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**Regulatory Reform-legal & other
analyses [1]**

Exceptions to Subchapters II and III

1) Where rule must be promulgated quickly

Excepted from the definition of "rule" is a rule which is exempt from notice and comment rulemaking under 5 U.S.C. § 533. § 621(10)(A). This should exempt rules which must be promulgated very quickly in order to implement the congressional will (such as USDA rules to implement the new Farm Bill in time for spring planting). However, section 625 extends all statutory deadlines during the next two years for six months to permit compliance with cost-benefit and risk assessment. That would indicate a statutory deadline is not a basis for exemption from these requirements.

Section 622(f) allows agencies to conduct these analyses after the rulemaking if doing the analyses in advance would be "contrary to the public interest due to an emergency, or health or safety threat that is likely to result in significant harm to the public or to natural resources." However, for many rules with a short turn-around, it will be a futile exercise to do the analyses after the fact.

Possible means of addressing problem:

Add to § 621(10)(I) [exceptions to covered rules]:

(I) a rule required to be promulgated at least annually or within a period of one year or less pursuant to statute;

Amend § 622(f)(1)(2) to add:

(2) If a major rule is adopted under paragraph (1), the agency shall promptly comply with the provisions of subsections (a) through (e) of this section upon receipt of a petition setting forth good cause, as provided by agency rule, [or if directed to do so by the Administrator].

2) Grants, contracts, and loans

This exception could be construed to be nonsensically narrow. Section 621(10)(K) excepts "a rule relating to a Federal grant, contract, or loan." Query whether this should be "a rule relating to Federal grants, contracts, or loans."



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DATE: 3/5/96

MESSAGE: See esp. p. 71, 76 of APA
treatise; pages 1-3 of brief
excerpt

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which urges use of notice-and-comment procedure, where possible, if a rule or statement will have a substantial impact on the public.¹²⁵

The Conference's Recommendation also states that where it is necessary for agencies to make such rules and statements effective immediately, agencies should give the public the opportunity to submit post-promulgation comments.¹²⁶ While a post-promulgation comment opportunity is not a *substitute* for pre-promulgation comment where required,¹²⁷ it is likely to put the agency in a much better posture on judicial review, especially where it has responded in good faith to post-promulgation comments.¹²⁸

3. "Good Cause" Exemptions

Sections 553(b)(B) and 553(d)(3) of the APA authorize agencies to dispense with certain procedures for rules when

¹²⁵Recommendation No. 76-5, "Interpretive Rules of General Applicability and Statements of General Policy," 1 C.F.R. § 305.76-5. Some agencies have followed this advice, see, e.g., EPA, Reporting Requirements for Risk/Benefit Information under Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), Final Interpretative Rule and Statement of Policy, 50 Fed. Reg. 38,115, 38,119 (1985) (requesting public comment although rule exempt from public participation requirements of APA as general statement of policy and interpretation of statute).

¹²⁶Recommendation No. 76-5 at ¶2. See Asimow, *supra* n. 73, 1985 Duke L.J. at 426 (noting the "modest benefit to the public from a post-adoption comment system would outweigh the modest additional costs that it would impose on agency staffs," and questioning the "much costlier requirement" that would add some form of "substantial impact" test into the APA.)

¹²⁷The general rule that a rule found invalid for failure to provide for notice and comment cannot be saved by providing for comment after promulgation is discussed in *Levesque v. Block*, 723 F.2d 175, 188 (1st Cir. 1988).

¹²⁸*Id.* See also Asimow, *supra* n. 73, 1985 Duke L.J. at 421-24 (discussing the benefits of post-promulgation comments).

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they find "good cause" to do so. Under section 553(b)(B), the requirements of notice and opportunity for comment do not apply when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Section 553(d)(3) allows an agency, upon finding good cause, to make a rule effective immediately, thereby avoiding the 30-day delayed effective date requirement in section 553.

These two exceptions give agencies flexibility by allowing them to dispense with procedures in promulgating rules not otherwise exempted, but like other exemptions, they are to be construed narrowly.¹²⁹ Moreover, an agency must give supporting reasons for invoking the good cause exemptions.¹³⁰ The agency's findings of good cause are judicially reviewable on the same basis as any other findings committed to the agency's judgment.¹³¹ Although the language of the exemption from the delayed effective date requirement is more general than the

¹²⁹See *Mobay Chemical Corp. v. Gorsuch*, 682 F.2d 419, 426 (3rd Cir.), cert. denied, 459 U.S. 988 (1982); Note, *The "Good Cause" Exceptions: Danger to Notice and Comment Requirements Under the Administrative Procedure Act*, 68 Geo. L.J. 765, 773 (1980).

¹³⁰Senate Comm. on Judiciary, *Administrative Procedure Act: Legislative History*, S. Doc. 248, 79th Cong., 2d Sess. (hereafter *Legislative History of the APA*) at 258 (1946). ("The exemption of situations of emergency or necessity is not an 'escape clause' in the sense that any agency has discretion to disregard its terms or the facts. A true and supported or supportable finding of necessity or emergency must be made and published."). 5 U.S.C. § 553(b)(B) requires that the agency "incorporate[] the [good cause] finding and a brief statement of reasons therefor in the rules issued."

¹³¹See *Bonfield, Military and Foreign Affairs Function Rule-making Under the APA*, supra n. 39, 71 Mich. L. Rev. at 292. Indeed, because public participation has been dispensed with, the courts may scrutinize these rules more carefully than others.

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standard for dispensing with notice and comment, several commentators have concluded that "good cause" under both sections must be predicated on similar findings.¹³²

The terms "impracticable," "unnecessary" or "contrary to the public interest" used in section 553(b)(B) indicate the circumstances in which the good cause exceptions may be employed. The APA's legislative history defines the terms this way:

"Impracticable" means a situation in which the due and required execution of the agency functions would be unavoidably prevented by its undertaking public rule-making proceedings. "Unnecessary" means unnecessary so far as the public is concerned, as would be the case if a minor or merely technical amendment in which the public is not particularly interested were involved. "Public interest" supplements the terms "impracticable" or "unnecessary"; it requires that public rulemaking procedures shall not prevent an agency from operating and that, on the other hand, lack of public interest in rulemaking warrants an agency to dispense with public procedure.¹³³

Ordinarily, situations potentially covered by the "good cause" exception are those in which advance notice would defeat the agency's regulatory objective; immediate action is necessary to reduce or avoid health hazards or other imminent harm to persons or property; or inaction will lead to serious dislocation in government programs or the marketplace.¹³⁴

¹³²See Note, *The "Good Cause" Exceptions*, *supra* n. 129, at 772 n. 61.

¹³³Legislative History of the APA, *supra* n. 130, at 200.

¹³⁴See generally Jordan, *The Administrative Procedure Act's "Good Cause" Exemption*, 1983 ACUS Recommendations & Reports 49; Jordan, *The Administrative Procedure Act's "Good Cause" Exemption*, 36 Admin. L. Rev. 113 (1984) (based on

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Reviewing courts have regularly applied the section 553(b)(B) good cause exemption narrowly to prevent agencies using it as an "escape clause" from notice-and-comment requirements. As the District of Columbia Circuit said in *Action on Smoking and Health v. CAB*,¹³⁵ "Bald assertions that the agency does not believe comments would be useful cannot create good cause to forgo notice and comment procedures. . . . To hold otherwise," the court said, "would permit the exceptions to carve the heart out of the statute."¹³⁶ The court there held invalid an agency rule issued without notice and an opportunity for comment, where the rule was reissued by the agency to correct a different procedural deficiency in an earlier proceeding in which notice and comment had been provided.¹³⁷

Courts applying the "contrary to the public interest" ground for exemption have often been inclined to err on the side of public safety and health.¹³⁸ At the same time, the fact that an action purports to be protective of the public does not necessarily justify not allowing for public participation.

report to the Administrative Conference). Some enabling statutes contain parallel provisions authorizing agencies to take "emergency" action without affording the normal opportunity for public participation. See, e.g., OSHA Act, 29 U.S.C. § 655(c) (authorizing OSHA to issue a "emergency temporary" occupational safety and health standard where there is a "grave danger" to employees and the standard is "necessary" to protect employees from the "grave danger."

¹³⁵713 F.2d 795 (D.C. Cir. 1983).

¹³⁶*Id.* at 800 (citations omitted).

¹³⁷The earlier rule was set aside and remanded in *Action on Smoking and Health v. CAB*, 699 F.2d 1209 (D.C. Cir. 1983), on the ground that the agency statement of basis and purpose was insufficient under the APA. Cf. *United Steelworkers v. Pendergrass*, 819 F.2d 1263 (3d Cir. 1987) (holding additional notice and comment unnecessary after court remand on rule).

¹³⁸See Jordan, ACUS Report, *supra* n. 134 at 58-59.

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particularly where the regulation has wide impact and is controversial. For example, in the famous Baby Doe case,¹³⁹ the district court rejected the government's argument that since lives were at stake, "good cause" existed for HHS' issuing its regulation on the treatment of defective newborn infants without notice and comment. The court stated that the argument "could as easily be used to justify immediate implementation of any sort of health or safety regulation no matter how small the risk for the population at large or how long-standing the problem."¹⁴⁰

In *Asbestos Information Association v. OSHA*,¹⁴¹ the Fifth Circuit vacated OSHA's asbestos standard issued under a statute authorizing temporary emergency standards where the agency finds that dispensing with notice and comment is "necessary" to protect employees from a "grave danger."¹⁴²

¹³⁹*American Academy of Pediatrics v. Heckler*, 561 F.Supp. 395 (D.D.C. 1983), *aff'd on other grounds sub nom. Bowen v. American Hospital Ass'n*, 476 U.S. 610, (1986).

¹⁴⁰561 F.Supp. at 401. The court emphasized that there was no indication of any "dramatic change in circumstances that would constitute an emergency justifying shunting off public participation in the rulemaking." *Id.* The government's argument that the regulation was "procedural" or "interpretive" was also rejected by the district court, saying that the regulation "was intended . . . to change the course of medical decisionmaking in these cases" and thus was more than a clarification or explanation of an existing rule or statute. *Id.*, quoting *Guardian Federal Savings and Loan v. FSLIC*, 589 F.2d 658, 664 (D.C. Cir. 1978). Apart from its procedural findings, the district court also found the regulation to be invalid as arbitrary and capricious, 561 F. Supp. at 399-400, 403, and expressed concern about the constitutionality of the regulation, *id.* at 402.

¹⁴¹727 F.2d 415 (5th Cir. 1984).

¹⁴²29 U.S.C. § 655(c). OSHA had issued an earlier asbestos emergency temporary standard in 1972, which was not challenged in court. For a history of OSHA regulation of asbestos to 1983, see generally Mintz, *OSHA: History, Law and Policy* 115-29 (1984).

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The court first agreed that an "emergency" standard may lawfully be issued even though new information on grave danger had not come to the attention of the agency.¹⁴³ However, the court concluded that the risk assessment analysis used in the rule,¹⁴⁴ while an "extremely useful tool," is "precisely the type of data that may be more uncritically accepted after public scrutiny through notice-and-comment rulemaking, especially when the conclusions it suggests are controversial or subject to different interpretations."¹⁴⁵

Another "good cause" issue that has arisen with increasing frequency is the extent to which congressionally-imposed deadlines justify an agency's issuance of rules without notice and comment. This issue was addressed in a series of cases challenging EPA's promulgation, without notice and comment, of lists of geographical areas not meeting federal air-quality standards under the Clean Air Act.¹⁴⁶ Courts in five circuits sustained challenges to EPA's action, rejecting its "good cause" argument largely on the ground that EPA could have published

¹⁴³727 F.2d at 423. The court of appeals added that the agency must offer some explanation of its timing of the emergency standard, "especially when, as here, for years it has known of the serious risk" and "has possessed, albeit in unrefined form, the substantive data forming the basis" of the standard. *Id.* See also *American Acad. of Pediatrics, supra* n. 139, 561 F. Supp. at 401.

¹⁴⁴Risk assessment analysis is a statistical technique utilized by regulatory agencies, among others, for extrapolating risk at high levels of exposure to lower levels. See generally Merrill, *Federal Regulation of Cancer-Causing Chemicals*, 1982 ACUS Recommendations & Reports 21, 83-85.

¹⁴⁵727 F.2d at 426. The court of appeals also held that the emergency standard was not "necessary" because increased protection of employees could be achieved through more effective enforcement of existing standards. *Id.* at 426-27.

¹⁴⁶Clean Air Act Amendments of 1977, Pub. L. No. 95-95, 91 Stat. 685, codified at 42 U.S.C. § 7401 *et seq.*

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¹⁴⁷The court Report, *supra* EPA, 597 F.2d *Corp. v. EPA*, U.S. 1035 (1980). Note: *The "Comment Request" supra* n. 129.

¹⁴⁸See, e.g., *Donovan*, 653 and Health Act notice and comment 645 F.2d 13 reduction of *National Fed'n* 611-12 (D.C. regulations).

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the lists as a proposal and obtained public comment with little delay.¹⁴⁷ In these and other similar cases, a factor that often surfaces in the judicial analysis is whether or not the agency made a good faith attempt to comply with the APA's requirements for public participation.

Courts are more inclined to uphold the agency's action if the agency responded to circumstances beyond its control, if the emergency rule is of limited scope or duration, and if the agency initiated prompt follow-up proceedings allowing for public participation.¹⁴⁸ The Fifth Circuit, in *American Transfer & Food Storage v. ICC*,¹⁴⁹ upheld the ICC "good cause" finding that notice and comment was not necessary in issuing rules under the Motor Carrier Act of 1980, saying: "[T]o make the new Act effective and to achieve the goals set by Congress, it was imperative that the Commission, in order to adapt its processes to the new order, adopt almost immediately new rules and procedures with as much notice as was practicable. This it did by issuance of interim rules with invited public

¹⁴⁷The cases are cited and discussed in Jordan, ACUS Report, *supra* n. 134, at 61-65. See, e.g., *Sharon Steel Corp. v. EPA*, 597 F.2d 377 (3d Cir. 1979). But see *United States Steel Corp. v. EPA*, 605 F.2d 283 (7th Cir. 1979), cert. denied, 444 U.S. 1035 (1980) (sustaining good cause finding). See also Note: *The "Good Cause" Exceptions: Danger to Notice and Comment Requirements Under the Administrative Procedure Act*, *supra* n. 129.

¹⁴⁸See, e.g., *Council of the Southern Mountains, Inc. v. Donovan*, 653 F.2d 573 (D.C. Cir. 1981) (upholding Mine Safety and Health Administration rule delaying effective date without notice and comment); *Northwest Airlines, Inc. v. Goldschmidt*, 645 F.2d 1309 (8th Cir. 1981) (upholding FAA emergency reduction of comment period and immediate effective date); *National Fed'n of Federal Employees v. Devine*, 671 F.2d 607, 611-12 (D.C. Cir. 1982) (upholding OPM emergency regulations).

¹⁴⁹719 F.2d 1283 (5th Cir. 1983).

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input before final regulations were issued."¹⁵⁰ As this case illustrates, however, rules labeled "interim rules" by an agency are final under the APA, and persons "adversely affected or aggrieved" may challenge the rules in court.¹⁵¹

 In a number of decisions, reviewing courts have given greater weight to congressional deadlines in justifying lack of notice and comment when the deadlines implemented budget-cutting measures. In *Philadelphia Citizens in Action v. Schweiker*,¹⁵² the Third Circuit held that HHS had "good cause" for not providing notice and comment in issuing rules to implement changes in the Aid to Families with Dependent Children Program (AFDC).¹⁵³ The court relied particularly on the fact that Congress imposed substantially shorter deadlines than those involved in the EPA Clear Air Act cases,¹⁵⁴ and that benefit programs, such as the AFDC program, often are statutorily exempt from notice-and-comment requirements.¹⁵⁵

¹⁵⁰*Id.* at 1294. The Motor Carrier Act became immediately effective and "provided no transition period for developing new procedures to implement the significant legislative changes." *Id.* at 1293. The interim rules were in effect until the final rules were issued.

¹⁵¹5 U.S.C. § 702.

¹⁵²669 F.2d 877 (3d Cir. 1982).

