certifications that the Administration could support. The provisions of the June 21st draft, however, do not include the appropriate safeguards. These provisions could consequently generate substantial amounts of new and unproductive litigation.

This list of concerns is not exhaustive, and our evaluation of regulatory reform legislation will depend as much on its cumulative effect as on its individual features. We remain committed to working with the Congress in order to produce a regulatory reform bill that the President can sign. We remain opposed, however, to any regulatory reform legislation that will impair rather than improve the regulatory process and, specifically, to any bill that would generate additional costs, additional paperwork, additional litigation, and additional delay instead of producing common sense, cost-effective regulations that will continue to protect our health, our safety, and our environment.

Sincerely,


Sally Katzen
Administrator

An Identical Letter Has Been Sent to the Hon. Thomas Daschle

ASSESSMENT OF S. 343

July 17, 1995

Over the last few days, S. 343 has improved in some respects:

- Passage of Senator Johnston's amendment revising the bill's threshold requirement for the definition of a major rule from \$50 million to \$100 million. This will return the threshold to the level used by every President since President Ford. (A step backward occurred, however, with passage of the Nunn-Coverdell amendment, which added to the definition of major rule any rule that will have a "significant economic impact on a substantial number of small businesses." This change will significantly increase the number of major rules.)
- Passage of Senator Johnston's amendment modifying the effective date of the bill to cover rules whose notices of proposed rulemaking were issued after April 1, 1995. (This modification still leaves at risk a significant number of rulemakings where a notice of proposed rulemaking was issued after April 1, 1995 but which may nevertheless have to go back to square one because the issuing agency unknowingly failed to follow one of the many provisions in S. 343 that alter the rulemaking requirements.)
- Passage of the Johnston/Baucus/Lautenberg "superfund" amendment deleting Section 628 of the bill which would have required that major hazardous waste cleanups, including superfund projects, comply with the bill's cost-benefit and risk assessment requirements. The effect of Section 628 would have been to halt many of these critical environmental cleanup projects in their tracks and to substantially delay many of those about to begin.
- Passage of the Dole/Levin "supermandate" amendment further clarifying that nothing in the bill's decisional criteria section (Section 624) "shall be construed to override any statutory requirement, including health, safety, and environmental requirements." (Some still question the sufficiency of the Dole/Levin language.)
- Passage of Senator Glenn's "sunshine" amendment which will help to ensure public accountability in the regulatory process by mandating that OMB and agencies

establish procedures to provide the public with access to information concerning regulatory review actions.

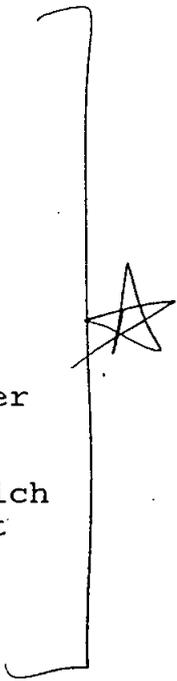
- Passage of Senator Feingold's amendment permitting agencies to exclude from the peer review process any expert who "has a potential financial interest in the outcome" of the review.

Despite these improvements, there continue to be several areas of significant concern:

- Unsound Regulatory Decisions -- "Least Cost" vs. "Most Cost-Effective". S. 343 would require agencies to issue unsound regulations by forcing them to choose the least costly regulation available to them, even if spending a few more dollars would yield substantially greater benefits.

Possible Approaches. The "least cost" alternative language in the bill's decisional criteria section (Section 624) could be replaced with one of the following:

- language identical to that used in the Unfunded Mandates Reform Act of 1995 which requires an agency to "select the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule";
- the language currently in the Glenn-Chafee substitute which requires that an agency explain whether the rule will achieve the objectives in a "more cost-effective" manner than alternatives;
- the approach proposed by Senator Chafee which requires that an agency make a finding that "there is no other reasonable alternative that provides equal or greater [the same level of] benefits at less cost [in a more cost effective manner]."



- Enormous Drain on Agency Resources -- Petitions. S. 343 contains four provisions (Section 553(l) (interpretation of rules), Section 623 (look back), Section 628 (old Section 629, alternative method of compliance), and Section 634 (major free-standing risk assessment)) which create numerous, often highly-convoluted, petition processes that will provide special interests with opportunities to tie agencies in knots. Further exacerbating the situation, the petition provisions do not permit agencies sufficient

time to conduct the required analyses and prepare the proper responses; contain inadequate standards to judge the adequacy of petitions; and contain inadequate limitations on who may file petitions.

Possible Approaches. Deletion of the four petition provisions would be the most effective means of avoiding the potential for enormous waste of valuable agency resources. (The APA already contains a provision, Section 553(e), which allows private parties to petition agencies for issuance, amendment, or repeal of a rule.) Short of this, the four petition provisions should be scaled back to: (1) limit the number of petitions that can be filed with an agency; (2) provide agencies with sufficient time to respond to petitions; (3) limit standing to those who are actually adversely affected by a rule; and (4) eliminate arbitrary sunset provisions which could cause effective regulations to terminate without going through the notice and comment process.

- Excessive Litigation. S. 343 contains a number of provisions that would vastly increase the opportunities for lawsuits challenging various aspects of the rulemaking process. Of most concern are the provisions in Section 625 and the Regulatory Flexibility section which would, contrary to traditional principles of administrative law, allow challenges to agency actions that are not yet final. Also of significant concern are provisions allowing for judicial review of the bill's numerous petition processes. All of these provisions, taken together, will permit special interests to flood the courts with legal challenges to proposed and final rules, further burdening our already overstretched court system and delaying the implementation of countless regulations designed to protect the health and safety of our citizens.

Possible Approaches. The interlocutory review provisions contained in Section 625 and the Regulatory Flexibility section should be deleted, and the provisions permitting judicial review of the various petitions should be scaled back along with the entire petition process.

- A Backdoor Regulatory Moratorium -- Effective Date. Even with the changes to the effective date provided by Senator Johnston's amendment, enactment of S. 343 as currently written could have the effect of a regulatory moratorium by requiring that regulations proposed after April 1, 1995 that have already been through notice and comment and cost-benefit analysis begin the process all over again because the rulemaking process did not comport precisely with the new requirements in the

bill. This problem will be exacerbated if the final version of this legislation requires that it take effect immediately upon enactment.

Possible Approaches. The bill's effective date language should be similar to that used in the Unfunded Mandates Reform Act: "This Act shall take effect six months after the date of enactment and shall apply only to any agency rule for which a general notice of proposed rulemaking is published on or after such date."

This assessment is based on action in the Senate at the close of business Friday, July 14, 1995. There are a number of pending amendments, however, which, if passed, would impose unnecessary costs and delays, and encourage excessive litigation, all of which the American people are trying to avoid.

DRAFT**ASSESSMENT OF S. 343 AS MODIFIED BY THE
CHAFEE AMENDMENTS AND THE MODERATE DEMOCRATS' PACKAGE**

July 28, 1995

In exchange for Chafee's vote for cloture on the Dole/Johnston substitute, Dole, Hatch and Roth agreed to a set of amendments proposed by Chafee that would modify the Dole bill. While the Chafee amendments improve the bill in several important respects (for example, the elimination of interlocutory appeals and deletion of the sunset provision in agency look-back), the Administration would continue to have the following concerns with the bill as modified by Chafee.