¹⁵³The changes were mandated by the Omnibus Budget Reconciliation Act (OBRA) of 1981, Pub. L. No. 97-35, 95 Stat. 357.

¹⁵⁴The OBRA statute was to become effective 49 days after enactment, 669 F.2d at 883, while in the EPA cases, EPA had three years to promulgate the regulations. *Id.* The court of appeals in *Philadelphia Citizens* also noted that EPA would have had sufficient time to allow comment on the unreviewed state-submitted plans under the Clear Air Act, an approach that was not available in the AFDC case. *Id.* at 883-84.

¹⁵⁵Notice and comment was only required for the regulations involved because HHS in 1971 had waived the exemption in the APA from notice-and-comment requirements for grants and benefits. 669 F.2d at 881. See also *Petry v. Block*, 737 F.2d 1193, 1201 (D.C. Cir. 1984) (involving OBRA of

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In many cases, agencies issuing rules without notice and comment following a "good cause" finding have referred to the rules as "interim rules," and then modified the rules, as appropriate, following post-promulgation comment.¹⁵⁶ This practice comports with a Recommendation of the Administrative Conference adopted in 1983.¹⁵⁷ Congress has

1981); *Sepulveda v. Block*, 782 F.2d 363 (2d Cir. 1986) (involving OBRA of 1982, Pub. L. No. 97-253, 96 Stat. 772).

¹⁵⁶*See, e.g.*, Department of Transportation, Federal Aviation Administration, "Transportation of Federal Air Marshals," Final Rule with Request for Comments, 50 Fed. Reg. 27,924 (1985). The FAA "emergency rule" required "certificate holders" to carry Federal Air Marshals in designated passenger operations. Because of the "emergency need for the regulations," including hijackings and terrorist attacks on U.S. aviation, the agency found that notice and comment was "impracticable; and contrary to the public interest." However, since under DOT Regulatory Policies and Procedures, 44 Fed. Reg. 11,034 (1979), agencies in the Department "should" provide an opportunity for comment on emergency regulations, the notice invited comment on the "final rule," which was immediately effective, and stated that the comments would be considered and the rule "may be changed in light of the comments received." *Id.* *See also* Department of Agriculture, Animal Plant Health Inspection Service, Imported Fire Ant Regulated Areas, Affirmation of Interim Rule, 50 Fed. Reg. 48,551 (1985). The Department of Labor issued rules implementing the Employee Polygraph Protection Act of 1988, 53 Fed. Reg. 41,494 (1988), making the rule effective on December 27, 1988, the effective date of the Act, but giving an additional two months for comment. *See also* National Oceanic and Atmospheric Administration, Subsistence Taking of North Pacific Fur Seals, Emergency Interim Rule and Request for Comment, 50 Fed. Reg. 27,914 (1985).

¹⁵⁷Recommendation No. 83-2, "The 'Good Cause' Exemption From APA Rulemaking Requirements," 1 C.F.R. §305.83-2. The Conference recommended that in all cases where an agency is relying on the exemption, it should take the following actions: 1. Frame the rule as "narrowly" as possible to accomplish the regulatory objective; 2. Develop "general criteria" through notice-and-comment rulemaking to be applied in issuing an emergency rule; 3. Promulgate the rule as an "interim" rule to be amended after post-promulgation procedures; 4. In any event, take "appropriate alternative steps" to obtain the views of interested person before adopting the rule.

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also expressly authorized this procedure in the context of implementing the 1987 amendments to the Medicare program.¹⁵⁸ Post-promulgation comment will not, however, save a rulemaking where "good cause" did not exist to support exemption from pre-promulgation notice and comment requirements.¹⁵⁹

A related issue is when an agency may lawfully suspend the effective date of a rule without engaging in notice-and-comment rulemaking. This issue arose after 1981, in connection with the issuance of Executive Order No. 12,291, when some agencies were required to suspend the effective date of a promulgated rule in order to reconsider the costs and benefits under the requirements of the new executive order.¹⁶⁰ Two issues were presented: first, whether suspension was rulemaking under the APA, and, if so, whether "good cause" existed for not providing an opportunity for comment. In *Natural Resources Defense Council v. EPA*,¹⁶¹ the Third Circuit ruled that EPA's indefinite suspension of rules issued under

¹⁵⁸OBRA of 1987, Pub. L. No. 100-203, § 4039(g), codified at 42 U.S.C. § 1395hh note.

¹⁵⁹But see *Levesque v. Block*, 723 F.2d 175, 188 (1st Cir. 1983), suggesting that good faith consideration of post-promulgation comments may support upholding an otherwise invalid rule. See also subs. (D)(2)(e), *supra*; Part III, Ch. 4(A), *infra*.

¹⁶⁰Exec. Order No. 12,291, reprinted in 5 U.S.C. § 601 note. Section 7(a) of the order required agencies, with some exceptions, to "suspend or postpone" the effective dates of major rules that were promulgated in final form but had not yet become effective "to the extent necessary to permit reconsideration" under the Order. See also Presidential Memorandum Postponing Pending Federal Regulations, Jan. 29, 1981, 1981 Pub. Papers 63.

¹⁶¹683 F.2d 752 (3d Cir. 1982). This and other cases on this issue are discussed in Holmes, *Paradise Postponed: Suspensions of Agency Rules*, 65 N. C. L. Rev. 645 (1987).

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¹⁶³*Id.* at 766.

¹⁶⁴*Supra* n. 148.

¹⁶⁵*Id.*, 653 F.2d at 51

¹⁶⁶*Supra* n. 133.

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Excerpt of brief sup. 1-3

III. THE INTERIM MIXTURE AND DERIVED-FROM RULES WERE PROPERLY PROMULGATED PURSUANT TO THE GOOD CAUSE EXCEPTION

Pursuant to the APA, an agency may promulgate regulations without notice and opportunity for comment if it finds that such procedures would be "impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. § 553(b)(3)(B). Although the good cause exception is to be "narrowly construed and only reluctantly countenanced," Tennessee Gas Pipeline Co. v. FERC, 969 F.2d 1141, 1144 (D.C. Cir. 1992), an "emergency" within the scope of the "good cause" exception can exist when "the agency's action was required by events and circumstances beyond its control, which were not foreseen in time to comply with notice and comment procedures." National Fed'n of Fed. Employees v. Devine, 671 F.2d 607, 611 (D.C. Cir. 1982); Council of the Southern Mountains, Inc. v. Donovan, 653 F.2d 573, 581 & n.35 (D.C. Cir. 1981) (good cause existed where, inter alia, time pressures were due to "hurdles created by other parties"). To demonstrate an emergency, EPA needs only show that delay "might threaten" some important public interest, or could be "potentially harmful." National Fed'n, 671 F.2d at 611. Under the unique circumstances presented here, good cause existed to allow EPA to promulgate the interim mixture and derived-from rules without notice and opportunity for comment.

A. The Vacatur Of The 1980 Mixture And Derived-From Rules Was Not Reasonably Foreseeable In Time To Comply With Notice And Comment Requirements.

During the entire 10-year pendency of the Shell litigation, petitioners there never once sought a judicial stay of the 1980 mixture and derived-from rules. Mobil's contention

notwithstanding, EPA submits that it had no duty under these circumstances to have a replacement rule ready in the event the Shell petitioners prevailed. Pet. Br. at 31-32.

Indeed, this Court has previously upheld rules issued without prior notice and comment to replace regulations vacated or guidelines enjoined by court order, and specifically suggested just such an approach here. See Shell, 950 F.2d at 752 (citing Mid-Tex Elec. Cooperative v. FERC, 822 F.2d 1123, 1131-34 (D.C. Cir. 1985) (regulations)); American Fed'n of Gov't Employees v. Block, 655 F.2d 1153, 1155-57 (D.C. Cir. 1981) ("AFGE") (informal guidelines) (distinguishing between situations where agency operated under deadline that gave it substantial time to take action and those where agency operated under judicial directive to take immediate action); see also Small Refiner Lead Phase-Down Task Force v. EPA, 705 F.2d 506, 545 (D.C. Cir. 1983).

Following notice-and-comment procedures would have required approval of notice by the Administrator; publication of notice in the Federal Register; a comment period for interested parties; EPA review of comments; determination of what changes should be made based on comments and a response to comments;¹ and final approval by the Administrator. Following such notice-and-comment procedures here between December 6, 1991 -- the date on which the decision was issued -- and January 21, 1992 -- when the mandate

¹ In response to the April Proposal, EPA received an enormous volume of public comments and technical information after a 60 day comment period. Although some commenters urged EPA to retain the April 1993 sunset provision, most conceded that revisions by then would be unlikely "given the complexity of issues and the relatively short timeframe." 57 Fed. Reg. at 49,278.

could issue -- was virtually impossible.² See Petry v. Block, 737 F.2d 1193, 1200-03 (D.C. Cir. 1984) (four and one-half months between date of enactment and effective date of certain aspects of new legislation not sufficient time to conduct notice and comment rulemaking with respect to mandated regulations that were complex, extensive and burdensome); Philadelphia Citizens in Action v. Schweiker, 669 F.2d 877, 884 (3d Cir. 1982) (following APA procedures not feasible in 49 days allowed); compare Union of Concerned Scientists v. NRC, 711 F.2d 370, 382-83 (D.C. Cir. 1983) (sufficient time to follow APA procedures where agency staff had recommended action ultimately taken 11 months earlier).

B. EPA's Finding Of Emergency Was Reasonable And Well-Supported By The Record.

Under the "good cause" exception, the agency must show potential or threatened harm to the public interest. Under such circumstances, an agency's determination is to be upheld if the Court finds that the agency has "explain[ed] the facts and policy concerns it relie[d] on and that, given these, a reasonable person could have made the judgment the agency did." Tennessee Gas, 969 F.2d at 1145. The record more than amply supports EPA's finding -- based on both facts and corroborating views of experts outside the Agency -- that the interim mixture and derived-from rules are "essential to prevent serious harm to human health and

² EPA ultimately filed a petition for rehearing on January 21, 1992, thus staying mandate issuance. Filing such a petition was not a certainty, however, and in any event, could have been quickly denied, with mandate issuing seven days thereafter. Thus, the operative deadline for action was the date the mandate could have issued (as early as January 21, 1992) not when it ultimately was issued (February 23, 1992).

the environment and to avoid substantial confusion for the regulated community." 57 Fed. Reg. at 7631 (J.A. 909).

As discussed above, EPA found that many wastes are still toxic after they are managed or mixed, often presenting the same hazard as when the waste was generated. EPA further concluded that members of the regulated community could mismanage these dangerous wastes if the interim mixture and derived-from rules were not promulgated, and that such mismanagement would threaten human health or the environment. 57 Fed. Reg. at 7629-30 (J.A. 907-8). In addition, 38 state attorneys general offered their independent, expert views that sudden deregulation of mixture and derived-from wastes would throw state hazardous waste programs into chaos and result in increased dangers to health and environment. 57 Fed. Reg. at 7630 (J.A. 908).³

EPA also noted that over 100 enforcement actions involving improper management of wastes regulated under the mixture and derived-from rules had recently been concluded or were still pending. *Id.* With that amount of mismanagement occurring with clear rules in place, it was certainly reasonable for EPA to

³ Mobil claims that EPA merely alleged that a lapse in the mixture and derived-from rules would create "confusion" without causing harm. Pet. Br. at 46, citing 57 Fed. Reg. 7630 (col.3). This claim, however, is based on a single statement taken out of context. EPA explained several times that it was concerned about the potential for mismanagement of dangerous wastes leading to endangerment of human health and the environment. Moreover, this Court has recognized that elimination of confusion and the maintenance of consistent regulations are factors that can support use of the good cause exception. Mid-Tex Elec., 822 F.2d at 1133; see also AFGE, 655 F.2d at 1157.

predict that waste handlers would mismanage mixture and derived-from wastes if the rules lapsed.⁴

EPA also predicted (and state enforcement officials concurred) that the disappearance of the federal mixture and derived-from rules would severely impair federal and state enforcement efforts. Contrary to Mobil's assertions (Pet. Br. at 47), these enforcement cases involved more than the assessment of penalties for violations that occurred in whole or in part before issuance of the mandate in Shell. Instead, many involved potential releases to the environment with real potential to endanger human health, 57 Fed. Reg. at 7630; 92-F-MDIF-S0013(A) (J.A. 908, 829), which require intervention, See, e.g., 42 U.S.C. { 6928(h), 6973.⁵

⁴ Contrary to Mobil's suggestion (Pet. Br. at 44), it was reasonable to predict that mismanagement of mixture and derived-from wastes could occur in the 14 months before the interim rules were due to expire under the sunset provision. Unlike the negotiation of construction contracts at issue in Tennessee Gas (cited by Mobil), unsafe disposal can be carried out hours or days after someone decides -- whether by mistake or design -- to dump hazardous waste in a solid waste landfill (or along the roadside) rather than sending it to a hazardous waste facility.

⁵ EPA reasonably concluded that it could not rest on the fact that many states had in place rules similar to the mixture and derived-from rules at issue here, because they were not in all instances independent of the vacated federal rules. Vacatur of the federal rule might affect the similar state rule, or lead to constriction of the scope of the state program. The record supports EPA's decision, identifying at least one known case where a court invalidated a state derived-from rule for just that reason. 57 Fed. Reg. at 7630; F-92-MDIF-S0021(citing Equidae Partners v. Oklahoma State Dep't of Health, No. C-91-532 (Dist. Ct. Okla. Jan. 16, 1992)) (J.A. 908, 859). EPA similarly concluded that it could not rely on the limited tracking system under the land disposal restrictions of 42 U.S.C. { 6924(m). 57 Fed. Reg. at 7629-30 (J.A. 907-8).

Similarly, EPA reasonably determined that there would be factual scenarios in which it could not rely entirely on the hazardous waste listings, even though the listings encompass at least some mixtures and minimally treated wastes. Because the listings do not clearly distinguish between regulated and unregulated mixtures (and residues), EPA believed that relying on them alone would not do enough to discourage both accidental and deliberate misclassifications of mixture and derived-from wastes. Again, because misclassified wastes would be difficult to track, remediation could be delayed and made more costly. 57 Fed. Reg. at 7629 (J.A. 907); Mid-Tex Elec., 822 F.2d at 1132 (irremediable consequences support good cause finding).

C. EPA Reinstated The Rules Only On A Temporary Basis.

EPA's actions here are further supportable under the "good cause" exception because the mixture and derived-from rules were promulgated as interim rules with an expiration date. The fact that the rules at issue are temporary weighs in favor of finding that the "good cause" exception was properly invoked. Council, 653 F.2d at 582; National Fed'n, 671 F.2d at 612; Mid-Tex Elec., 822 F.2d at 1132; cf. AFGE, 655 F.2d at 1157 (regulations justified on an interim basis only). EPA not only consistently labeled the rules as "interim final," it requested comment on revisions in a companion notice published in the Federal Register on the same day, described the rulemaking schedule that it intended to follow to reconsider the rules, and included a "sunset provision", or expiration date, for the replacement rules. 57 Fed. Reg. at 7628 ("Action" heading), 7630, 7633 (J.A.

906, 908, 911-12); see also 57 Fed. Reg. 7636 (request for comment on interim rules).

Nor does the congressional action in the 1992 Act removing the sunset provision change this result. In its place, Congress imposed an enforceable deadline for promulgation of revisions to these interim rules, thus reaffirming -- and ensuring -- their interim nature. For all these reasons, "good cause" existed to allow EPA to promulgate the interim mixture and derived-from rules without formal notice and opportunity to comment.

Bess O.

Report a Mtg - we gave all concensus.

Geshits said: if we
propose bill.

But not very committal.
Sounded - whing in DC
along lines of Tim Simen
suggestion.

Further conc. anticipated/
not scheduled.

Conveyed to her - env SPS
getting viled up.

Sr level mtg soon - principals.

994 - pulled for tomorrow.

FZ provision

~~Abroad~~ Rules that have to go out very soon

BO: "it must be adopted in less than 6 mos."
[change I ~~is~~ on p. 7.
include in that list.

NE:

AGENCY DESIRES

Decisional Criteria/Supermandate

- Broaden uncertainties language (e.g., “infeasible”).
- Apply uncertainties language to cost-effective decisional criterion.