- **Decisional Criteria:** The Chafee amendments would strike the "least cost" and "significant risk reduction" decisional criteria and substitute language requiring that the agency select the reasonable alternative with the "greater net benefits." While better than the "least cost" language, there is a division of opinion as to whether the "greater net benefits" language provides a sufficient alternative. Some agencies also remain concerned that the Chafee language intended to clarify that underlying statutes shall govern when in conflict with the requirements of Section 624 does not solve the "supermandate" problem.
- **Judicial Review:** While the Chafee amendments solve the interlocutory review problem, some agencies remain concerned with Chafee's language addressing standard of review. The concern is that the Chafee language (essentially the Levin fix) does not adequately protect agencies from challenges asserting that a rulemaking is arbitrary or capricious because the agency committed a procedural misstep in conducting the cost/benefit analysis or the risk assessment set forth in the bill.
- **Petitions:** While the Chafee amendments attempt to streamline and consolidate the bill's various petition processes (for example, by providing for a single consolidated court proceeding to review all petitions with regard to the look-back schedule issued by an agency), these processes would remain overly burdensome. For instance, Chafee's amendments do not address the Section 629 (alternative means of compliance) or Section 634 (major free-standing risk assessment) petitions. And while the Chafee amendments return the Section 553(l) petition process to existing law, they maintain the 18-month deadline for agency response added by the Dole bill. Furthermore, the changes do not address the 3-year deadline for responding to Section 623 major rule petitions and do not fully resolve the problem that special interests may manipulate the petition process by filing petitions under both Sections 553(l) and 623.
- **Effective Date:** The Chafee amendments contain no effective date fix. The Dole bill's effective date provision remains one of the Administration's most serious concerns.
- **Risk Assessments:** The Chafee amendments contain no fix for remaining problems with the bill's risk assessment sections (including making the peer

review requirements more flexible and less burdensome, eliminating certain scientific assumptions that will lead to biased results, limiting the consideration of substitute risk, and restricting the agencies subject to the bill's strict risk assessment requirements to those that regularly issue rules involving risk). These problems continue to be of considerable concern to some agencies.

- Definition of "Major Rule": The Chafee amendments do not address the Nunn-Coverdell Amendment's substantial expansion of the definition of "major rule," which will increase the scope and burden of the bill's requirements.
- Special Interest Provisions: The Chafee amendments contain no fixes for the bill's special interest provisions, including TRI and Delaney, both of which remain issues of substantial concern to some agencies.
- Regulatory Flexibility: The Chafee amendments contain no fixes for the reg flex problems, other than the elimination of interlocutory appeals and the requirement that the bill's new reg flex decisional criterion must be exercised consistent with the "greater net benefits" criterion in Section 624 (Chafee does not articulate precisely how the two criteria will be made consistent). Remaining problems include: mandatory stays, the "substantial evidence" standard of review, decisional criteria, and the one-year statute of limitations.
- APA Changes: The Chafee amendments strike the Dole bill's new "substantial support" standard of review and essentially return the Section 553(l) petition process to current law. They do not, however, address a number of the bill's minor, and somewhat problematic, changes to the APA (Chevron language, APA definition of rule (IRS guidance)).
- Sections 708/709: Some agencies, particularly DOJ, remain concerned by the Dole bill's treatment of affirmative defenses in Section 708, as well as the changes made by the Hutchison Amendment which added back Section 709 (estoppel/reliance on agency interpretation). These provisions would undercut the federal government's ability to enforce health, safety, and environmental laws by making it harder to prosecute, and to penalize, businesses who violate such laws.

A broad-based group of Democrats, led by Robb and Conrad, and including Glenn and Levin, have drafted an additional package of amendments to the Dole bill, which incorporate but go beyond the changes contained in the Chafee amendments. If Dole was to accept these changes, in addition to the Chafee amendments, the bill would be substantially improved over the version subject to the third cloture vote. Nevertheless, some agencies continue to have significant concerns.

- Decisional Criteria: The Democrats' changes improve the "supermandate" language, and improve the "greater net benefits" criterion by narrowing the definition of "reasonable alternatives" and by defining "net" to permit consideration of nonquantifiable benefits and other qualitative factors. Most agencies find the new criteria acceptable (though far from ideal), although a

few agencies continue to believe that the new "greater net benefits" language is unacceptable, and a few others remain dissatisfied with the Dems' "supermandate" language.

- Judicial Review: The standard of review issue (can a decision be remanded because of a procedural misstep) remains unaddressed by the Dems' changes.
- Petitions: The Dems' changes substantially improve many of the problems left unaddressed by the Chafee amendments: elimination of the Section 634 petition process (major free-standing risk assessments); elimination of any review priority for major rules placed on an agency's look-back schedule as a result of a Section 623 petition; elimination of judicial review of the grant or denial of Section 623 petitions; and establishing Section 623 as the sole avenue for petitions to amend or repeal major rules. It is still unclear how the Dems propose to address problems with the Section 629 petitions (alternative means of compliance) -- the most likely scenario is a sidebar agreement between Bond and Robb to replace the provision with a Sense of the Senate that the process will be addressed in separate legislation. While most agencies find the altered petition processes acceptable, EPA continues to object to the 18-month response deadline in Section 553(l).
- Effective Date: The Dems' change (exempting NPRMs filed 180 days after enactment) significantly improves the bill's effective date. While this fix is acceptable, there is some concern about the addition of judicially reviewable certifications that NPRMs published before the effective date have complied with E.O. 12866.
- Risk Assessments: Like Chafee, the Dems offer no fix for remaining problems with the bill's risk sections (peer review, scientific assumptions, substitute risk, and covered agencies).
- Definition of "Major Rule": The Dems' changes limit the effect of Nunn-Coverdell to 100 rules per year, government-wide, as identified by OIRA and the SBA's Chief Counsel for Advocacy. This is an improvement over current Nunn-Coverdell, but the concern remains that, even with this change, the provision still substantially increases (doubles) the number of major rules.
- Special Interest Provisions: The Dems offer no fix (as of yet) for Delaney (though Kennedy and Conrad would replace the bill's existing language with a Sense of the Senate that the issue should be addressed in separate legislation). The Dems do offer a TRI fix, which is intended to codify existing EPA practice. These issues remain unresolved and troublesome.
- Regulatory Flexibility: The Dems' changes significantly improve the reg flex problems (mandatory stay, standard of review, decisional criteria, and statute of limitations), and are acceptable.

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- Sections 708/709: The Dems offer no fixes to the problems posed by the bill's affirmative defense and estoppel/reliance provisions.
 - Snakes: A few lesser problems remain unaddressed: FEC and FCC exemption from the bill; elimination of FERC's exemption; exemption of rules authorizing removal of a product from commerce; SIPs; Section 707 (consent decrees); statutory deadlines; regulatory accounting; and several minor changes to the APA (Chevron language, APA definition of rule (IRS guidance)).

DRAFT

**UPDATED ASSESSMENT:
FINAL DEMOCRATIC PACKAGE OF MODIFICATIONS
TO THE DOLE SUBSTITUTE**

August 4, 1995

The final Democratic package of changes to the Dole substitute remains essentially unchanged from the original Democratic package that was the subject of the July 28, 1995 assessment. The new package is still premised on the assumption that the Dole substitute will also be modified per the Chafee amendments. There have been, however, several important changes to the original package, most of which improve it, but a few of which are troubling. These changes are the focus of this assessment update. Because, on balance, the modifications to last week's Dem package are favorable, the overall assessment remains as it was in the July 28, 1995 assessment: If Dole was to accept the Dem's changes along with the Chafee amendments, the bill would be substantially improved over the version subject to the third cloture vote.

- Decisional Criteria: With regard to decisional criteria, the new Dem package improves upon the original Dem package by striking the "preclude" language and replacing it with "agency cannot make the finding under subparagraph (A)" and by clarifying that "to the extent practicable" applies to both flexible "reasonable alternatives" (a) of the type described in Section 622 and (b) which minimize economic impact on small entities. With regard to the "Construction With Other Laws" section, the bill's "supplement and supersede" language is deleted, and the "supermandate" issue is clarified by allowing reasonable interpretations by agencies whether the requirements of subchapter II are inconsistent with the requirements of their authorizing statute.
- Section 625 Judicial Review: The new Dem package favorably addresses the standard of review issue (can a decision be remanded because of a procedural misstep) by deleting the "failure to comply" language.
- Petitions: The new Dem package improves the Dem's original petition proposal by striking the "on its face" language, but muddies the Section 623 judicial review issue by appearing to permit judicial review of the denial of major rule petitions rather than the schedule as a whole. Section 629 petitions (alternative means of compliance) are still not addressed explicitly; the word continues to be that Bond and Robb have a sidebar agreement to deal with this issue in separate legislation. (Note: Section 623 agency look-back has also been improved with the addition of language permitting an agency to extend the 11-year deadline if it encounters resource problems.)
- Effective Date: The new Dem package improves the effective date by deleting the original proposal's judicially reviewable requirement that agencies certify that NPRMs published before the effective date have complied with E.O. 12866. The new package, however, reduces the effective date from 180 to 90

days after enactment. The legislative veto provision will become effective on the date of enactment.

- Risk Assessments: The new Dem package continues to offer no fix for remaining risk assessment problems (peer review, scientific assumptions, substitute risk, and covered agencies).
- Definition of "Major Rule": The new Dem package takes a substantial step backwards over the original package by raising the Nunn-Coverdell limit from 100 to 150 rules that significantly affect a substantial number of small entities. Thus, the provision could more than double the number of major rules subject to the bill's requirements.
- Special Interest Provisions: The new Dem package substantially improves on the original Dem package by deleting the TRI language entirely and by offering two Delaney fixes: (1) delete the Delaney language entirely; or (2) substitute the Kennedy-Conrad language (Sense of the Senate, suspension of Delaney pesticide enforcement, NAS study, fast track Senate action).
- Regulatory Flexibility: The changes in the new Dem package are essentially identical to those in the original Dem package (original Dole language, no decisional criteria).
- Sections 708/709: Like the original Dem package, the new Dem package offers no fixes to the problems posed by the bill's affirmative defense and estoppel/reliance provisions.
- Snakes: Like the original Dem package, the new Dem package fails to address a few remaining minor problems with the Dole bill: FEC and FCC exemption; elimination of FERC's exemption; exemption of rules authorizing removal of a product from commerce; SIPs; Section 707 (consent decrees); statutory deadlines; regulatory accounting; and several minor changes to the APA (Chevron language, APA definition of "rule" (IRS guidance)).

The Agencies: After reviewing the new Dem changes on today's 5:00 p.m. conference call, the consensus (if not unanimous) opinion of the agencies was that, while far from ideal, the Chafee amendments and the new Dem package represent a substantial move in the right direction on the Dole bill, and that if Dole accepted all of these changes, the bill would be significantly less onerous than the version subject to the last cloture vote. Some agencies continued to express concerns with certain specific provisions (DOJ -- Section 625 judicial review; EPA/FDA -- Delaney fix #2; USDA -- Nunn-Coverdell 150 limit; several agencies -- judicial review of denials of Section 623 petitions).

DRAFT

ASSESSMENT OF ROBB PACKAGE OF MODIFICATIONS TO THE DOLE SUBSTITUTE

September 26, 1995

Senator Robb has approached Senator Dole with a package of changes to the Dole/Johnston substitute to be made in exchange for his vote for cloture. The package is a modified version of the package presented to Dole on August 4 by a group of Democrats, including Robb and Conrad, which Dole summarily rejected. It appears that Robb is acting alone in making this offer to Dole, but other rump Democrats are keeping a close eye on how the discussions progress (this group no longer includes Conrad, who is still seething over the dismissive reception given to the original Dem package in August). It is unclear whether Robb is willing to discuss further changes to this package or whether this is a "take it or leave it" offer.

The new Robb package retains most of the elements in the original Dem package. It continues to be premised on the assumption that the Dole bill will be modified per the amendments offered by Senator Chafee in exchange for his cloture vote. However, Robb has made several modifications to the August 4 package, some of which are troubling. These changes are the focus of this assessment. The bottom line remains the same as in the August 4 assessment: If Dole were to accept all of Robb's changes along with the Chafee amendments, the bill would be substantially improved over the version subject to the third cloture vote.

Provisions Modified by Robb Proposal

- Decisional Criteria: The Robb offer makes several changes to the decisional criteria language in the August 4 package. These changes are likely to be the most troublesome to the agencies. On the positive side, Robb has added language intended to highlight that the agency has considerable discretion and flexibility when deciding what are the "reasonable alternatives" to which the decisional criteria will apply.

On the down side, Robb has removed language from Section 624 (a) and (b) which provide agencies an escape hatch to select an alternative that does not satisfy the decisional criteria if such a finding cannot be made because of scientific, technical, and economic uncertainties. Instead, Robb has added language permitting agencies to consider "uncertainties" when selecting from among the reasonable alternatives that which provides the "greatest net benefits." In addition, Robb has modified the "supermandate" language, reinserting the "supplement not supersede" language and adding "or amend" to "override," while at the time deleting a sentence which made clear that the decisional criteria shall not apply in situations where they are inconsistent with an agency's other statutory requirements, as reasonably interpreted by the agency." The agencies consider these two changes (and the decisional criteria section as a whole) to be the most troubling.

- Section 625 Judicial Review: The Robb offer adds back the “failure to comply language” some agencies (particularly DOJ) found troubling. A few agencies continue to be concerned that a rule can be remanded because of any misstep in fulfilling the bill’s procedural requirements. Robb attempts to address this concern by adding language making clear that the failure to comply with the bill’s requirements must “materially affect the outcome of the agency’s decision.” Some agencies feel the “materially affect” language will limit procedural review only to those missteps so significant as to clearly affect the substantive decision.
- Petitions: The Robb offer essentially mirrors the treatment of petitions in the August 4 package, with the exception of three changes. First, Robb does not propose to make Section 623 the sole avenue for petitions to amend or repeal major rules. Instead, he proposes to ensure that a private party may not file petitions under *both* Sections 553(l) and 623. Thus, if a petition filed under Section 553(l) is granted, it will extinguish any Section 623 petition relating to that rule, or remove the rule addressed by the 553(l) petition from the agency’s review schedule. Second, Robb adds a provision which gives Congress the authority to appropriate the funds necessary for an agency to complete review of the rules on its schedule in 5 years as opposed to 10.
- Special Interest Provision: Like the August 4 package, the Robb offer deletes the TRI language entirely. The Robb proposal no longer offers the two Delaney fixes included in the August 4 package. Instead, it accepts the original Dole language on Delaney, although it appears Robb is attempting to work out an agreement whereby the Dole language will be dropped and the Republicans will bring it to the floor separately shortly after the vote on the bill. Three agencies remained very concerned about Delaney.

Provisions Not Modified by Robb Proposal Which Remain Problematic

- Risk Assessments: Like the August 4 package, the Robb proposal continues to offer no fix for remaining risk assessment problems (peer review, scientific assumptions, substitute risk, and covered agencies). The risk section is still much improved over the original Dole risk language, and only a few agencies (particularly DOL) continue to feel that this is a major problem area.
- Definition of “Major Rule”: The Robb offer does not change the August 4 package, which raises the Nunn-Coverdell limit to 150 rules that significantly affect a substantial number of small businesses.
- Sections 708/709: Like the August 4 package, the Robb offer provides no fixes to the problems posed by the Dole bill’s affirmative defense and estoppel/reliance provisions. DOJ remains extremely concerned about these provisions.

- Snakes: Like the August 4 package, the Robb offer does not address several remaining minor problems with the Dole bill: FEC and FCC exemption; elimination of FERC's exemption; exemption of rules authorizing removal of a product from commerce; SIPs; Section 707 (consent decrees); statutory deadlines; regulatory accounting; and several minor changes to the APA (Chevron language, APA definition of "rule" (IRS guidance)).

The Agencies: As was noted in the August 4 assessment of the original Dem package, the agencies were in near unanimous agreement that, while far from ideal, the Chafee amendments and the original Dem package represented a significant move in the right direction on the Dole bill, making it substantially less onerous than the version subject to the last cloture vote. Most agencies continue to agree with this assessment despite the ground lost as a result of Robb's modifications. Several agencies, however, continue to express concern over a few of Robb's changes, most significantly the removal of the escape hatch and the backtracking on the "supermandate" language, and to a lesser degree, the changes made to the judicial review provision.