Question -- Should decisional criteria be a requirement or merely to inform?

Judicial Review

- Simple statement that cost/benefit analysis and determination under decisional criteria is part of whole rulemaking record and agency decision is considered on basis of whole rulemaking record under current APA 706 (both substantive and procedural review).

Question -- Should there be any judicial review of decisional criteria?

Risk Assessment

- Remove section in its entirety.
- Fallback is to have a group of risk experts from the agencies scrub this section.

Effective Date

- Grandfather any rule whose notice of proposed rulemaking is published up to 6 months after enactment.

Question -- Should the grandfather period be longer than 180 days?

Affirmative Defenses (Hutchinson Amendment)

- Remove this section in its entirety.
- Fallback is to amend so that it lays forth factors for a court to consider in deciding whether to impose penalties, not an absolute bar on such penalties.

**Defenders of Wildlife • Environmental Defense Fund • Environmental Information Center
Environmental Working Group • Friends of the Earth • League of Conservation Voters
National Wildlife Federation • Natural Resources Defense Council • Physicians for Social
Responsibility • Population Action International • Sierra Club • Sierra Club Legal
Defense Fund • United States Public Interest Research Group**

March 7, 1996

**The Honorable Carl Levin
United States Senate
Washington, D.C. 20510**

Dear Senator Levin:

The undersigned national environmental organizations are writing on behalf of our members to express our strong objections to a proposed comprehensive "regulatory reform" proposal that you are evaluating. First, we want to thank you for your vigorous and effective opposition to the many irresponsible proposals on this topic that have plagued this Congress. While recognizing that reasonable steps can be taken to improve how agencies develop rules, you have fought hard against ill-considered proposals that would damage the government's ability to protect its citizens from environmental, health, and safety threats. However, we fear that the new proposal before you could threaten the values you have worked so hard to protect.

We understand you are close to deciding whether to move forward with a comprehensive "regulatory reform" proposal. We believe the proposal before you fails the test you have applied correctly to other proposals: will the bill weaken the government's ability to address important environmental, health, and safety threats? Since we would not expect you or your staff to support a proposal that has these impacts, we want to share our assessment of the proposal's defects.

It is our understanding the proposal you are evaluating would establish new requirements for detailed analyses of the costs and benefits of proposed new major rules, such as rules to protect the environment, health, or safety. The proposal also would establish requirements for conducting risk assessments for such rules. In addition, the proposal would create new tests that agencies would have to prove they had passed before new major rules could be issued. Finally, the courts would be authorized to set aside rules that could not be proven to comply with these new requirements.

We strongly believe that the proposal has numerous serious flaws. A central problem is the creation of highly constraining new "decisional criteria" tests that must be passed before new major rules can be issued, combined with broad opportunities for industry to overturn rules in court based on claims that the new tests were not met or that procedures were not followed properly. These provisions will lead to substantial delays in agency decisionmaking and will introduce a bias for agency selection of less protective rules simply because they are cheaper and less likely to be challenged by regulated industries. When agencies do not follow this path of least resistance, the demanding requirements of the bill, combined with agency resource constraints, will lead to many sound rules being overturned in court.

Most current environmental, health, and safety laws allow agencies to adopt rules that are effective in addressing threats, with the basic "hurdle" being a requirement that the agency must provide a clear explanation for its decision and show that the rule is within the authority granted it by law. Current laws do not force agencies to prove that the adopted rule is the single "best"

possible outcome. In contrast, the proposal before you would erect substantial new barriers to agency decisionmaking.

Under the proposal, an agency would face a pyramid of hurdles. First, the agency would have to show that the rule had benefits that justify its costs. This test is designed to show the rule is a clear "winner" judged from a societal standpoint - collectively we'll be better off with the rule than without it. A number of alternatives might be able to pass this test in any particular program. But the agency is not allowed to stop there. Not only must the agency show the rule is a winner, it must show the rule is the best of all possible winners. And the yardstick it must use to judge "best" will always be warped in the direction of exaggerating costs and understating benefits in the critical areas of environmental, health, and safety protections.

To sustain a rule, an agency must prove that it either will "maximize net benefits" or be more "cost-effective" than any other reasonable alternatives that achieve the rule's benefits. The requirement to prove that a rule is superior to all other outcomes will impose a heavy burden on agencies that already are laboring under nearly unmanageable resource shortages. Moreover, both of these tests would in operation emphasize costs and discount benefits. Factors that are easily quantified will dominate decisions. Regulated industries can be counted on to use these tests to blizzard agencies with reams of detail on the projected costs of disfavored rules. The agency will face the more daunting task of countering these cost claims with less quantifiable descriptions of the benefits of more protective rules. While the agency may possess sufficient information to show that a proposed rule will clearly provide more benefits at reasonable costs than a weaker, industry-supported option, under the proposal this will not be enough. The agency must also show that its alternative is more cost-effective than any other option that is claimed to achieve similar benefits.

While we understand the proposal contains an exception from these decision hurdles, it is so limited and conditioned as to not provide a workable remedy. First, the exception undercuts accountability by displacing the agency head's judgment with that of a less publicly accountable person in the Executive Office of the President. Congress takes pains to assign public duties in environment, health, and safety areas to specific agencies with expertise and to highly visible and accountable persons who are selected by the President and confirmed by the Senate based on an assessment of their capacity to perform those particular duties. These are the individuals who should exercise judgment on whether an exception is needed to carry out the duties imposed by Congress. It is Congress that should be the guardian against abuse, not a much less accountable official in the White House whose expertise in the area has never been examined.

Second, the exception does not allow agencies to consider other compelling factors that they may now consider under current law to explain a rulemaking choice as reasonable and in the public interest. All considerations must be fit into the rigid mold of cost-effectiveness or maximized net benefits.

Finally, the exception is limited to the "benefits justify costs" test. However, proving the rule is the most "cost-effective" option will often be the impossible challenge, especially in environmental and health areas where uncertainties in quantifying benefits will make it easy to challenge conclusions that a particular rule is superior to all others.

Faced with broad judicial review of the new decision hurdles, agency lawyers will advise the agency to gather more information in order to sustain rules that face heavy industry opposition. Agency heads will then face three negative choices: delay the rule, perhaps for additional years and divert resources from other pressing needs to supplement the record to refute industry claims; concede to the industry and adopt a weaker rule that denies the public needed protection; or go forward without additional efforts to bolster the record and risk more years of delay if a court then overturns the rule.

This process will not produce wiser or better rules. It is certain to increase the taxpayer dollars that must be spent for each rule; it is certain to delay the government's ability to make decisions; it is certain to divert agency resources to attend to the claims of those interests that are the best financed and best organized. Thus, it will not address the legitimate concerns with agency decisionmaking.

For example, many small businesses are understandably frustrated with the multiplicity of requirements they must meet. The system is not as "user-friendly" as it should be. However, agencies have not deliberately designed their rules to be frustrating to small business. Rather, current rules are shaped in response to the regulated interests that have the resources to dominate an agency's attention. Imposing new judicially reviewable decision hurdles on agencies will simply exacerbate the agency focus on well-financed, highly-organized interests who will be best positioned to use the new hurdles as weapons against agency efforts to protect the public. The result will be fewer resources available for agencies to develop small business outreach programs and rules that are more tailored to the needs of "mom and pop" operations.

New judicially reviewable decision hurdles will not increase accountability. The new hurdles will be most damaging to those health and environmental decisions where precise information is the hardest to develop; in other words, decisions where accountability, transparency, and good judgment are needed rather than an expensive and fruitless search for more "facts." But these are the policy-laden judgments that the courts are least well-suited to address.

Congress has delegated rulemaking power to agencies and it is Congress that should be responsible for reviewing the exercise of that power. Turning this task over to lawyers for regulated interests will not focus review on those rules where the broadest societal interests are at stake. Instead it will fill court dockets with challenges to rules by firms with the resources to use the decision hurdles to stop rules that adversely affect their narrow interests.

We know that responsible efforts to address legitimate concerns with the regulatory process have been a long-standing interest of yours and that you have continued to work in this Congress to see if workable legislation could be developed in this area. We are grateful to you and your staff for spending hours with members of our community in discussing various "regulatory reform" approaches.

However, we believe the proposal before you is the wrong medicine for the ailments in government decisionmaking. It would delay and frustrate important efforts to protect our environment, health, and safety while leaving unresolved the sources of today's friction and frustration. Imposing new judicially reviewable decision hurdles guarantees that agency decisionmaking will become more tortured and complicated. This would leave our citizens less protected and our air, water, and lands more damaged.

The hole in the earth's protective ozone layer was not caused by hasty government action; it was caused by the government's failure to act when appropriate. The toxins in the Great Lakes are not there due to excessive regulation; they are still there because impediments to government action are excessive. The critical need is to empower agencies so that they may act to protect the public interest. We urge in the strongest possible terms that you not support the proposal before you, or any other bill that would make it even more difficult for agencies to protect us against abuses to the environment, health, and safety.

Sincerely,

John Adams

John Adams
Executive Director
Natural Resources Defense Council
Chair, Green Group

Gene Karpinski

Gene Karpinski
Executive Director
U.S. Public Interest
Research Group

Brent Blackwelder

Brent Blackwelder
President
Friends of the Earth

Fred D. Krupp

Fred D. Krupp
Executive Director
Environmental Defense Fund

Deb Callahan

Deb Callahan
President
League of Conservation Voters

Robert K. Musil

Robert K. Musil
Executive Director
Physicians for Social Responsibility

Phil Clapp

Phil Clapp
Executive Director
Environmental Information Center

Carl Pope

Carl Pope
Executive Director
Sierra Club

Kenneth A. Cook

Kenneth A. Cook
President
Environmental Working Group

Rodger Schlickeisen

Rodger Schlickeisen
President
Defenders of Wildlife

Hugo Hoogenboom

Hugo Hoogenboom
President
Population Action International

Victor Sher

Victor Sher
President
Sierra Club Legal
Defense Fund

William W. Howard

William W. Howard
President and CEO
National Wildlife Federation

Judicial review of the regulatory reform bill is unworkable.

Excessive litigation was a key winning point in the public debate on S. 343. This point will be lost if we agree to judicial review of the cost-benefit and risk assessment requirements and of mandatory single-point decisional criteria.

The regulatory reform bills authorize courts to set aside rules which fail to comply with the new cost-benefit and risk assessment requirements and super-mandates. This is a radical change in the way courts have reviewed agency action.

Currently, courts reviewing agency rules recognize that judgment calls are for the agency, not the courts. Further, the court will defer to the agency's expertise in evaluating costs, benefits, and other relevant factors. Once the court decides the alternative selected was within the realm of reasonableness, its review is over.

Judicial review under regulatory reform will change all of that. Agency heads will be required to select the one alternative that is either "the most cost-effective" or the "greatest net benefits." Either way, there is only one alternative that meets the test, and a court can set aside a reasonable rule if it finds it was not that one alternative that met this test.

Because the agency must select the one alternative that is the cheapest, any alleged error in the cost-benefit analysis that would change that cost determination is ground for invalidating the rule.

The many prescriptive, and often unworkable, requirements for analysis of every "reasonable alternative" in these bills encourages courts to second-guess agency analyses.

The harmless error requirement provides little comfort. If any alleged error affected the ultimate conclusion as to which regulatory alternative was the cheaper, this would be outcome determinative and therefore pass any prejudicial error or materiality test. When the test for agency action is selection of the most cost-effective alternative, rather than reasonableness, even a technical error in the cost-benefit analysis may be outcome-determinative, and thus material.

Decisional criteria that require every major rule to be the most cost-effective of all available alternatives will bar agencies from carrying out significant policies, such as assuring environmental justice, preservation of small business or the nuclear family, or encouraging diversity.



U.S. Department of Justice

Environment and Natural Resources Division

Office of the Assistant Attorney General

Washington, D.C. 20530

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TO: Wes Warren

TELEPHONE NO.: 456-6224

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FROM: Ben Ombaugh 514-2744

DATE: 2/28/96

MESSAGE: Please review & call.
Thanks.
Ben

[See esp. cases in # 1 and point 5]

PLEASE NOTIFY SENDER IMMEDIATELY IF YOU HAVE ANY PROBLEMS RECEIVING THESE PAGES.

February 28, 1996

I. The combination of mandatory decisional criteria and judicial review deprive agencies of discretion to weigh factors other than cost-effectiveness.

Under the proposed decisional criteria, an agency judgment to select an alternative other than the "most cost-effective" would constitute an abuse of discretion. The decisional criteria make a finding of greatest cost-effectiveness mandatory; an agency could not justify its decision on other grounds. Under current law, an agency can rely on its "best judgment" in balancing cost, along with other relevant factors. For example, in Florida Manufacturing Assn v. Cisneros, 53 F.3d 1565, 1580-1581 (11 Cir 1995), the court upheld new wind standards for mobile homes. The court found it unnecessary to review a challenge to the agency's finding the rule would produce a net economic benefit because the agency had also concluded that the need to increase safety and prevent devastation to communities in hurricanes justified the increased cost. Because Congress instructed HUD to consider safety as well as cost, the agency was able to rely on "its best judgment in balancing the substantive issues," and the Court refused to substitute its judgment for the agency's. See also BP Exploration & Oil, Inc. (93-3310) v. U.S. E.P.A., 66 F.3d 784, 799-800 (6th Cir. 1995), where the Court in construing the Clean Water Act requirements for best available technology (BAT), said:

The CWA does not require a precise calculation of BAT and NSPS costs. [NRDC v. EPA, 863 F.2d 1420, 1426 (9th Cir. 1988).] Congress intended that EPA have discretion "to decide how to account for the consideration factors, and how much weight to give each factor." [Weverhauser Co. v. Costle, 590 F.2d 1011, 1045 (D.C. Cir. 1978).]

By stark contrast, under the single-point decisional criteria, the agency would be required to find that the rule selected was the most cost-effective or provided the greatest net benefits. This would be a mandatory finding; the agency could not justify its decision on other grounds.

Corrosion Proof Fittings v. E.P.A., 947 F.2d 1201, 1215-1230 (5th Cir. 1991), provides a valuable preview of the extent to which single-point cost decisional criteria both constrain agency discretion and encourage judicial second-guessing of agency expertise. There the Toxic Substances Control Act required the agency to choose the "least burdensome requirements" that would adequately protect the public from chemical substances causing unreasonable risk of injury. The Court struck an EPA rule which would eventually ban all uses of asbestos. In doing so, it ruled that the "least burdensome" requirement meant that EPA was

required to show that there was no less burdensome alternative that would achieve an acceptable level of risk. 947 F.2d at 1216-1217. EPA abused its discretion because it failed to "consider each regulatory option, beginning with the least burdensome..." and calculate the costs and benefits of each. Id. Further, the Court said EPA could not consider nonquantifiable benefits as a "trump card." EPA could make allowance for unquantified benefits or costs in deciding which alternative was the "least burdensome" but could not "improperly [transform] permissible considerations into determinative factors." 947 F.2d at 1219, n. 20. The Court also held that the requirement that EPA consider the benefits of substances and the availability of substitutes meant that EPA was required to consider the comparative toxic costs and benefits of each substitute if any interested party provided credible evidence "suggesting the toxicity" of the substitute. 947 F.2d at 1221. The Court clearly engaged in much second-guessing of the agency's scientific studies, risk assessments, and economic analyses. 947 F.2d at 1218-1227. At one point the Court stated:

The EPA is required to support its analysis with substantial evidence under TSCA. When one figure is challenged, it cannot back up its position by changing an unrelated figure to yield the same result. Allowing such behavior would require us only to focus on the final numbers provided by the agency, and to ignore how it arrives at that number. Because a conclusion is no better than the methodology used to reach it, such a result cannot survive the substantial evidence test.

947 F.2d at 1227.

Corrosion Proof Fittings not only illustrates the difference between judicial review of a single-point decisional criteria, but it also illustrates how a cost-effectiveness standard will encourage courts to intrude into the underlying bases for the agency action. The many prescriptive requirements for analysis of every "reasonable alternative" encourages courts to second-guess agency analyses.¹

Further, if any alleged error affected the ultimate conclusion as to which regulatory alternative was the cheaper, this would be outcome determinative and therefore pass any prejudicial error or materiality test. When the test for agency action is selection of the most cost-effective alternative, rather than reasonableness, even a technical error in the cost-benefit analysis may be outcome-determinative, and thus material.