October 10, 1995

PROBLEMS WITH DOLE BILL NOT ADDRESSED BY CONRAD/ROBB PROPOSAL

The August 4 package of changes to the Dole bill, offered by Senators Conrad and Robb, left untouched the following problematic areas:

- Definition of "Major Rule": The August 4 package limits the effect of the Nunn-Coverdell Amendment to 150 rules per year, government-wide, as identified by OIRA and the SBA's Chief Counsel for Advocacy. While this represents a small improvement over current Nunn-Coverdell, the concern remains that the provision, even as modified by the August 4 package, will more than double the number of major rules subject to the bill's requirements. In addition, there are potential practical problems with implementing this provision.
- Sections 708/709: The August 4 package does not address the problems raised by the bill's affirmative defense provision (Section 708) or the changes made by the Hutchison Amendment, which added back the provision addressing estoppel and reliance on agency interpretations (Section 709). The Administration remains concerned that these provisions will undercut the federal government's ability to enforce health, safety, and environmental laws by making it harder to prosecute, and to penalize, businesses who violate such laws.
- Section 707: This provision is bad policy. It would undo, after the fact, consent decrees that agencies have entered in to in order to settle litigation. In addition, it will provide a strong disincentive for agencies to enter into future consent decrees even if doing so would be in the public interest.
- Risk Assessments: Fixes are needed for several remaining problems with the bill's risk assessment sections, including: (1) making the peer review requirements more flexible and less burdensome; (2) eliminating superlatives such as "most," "greatest," and "best" in the data collection section, which will lock agencies into a single data point in areas where the most useful information might be expressed in the form of a range of probabilities or consequences; (3) limiting the consideration of substitute risk to risks that flow directly from the implementation of a regulation; and (4) applying the bill's risk assessment requirements only to those agencies that regularly issue rules involving risk.
- Regulatory Accounting: The bill currently requires that each agency, under OMB supervision, prepare an accounting statement of the overall costs and

benefits of its major regulations. This proposal does not pass the cost-benefit test itself. First, the requirement could apply to literally hundreds of major rules each year -- in its present form, Nunn-Coverdell alone could add up to 150 major rules per annum. Second, many of these rules will be non-controversial, making it unnecessary to force an agency to go through the costly and time consuming process of preparing a statement. In short, the costs of preparing such statements will far exceed the benefits, particularly given the absence of sound methodologies for estimating the aggregate costs and benefits of regulation.

- APA Changes: A number of seemingly minor, yet potentially quite troublesome, changes to the APA remain in the bill. If not corrected, these problems will make the current informal rulemaking process even more cumbersome and litigious.

-- It appears that the language on page 8, lines 1-10, is intended to codify the Chevron decision. If this is so, the language incorrectly states Chevron's holding and should be modified to correctly reflect the decision's two-pronged test for determining whether to give deference to an agency's interpretation of a statute.

-- There are problems with the bill's definition of a rule under the APA. The APA's current exemption of grants and loans from the definition of rule is not carried over in this bill. As a result, grants and loans would be subject to the bill's myriad requirements, including risk assessments and peer review. (Note: Our most recent version of S. 343 (#783) is missing page 2, which contains the definition of a rule. The above discussion assumes that page 2 contains no exemption for grants and loans.)

-- On page 7, lines 19-25, the bill requires that each agency's statement of basis and purpose shall include a discussion of, and a response to, "any significant factual or legal issues presented by the rule, or raised by the comments" on the rule. This language should be modified to limit the required discussion and response to those legal and factual issues raised in the comments only. Otherwise, an agency will be in the untenable position of discussing and responding to any conceivable legal or factual issue raised by the rule.

-- If the legislation is going to place an 18 month time limit on agency decisions regarding Section 553(l) petitions, and provide for judicial review, it must also include either a limit on standing (those "adversely affected") or a requirement that petition make a threshold showing to be approved. Without such limitations, parties who are not adversely affected by a rule, or whose do not have a meritorious claim, will

nevertheless be able to tie an agency in knots by flooding it with Section 553(l) petitions.

-- The Administration continues to have no idea what the language on page 12, lines 6-8 means. The concern is that it could be read to allow someone to sue an agency any time a rulemaking file is missing any piece, no matter how insignificant. Thus, this provision, like so many others in the bill, will provide yet another opportunity for private parties to tie-up agencies in court.

-- As currently drafted, S. 343 does not exempt the FEC from the bill's requirements. However, it would be improper for the FEC to be subject to White House review and oversight. Similarly, the FCC issues regulations regarding political advertising which should not be subject to review by the executive branch. It is for this reason that these are independent agencies.

-- The bill exempts from its requirements any rule or agency action that authorizes a product's introduction into commerce, but requires that an agency must jump through the bill's many hoops in order to remove a product from commerce. This is unfair and bad public policy.

DRAFT

DRAFT
October 13, 1995

There are several problematic provisions in the recent Robb package of changes to the Dole bill which would require modification before the Administration could sign-on to the legislation, as follows:

Decisional Criteria/Supermandate. The Administration would not object to judicially reviewable decisional criteria with the following changes to the current Robb language:

- Reinsert the “escape hatch” language from the August 4 Conrad/Robb package, which would allow agencies to choose a regulatory option that does not meet the decisional criteria if substantial economic, technical, or scientific uncertainties exist and if they provide a written explanation of their decision.
- Reinsert the sentence added by Chafee (as drafted by Chafee) which clarifies that the bill’s decisional criteria will not apply in situations where they are inconsistent with an agency’s existing statutory requirements.
- Replace the “greater net benefits” language with the criterion used in the Unfunded Mandates Reform Act of 1995, which requires an agency to “select the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule.”
- Delete the new language requiring an agency to submit to Congress a written explanation of why it has promulgated a rule that does not satisfy the decisional criteria. The bill already provides Congress with a 45-day review period, thus ensuring that Congress will both receive, and have an opportunity to review, an agency’s written explanation.

Judicial Review. The Administration would not object to the Robb proposal’s current formulation of the judicial review language, with one change:

- The final sentence to Section 625 should be modified to read: “A failure to comply with this subchapter or Subchapter III may not serve as a basis for invalidating a rule *unless* such failure *did* materially affect the outcome of the agency’s decision.” This change would clarify that the burden rests on the party challenging the agency action to show that the procedural misstep materially affected the outcome, not on the agency to show that it did not.

Petitions/Look-Back. The Administration would not object to the Section 623 and Section 553(l) petition processes set forth in the August 4 package. The Administration cannot accept the two changes made to this language in the Robb proposal for the following reasons:

- As currently drafted, the Robb package eliminates language in the August 4 package which would have greatly reduced the opportunities to use the various potentially duplicative petition processes to overwhelm and tie-up agencies by designating Section 623 as the proper, and only, means of petitioning for review of major rules and Section 553(l) as the avenue for petitioning for review of non-major rules. Instead, under the Robb proposal, if a petition filed under Section 553(l) is granted, it would extinguish any Section 623 review relating to the same rule. This would provide a perverse incentive for parties to file petitions for review of major rules under Section 553(l) (because of the absence of any threshold showing in a Section 553(l) petition and the presence of an 18-month deadline for agency action).
- The new language providing Congress with authority to force an agency to review all of the rules on its review schedule in 5 years rather than 10 if Congress appropriates extra funds is not sufficient guarantee of funds since agency appropriations occur on an annual basis and Congress cannot bind future Congresses to continue the extra [appropriations]. In any event, the bill already provides Congress with authority to amend an agency's review deadlines with respect to individual rules through the annual appropriations bills.

Delaney Clause. S. 343 is a procedural bill and it is inappropriate to resolve significant substantive issues in such a bill. Accordingly, the Administration has objected to inclusion of the provision addressing TRI, which is deleted in both the August 4 package and the Robb proposal. Similarly, the Administration objects to the inclusion of any language regarding the Delaney Clause.

Nunn-Coverdell Definition of "Major Rule." The Nunn-Coverdell Amendment substantially raises the number of rules that are subject to cost-benefit and risk analyses (it adds 150 rules that affect small businesses) and is unworkable (how to apportion the aggregate number among the agencies and over the year). Suggestions include reducing the number of rules to 100 or fewer; explicitly restricting the scope of the amendment to Section 622 (cost-benefit analysis); and explicitly authorizing OMB to develop implementation.

The Dole bill contains a number of additional provisions which would have to be changed before the Administration could support the legislation. None of these problems is addressed in either the August 4 package or the Robb proposal.

Section 707 -- Consent Decrees. The prohibition against court enforcement of settlement agreements that restrict agency discretion would effectively eliminate settlement agreements as a method of resolving litigation since no one signs a settlement agreement without giving up some amount of discretion. If agencies cannot settle, it means more litigation.

Section 708 -- Affirmative Defenses. While reasonable reliance on an agency rule or directive inconsistent with the rule being enforced could be an affirmative defense against any penalty or other sanction sought as punishment for past activities, such reliance should not bar a court from ordering prospective compliance with an agency rule or directive.

Section 709 -- Reliance on Agency Interpretation. While reasonable reliance on a good faith interpretation of a regulation should be credited, it is important that there be sufficient safeguards that such an interpretation is reasonable and does not simply allow parties carte blanche to determine for themselves whether or not they are in compliance with health and safety rules.

Regulatory Accounting. The requirement that each agency prepare annually an accounting statement of the actual costs and benefits of all of its major regulations over the following 5 years would not pass a cost-benefit test for two reasons. First, there are a number of major regulations that are neither controversial nor contentious and engaging in such analysis would be “make work” for agencies already strapped for resources. Second, the bill’s current definition of “major rule” is overly expansive -- see e.g., the discussion of Nunn-Coverdell above. Some significant narrowing of the universe is required -- either by the leadership of the Congress, OMB, etc.

Risk Assessments. The risk assessment and peer review language still needs to be scrubbed to eliminate several remaining problems, including: (1) ensuring that the bill’s risk assessment requirements apply only to those agencies that regularly issue rules involving risk; (2) limiting the consideration of substitute risk to risks that flow directly from the implementation of a regulation; (3) making the peer review requirements more flexible and less burdensome; and (4) eliminating superlatives such as “most,” “greatest,” and “best” in the data collection section, which will lock agencies into a single data point in areas where the most useful information might be expressed in the form of a range of probabilities or consequences.

APA Changes. A number of seemingly minor, yet potentially quite troublesome, changes to the APA remain in the bill.

- It appears that the language on page 8, lines 1-10, is intended to codify the Chevron decision. If this is so, the language incorrectly states Chevron’s first prong of its test for determining whether to give deference to an agency’s interpretation of a statute.
- The APA currently exempts grants and loans from the definition of a rule. It appears that such action would no longer be exempt and thus would be subject to the bill’s many requirements, including risk assessments and peer review.

- On page 7, lines 19-25, the bill requires that each agency's statement of basis and purpose shall include a discussion of, and a response to, "any significant factual or legal issues presented by the rule, or raised by the comments" on the rule. This language should be modified to limit the required discussion and response to those legal and factual issues raised in the comments; otherwise, an agency will be in the untenable position of discussing, and responding to, any conceivable legal or factual issue raised by the rule.
- If the legislation is going to place an 18-month time limit on agency grants or denials of Section 553(l) petitions, with judicial review, it must be limited in terms of who can file such petitions (those "adversely affected") and what threshold showing they should make ("substantial likelihood").
- The language on page 12, lines 6-8 could be read to allow someone to sue an agency any time a rulemaking file is missing any listed document, no matter how insignificant.
- The bill exempts from its requirements any rule or agency action that authorizes a product's introduction into commerce, but requires that an agency must jump through the bill's many hoops in order to remove a product from commerce.

We assume the Dole bill as amended during the floor debate (e.g., \$100 million rather than \$50 million threshold), and adoption of the Chafee amendments (e.g., no interlocutory appeals, no sunset of existing rules pending review, and no conflict with agencies' underlying statutes) PLUS the Democratic Senators' August 4 offer (as modified by Robb) which eliminated many of the problems we had earlier identified.

I. Remaining issues that are troublesome on their own and which, if not fixed, would provide grounds to veto the bill.

- Decisional Criteria/Supermandate -- ensure no supermandate and sufficient flexibility where scientific or other uncertainties exist.
- Petitions/Look-Back Review -- burdensome and overlapping processes would tie agencies in knots and waste increasingly scarce resources.
- Repeal of the Delaney Clause -- the Administration has objected to inclusion of this provision, like the TRI provision, on the ground that significant substantive issues should not be resolved in what is a "process" bill; at the same time, however, the Administration has acknowledged that the Delaney Clause needs to be fixed.
- Effective Date -- backdoor regulatory moratorium if applicable retroactively.

II. Issues that are troublesome but which, individually, would not support a veto message.

- Nunn-Coverdell Amendment's Definition of "Major Rule" -- expands rules subject to the bill's requirements to include up to 150 rules that affect small businesses.
- Risk Assessments -- applies to all agencies rather than just those that routinely regulate risk; micromanages peer review; requires extensive consideration of substitute risk; and pushes agencies toward single-point estimates rather than ranges.
- Judicial Review -- possibility that minor procedural misstep with cost or risk analysis could be ground for remand.
- Consent Decrees -- prohibits court enforcement of settlement agreements that restrict agency discretion; but *any* settlement agreement restricts the signers' discretion.
- Affirmative Defenses -- bars penalties where a party "reasonably" relies on rule inconsistent with rule being enforced or party's "good faith" interpretation of rule.
- Changes to APA -- changes 50-year old law in lots of minor ways that will engender much uncertainty and/or litigation.
- Regulatory Accounting -- burdensome and costly "make-work" requirement to calculate annually the costs and benefits of *all* major rules for 5-year period.

Message to be delivered: The President is a strong supporter of health, safety, and the environment. He also favors sensible regulations and recognizes the need for responsible regulatory reform. (The press this summer was very favorable on the former point; the latter was less clear and resulted almost entirely from REGO II.)

There are, at this point, three basic strategies to advance this message:

1. **Unequivocally pursue a veto strategy** on the grounds that the Republicans are extreme and are doing reg reform the "wrong" way.

Pros

- Sends a clear and unambiguous message on health, safety, and the environment.
- Gives reassurance to skeptics on the left, who we may disappoint on specific matters, that we are with them on this overarching issue.
- Gives wavering Democrats clear signal to be firm against Dole bill, even with variations.

Cons

- Having stated we support responsible regulatory reform, this strategy risks (i) losing credibility that we do support reform and (ii) angering the business community, including small business.
- Risks pushing critical 2 or 3 Democrats, who want to vote for **something**, into Dole's arms, thereby losing opportunity to improve bill.
- Increases likelihood that, once the bill has a majority, many more Democrats will vote for it, thereby (i) risking veto-proofing the bill and (ii) making a veto anti-Democrat as well as anti-Republican.

2. **Set a high bar for improvements to the Senate bill and hold to it firmly, promising a veto on anything not meeting this standard.**

Pros

- Continues our support for responsible regulatory reform within parameters most Democrats can accept.
- Gives wavering Democrats something to be in favor of, helping them with reelection, and inoculating ourselves from charges of being against reform if the President must veto a bad bill.
- We can claim victory if Dole moves to the left, but hold out a veto threat if the House pulls the bill to the right in conference.

Cons

- May anger many on the left, who feel they have gone far enough or who want no bill at all.
- If a bill passes the Senate that meets the high bar, Dole may claim a victory even if the ultimate conference bill is vetoed.
- If wavering Democrats reject our last best offer, we may look ineffective, even within our own party.

3. **Set a high bar, but one we're willing to negotiate from, both in the Senate and in conference.**

Pros

- Continues our support for responsible regulatory reform and allows us to stay at the table as long as we want to.
- Recognizes that wavering Democrats may well move toward Dole prior to the 1996 election no matter what we do, and enables us to work with them.
- Maximizes chances of Senate -- and perhaps Congress -- passing a bill we can support and inoculates us if the President ultimately must veto.

Cons

- Many vocal supporters on the left would assert that the Administration is not only against health, safety, and the environment, but also unprincipled.
- Members may think any movement to negotiate means the Administration will sign any bill, reducing our ability to negotiate effectively.
- Makes it very difficult to have a clear message.