¹Under most bills, "reasonable alternative" is defined as every alternative within the statutory authority, including taking no action.

Under current APA standards, uncertainty in the cost-benefit analysis or consideration of factors other than cost are not themselves a basis for reversal. Instead, these are simply factors for the agency to evaluate in reaching a reasonable result. In IBEW, Local 1245 v. Skinner, 913 F.2d 1454, 1459 (9th Cir 1990), a challenge to a rule requiring drug testing of pipeline employees, the Court said, "Although we agree with petitioners that the cost-benefit figures are uncertain, we nonetheless regard the drug testing program as a reasonable measure properly geared to safety needs. The legislative history of this provision supports our view that public safety, and not cost, shall be the predominate concern." Again, the result would be different if Congress required selection of the most cost-effective alternative -- and certainly the litigation would be much more extensive.

Agencies must be able to consider other factors, when relevant under their statutory authority. This President has, for example, ordered agencies to consider the effects of their actions on environmental justice and working families. It is clearly cheaper to place hazardous waste sites in poor neighborhoods where land values are less, but couldn't a reasonable agency also consider the unfairness to the residents of bearing all of these adverse societal costs? The Executive Order recognized that distributional effects and equity are important factors.² Even the pro-business American Enterprise Institute recently recognized that agencies "should not be bound by a strict benefit-cost test" because they may reasonably want to place greater weight on particular factors, such as potentially irreversible consequences. Report, p. 7.

These decisional criteria force agencies and reviewing courts into quantification formulas. It is not always possible to reduce rulemaking decisions to algebraic equations. In cases in which the costs of regulation are on the person causing the harm, and all of the benefits are on those affected, are agencies to give these equal weight? Are agencies to assume that those causing the harm will spread some of the benefits of reduced cost

²The Executive Order included these in the definition of costs and benefits. While that helps assure consideration in the economic analysis, it is also important that the agency head be able to weigh the significance of these factors in the ultimate decision -- and not have courts second-guessing agency attempts to quantify these factors into a "cost-effectiveness" mandate. The Executive Order avoided those consequences because it is not judicially enforceable.

of regulation to those injured by their conduct?' Maybe an agency can stretch cost estimation enough to achieve these results, but should it have to and should these judgments be concealed in the cost analysis?

Some proponents claim that S.343 merely protects the regulated industry by requiring consideration of cost in a manner similar to the consideration of environmental factors under the National Environmental Policy Act. Actually, this bill goes far beyond NEPA in both limiting agency discretion and providing "hooks" upon which to invalidate agency action. Under NEPA, courts review only for procedural compliance and must defer to agencies' scientific and policy judgments. See Strycker's Bay Neighborhood Council, Inc. v. Karlen, 444 U.S. 223 (1980). As the Supreme Court explained in Strycker's Bay,

once an agency has made a decision subject to NEPA's procedural requirements, the only role for a court is to insure that the agency has considered the environmental consequences; it cannot "interject itself within the area of discretion of the executive as to the choice of the action to be taken."

444 U.S. at 227 (citations omitted). Notably, NEPA does not require the agency to select the environmentally preferred alternative nor does it otherwise substantively constrain the scope of agency decisionmaking, Robertson v. Methow Valley Citizens Council, 490 U.S. 332, 350 (1989). Furthermore, NEPA does not require the courts to delve into the relative validity of conflicting methodologies. Suburban O'Hare Commission v. Dole, 787 F.2d 186, 197-198 (7th Cir. 1986). A NEPA-type bill would require agencies to give a "hard look" to the results of cost-benefit analyses and risk assessments, but would not mandate a particular decision.

II. The Act contains many requirements which would make it very difficult for contested rules to survive judicial review.

Section 625 expressly permits judicial review of noncompliance with the requirements of subchapters II (cost-benefit) and III (risk assessment) by providing that "failure to comply" with those requirements may be considered by the court in

³So Ford Motor Company allegedly concluded it was cheaper to pay burn victims tort judgments in the few cases where they recovered than to make a safer gas tank for the Ford Pinto. If the cost of regulation exceeded the "quantifiable" costs to burn victims, would an agency have to forego requiring safer gas tanks even if it cost only a few dollars per car?

determining whether the final agency action is arbitrary and capricious, an abuse of discretion, or unsupported by substantial evidence. Petitioners will surely argue that failure to comply with statutory requirements is itself arbitrary and capricious. See, e.g., Motor Vehicle Manufacturers v. Ruckelshaus, 719 F.2d 1159, 1164 (D.C. Cir. 1983) ("Agency action is arbitrary and capricious if the agency has failed to meet statutory, procedural, or constitutional requirements")

Judicial review is particularly problematic because the bill's requirements are so detailed and prescriptive. The nature of these requirements often lend themselves to argument and litigation because of uncertainty in application or lack of adequate definition.

A few examples of reviewable requirements in the July draft of S. 343 are:

-- interlocutory challenges to the agency's determination as to whether the rule is a "major" rule, including whether a rule should be considered part of a closely related group of rules for purposes of the major rule cost threshold;

-- challenges to the adequacy of the agency's final cost benefit analysis, including the adequacy of the agency's quantification of its estimate of benefits, its use of appropriate units of measurement (using comparable assumptions and time periods), its specification of ranges of predictions and explanations of margins of error;

-- challenges alleging that an agency has failed to consider the costs and benefits of the proposed or final rule on "all of the affected persons or classes of persons (including specially affected subgroups)";

-- challenges to the agency's determination of industry-by-industry effects or its determination that such an industry-by-industry description is "not practicable";

-- challenges to the agency's determination that a rule meets the requirements of section 624(b) or (c), including whether it adopts "the least cost alternative" of any of the reasonable alternatives;

-- challenges that the agency did not base each risk assessment "only on the best reasonably available scientific data and scientific understanding"

-- challenges that the agency did not discuss "all relevant information" when conflicts among scientific data appear;

-- challenges that an agency used a "policy judgment" when "relevant and adequate scientific data and scientific understanding . . . are available" or inappropriately combined or compounded multiple "policy judgments";

-- challenges to an agency certification that the final agency action is not "likely to significantly reduce the human health, safety, and environmental risks to be addressed" or that specified factors preclude making such a finding but that the rule is nevertheless justified for reasons "consistent with subchapter III."

III. When an agency must choose the single alternative that is the most cost-effective, disputes over these requirements will often be outcome-determinative and thus survive a materiality test.

Because the agency must choose the least cost alternative, any of the underlying estimates may be outcome determinative. This creates great incentive for litigation, invites the courts to second-guess agency decisionmaking, and provides numerous opportunities for reversal. And while the bill dictates choice of the most cost-effective, it fails to acknowledge that the tools of risk assessment or cost-benefit analysis produce estimates which are subject to much dispute.

Courts are not well situated to review the underlying basis of cost-benefit analyses and risk assessments against the prescriptive standards of the bill.

[T]he crowded states of judicial dockets offers a highly practical reason why judges will not, and probably should not, devote the considerable time and effort needed to review a several-thousand-page agency record, informed by a thorough understanding of the substance of risk-related regulatory problems, in order to see whether or not that agency determination was arbitrary.

Justice Breyer, Breaking the Vicious Circle: Toward Effective Risk Regulation (Cambridge, Mass.: Harvard University Press 1973), p. 58-59 (describing why courts are not institutionally suited to resolve risk issues).

4. Some of the criteria are simply not reasonable.

For example, [Johnston 634, p. 48] states, "An agency shall use policy judgments only when relevant and adequate scientific information, including situation-specific information is not available." Does this provision mean what it says -- that an agency can never consider policy in risk assessments -- that it

must ignore equity? Can an agency siting rule for noxious activity protect existing residences? Nuisance law surely does, but this statute repeatedly appears to displace common law, agency expertise, and equity. Instead, cost-effectiveness and scientific understanding are apparently always the ultimate test. This will make it difficult for agencies to promote small business, the nuclear family, freedom of speech or religion, and other non-quantifiable and non-scientific values.

5. Judicial review and decisional criteria should be a significant policy issue in the congressional debate.

Attached are the Doonesbury cartoons for the week of July 31, 1995. The fifth set neatly illustrates the point made firmly in the Congressional debate that S. 343 would give regulated industry plenty of "hooks" on which to sue and overturn regulations. This is one of the main reasons that S. 343 would impair food, health, safety, and environmental regulation.

If the bill's opponents accede to a bill that requires agencies to select a single alternative based on cost and permits judicial review of the requirements of the bill, this key point will be lost.

6. Courts should not second-guess the cost-benefit analysis or risk assessment. Instead, judicial review should be limited as it is today to determining whether the agency action is reasonable, considering the results of the analysis.

The following draft would assure that agencies must take cost estimates into account but would permit judicial review only of the ultimate reasonableness of their actions.

(a) **REVIEW.--**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 section.

(b) **JURISDICTION.--**(1) Subject to paragraph (2) and to any limitations on judicial review which are applicable to the final agency action, the court with jurisdiction to review the final agency action has jurisdiction to review claims of noncompliance with this subchapter or subchapter III.

(2) No claims of noncompliance with this subchapter or subchapter III shall be reviewed separate or apart from judicial review of the final agency action to which they relate.

(c) **RECORD.--**Any cost-benefit analysis or risk assessment required under this subchapter or subchapter

III shall constitute part of the rulemaking record of the final agency action to which it pertains for the purpose of judicial review.

(d) **STANDARD FOR REVIEW.**--In any judicial review proceeding, the information contained in any cost-benefit analysis or risk assessment required under subchapter II or III may be considered by the court, to the extent relevant, as part of the administrative record solely for the purpose of determining whether the final agency action is arbitrary, capricious, or an abuse of discretion. The adequacy of compliance or the failure to comply with subchapter II or III shall not be grounds for remanding or invalidating a final agency action, unless the agency wholly omitted to perform a required cost benefit analysis or risk assessment.

February 27, 1996

From: David Hawkins
Re: Reg Reform Proposal

Attached is my analysis of the current reg reform proposal we have discussed. Please do not circulate this to other offices, since we want to pursue the opportunity to meet with the principal and urge that the indicated changes be made.

CRITICAL PROBLEMS WITH DECISIONAL CRITERIA AND JUDICIAL REVIEW PROPOSAL

While major strides have been made in the direction of a workable set of requirements, the current proposal still poses a threat to government's ability to make and sustain timely decisions to address threats to environment, health, and safety. Two areas present the greatest problems: overly narrow grounds for departing from decisional criteria and an overly broad scope of judicial review.

I. BASIS FOR DEPARTURE FROM DECISIONAL CRITERIA.

Unless otherwise required by law, the proposal would require all new major rules (and all existing major rules reviewed under lookback procedures) to pass three tests before the rule could be issued or continued. The rule must –

- (A) employ flexible regulatory options;
- (B) maximize net benefits or be more cost-effective than other alternatives that achieve the same level of benefits; and
- (C) provide benefits that justify the costs of the rule.

Without a reasonable exception from the last two tests in particular, agencies will be unable to sustain sensible decisions that would be upheld under present law. The exception provision in the current proposal is not adequate to protect sound decisions.

First, the exception is available only for the "benefits justify costs" test. However, the maximum net benefits/most cost-effective test will often be a more demanding test, especially when data on costs or benefits contain significant uncertainties. In such situations it may be impossible for an agency to meet its burden of proving the rule is more cost-effective than other alternatives. **Accordingly, it is vital that the exception be available for both the second and the third test.**

Second, the exception should be available when other compelling factors that the agency is allowed to consider under the existing law can be demonstrated to justify a departure. Without this exception the decisional criteria could place agencies in a "catch-22" where the most cost-effective option is otherwise so unreasonable that the rule will be overturned by Congress. While cost-effectiveness considerations often may be a reliable basis to select the "best" alternative, there are situations when cost-effectiveness should not be paramount and the decisional criteria should recognize this.

For example, a strict comparison of costs and emissions reductions might show that a rule banning the registration of cars older than 8 years is the most cost-effective way to achieve a given level of auto pollution reduction. Yet this option would be so burdensome, unfair and rigid, that EPA would reject such an option under current law. However, if the numbers show it is more cost-effective (expressed in terms of dollars of costs per ton reduced) the proposed decisional criteria could force EPA to choose this option. To avoid this type of result the criteria should allow the agency to select an alternative other than the most "cost-effective" one, provided the agency justifies its choice on the record based on factors that it is authorized to consider under the law governing the rulemaking.

Some may argue that preserving the ability to consider other factors would make the decision criteria meaningless. This is not correct. Such an exception would contain numerous safeguards against agency abuse. The agency would first have to identify the most "cost-effective" option. Then it would have to justify a departure from that option, but only based on factors that the underlying law allows the agency to consider. An inadequate justification or one based on impermissible factors would be grounds for judicial remand of the rule. In addition, congressional review would deter agencies from reliance on the exception unless the agency had a strong case. Under such an approach there would be a transparent rulemaking record with the most cost-effective option clearly identified and a requirement for the agency to explain why it had not chosen that option based on grounds limited to factors authorized by law. Congress would thus be in a position to compare the "most cost-effective" option with the one selected by the agency and to assess the adequacy of the agency justification. Agencies would rightly conclude that weak justifications would make their rules prime targets for congressional veto.

The third problem with the current exception language is the requirement for a supporting Presidential determination. The real effect of this requirement would be to give the delegated official (almost certainly the OMB OIRA Administrator) a veto over legitimate agency rulemaking choices. Agency heads are confirmed by the Senate based on their fitness for their particular agencies. They are more visible and publicly accountable than the OIRA Administrator. In addition they are in a better position to understand the significance of factors that may warrant a departure from the applicable decisional test. Finally, the Presidential determination requirement will add to the length and complexity of rulemaking processes. Such a requirement would force two cycles of decisionmaking regarding rule selection. First, the agency head would have to be convinced that a departure was appropriate. Then the Presidential delegated official would have to be convinced of the need for the departure. Given the checks of judicial review and congressional review, the third check of Presidential approval is an unneeded additional key that should be deleted.

II. SCOPE OF JUDICIAL REVIEW

The current proposal allows both judicial review of all decisional criteria determinations as well as judicial review of claims of noncompliance with all other procedural requirements of the bill. Given the detailed nature of the analytical requirements of the bill, judicial review of all analytical compliance issues will result in rules being overturned for good-faith procedural missteps. Agency fear of being overturned will allow regulated entities to drag out rulemaking analyses to unreasonable lengths as agency lawyers seek to protect the agency from judicial remand on procedural grounds by advising that nearly all demands for additional and more elaborate analyses be agreed to as a defensive strategy.

For example, the risk assessment principles section of the bill requires the agency to describe the "major uncertainties in each component of the risk assessment." While this may be an appropriate requirement, judicial review of the final rule should not be consumed with lengthy disputes about whether particular uncertainties were or were not "major" or whether the agency described the influence of the uncertainty with sufficient precision.

Under the proposal, procedural error challenges are limited to situations where the

court finds the error likely had a material effect on the decision. While desirable in principle, this proviso does not prevent judicial review from tying up rules in a morass of procedural error claims. Standard practice in briefing a challenge to a rule will be to assert a variety of procedural errors and to claim that the decision would have been different if the errors had not occurred. The government response will have little, if any, information to refute claims that the errors materially affected the outcome, since there will be no "error-free" analyses available to demonstrate that the same result was reached. The only foolproof defense for the agency would be to redo its analyses — something that could be done only at a cost of significant taxpayer dollars and lengthy delays in issuing rules designed to remedy present threats.

It may be argued that egregious procedural flaws should be grounds for remanding agency decisions. This is correct but the judicial review already provided for the agency determinations under the decisional criteria section will allow courts to reject determinations based on fatally flawed procedures. The arbitrary and capricious test will allow courts to set aside determinations where major errors in procedure call into question the legitimacy or correctness of those determinations. Extending judicial review beyond the core issue of whether the agency has made the legally required determinations and has supported them with a sound rulemaking record invites the use of litigation as a delaying tactic that will frustrate legitimate programs to protect the public. Accordingly, judicial review should be limited to the agency's decisional criteria determinations.

what about a/c ref?