4136

United States Senate

WASHINGTON, D.C. 20510

August 5, 1995

The Honorable Charles S. Robb
United States Senate
Washington, D.C. 20510

The Honorable Kent Conrad
United States Senate
Washington, D.C. 20510

Dear Chuck:

Dear Kent:

We would like to thank you and your colleagues for your proposed package of changes to the Dole-Johnston substitute to S.343, the Comprehensive Regulatory Reform Act of 1995. We believe that obtaining a strong regulatory reform bill is a common objective of yours and the proponents of S.343. Some aspects of your package are very straightforward and could be accepted without difficulty. Other parts of the proposal are ambiguous, at best, and appear to weaken the chances for getting a strong regulatory reform bill. Others are simply unacceptable. We are responding to you on an expedited basis because we believe that it is essential to reach closure now.

The following are our comments on each of your proposals.

1. Proposals on increasing emphasis on performance-based standards. These are acceptable. We believe that they strengthen the bill's existing commitment to performance-based standards.
2. Proposal to limit regulatory flexibility coverage. This proposal builds on and clarifies an amendment that has been filed by Senator Nunn. We accept your provision limiting the application of major rule analysis under the Nunn/Coverdell amendment to 150 rules per year.
3. Proposal on reasonable alternatives. You propose that the definition of "reasonable alternatives" include sets of closely related options. While this might be a workable concept in the context of a free-wheeling analysis, S.343 also requires an agency to pick one reasonable action, and not a set of closely related, but different actions, when promulgating a final rule. Your proposed definition would not work in this latter context. We understand that your concern is that the existing definition in S.343 is susceptible to the interpretation that agencies must analyze a virtually infinite number of reasonable alternatives. This was never our intent, and we have so stated in informal discussions on numerous occasions. While we do not believe that courts would actually construe S.343 in this manner since similar language in other statutes has presented no difficulty, we would be willing to accept statutory

language that addresses this concern, as well as an accompanying colloquy to the effect that the number, nature, and range of alternatives analyzed must be reasonable and appropriate. Our proposed revision to the definition of reasonable alternatives would draw on language in the Glenn substitute and be as follows:

"(8) the term 'reasonable alternatives' means an appropriate number of reasonable regulatory options reflecting the range that the agency has authority to consider under the statute granting rulemaking authority, including flexible regulatory options of the type described in section 622(c)(2)(C)(iii), unless precluded by the statute granting the rulemaking authority;"

4. Agency review process. Your proposal presents a number of ambiguities and problems. The principal problem is one of process. This section was completely rewritten once before, in response to strong criticism from the Administration and Democratic members that it was too cumbersome and unworkable. It is our recollection of those discussions, including discussions at the Member level involving Democratic representatives of your Caucus, that the compromise achieved on the major elements of section 623, while not perfectly satisfactory to either all the Democratic Members or all the Republican Members, was an acceptable middle ground, nonetheless. To reopen major elements of this section (i.e., the 3-year scheduling of successful petitions) for further change from your side is unacceptable.

In terms of specifics, we have the following reactions to your proposal:

a. On page 4, before line 15, and on page 6, before line 11, you have deleted two instances of a virtually identical subparagraph, providing agencies with guidance on how to consider and prioritize rules that might be amended. We have no idea why this language would be objectionable now, as it was reviewed and edited during the bipartisan discussion on this section, and not objected to at that time.

b. On page 5, lines 1-8, you provide a different mechanism for dealing with the problem of agency overload--allowing the scheduling of the review of rules beyond the 11-year time frame if the agency "reasonably determines" that the resources would not be available to carry out the task. This determination would be subject to judicial review. While we are not unsympathetic to the problem of agency overload, we know of no way in which any agency can "reasonably determine" what its fiscal and personnel resources would be over a period of 11 years. Thus, your proposal would put agencies in an indefensible position, if they wished to avail themselves of the mechanism. We do not see that as a solution to agency overload. Your proposal also deletes a provision contained on page 30, lines 23-25 of the

Dole/Johnston substitute that allows the United States Court of Appeals for the D.C. Circuit to extend by 1 year the 3-year deadline for review of a rule that was the subject of a successful petition. If agency overload is of continuing concern, we would be willing to consider a 2-year good-cause extension to the 3-year deadline. We see this as a more realistic remedy than a judicially reviewable agency determination about resources that are likely to exist two Presidential terms, and six Congresses, in the future.

c. On page 5, lines 13-15, you provide a different relationship between the petition process in section 623 and the petition right under section 553. Under current law, any interested person has the right to petition for the issuance, amendment, or repeal of a rule and is entitled to a written response within a reasonable time. Such response, under current law, is subject to judicial review, albeit under a lenient standard. Under current law, the definition of "rule" for the purposes of this right includes interpretative rules, general statements of policy, and guidance. This existing right to petition to amend or repeal a rule can be exercised on many grounds--for example, because a rule is unconstitutional or because the rule exceeds the bounds of the underlying statute.

S.343 does not seek to change rights that citizens enjoy under current law. However, because S.343 does create new criteria that govern the issuance of major rules, and because there is widespread bipartisan consensus that these same criteria should be used to look at existing rules, the Dole/Johnston substitute seeks to create a rational process for the exercise of the existing right to petition, where the petition involves a major rule and the issue is related to the new decisional criteria provided in the bill. We did this to clarify the special procedures that apply in the case of major rules, not to undo the rights that citizens currently enjoy under section 553.

We also believe that it would be inappropriate to shoehorn every issue that a citizen might want to petition an agency about with respect to a major rule into the process defined in section 623. For example, a petition on the constitutionality of a rule would not be rationally reviewed by the standards provided on page 28, lines 19-23, while a petition that challenged a cost-benefit analysis or a risk assessment underlying a rule would. Section 623(c) would probably be unacceptably complex if we tried to anticipate, and provide standards for agency action on, every possible reason for filing a petition to amend or repeal a rule.

d. On page 6, before line 15, you apparently would repeal Amendment No. 1490, offered by Mr. Abraham, that was adopted on a 96-0 recorded vote. If this is your intent, such a proposal would not be acceptable.

e. On page 6, lines 15-30, you provide some rewritten language on judicial review that permits the consolidation of all judicial challenges to a review schedule into a single proceeding. With the addition of the following language from page 30, lines 23-25 of the Dole-Johnston substitute (as discussed above), your proposed language would be acceptable:

"The court upon review, for good cause shown, may extend the 3-year deadline under subsection (c)(2) for a period not to exceed 2 additional years."

f. You do not provide suggestions for any other changes to section 623 than the ones discussed above, but we would like to reiterate our commitment to accept Amendment No. 1864, proposed by Mr. Chafee, replacing the sunset of a rule with a rulemaking to repeal the rule. This language is identical to the language proposed for this subsection in Amendment No. 1647, proposed by Mr. Levin.

g. You propose to delete section 634, providing a petition for agency review of a major free-standing risk assessment. This would leave no avenue for independent technical critique of risk assessments that drive, through non-regulatory means, agency actions with substantial impacts (more than \$100 million per year) on the U.S. economy. This is unacceptable.

5. Decisional criteria. The biggest issue in this section is your proposed formulation of the "Construction with other laws." This formulation cannot be accepted by our side.

a. First, your proposed language would repeal Amendment No. 1496, a Dole-Levin-Hatch-Roth-Johnston amendment "to clarify that the bill does not contain a supermandate." At the time of its adoption, the Democratic floor manager stated that he had "checked on our side of the aisle. We would be glad to accept this amendment." We do not believe it is acceptable to drop language in the bill that is clear and concise and that was formally declared "acceptable" by all sides at the time of its adoption.

b. Second, your new language in this subsection states that the entire section related to decisional criteria shall not apply if the requirements are "inconsistent with the relevant provisions of the statute, as reasonably interpreted by the agency, that authorize the promulgation of a rule...." This would appear to be the same exclusion as the one in the Glenn bill (S.1001), governing determinations of whether benefits justify costs (page 11, lines 14-24). S.1001 excludes the use of cost-benefit analysis in decision making if "explicitly or implicitly inconsistent with the statute under which the agency

is acting." If agencies are to be given broad discretion to interpret whether cost-benefit analysis is "consistent" with the statute under which they are promulgating a rule, and if they may void the decisional criteria of the S.343 on the basis of that determination, then those agencies that are most in need of the discipline of cost-benefit analysis in making decisions will likely be the agencies that are least affected by this bill.

c. We would like to reiterate our commitment to change the test within the decisional criteria section from a "least cost alternative" test with broad exemptions to a more streamlined "greater net benefits" test. We believe that this improved formulation, proposed by Mr. Roth after extensive discussion with Senators Glenn and Levin, and accepted by Mr. Chafee in his Amendment No. 1865, is consistent with sound economics and public policy. Further changes to this formulation that place unbridled discretion in the hands of agencies to avoid decisional criteria, or that confuse the different tests provided by cost-benefit analyses and those analyses required by the Regulatory Flexibility Act, would be unacceptable.

6. **Judicial review.** Your language for "Standards for Review" is confusing and therefore unacceptable. This section in the bill begins by stating that "Compliance or noncompliance by an agency with the provisions of this subchapter and subchapter III shall be subject to judicial review only in accordance with this subsection." Yet your proposed standard for review does not relate to what is being reviewed. Because your language is ambiguous, it could be construed to prohibit not only procedural review, but also substantive review of a rule for which the cost-benefit analysis or the risk assessment was fatally flawed. None of us want a nit-picking procedural review of the requirements of subchapters II and III of the Dole-Johnston substitute. We believe that the existing language of the substitute makes this clear, but would be willing to consider additional steps (e.g., a colloquy) to make our common intention even more explicit.

7. **Regulatory flexibility.** Your proposal, unfortunately, cannot be accepted. Among its problems is the apparent lack of any enforceable duty on an agency, once it has conducted a regulatory flexibility analysis for a non-major rule, to do anything to minimize burdens to small business, and no prospect of judicial review if the agency wholly ignores the requirement to either carry out a regulatory flexibility analysis or make a certification that it is not required. The current language in the Dole/Johnston substitute has these essential features, as well as others.

8. **Delaney Clause.** We believe that a common negligible risk standard for all potentially cancer-causing substances in the food supply is sensible and is overwhelmingly supported by the scientific community.

The 1987 report of the National Academy of Sciences (*Regulating Pesticides in Food: The Delaney Paradox*) lays out a very detailed case for the standard in the bill with respect to pesticides in processed food. It shows that a consistent negligible risk standard for pesticides would actually improve the safety of the food supply and lead to lower overall risk of cancer from pesticides and pesticide residues in our diet. According to a letter dated August 2, 1995 from the President of the Institute of Medicine of the National Academy of Sciences, the findings of this report are still relevant today.

The 1979 report of the National Academy of Sciences (*Food Safety Policy*) examined the broader issue of safety of other food additives, food colorings, and animal drugs, in addition to pesticides. It is a far-ranging report of about 500 pages, with several hundred scientific references and notes. According to the August 2 letter from the National Academy of Sciences, its findings and recommendations are also still relevant today. The report's principal statutory recommendation is that "The Congress should revise the food safety provisions of the Federal Food, Drug and Cosmetic Act to abolish differences in the statutory standards among categories of substances, and create a single standard for food safety regulation applicable to all food substances." (page 9-11) In addition to considering risk, the report advocates consideration of whether risks and benefits apply differentially to specific groups--such as the young or aged, and pregnant women. (page 9-12) The report endorses different treatment of substances in food based on whether they pose "high," "medium," or "low" risk. (pages 9-16 to 9-18) "Low risk foods should be exempt from special regulatory control, but not necessarily from educational efforts to reduce the risk still further by acquainting the public with the risks they may pose, particularly in combination with other substances." (page 9-18) "When benefits can be estimated or objectively assessed so as to assist the judgment of the consumer or of the agency, FDA should be responsible for obtaining such assessment. However, it should continue primarily to be risk that triggers government intervention in the food supply, and the government must remain cognizant of the centrality of risks in food safety regulation." (page 9-19)

While the provision of the Dole/Johnston substitute does not implement every recommendation made in the *Food Safety Policy* report, and while a technical change is required in the section references of the substitute, our language is consistent with the Academy's direct recommendation to move to a more consistent safety basis for food additives, based on risk. Removing the bar on the introduction of food additives that pose a negligible risk is consistent with the Academy's position that low-risk substances do not require special regulatory attention and that risk itself should be the central consideration for action by the agency.

The *Food Safety Policy* report also illustrates the pitfalls of the proposal that you have made. Congress asked for this broad study in November 1977 in P.L. 95-203, the Saccharin Study and Labeling Act. The report was transmitted 14 months later. To suppose that the Academy carry out a new, independent study of food safety and report on "appropriate health based safety standards for pesticide residues, food additives, and animal drugs, in both raw and processed food" within 7 months is not practical, unless the Academy were to simply review its existing reports. The report also illustrates the difference between asking the Academy to do a report and acting on its recommendations. Beginning in 1977, the National Academy assembled a stellar committee that made a number of far-reaching recommendations for food safety reform. Those recommendations apparently have gathered dust for 16 years. Indeed, on the specific topic of Delaney reform, Congress has conducted numerous hearings over the years, and the scientific obsolescence of the Delaney Clause has been identified again and again.

We do not believe that our recommendation for comprehensive reform of the Delaney Clause is contrary to the mainstream recommendations of the U.S. scientific community. We see no compelling need to ask the Academy to repeat a report that the President of the Academy's Institute of Medicine (which would carry out any new study requested by Congress) states is still relevant. Your provision would have the effect of keeping old cancer-causing pesticides, grandfathered at the time of enactment of Delaney, on the market and in the food supply for another year. Our provision would allow the introduction of safer pesticides to displace them. We believe that there is compelling case for the basic thrust of our provision. After so many failed attempts to produce legislation to reform the Delaney Clause over the last few Congresses, we believe that Senators deserve the chance to vote on a proposal that is in the mainstream of the best scientific recommendations on the safety of the food supply.

9. **Toxics Release Inventory.** Your conceptual paper that you presented earlier in the week mentioned that you would propose specific language on this topic. In staff discussions when the bill was still being actively considered, considerable progress was being made on this topic. Given this background and the fact that the Senate has already voted against an amendment to strike this subsection altogether, we are disappointed not to see a proposal that would move in the direction of closure.

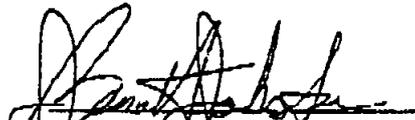
10. **Finding on Congressional Review.** Your language would be acceptable, if you are willing to change "on legislative intent" to "in legislative language".

11. **Effective Date.** Your proposal is unclear as to whether "such date" refers to the date of enactment or to the date that is 90 days later. While we understand the concern that is leading you to propose an adjustment to the way in which the Act takes effect, we cannot accept any proposal that creates incentives for agencies to

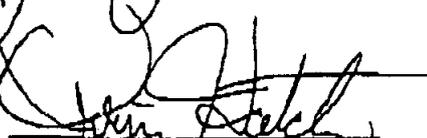
"game" the passage of S.343 by rushing out notices of proposed rulemaking before some future date and thereby bypassing the provisions of the Act.

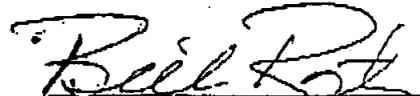
In summary, while we cannot agree to a number of your proposals in their present form, we welcome and respect your good-faith attempt to address the issues in the debate over S.343 and to attempt to bridge the gaps between proponents of the bill and some of those who have not supported the bill, to date. We have identified those provisions that we are willing to incorporate into the bill. With respect to those proposals with which we cannot agree, we would propose a time agreement so that they can be debated and resolved on the Senate floor. In that regard we would be happy to have a separate vote on each proposal that we cannot accept followed by a vote on final passage.