U.S. Department of Justice

Environment and Natural Resources Division

Office of the Assistant Attorney General

Washington, D.C. 20530

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TO:

Elena Kagan

TELEPHONE NO.:

456-7901

FAX NO.:

456-1647

FROM:

Bess Osenbaugh 514-2744

DATE:

2/27/96

MESSAGE:

Jim Simon asked me to send you some materials - Unfortunately, I have not consolidated the various memos ~~to~~ recently. Attached is a discussion of 2 case examples and a list of attachments.

The fastest might be for me to talk you through these.

Let me know if I can answer any questions. Bess

PLEASE NOTIFY SENDER IMMEDIATELY IF YOU HAVE ANY PROBLEMS RECEIVING THESE PAGES.

Examples where
life would be
different under
new stats

February 26, 1996

Please see:

1. Florida Manufacturing Assn v. Cisneros, 53 F.3d 1565, 1580-1581 (11 Cir 1995) -- Here the agency had concluded that new wind standards for mobile homes would produce a net economic benefit. A challenge to that finding was rendered unnecessary because the agency had also concluded that the need to increase safety and prevent devastation to communities in hurricanes justified the increased cost. Because Congress instructed HUD to consider safety as well as cost, the agency was able to rely on "its best judgment in balancing the substantive issues," and the Court refused to substitute its judgment for the agency.

Under the language we have seen, the agency would be required to not only find that benefits justified costs but also that the rule selected was the most cost-effective or provided the greatest net benefits. This would be a mandatory finding; the agency could not justify its decision on other grounds, as in Florida Manufacturing. Further, if any alleged error affected the ultimate conclusion as to which regulatory alternative was the cheaper, this would be outcome determinative and therefore pass any prejudicial error or materiality test. (See discussion in case of agency discretion to make judgments among alternatives.)

2. IBEW, Local 1245 v. Skinner, 913 F.2d 1454, 1459 (9th Cir 1990) -- Here, the court rejected a challenge to the reasonableness of a rule requiring drug testing of pipeline employees. The challenge was based on the cost-benefit analysis. The Court said, "Although we agree with petitioners that the cost-benefit figures are uncertain, we nonetheless regard the drug testing program as a reasonable measure properly geared to safety needs. The legislative history of this provision supports our view that public safety, and not cost, shall be the predominate concern."

Again, the result would be different if Congress required selection of the most cost-effective alternative -- and certainly the litigation would be much more extensive. The bills we have seen would take away agency authority to weigh other factors in the selection of an alternative. Instead, the result of the cost-benefit analysis would dictate the regulatory choice.

This is also an example where issues of uncertainty in the figures would affect the outcome.

[See also the discussion in the case of the constitutional issue of invasion of privacy for random urine analysis. Could an agency factor in the tailoring appropriate to protect reasonable

expectation of privacy independently of the cost-benefit analysis? --- or does protection of underlying constitutional values only provide a factor for economic analysis in the cost-benefit analysis?]

3. Attached is an October 1995 one-pager explaining why "prejudicial error" is not the sole problem with judicial review.

4. A July 1995 memo laying out some of the problems with judicial review of the decisional criteria in S. 343.

5. Following is a discussion of some of the standards these bills would make judicially reviewable. This is based on a draft in early July 1995.

A. The Judicial Review Provisions Will Permit Frivolous Procedural Attacks on Every Major Rule.

We understand that the re-write of section 625 was intended to resolve the significant concerns with judicial review of risk assessment and cost-analysis requirements which the Administration and others have previously raised. However, we believe the revision fails in this regard, and that it would encourage procedural attacks on virtually every major rule.

Section 625 permits judicial review of noncompliance with subchapters II (cost-benefit) and III (risk assessment) by providing that "failure to comply" with those requirements may be considered by the court in determining whether the final agency action is arbitrary and capricious, an abuse of discretion, or unsupported by substantial evidence. Thus, the alleged failure to comply with any of the many detailed requirements for risk-assessment or cost-benefit analysis can be the subject of litigation. Petitioners will surely argue that failure to comply with procedural requirements is itself arbitrary and capricious.

Judicial review of these requirements is particularly problematic because the bill's requirements are so detailed and prescriptive. The nature of these requirements will often lend themselves to argument and litigation because of uncertainty in application or lack of adequate definition. For example, section 633(d)(3) states, "An agency shall not inappropriately combine or compound multiple policy judgments." This and other provisions provide difficult judicial criteria for assessing agency action.

A few examples of how S. 343 will be used to claim agency action is arbitrary or capricious or an abuse of discretion are:

- interlocutory challenges to the agency's determination as to whether the rule is a "major" rule, including whether a rule should be considered part of a closely related group of rules for purposes of the major rule cost threshold;

July draft

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*mt will affect outcome
under current law,
not a+c.*

- July 31/95*
- challenges to the adequacy of the agency's final cost benefit analysis, including the adequacy of the agency's quantification of its estimate of benefits, its use of appropriate units of measurement (using comparable assumptions and time periods), its specification of ranges of predictions and explanations of margins of error;
 - challenges alleging that an agency has failed to consider the costs and benefits of the proposed or final rule on "all of the affected persons or classes of persons (including specially affected subgroups)";
 - challenges to the agency's determination of industry-by-industry effects or its determination that such an industry-by-industry description is "not practicable";
 - challenges to the agency's determination that a rule meets the requirements of section 624(b) or (c), including whether it adopts "the least cost alternative" of any of the reasonable alternatives;
 - challenges that the agency did not base each risk assessment "only on the best reasonably available scientific data and scientific understanding...";
 - challenges that the agency did not discuss "all relevant information" when conflicts among scientific data appear;
 - challenges that an agency used a "policy judgment" when "relevant and adequate scientific data and scientific understanding...are available" or inappropriately combined or compounded multiple "policy judgments";
 - challenges to an agency certification that the final agency action is not "likely to significantly reduce the human health, safety, and environmental risks to be addressed..." or that specified factors preclude making such a finding but that the rule is nevertheless justified for reasons "consistent with subchapter III."

As these examples demonstrate, the combination of prescriptive and detailed procedural and substantive requirements with broad judicial review would lead to an enormous amount of litigation. We believe that this litigation-oriented approach is contrary to the goal of making the federal government more efficient and effective.

6. Attached are the Doonesbury cartoons for the week of July 31, 1995. The fifth set neatly illustrates the point made firmly in the Congressional debate that S. 343 would give regulated industry plenty of "hooks" on which to sue and overturn regulations. This is one of the main reasons it could be

accurately said that S. 343 would impair food, health, safety, and environmental regulation.

7. Pages 7 through 10 of the American Enterprise Institute report that concludes that agencies "should not be bound by a strict benefit-cost test" because they may reasonably want to place greater weight on particular factors.

8. A two-pager explaining how the judicial review and decisional criteria provisions of S. 343 would provide much more intensive judicial second-guessing of all agency rules than is provided by N.E.P.A. for a class of federal actions.

9. The approach to judicial review recommended by the work group of agencies who addressed this issue last summer.

3

October 4, 1995

Proposed Judicial Review Amendments to S. 343

The decisional criteria and judicial review provisions do provide some relief from the serious problems associated with the Dole-Johnston draft. Section 624 still requires selection of one alternative, the most "cost-effective," but only after consideration of "uncertainties." This provides greater flexibility for the agency because the exception was previously limited to only certain types of uncertainties. Additionally, section 625 now contains a materiality standard for reversal; this sends a message to the Court that a procedural error must meet a prejudicial error test.

However, a materiality or prejudicial error test does not address basic problems with the statutory criteria. When the test is the most cost-effective, rather than reasonableness, even a technical error in the cost-benefit analyses may be outcome-determinative, and thus material.

Converting aspirational goals to mandatory requirements subject to judicial review invites challenges to agency action. For example, the bill prohibits the use of policy judgments in risk assessments -- perhaps a worthy goal, but how can an agency reasonably interpret and apply this prohibition with any certainty that its actions will be upheld on judicial review?

Further, the decisional criteria still substitutes one choice for the current concept of reasonableness; thus it is error for the agency to choose another alternative, even if reasonable -- the only exception will be "uncertainties." (Suppose an agency is considering a rule addressing feedlot odors and requiring that animal waste lagoons be separated from residences, can the agency consider whether farm residences preceded the feedlot by 200 years? Must it treat costs to the feedlot owner as equal to the costs to those harmed -- whether or not the feedlot will compensate the injured parties for their losses? May the agency assume that preservation of existing farm communities is a value and thus set a minimum level to assure families can continue to live in their homes?)

July draft

4

ARGUMENT

S. 343 PROMOTES JUDICIAL INTRUSION INTO RULEMAKING.

1. Increased judicial review -- Although the re-write of section 625 may have been intended to limit judicial review, it does not do so. Section 625 expressly provides for judicial review in accordance with that section. The re-write expressly provides that failure to comply with S. 343 may be considered by the court in determining whether the final agency action is arbitrary and capricious or an abuse of discretion. Thus, the alleged failure to comply with any of the many detailed requirements for risk-assessment or cost-benefit analysis could be the subject of litigation. See, e.g., Motor Vehicle Manufacturers v. Ruckelshaus, 719 F.2d 1159, 1164 (D.C. Cir. 1983) ("Agency action is arbitrary and capricious if the agency has failed to meet statutory, procedural, or constitutional requirements") (emphasis added, citations omitted); Puerto Rico Sun Oil Co. v. EPA, 8 F.3d 73, 77 (1st Cir. 1993) (agency action entitled to deference "so long as procedural corners are squarely turned").

2. Judicial intrusion into agency scientific and policy decisions -- Courts are not well situated to review the underlying basis of cost-benefit analyses and risk assessments against the prescriptive standards of the bill.

...the crowded states of judicial dockets offers a highly practical reason why judges will not, and probably should not, devote the considerable time and effort needed to review a several-thousand-page agency record, informed by a thorough understanding of the substance of risk-related regulatory problems, in order to see whether or not that agency determination was arbitrary.

Justice Breyer, Breaking the Vicious Circle: Toward Effective Risk Regulation (Cambridge, Mass.: Harvard University Press 1973), p. 58-59 (describing why courts are not institutionally suited to resolve risk issues).

3. Clogging the Courts. -- The language of section 625 will encourage years of litigation before even the question of what is reviewable is resolved. This bill gives regulated industry many hooks to delay rulemaking and then to challenge the final result. If those steps are subject to judicial review, there will be every incentive to stop regulation through complex and lengthy judicial review proceeding. When this is combined with the increased time and cost of rulemaking under this bill, the result may be gridlock. This frustration of law is not a desirable goal.

4. Ridiculous Requirements -- Example is the elimination of use of "policy judgments" in risk assessments. This bill contains many requirements which will make judicial review

difficult and uncertain. For example, section 633(d) on page 54 prohibits an agency from using policy judgments (not defined but expressly includes inferences) "when relevant and adequate scientific data and scientific understanding, including site specific data, are available. If a risk assessment involves a choice of policy judgment, the agency has to identify the policy judgment, its scientific basis, explain the basis for any choices, etc., and describe reasonable alternative policy judgments that were not selected, etc. The agency also has to do guidelines for "default policy judgments."

What does this mean in the context of a rule? Suppose an agency receives a petition to do a rule requiring that animal waste lagoons be located over 1500 feet from private residences to prevent odor and health-related problems and to require that manure be sliced into the ground to prevent run-off. Can the agency conclude that people prefer to live in places where the air does not smell like manure? Can the agency choose to treat those whose residences preceded the lagoon differently from those who move in later? (Nuisance law does, but does this displace common law, agency expertise, and common understanding so that only "scientific understanding" can be used for policy choices?) Can the agency conclude that reducing housing stock in rural areas will adversely affect community structure?

Further, must the agency accumulate scientific data for every statement it makes in the risk analysis or only those where a genuine issue of fact has arisen from the agency or from a commenter?

If an agency can only consider scientific understanding, can it provide a religious exemption for a rule regarding provision of abortion services or for mandatory vaccinations? One's religion is scientifically irrelevant to the risks but may be another value to protect.

This is an example of aspirational and vague goals turned into mandatory requirements in this bill.

This section also illustrates the absurdity of placing scientific understanding as the only criterion (at least for risk assessment). Does this displace "family values"? Does it prevent agencies from regarding the following as valid policy goals: encouraging small businesses, encouraging the nuclear family, protecting constitutional values such as freedom of speech or religion?

5. Underlying data will generate challenges -- The attached Greenwire story includes criticism that cost-benefit analyses may be off by a magnitude of hundreds. This makes it difficult for agencies to achieve any certainty concerning application of cost-benefit analyses. If agencies must constantly be looking over their shoulder at the possibility of

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judicial review, it is clear this will provide many opportunities for challenges to rules by the regulated industry.

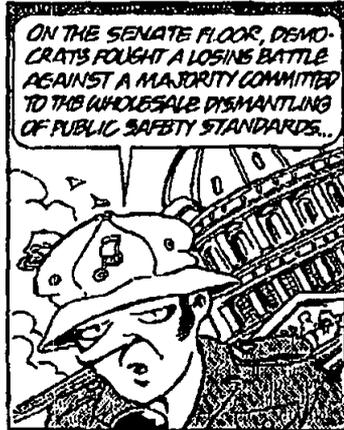
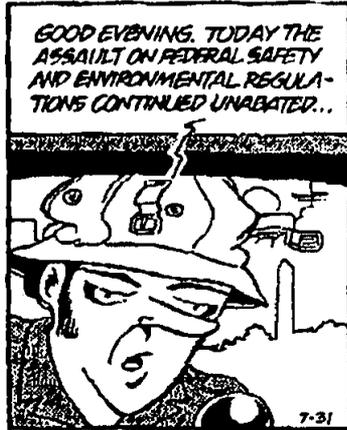
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Doonesbury

BY G.B. TRUDEAU To: B 210

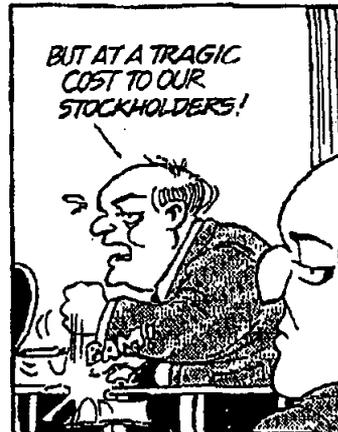
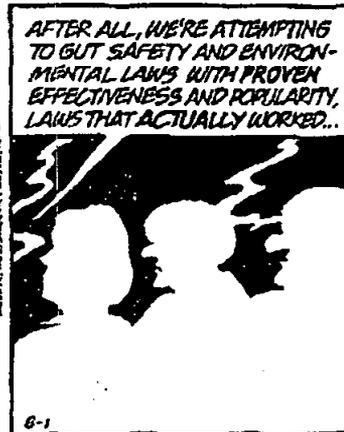
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BY GARRY TRUDEAU