Sincerely,


J. Bennett Johnston


Bob Dole


Orrin G. Hatch


William V. Roth, Jr.



ALLIANCE FOR REASONABLE REGULATION

95-ARR-15

FOR IMMEDIATE RELEASE

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DEMOCRATIC REGULATORY REFORM PROPOSAL UNACCEPTABLE

WASHINGTON, D.C., August 5, 1995 -- "This latest Democratic regulatory reform proposal is unacceptable because it would preclude the application of sound science and common sense cost considerations to major regulatory decisions," said Jerry Jasinowski, chairman of the Alliance for Reasonable Regulation (ARR) and president of the National Association of Manufacturers.

"There are significant constructive suggestions in this package and we appreciate the efforts of Senators Robb and other moderate Democrats who want reasonable regulatory reform.

"But what is amazing about this proposal is that it would be weaker than even President Clinton's Executive Order addressing regulatory reform, and would turn back the clock on the regulatory progress of recent years.

"The outrageous 'construction with other laws' language would completely negate the application of the most important provisions of S. 343. It's a sham to say you support regulatory reform and then exempt government agencies from taking any actions."

In letters to Senator Robb and Conrad, Jasinowski said, "For the ARR and others who expect that S. 343 will produce smarter, more cost-effective, and productive rules, this change to Section 624 totally emasculates the application of common sense and cost-benefit analysis to regulations and makes the bill ineffectual."

"We would be better off with no bill than adopting this provision that takes the heart out of S. 343 and kills the prospects for real regulatory reform," Jasinowski added.

"The proposal to delete the Delaney clause reform provision rejects the recommendation of the broad scientific community. As former Surgeon General Koop said: 'Repeal of the Delaney clause that combines the best of modern science with wise public policy, as contained in S. 343, can make the safest food supply in the world even better and at less cost to the taxpayer,'" Jasinowski said.

In the letter, Jasinowski concluded, "In sum, we find the proposed modifications to be inconsistent and confusing. A number of the proposals have merit, and we look forward to working with you on those. On the other hand, we find proposed modifications to the decisional criteria eviscerate the core of the bill and undermine the principal goal of achieving greater overall benefits at less cost to the American public."

The ARR, a coalition of more than 2,600 groups, represents the entire business community.

-ARR-

A copy of the ARR letter follows.



ALLIANCE FOR REASONABLE REGULATION

August 5, 1995

The Honorable Charles Robb
United States Senate
SR-154
Washington, DC 20510

The Honorable Kent Conrad
United States Senate
SH-724
Washington, DC 20510

Dear Senators Robb and Conrad:

On behalf of the Alliance for Reasonable Regulation (ARR) I am writing to express the views of ARR on the Proposed Modifications to the Dole/Johnston Amendment to S.343 (dated August 4, 1995). ARR greatly appreciates the time and effort that you have devoted to developing the proposed modifications.

Our aim for this legislation has always been to preserve the protection for human health, safety, and the environment that we currently enjoy and to do so in a more efficient and effective manner. We are looking for and will accept, legislative language that strikes the optimum balance between these two goals. Any language however, must meet three essential tests: (1) it must mandate that, to the maximum extent possible and permitted by existing law, the cost-benefit analysis is a major factor in the regulatory decision; (2) it must hold the agency accountable for complying with the requirements of the legislation; and (3) it must provide an adequate means for the affected public to petition agencies to reexamine old regulations whose efficiency or effectiveness are not consistent with the standards set forth in the legislation.

There are significant elements in the proposal that ARR recognizes have merit. However, on the basis of these criteria, we find a number of the proposed modifications to be unworkable and unacceptable.

In this letter, I want to discuss briefly four elements of the proposal that we find to be most objectionable -- the provisions dealing with (1) decisional criteria, (2) the petition process, (3) judicial review, and (4) the treatment of TRI and the Delaney Clause.

Decisional Criteria

In our view, the proposed changes to Section 624 would essentially commit to an agency's unreviewable discretion the decision of whether, and how to, apply the new decisional

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criteria to major rules. Subsection 624(b)(3) would create an enormous loophole, allowing agencies to dispense with findings relating to a comparison of the net benefits of various alternatives. And subsection 624(d) would give agencies enormous discretion to avoid implementing the new decisional criteria completely. Indeed, agencies would be given even more leeway to decide whether to take cost-benefit and related considerations into account than they have under President Clinton's Executive Order on Regulatory Planning and Review (E.O. 12866). Moreover, agency decisions to dispense with the decisional criteria of Section 624 in promulgating a major rule would not even be reported to Congress, as is required in the current version of S.343, thereby detracting from the accountability and transparency of the process. Finally, the proposed change to engraft a fragment of the Regulatory Flexibility requirements into the requirements for flexible standards is very confusing and is likely to undercut the value of both provisions.

We fear that the proposed modifications would turn Section 624 into a sham requirement and undermine the fundamental objective of S.343 -- to establish cost-benefit and related decisional criteria that will really make a difference in agency decision-making on major rules. For ARR and others who expect that S.343 will produce smarter, more cost-effective, and productive rules, this change to Section 624 totally emasculates the application of common sense and cost-benefit analysis to regulations and makes the bill ineffectual.

Petition Process

The petition process for reviewing existing major rules and other actions established by Section 623 has been seriously weakened. Petitions could no longer be filed at all to review free-standing risk assessments. In addition, petitions to amend or repeal major rules could only be filed within a limited 180-day period and would thereafter be barred, even if based on new information or grounds unrelated in those in Section 623. Thus, the petition opportunities afforded under existing law, (5 U.S.C. Section 553(l)), would be arbitrarily curtailed. Moreover, even where an agency itself has recognized that a petition is meritorious, it could delay review of the rule for as long as eleven years instead of the three years specified in S.343.

Indeed, even this eleven year deadline would be unenforceable and could be extended indefinitely by the agency while the rule itself remained in effect. The cumulative impact of these changes will be to undermine the incentives for agencies to reexamine rules which have a major impact on the economy and contain serious technical, legal or scientific flaws that require correction.

Judicial Review

The carefully worded judicial review provisions of section 625 have been reworked in a manner that is both confusing and could eliminate agency accountability for implementing the reforms mandated by the legislation. By deleting any reference to agency compliance with the new requirements from section 625(d), the proposed modifications could prevent courts from

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overturning agency rules even where a required cost-benefit analysis or risk assessment has been entirely omitted or the decisional criteria in section 624 have been completely ignored. As a result, these requirements could become effectively unenforceable.

Delaney Clause and TRI

The proposed modifications would eliminate what we believe is a key provision in S. 343 reforming the Delaney Clause. There is consensus within the scientific community and the Congress that the Delaney Clause is outdated and should be replaced with a negligible or insignificant risk standard as contained in S.343. Deleting or deferring this essential reform is simply not acceptable.

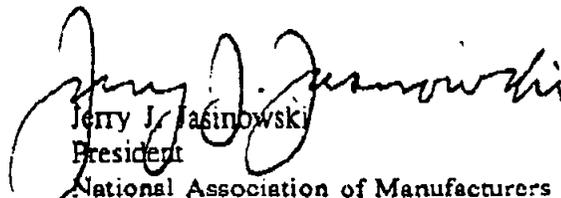
In addition, deleting the TRI provision from S.343, making needed changes to this important program, is a serious mistake.

As a final matter, we are curious about the omission of subsections (e) and (f) of the "New Proposal on Agency Review Process" (page 6 of proposed modifications). There appears to be missing language -- including the Sen. Abraham amendment (no. 1490) relating to small business.

In sum, we find the proposed modifications to be inconsistent and confusing. A number of the proposals have merit, and we look forward to working with you on those. On the other hand, we find the proposed modifications to the decisional criteria eviscerate the core of bill and undermine the principal goal of achieving greater overall benefits at less cost to the American public.

Once again, we thank you for your efforts and look forward to working with you

Sincerely,


Jerry J. Jasinowski
President
National Association of Manufacturers
Chairman
Alliance for Reasonable Regulation