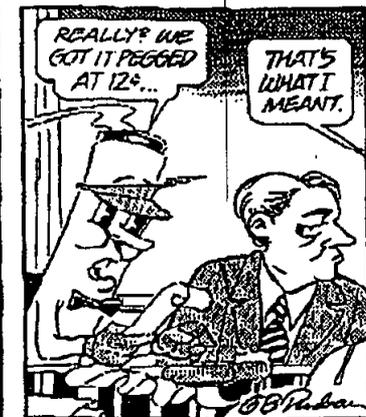
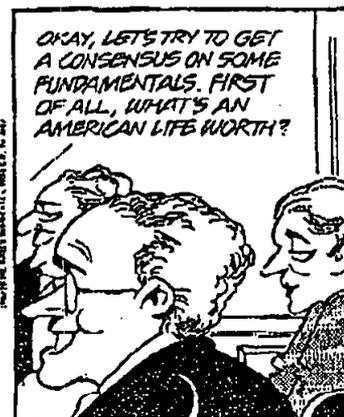
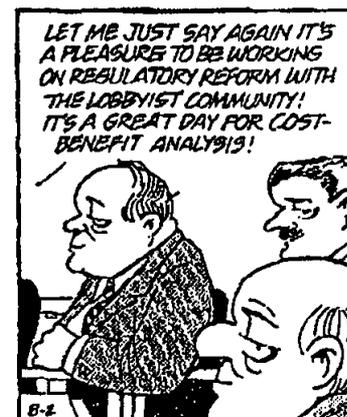
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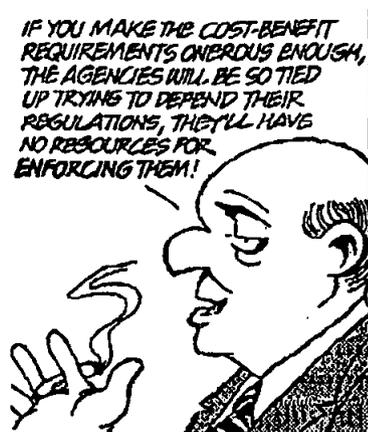
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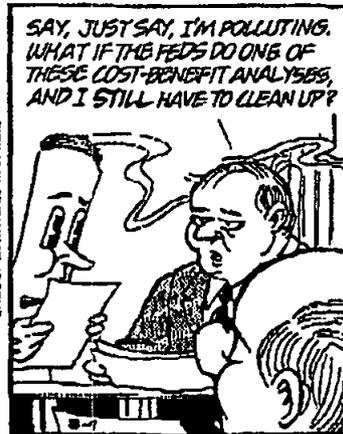
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BY GARRY TRUDEAU



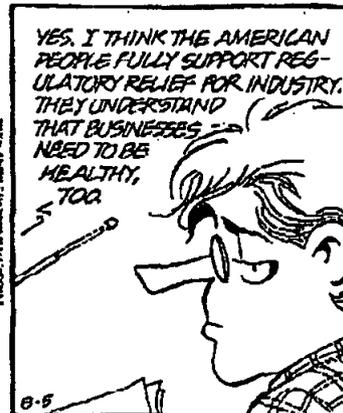
Doonesbury

BY GARRY TRUDEAU



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BY GARRY TRUDEAU



BENEFIT-COST ANALYSIS IN ENVIRONMENTAL, HEALTH, AND SAFETY REGULATION

A STATEMENT OF PRINCIPLES

Kenneth J. Arrow, Maureen L. Cropper,
George C. Eads, Robert W. Hahn,
Lester E. Lave, Roger G. Noll,
Paul R. Portney, Milton Russell,
Richard Schmalensee, V. Kerry Smith,
and Robert N. Stavins

American Enterprise Institute,
The Annapolis Center, and
Resources for the Future

1996

ARROW ET AL.

Benefit-cost analysis should be required for all major regulatory decisions.

While the precise definition of *major* requires some judgment, we believe that a major regulation should be one whose annual economic cost is expected to be greater than \$100 million. We also believe that this requirement should be applied to independent agencies as well as to executive branch agencies. An important benefit of mandatory benefit-cost analysis is that it facilitates external monitoring of an agency's performance and thus makes it easier to hold agency heads accountable.

The scale of a benefit-cost analysis should depend on both the stakes involved and the likelihood that the resulting information will affect the ultimate decision. Other things equal, agencies should devote more resources to analyzing problems where the stakes are greater. A full-blown benefit-cost analysis, however, can be costly. Therefore, the agency should not perform the analysis unless there is some likelihood that doing so will actually inform the regulatory decision. Informing the decision could involve changing the goal of the regulation or the means by which a particular goal is achieved.

Agencies should not be bound by a strict benefit-cost test, but should be required to consider available benefit-cost analyses. For regulations whose expected costs far exceed expected benefits, agency heads should be required to present a clear explanation justifying the reasons for their decision.

There may be factors other than economic benefits and costs that agencies will want to weigh in decisions, such as equity within and across generations. In addition, a decisionmaker may want to place greater weight on particular characteristics of a decision, such as potential irreversible consequences.

BENEFIT-COST ANALYSIS AND REGULATION

For legislative proposals involving major health, safety, and environmental regulations, the Congressional Budget Office should do a preliminary benefit-cost analysis that can inform legislative decisionmaking.

Because laws give rise to regulations, some kind of benefit-cost analysis is likely to be useful in informing the policy process. Such a benefit-cost analysis will, of necessity, be quite rough since it is difficult to estimate the economic impact of a proposed law before the regulations based on that law are written. Although a full-blown benefit-cost analysis may not be warranted in many cases, a rough benefit-cost analysis will often be quite useful.

PART TWO

SUGGESTIONS FOR IMPROVING THE QUALITY OF ECONOMIC ANALYSIS USED IN REGULATORY DECISIONMAKING

While benefit-cost analysis should focus primarily on the overall relationship between benefits and costs, a good benefit-cost analysis will identify important distributional consequences of a policy.

Available data often permit reliable estimation of major policy impacts on important subgroups of the population. If a regulation results in economic spillovers that contribute to significant job losses or increased costs to a specific industry in a local economy, then it is appropriate to consider those in a benefit-cost analysis. Agencies should, however, weigh those impacts against positive impacts that result elsewhere in the larger economy. Usually, it is better to address concerns about local economic spillover effects of regulation by using tax and transfer policies rather than regulatory policy.

Regulation typically affects the distribution of employment among industries rather than the general employment level. Usually, any specific regulation has a very minor effect on either

ARROW ET AL.

wages or employment in the industry to which it applies. Regardless of the size of the employment effect, the appropriate measure of regulatory costs is the transition costs of employees who are forced to switch jobs because of the regulation. In those few cases where regulation can have a significant impact on total employment, such as the minimum wage, the effect on consumers and producers should also be estimated.

It is important to identify the incremental costs and benefits associated with different regulatory policies.

A problem with many regulatory analyses is that they fail to specify a clear baseline. Doing so is a necessary first step in identifying the incremental costs and benefits of a proposed policy. Defining a clear baseline can help avoid problems with double counting. For example, some regulatory analyses have counted as benefits positive changes that would have occurred even if the regulations were not implemented.

In addition to specifying a clear baseline, we think it is useful for the analyst to consider an array of practical alternatives for pursuing a particular statutory or regulatory objective, while carefully noting the incremental costs and benefits associated with those alternatives. For example, almost all of the harm from a polluting process can frequently be eliminated for a reasonable cost, while an astronomical cost is required to remove the last, small amount of harm. A benefit-cost analysis that considers only a no-treatment baseline and a full-treatment alternative may find that benefits exceed the costs under full treatment. If the analysis had considered a partial-treatment case, however, the net benefits to consumers could be higher still. In this example, separate consideration of low-cost and high-cost alternatives makes it easier for the decisionmaker to select the low-cost remedy when it is appropriate.

BENEFIT-COST ANALYSIS AND REGULATION

Benefits and costs of proposed policies should be quantified whenever possible. Best estimates should be presented along with a description of the uncertainties.

In most instances, it should be possible to describe the effects of proposed policy changes in quantitative terms. Quantification of benefits and costs is useful, even where there are large uncertainties. Available methods and data generally imply ranges of possible values of costs and benefits, not single numbers. Benefit-cost analysis contributes most to intelligent decisionmaking when those ranges are clearly described along with best estimates. Best estimates should reflect expected values.

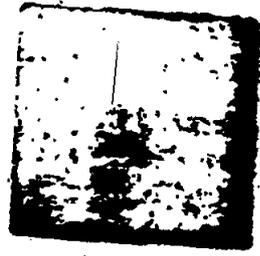
If the decision maker wishes to introduce a "margin of safety" into his decision, he should do so explicitly. Assumptions should be stated clearly rather than be hidden within the analysis.

Not all impacts of a decision can be quantified or expressed in dollar terms. Care should be taken to assure that quantitative factors do not dominate important qualitative factors in decisionmaking.

A common critique of benefit-cost analysis is that it does not emphasize factors that are not easily quantified or monetized. That critique has merit. There are two principal ways to address it: first, quantify as many factors as are reasonable and quantify or characterize the relevant uncertainties; and second, give due consideration to factors that defy quantification but are thought to be important.

The more external review regulatory analyses receive, the better they are likely to be.

External review includes peer-reviewed studies as well as studies reviewed by an agency other than the one doing the study. Historically, the Office of Management and Budget has played a key role in reviewing selected major regulations, particularly those



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aimed at protecting the environment, health, and safety. We think that such a role is appropriate for any regulation whose annual economic cost is expected to be greater than \$100 million.

Peer review of economic analyses should be used for regulations with potentially large economic impacts (for example, those whose annual economic cost exceeds \$1 billion). The reviewers should be selected on the basis of their demonstrated expertise and reputation.

Retrospective assessments of selected regulatory impact analyses should also be done periodically by an independent group of scholars to address systematic problems that have arisen. Because environmental, health, and safety regulatory decisions can have important impacts on the economy, it is useful to review periodically the quality of economic analysis that aids in the decisionmaking process. An outside panel of experts, primarily consisting of economists and other scientists, could provide recommendations on how such analyses could be improved. The panel could be selected by the National Academy of Sciences.

A core set of economic assumptions should be used in calculating benefits and costs associated with environmental, health, and safety regulation. Key variables include the social discount rate, the value of reducing risks of dying and accidents, and the value associated with other improvements in health.

There are benefits from being able to compare results across analyses, including potentially large gains in economic efficiency. A common set of economic assumptions facilitates such comparisons. For example, a common set of assumptions can be used to develop values for improvements in environmental quality.

Agencies should be allowed to use alternative assumptions, so long as those assumptions are clearly stated. They should then compare the results based on those assumptions with the results based on the common set of assumptions. Where possible, agencies should explain the economic rationale for employing alternative assumptions.

8

Revised June 9, 1995

Why should a reasonable legislator oppose judicial review in the Hatch risk assessment bill and support judicial review of NEPA compliance?

The risk assessment bill combines very prescriptive and detailed substantive requirements and stringent limitations on agency discretion with broad judicial review. The result is that the courts would be encouraged to substitute their judgment for that of the agency on scientific, economic, and policy issues. This would create significant incentives to judicially challenge agency regulations. Additionally the bill would subject all existing rules to the same standards, thus encouraging litigation to un-do existing rules.

Section 624 prohibits promulgation of a rule unless the agency finds that the rule adopts the alternative which is the least cost [or provides greater net benefits]. Thus, the agency's choice is limited to a single alternative, and there is no agency discretion to choose between different reasonable alternatives. And while the bill dictates this choice, it fails to acknowledge that the tools of risk assessment or cost-benefit analysis produce estimates which are subject to much dispute. Any of the underlying estimates may be outcome determinative because the agency must choose the most cost effective. This creates great incentive for litigation, invites the courts to second-guess agency decisionmaking, and provides numerous opportunities for reversal.

S. 343 also contains many other procedural traps. For example, an agency risk assessment may not use policy judgments when scientific data is available. § 633(d), p. 54.

By contrast, under NEPA, courts review only for procedural compliance and must defer to agencies' scientific and policy judgments. See Strycker's Bay Neighborhood Council, Inc. v. Karlen, 444 U.S. 223 (1980). As the Supreme Court explained in Strycker's Bay,

once an agency has made a decision subject to NEPA's procedural requirements, the only role for a court is to insure that the agency has considered the environmental consequences; it cannot "interject itself within the area of discretion of the executive as to the choice of the action to be taken."

444 U.S. at 227 (citations omitted). Notably, NEPA does not require the agency to select the environmentally preferred alternative nor does it otherwise substantively constrain the scope of agency decisionmaking, Robertson v. Methow Valley Citizens Council, 490 U.S. 332, 350 (1989). Furthermore, NEPA does not require the courts to delve into the relative validity

of conflicting methodologies. Suburban O'Hare Commission v. Dole, 787 F.2d 186, 197-198 (7th Cir. 1986).

Even though the role of the courts in reviewing agency NEPA compliance is limited, NEPA has generated much litigation. S. 343 will generate even more and it will be more problematic because S. 343 is a more complex statutory scheme.

While majority staffers have argued S. 343 will "level the playing field" and give regulated industry standing to challenge agency action, this will be a tool by which competitors and a range of interest groups can challenge the underlying bases of agency rules. The "zone of interests" protected by NEPA is more narrow.

The petition process in S. 343 subjects all existing rules to the criteria and judicial review provisions of the bill. In contrast, NEPA is not retroactive.

9

- * ~~Substitute the language of § 623 of S. 1001 for § 625 of § 343¹, or~~
- * ~~Adopt the following revised judicial review language:~~

Strike line 15 of page 38 through line 7 on page 40, and insert in place thereof the following:

(a) REVIEW.--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 section.

(b) JURISDICTION.--(1) Subject to paragraph (2) and to any limitations on judicial review which are applicable to the final agency action, the court with jurisdiction to review the final agency action has jurisdiction to review claims of noncompliance with this subchapter or subchapter III.

(2) No claims of noncompliance with this subchapter or subchapter III shall be reviewed separate or apart from judicial review of the final agency action to which they relate.

(c) RECORD.--Any cost-benefit analysis or risk assessment required under this subchapter or subchapter III shall constitute part of the rulemaking record of the final agency action to which it pertains for the purpose of judicial review.

(d) STANDARD FOR REVIEW.--In any judicial review proceeding, the information contained in any cost-benefit analysis or risk assessment required under subchapter II or III may be considered by the court, to the extent relevant, as part of the administrative record solely for the purpose of determining whether the final agency action is arbitrary, capricious, or an abuse of discretion. The adequacy of compliance or the failure to comply with subchapter II or III shall not be grounds for remanding or invalidating a final agency action, unless the agency wholly omitted to perform a required cost benefit analysis or risk assessment.

¹ We have technical corrections to the S.1001 language.



U.S. Department of Justice

Environment and Natural Resources Division

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TO: Elena Kagan

TELEPHONE NO.: 456-7901

FAX NO.: 456-1647

FROM: Bess Osenbaugh

DATE: 2/28/96

MESSAGE: Please see discussion of Corrosion Pipe Fittings, 947 F.2d 1201, 1215-1230 (5th Cir. 1991), on pages 1 and 2 - keep case - only major change.

PLEASE NOTIFY SENDER IMMEDIATELY IF YOU HAVE ANY PROBLEMS RECEIVING THESE PAGES.

February 28, 1996

I. The combination of mandatory decisional criteria and judicial review deprive agencies of discretion to weigh factors other than cost-effectiveness.

Under the proposed decisional criteria, an agency judgment to select an alternative other than the "most cost-effective" would constitute an abuse of discretion. The decisional criteria make a finding of greatest cost-effectiveness mandatory; an agency could not justify its decision on other grounds. Under current law, an agency can rely on its "best judgment" in balancing cost, along with other relevant factors. For example, in Florida Manufacturing Assn v. Cisneros, 53 F.3d 1565, 1580-1581 (11 Cir 1995), the court upheld new wind standards for mobile homes. The court found it unnecessary to review a challenge to the agency's finding the rule would produce a net economic benefit because the agency had also concluded that the need to increase safety and prevent devastation to communities in hurricanes justified the increased cost. Because Congress instructed HUD to consider safety as well as cost, the agency was able to rely on "its best judgment in balancing the substantive issues," and the Court refused to substitute its judgment for the agency's. See also BP Exploration & Oil, Inc. (93-3310) v. U.S. E.P.A., 66 F.3d 784, 799-800 (6th Cir. 1995), where the Court in construing the Clean Water Act requirements for best available technology (BAT), said:

The CWA does not require a precise calculation of BAT and NSPS costs. [NRDC v. EPA, 863 F.2d 1420, 1426 (9th Cir. 1988).] Congress intended that EPA have discretion "to decide how to account for the consideration factors, and how much weight to give each factor." [Weyerhaeuser Co. v. Costle, 590 F.2d 1011, 1045 (D.C. Cir. 1978).]

By stark contrast, under the single-point decisional criteria, the agency would be required to find that the rule selected was the most cost-effective or provided the greatest net benefits. This would be a mandatory finding; the agency could not justify its decision on other grounds.

Corrosion Proof Fittings v. E.P.A., 947 F.2d 1201, 1215-1230 (5th Cir. 1991), provides a valuable preview of the extent to which single-point cost decisional criteria both constrain agency discretion and encourage judicial second-guessing of agency expertise. There the Toxic Substances Control Act required the agency to choose the "least burdensome requirements" that would adequately protect the public from chemical substances causing unreasonable risk of injury. The Court struck an EPA rule which would eventually ban all uses of asbestos. In doing so, it ruled that the "least burdensome" requirement meant that EPA was

required to show that there was no less burdensome alternative that would achieve an acceptable level of risk. 947 F.2d at 1216-1217. EPA abused its discretion because it failed to "consider each regulatory option, beginning with the least burdensome..." and calculate the costs and benefits of each. Id. Further, the Court said EPA could not consider nonquantifiable benefits as a "trump card." EPA could make allowance for unquantified benefits or costs in deciding which alternative was the "least burdensome" but could not "improperly [transform] permissible considerations into determinative factors." 947 F.2d at 1219, n. 20. The Court also held that the requirement that EPA consider the benefits of substances and the availability of substitutes meant that EPA was required to consider the comparative toxic costs and benefits of each substitute if any interested party provided credible evidence "suggesting the toxicity" of the substitute. 947 F.2d at 1221. The Court clearly engaged in much second-guessing of the agency's scientific studies, risk assessments, and economic analyses. 947 F.2d at 1218-1227. At one point the Court stated:

The EPA is required to support its analysis with substantial evidence under TSCA. When one figure is challenged, it cannot back up its position by changing an unrelated figure to yield the same result. Allowing such behavior would require us only to focus on the final numbers provided by the agency, and to ignore how it arrives at that number. Because a conclusion is no better than the methodology used to reach it, such a result cannot survive the substantial evidence test.

947 F.2d at 1227.

Corrosion Proof Fittings not only illustrates the difference between judicial review of a single-point decisional criteria, but it also illustrates how a cost-effectiveness standard will encourage courts to intrude into the underlying bases for the agency action. The many prescriptive requirements for analysis of every "reasonable alternative" encourages courts to second-guess agency analyses.¹

Further, if any alleged error affected the ultimate conclusion as to which regulatory alternative was the cheaper, this would be outcome determinative and therefore pass any prejudicial error or materiality test. When the test for agency action is selection of the most cost-effective alternative, rather than reasonableness, even a technical error in the cost-benefit analysis may be outcome-determinative, and thus material.

¹Under most bills, "reasonable alternative" is defined as every alternative within the statutory authority, including taking no action.

Under current APA standards, uncertainty in the cost-benefit analysis or consideration of factors other than cost are not themselves a basis for reversal. Instead, these are simply factors for the agency to evaluate in reaching a reasonable result. In IBEW, Local 1245 v. Skinner, 913 F.2d 1454, 1459 (9th Cir 1990), a challenge to a rule requiring drug testing of pipeline employees, the Court said, "Although we agree with petitioners that the cost-benefit figures are uncertain, we nonetheless regard the drug testing program as a reasonable measure properly geared to safety needs. The legislative history of this provision supports our view that public safety, and not cost, shall be the predominate concern." Again, the result would be different if Congress required selection of the most cost-effective alternative -- and certainly the litigation would be much more extensive.

Agencies must be able to consider other factors, when relevant under their statutory authority. This President has, for example, ordered agencies to consider the effects of their actions on environmental justice and working families. It is clearly cheaper to place hazardous waste sites in poor neighborhoods where land values are less, but couldn't a reasonable agency also consider the unfairness to the residents of bearing all of these adverse societal costs? The Executive Order recognized that distributional effects and equity are important factors.² Even the pro-business American Enterprise Institute recently recognized that agencies "should not be bound by a strict benefit-cost test" because they may reasonably want to place greater weight on particular factors, such as potentially irreversible consequences. Report, p. 7.

These decisional criteria force agencies and reviewing courts into quantification formulas. It is not always possible to reduce rulemaking decisions to algebraic equations. In cases in which the costs of regulation are on the person causing the harm, and all of the benefits are on those affected, are agencies to give these equal weight? Are agencies to assume that those causing the harm will spread some of the benefits of reduced cost

²The Executive Order included these in the definition of costs and benefits. While that helps assure consideration in the economic analysis, it is also important that the agency head be able to weigh the significance of these factors in the ultimate decision -- and not have courts second-guessing agency attempts to quantify these factors into a "cost-effectiveness" mandate. The Executive Order avoided those consequences because it is not judicially enforceable.

of regulation to those injured by their conduct?³ Maybe an agency can stretch cost estimation enough to achieve these results, but should it have to and should these judgments be concealed in the cost analysis?

Some proponents claim that S.343 merely protects the regulated industry by requiring consideration of cost in a manner similar to the consideration of environmental factors under the National Environmental Policy Act. Actually, this bill goes far beyond NEPA in both limiting agency discretion and providing "hooks" upon which to invalidate agency action. Under NEPA, courts review only for procedural compliance and must defer to agencies' scientific and policy judgments. See Strycker's Bay Neighborhood Council, Inc. v. Karlen, 444 U.S. 223 (1980). As the Supreme Court explained in Strycker's Bay,

once an agency has made a decision subject to NEPA's procedural requirements, the only role for a court is to insure that the agency has considered the environmental consequences; it cannot "interject itself within the area of discretion of the executive as to the choice of the action to be taken."

444 U.S. at 227 (citations omitted). Notably, NEPA does not require the agency to select the environmentally preferred alternative nor does it otherwise substantively constrain the scope of agency decisionmaking, Robertson v. Methow Valley Citizens Council, 490 U.S. 332, 350 (1989). Furthermore, NEPA does not require the courts to delve into the relative validity of conflicting methodologies. Suburban O'Hare Commission v. Dole, 787 F.2d 186, 197-198 (7th Cir. 1986). A NEPA-type bill would require agencies to give a "hard look" to the results of cost-benefit analyses and risk assessments, but would not mandate a particular decision.

II. The Act contains many requirements which would make it very difficult for contested rules to survive judicial review.

Section 625 expressly permits judicial review of noncompliance with the requirements of subchapters II (cost-benefit) and III (risk assessment) by providing that "failure to comply" with those requirements may be considered by the court in

³So Ford Motor Company allegedly concluded it was cheaper to pay burn victims tort judgments in the few cases where they recovered than to make a safer gas tank for the Ford Pinto. If the cost of regulation exceeded the "quantifiable" costs to burn victims, would an agency have to forego requiring safer gas tanks even if it cost only a few dollars per car?

determining whether the final agency action is arbitrary and capricious, an abuse of discretion, or unsupported by substantial evidence. Petitioners will surely argue that failure to comply with statutory requirements is itself arbitrary and capricious. See, e.g., Motor Vehicle Manufacturers v. Ruckelshaus, 719 F.2d 1159, 1164 (D.C. Cir. 1983) ("Agency action is arbitrary and capricious if the agency has failed to meet statutory, procedural, or constitutional requirements")

Judicial review is particularly problematic because the bill's requirements are so detailed and prescriptive. The nature of these requirements often lend themselves to argument and litigation because of uncertainty in application or lack of adequate definition.

A few examples of reviewable requirements in the July draft of S. 343 are:

- interlocutory challenges to the agency's determination as to whether the rule is a "major" rule, including whether a rule should be considered part of a closely related group of rules for purposes of the major rule cost threshold;
- challenges to the adequacy of the agency's final cost benefit analysis, including the adequacy of the agency's quantification of its estimate of benefits, its use of appropriate units of measurement (using comparable assumptions and time periods), its specification of ranges of predictions and explanations of margins of error;
- challenges alleging that an agency has failed to consider the costs and benefits of the proposed or final rule on "all of the affected persons or classes of persons (including specially affected subgroups)";
- challenges to the agency's determination of industry-by-industry effects or its determination that such an industry-by-industry description is "not practicable";
- challenges to the agency's determination that a rule meets the requirements of section 624(b) or (c), including whether it adopts "the least cost alternative" of any of the reasonable alternatives;
- challenges that the agency did not base each risk assessment "only on the best reasonably available scientific data and scientific understanding"
- challenges that the agency did not discuss "all relevant information" when conflicts among scientific data appear;

-- challenges that an agency used a "policy judgment" when "relevant and adequate scientific data and scientific understanding . . . are available" or inappropriately combined or compounded multiple "policy judgments";

-- challenges to an agency certification that the final agency action is not "likely to significantly reduce the human health, safety, and environmental risks to be addressed" or that specified factors preclude making such a finding but that the rule is nevertheless justified for reasons "consistent with subchapter III."

III. When an agency must choose the single alternative that is the most cost-effective, disputes over these requirements will often be outcome-determinative and thus survive a materiality test.

Because the agency must choose the least cost alternative, any of the underlying estimates may be outcome determinative. This creates great incentive for litigation, invites the courts to second-guess agency decisionmaking, and provides numerous opportunities for reversal. And while the bill dictates choice of the most cost-effective, it fails to acknowledge that the tools of risk assessment or cost-benefit analysis produce estimates which are subject to much dispute.

Courts are not well situated to review the underlying basis of cost-benefit analyses and risk assessments against the prescriptive standards of the bill.

[T]he crowded states of judicial dockets offers a highly practical reason why judges will not, and probably should not, devote the considerable time and effort needed to review a several-thousand-page agency record, informed by a thorough understanding of the substance of risk-related regulatory problems, in order to see whether or not that agency determination was arbitrary.

Justice Breyer, Breaking the Vicious Circle: Toward Effective Risk Regulation (Cambridge, Mass.: Harvard University Press 1973), p. 58-59 (describing why courts are not institutionally suited to resolve risk issues).

4. Some of the criteria are simply not reasonable.

For example, [Johnston 634, p. 48] states, "An agency shall use policy judgments only when relevant and adequate scientific information, including situation-specific information is not available." Does this provision mean what it says -- that an agency can never consider policy in risk assessments -- that it

must ignore equity? Can an agency siting rule for noxious activity protect existing residences? Nuisance law surely does, but this statute repeatedly appears to displace common law, agency expertise, and equity. Instead, cost-effectiveness and scientific understanding are apparently always the ultimate test. This will make it difficult for agencies to promote small business, the nuclear family, freedom of speech or religion, and other non-quantifiable and non-scientific values.

5. Judicial review and decisional criteria should be a significant policy issue in the congressional debate.

Attached are the Doonesbury cartoons for the week of July 31, 1995. The fifth set neatly illustrates the point made firmly in the Congressional debate that S. 343 would give regulated industry plenty of "hooks" on which to sue and overturn regulations. This is one of the main reasons that S. 343 would impair food, health, safety, and environmental regulation.

If the bill's opponents accede to a bill that requires agencies to select a single alternative based on cost and permits judicial review of the requirements of the bill, this key point will be lost.

6. Courts should not second-guess the cost-benefit analysis or risk assessment. Instead, judicial review should be limited as it is today to determining whether the agency action is reasonable, considering the results of the analysis.

The following draft would assure that agencies must take cost estimates into account but would permit judicial review only of the ultimate reasonableness of their actions.

(a) REVIEW.--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 section.

(b) JURISDICTION.--(1) Subject to paragraph (2) and to any limitations on judicial review which are applicable to the final agency action, the court with jurisdiction to review the final agency action has jurisdiction to review claims of noncompliance with this subchapter or subchapter III.

(2) No claims of noncompliance with this subchapter or subchapter III shall be reviewed separate or apart from judicial review of the final agency action to which they relate.

(c) RECORD.--Any cost-benefit analysis or risk assessment required under this subchapter or subchapter

III shall constitute part of the rulemaking record of the final agency action to which it pertains for the purpose of judicial review.

(d) STANDARD FOR REVIEW.--In any judicial review proceeding, the information contained in any cost-benefit analysis or risk assessment required under subchapter II or III may be considered by the court, to the extent relevant, as part of the administrative record solely for the purpose of determining whether the final agency action is arbitrary, capricious, or an abuse of discretion. The adequacy of compliance or the failure to comply with subchapter II or III shall not be grounds for remanding or invalidating a final agency action, unless the agency wholly omitted to perform a required cost benefit analysis or risk assessment.

**Department of Justice Comments
on "Issues of Concern"
March 1, 1996**

The excessive litigation that would be generated by these various regulatory reform bills has been a key concern of the Department of Justice. In particular, we have serious concerns with the following issues and wish to be included in decision-making concerning them.

I. Judicial Review

We agree that, if there must be judicial review of the requirements of the bill, a prejudicial error or materiality requirement is essential. We also agree that any judicial review must be of the final agency action (and, therefore, no interlocutory review), based on the entire record, and applying current APA judicial review standards.

However, we concur with Gary Guzy's statement in yesterday's conference call that a key component of the judicial review question that is left unanswered in the above formulation is what the courts should be allowed to review. Judicial review of the current decisional criteria and of prescriptive requirements such as those in S. 343 would be unworkable.

We believe the best approach would require agencies to take cost estimates into account but would permit judicial review only of the ultimate reasonableness of their actions as measured against the standards in the law that authorizes the action. Unlike the latest proposal from the Hill, this formulation would not permit judicial review of the selection of the least cost alternative requirement in the reg reform bill. Nor would it permit judicial review of such other requirements in the reg reform bill as that agencies must consider "all relevant scientific information" and cannot use "policy judgments" in risk assessments. It would allow the court to reverse action where the agency wholly failed to do the analysis or where its decision was unreasonable, given the entire record, including the cost-benefit analysis and risk assessment.

We recommend either the language which was drafted as part of the interagency work group last summer (a copy of which we would be happy to provide) or the following language proposed by the minority on July 20, 1995, toward the end of the regulatory reform debate. (See Cong. Rec. S10397 (July 20, 1995).)

* * *

(d) Standards for Review.--In any proceeding involving judicial review under section 706 or under the statute granting the rulemaking authority, the information contained in any cost-benefit analysis or

risk assessment required under subchapter II or III may be considered by the court as part of the administrative record solely for the purpose of determining whether the final agency action is arbitrary, capricious, or an abuse of discretion. The adequacy of compliance or the failure to comply with subchapter II or III shall not be grounds for remanding or invalidating a final agency action, unless the agency entirely failed to perform a required cost benefit analysis or risk assessment.

* * *

In discussing the appropriate standards for judicial review in these bills, we think it is important to link the issue to the relevant congressional review provisions. It seems we have an even stronger argument to make in favor of reasonable judicial review provisions when Congress is given the opportunity to review covered rules. Congressional review with judicial review of the reasonableness of the agency action seems sufficient to ensure that the agencies do not abuse their regulatory authority.

Finally, as has been often observed, the effects of the decisional criteria and the judicial review provisions can be understood only when read together. Although we prefer the judicial review provision above, we think there may be acceptable alternatives if the decisional criteria are made less prescriptive and more flexible.

II. Decisional Criteria

We agree that any decisional criteria must not impose a super-mandate that would either overrule or modify the applicable statutory criteria. Further, any criteria must provide flexibility, not just to address uncertainty but also to allow the decision-maker to consider non-quantifiable factors, such as environmental justice or equity.¹

A requirement that an agency choose the "most cost-effective" alternative, if judicially enforceable, is a serious

¹Inclusion of non-quantifiable costs and benefits in the definitions may not be sufficient to permit the decision-maker to weigh the non-quantifiable factors against cost in selecting the rulemaking alternative. See Corrosion Proof Fittings v. E.P.A., 947 F.2d 1201, 1215-1230 (5th Cir. 1991), where the Court held EPA could not consider nonquantifiable benefits as a "trump card." EPA could make allowance for unquantified benefits or costs in deciding which alternative was the "least burdensome" but could not "improperly [transform] permissible considerations into determinative factors." 947 F.2d at 1219, n. 20.

problem because it mandates that the agency select a single result driven by cost. It also makes any alleged error that would change the cost outcome-determinative and encourages extensive litigation over the underlying cost-benefit analyses. This provides great opportunity for judicial second-guessing of agency expertise and judgment calls. Compare Corrosion Proof Fittings v. E.P.A., 947 F.2d 1201, 1215-1230 (5th Cir. 1991) (very stringent review where toxic substances act required selection of "least burdensome" alternative), with Florida Manufacturing Assn v. Cisneros, 53 F.3d 1565, 1580-1581 (11 Cir 1995) (HUD authorized to consider safety as well as cost in mobile home wind requirements and could therefore rely on "its best judgment in balancing the substantive issues").

Of course, if the preferred judicial review language identified above is adopted, our concerns regarding decisional criteria are reduced.

III. Affirmative Defenses

The importance of this issue to the Department of Justice's civil and criminal enforcement would be difficult to overstate. We oppose provisions that would create factual issues in many cases and which would delegate to states and to "appropriate" federal officials authority to set aside environmental, health and safety requirements. This is an issue on which Justice has taken the lead in consultation with the White House and other agencies. We would like to continue in that role.

IV. Risk Assessments

We concur with the strategy articulated by Sally during the February 29, 1996, conference call on this issue.

V. Effective Date

We defer to other agencies on this, but do not see any problem with the effective date provision as described by Sally yesterday.

I. Delete § 624(e), (f) and (g), p. 16, lines 10-25, and change to read as follows:

~~(d) Standards for Review:--In any proceeding involving judicial review under section 706 or under the statute granting the rulemaking authority, the information contained in any cost-benefit analysis or risk assessment required under subchapter II or III may be considered by the court as part of the administrative record solely for the purpose of determining whether the final agency action is arbitrary, capricious, or an abuse of discretion. The adequacy of compliance or the failure to comply with subchapter II or III shall not be grounds for remanding or invalidating a final agency action, unless the agency entirely failed to perform a required cost benefit analysis or risk assessment.~~

II. Sec. 624 (Decisional Criteria) -- Permit agency head to select alternative other than that provided by decisional criteria "for reasons stated in the record."

624(a)(1) In promulgating a major rule subject to this subchapter, an agency shall, ~~except for good reason stated in the record,~~ select the reasonable alternative that it determines is likely to --

III. Also need to eliminate specific requirements for determination of uncertainties by the President, etc. Delete page 13, lines 10-24. [If there is no general good cause safety valve for all decisional criteria, the uncertainties escape valve needs to apply to all decisional criteria.]

IV. There are additional technical concerns with the judicial review language which would ultimately need to be addressed. Among these are:

Need to assure that all judicial review is on the rulemaking record -- review of issue whether a rule is a major rule (§624(c), p. 15, line 17, insert after "showing" in the rulemaking record; review of decisional criteria determination in 624(e) is stated to be on "rulemaking file," should be "rulemaking record."

If agency made a mistake and concluded a rule is not a major rule and therefore did no cost-benefit analysis, etc., the Court should be able to give the agency additional time to complete the analysis without automatically invalidating the rule. The language of 624(f) as now written appears to call for automatic invalidation. There should be language as in the regulatory flexibility section to permit the agency to correct the violation before invalidation results.

Definitions

Sec. 621(1) the term 'benefit' means the reasonably identifiable significant favorable effects, quantifiable and nonquantifiable, including social, health, environmental, economic, safety, distributive impacts, and equity that are expected to result directly or indirectly from implementation of, or compliance with a rule or an alternative to a rule.

COMMENT: The added language is contained in the Executive Order. Its inclusion will assure that the agency can consider non-economic factors, such as equity, and can also consider the distribution of benefits and costs among various groups, such as poorer neighborhoods, small business, etc.

Sec. 621(2) [Add same underlined language]

Sec. 621(3) the term 'cost-benefit analysis' means an evaluation of the costs and benefits of a rule, quantified to the extent feasible and appropriate and otherwise qualitatively described, that is prepared in accordance with the requirements of this subchapter at the level of detail appropriate and practicable for reasoned decision making on the matter involved, taking into consideration the significance of the decision and any need for expedition. In doing a cost-benefit analysis, the agency shall/may consider incentives for innovation, consistency, predictability, the costs of enforcement and compliance (to the government, regulated entities, and the public), flexibility, distributive impacts, and equity.

COMMENT: The underlined language is contained in the section of the Executive Order addressing the design of a regulation in the most cost-effective manner. Sec. b(5).

Decisional Criteria

(a)(1) In promulgating a major rule subject to this subchapter, an agency shall, unless otherwise ~~required by law and provided by law or~~ except for the provisions of paragraph (b) and (e), select the reasonable alternative that it ~~determines~~ ~~deems~~ is likely to --

(A) ~~achieve the purpose of the statute;~~

(B) employ to the extent practicable flexible regulatory options;

(C) ~~achieve the level of the benefits which is the objective of the rulemaking in a more cost-effective manner than the other reasonable alternatives evaluated by the agency;~~ and

COMMENT: This forces the agency to select one result. This will foster arguments that the court should review the decision whether an alternative is the most cost-effective as a non-discretionary duty imposed on the agency. It also makes any alleged error which would change the cost result outcome-determinative, and thus material. It further arguably excludes factors which do not relate to cost-effectiveness (e.g., environmental justice, religious freedom, preservation of small business; "family values," etc).

Alternative I:

[ADD at end of 623(a)(1):]

~~The agency shall explain why it selected the alternative in light of any cost-benefit analysis or risk assessment and other relevant factors.~~

COMMENT: This alternative would preserve the status quo under the executive order. The agency would retain reasonable discretion to select an alternative; any cost-benefit analysis or risk assessment could be considered by a reviewing court in determining whether the agency action is reasonable.

Alternative II:

[revise proposed 623(a)(1)(B)/(C):]

~~achieve the benefits of the rulemaking in a [more] cost-effective manner [than the other reasonable alternatives evaluated by the agency], unless the agency provides a rational basis for selecting a different alternative;~~

COMMENT: This alternative would preserve the status quo under the executive order. The agency would retain reasonable discretion to select an alternative; any cost-benefit analysis or risk assessment could be considered by a reviewing court in determining whether the agency action is reasonable.

Alternative III:
[revise 623(a)(1)(B)/(C):]

achieve the benefits which are the objective of the rulemaking in a cost-effective manner;

COMMENT: This alternative would not force the agency to select a single result. However, it would require all decisions to be justified on cost-effectiveness and not by other criteria [except as other sections preserve inconsistent statutory criteria]. Thus, the agency would be required to translate non-cost factors such as environmental justice into cost-effective terms and the court would so review the result.

(2) The agency shall publish in the Federal Register at the time of promulgation of the final rule a full explanation of the determinations made with respect to this subsection.

(b) If the agency is unable to make a determination that the benefits of the reasonable alternative it selected justify the costs of [such reasonable alternative / the rule] because either:

(1) the law upon which the rule is based requires the selection of another reasonable alternative which would not meet this test or mandates the alternative in question ???;

Alternative II:

the law upon which the rule is based precludes the selection of an alternative meeting this test;

(2) significant economic, scientific, or technical, or other uncertainties make such a determination unreasonable and the risk problem addressed by the rulemaking is potentially so significant that the agency determines it is in the public interest to issue a rule,

COMMENT: Some agencies do not address risk, as defined in this act, but may well have significant need to promulgate a rule despite uncertainty. There may be uncertainties which are not economic, scientific, or technical: for example, uncertainty about the likelihood that a public education campaign or ineligibility for welfare benefits will reduce teen pregnancy.

Alternative II:

significant economic, scientific, or technical, or other uncertainties make such a determination unreasonable and the risk addressed by the rulemaking the need for the rule is potentially so significant great that the agency determines it is in the public interest to issue a rule,

the agency shall promulgate such reasonable alternative as a final rule and, at the time the final rule is published in the Federal Register, place in the Federal Register and forward to Congress an explanation of the reason why such a determination cannot be made.

[In lieu of (c):

If a statute precludes a determination that the benefits of the alternative selected justify the costs of the rule, the agency shall also forward to Congress any recommendations for amendments to the statute.

(d) [Reduce 180 days delay for rules within (b) to ____ days.]

(e) [from EK]

Judicial Review

COMMENT: This draft very clearly authorizes judicial review of procedural errors and judicial second-guessing of an agency's determination of cost-effectiveness. It thus goes far beyond the status quo under the Executive Order.

The prejudicial error requirement improves it somewhat. However, this would still permit parties to argue that the agency's underlying assumptions in its cost-benefit analysis were incorrect. If there is a substantial likelihood the challenge could result in a different alternative being "more cost-effective," the challenge would meet a materiality test.

Alternative I:
[Substitute:]

No claim of noncompliance with this subchapter or subchapter III [this Act?] shall be reviewed separate or apart from judicial review of the final agency action to which they relate.

Except as otherwise provided by law, the information contained in any cost-benefit analysis or risk assessment required under subchapter II or III may be considered by the court, to the extent relevant, solely for the purpose of determining whether the final agency action, based upon the entire record, is arbitrary, capricious, or an abuse of discretion [or not supported by substantial evidence...]. The adequacy of compliance or the failure to comply with subchapter II or III shall not be grounds for remanding or invalidating a final agency action, unless the agency wholly omitted to perform a required cost benefit analysis or risk assessment.

COMMENT: This is the language developed in the workgroup process earlier. It would reflect the status quo under the Executive Order. A reviewing court could consider the agency's analysis in determining whether its decision was reasonable. However, the court would not itself review "cost-effectiveness" or the details of the agency's cost-benefit analysis or risk assessment.

Alternative II: [attached]

COMMENT: This is derived from the Unfunded Mandates Act, PL 104-4, sec. 401(a)(2)(4).

Alternative III:

[Amend the proposal by adding to the end of the first paragraph:

....and then only if the court finds on the basis of the entire record that there is a substantial likelihood that such failure materially affected the outcome of the agency's decision.

Omit the second paragraph:

COMMENT: This new second paragraph suggests a different standard for review of decisional criteria (for example, it would omit the materiality requirement). It underscores that the bill authorizes judicial review of agency determinations of cost-effectiveness and of procedural challenges. It also limits review to the rulemaking file, rather than the entire record.

Omit the third paragraph:

COMMENT: This paragraph is totally backward of earlier versions. It would mandate vacation of a rule, even where the court might otherwise permit the agency to correct a procedural error while a critical rule remained in place. This concept should be turned around as in last sentence of Alternative I above.

TITLE IV—JUDICIAL REVIEW

A

SEC. 401. JUDICIAL REVIEW.

(a) AGENCY STATEMENTS ON SIGNIFICANT REGULATORY ACTIONS.—

(1) IN GENERAL.—Compliance or noncompliance by any agency with the provisions of sections ~~202 and 203(a) (1) and (2)~~ shall be subject to judicial review only in accordance with this section.

*this Act/
Subch. II
and III*

(2) LIMITED REVIEW OF AGENCY COMPLIANCE OR NONCOMPLIANCE.—(A) Agency compliance or noncompliance with the provisions of sections ~~202 and 203(a) (1) and (2)~~ shall be subject to judicial review only under section 706(1) of title 5, United States Code, and only as provided under subparagraph (B).

(B) If an agency fails to prepare the written statement (including the preparation of the estimates, analyses, statements, or descriptions) under section 202 or the written plan under section 203(a) (1) and (2), a court may compel the agency to prepare such written statement.

(3) REVIEW OF AGENCY RULES.—In any judicial review under any other Federal law of an agency rule for which a written statement or plan is required under sections 202 and 203(a) (1) and (2) the inadequacy or failure to prepare such statement (including the inadequacy or failure to prepare any estimate, analysis, statement or description) or written plan shall not

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109 STAT. 70

Conform marked sections.

Mar. 22

UNFUNDED MANDATES REFORM ACT

P.L. 104-4
Sec. 401

be used as a basis for staying, enjoining, invalidating or otherwise affecting such agency rule.

(4) CERTAIN INFORMATION AS PART OF RECORD.—Any information generated under sections 202 and 203(a) (1) and (2) that is part of the rulemaking record for judicial review under the provisions of any other Federal law may be considered as part of the record for judicial review conducted under such other provisions of Federal law.

(5) APPLICATION OF OTHER FEDERAL LAW.—For any petition under paragraph (2) the provisions of such other Federal law shall control all other matters, such as exhaustion of administrative remedies, the time for and manner of seeking review and venue, except that if such other Federal law does not provide a limitation on the time for filing a petition for judicial review that is less than 180 days, such limitation shall be 180 days after a final rule is promulgated by the appropriate agency.

enactment (6) EFFECTIVE DATE.—This subsection shall take effect on ~~October 1, 1995~~, and shall apply only to any agency rule for which a general notice of proposed rulemaking is promulgated on or after such date.

(b) JUDICIAL REVIEW AND RULE OF CONSTRUCTION.—Except as provided in subsection (a)— *assessment,*

(1) any estimate, analysis, statement, description or report prepared under this Act, and any compliance or noncompliance with the provisions of this Act, and any determination concerning the applicability of the provisions of this Act shall not be subject to judicial review; and

(2) no provision of this Act shall be construed to create any right or benefit, substantive or procedural, enforceable by any person in any administrative or judicial action.



U.S. Department of Justice

Environment and Natural Resources Division

Office of the Assistant Attorney General

Washington, D.C. 20530

CONFIRMATION NUMBER (202) 514-2701

FAX NUMBER (202) 514-0557

To: ① Joe Woodward
219-7725

NO. OF PAGES: 9 (INCLUDING COVER PAGE) FAX 219-7147

TO: ② Gary Guzy ③ Seth Harris ④ Elena Kagan

TELEPHONE NO.: 219-6197 456-7901

FAX NO.: 260-3684 219-9216 456-1647

FROM: Bess Osenbaugh

DATE: 2/8/96

MESSAGE:

Deliver immediately please.
Preliminary, not revealed -
discussion

CONFIDENTIAL

PLEASE NOTIFY SENDER IMMEDIATELY IF YOU HAVE ANY PROBLEMS RECEIVING THESE PAGES.

Decisional Criteria

(a)(1) In promulgating a major rule subject to this subchapter, an agency shall, unless otherwise required by law and provided by law or except for the provisions of paragraph (b) and (e), select the reasonable alternative that it determines ~~deems~~ is likely to --

~~(A) achieve the purpose of the statute;~~

(B) employ to the extent practicable flexible regulatory options;

~~(C) achieve the level of the benefits which is the objective of the rulemaking in a more cost-effective manner than the other reasonable alternatives evaluated by the agency; and~~

COMMENT: This forces the agency to select one result. This will foster arguments that the court should review the decision whether an alternative is the most cost-effective as a non-discretionary duty imposed on the agency. It also makes any alleged error which would change the cost result outcome-determinative, and thus material. It further arguably excludes factors which do not relate to cost-effectiveness (e.g., environmental justice, religious freedom, preservation of small business; "family values," etc).

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[ADD at end of 623(a)(1):]

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[revise proposed 623(a)(1)(B)/(C):]

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[revise 623(a)(1)(B)/(C):]

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If a statute precludes a determination that the benefits of the alternative selected justify the costs of the rule, the agency shall also forward to Congress any recommendations for amendments to the statute.

(d) [Reduce 180 days delay for rules within (b) to ____ days.]

(e) [from EK]

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[Substitute:]

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[Amend the proposal by adding to the end of the first paragraph:

....and then only if the court finds on the basis of the entire record that there is a substantial likelihood that such failure materially affected the outcome of the agency's decision.

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TITLE IV—JUDICIAL REVIEW

A

1571.

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*this Act /
Subch. II
and III*

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(B) If an agency fails to prepare the written statement (including the preparation of the estimates, analyses, statements, or descriptions) under section 202 or the written plan under section 203(a) (1) and (2), a court may compel the agency to prepare such written statement.

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109 STAT. 70

Conform marked sections.

Mar. 22

UNFUNDED MANDATES REFORM ACT

P.L. 104-4
Sec. 401

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(5) APPLICATION OF OTHER FEDERAL LAW.—For any petition under paragraph (2) the provisions of such other Federal law shall control all other matters, such as exhaustion of administrative remedies, the time for and manner of seeking review and venue, except that if such other Federal law does not provide a limitation on the time for filing a petition for judicial review that is less than 180 days, such limitation shall be 180 days after a final rule is promulgated by the appropriate agency.

enactment

(6) EFFECTIVE DATE.—This subsection shall take effect on ~~October 1, 1995~~, and shall apply only to any agency rule for which a general notice of proposed rulemaking is promulgated on or after such date.

(b) JUDICIAL REVIEW AND RULE OF CONSTRUCTION.—Except as provided in subsection (a)— *assessment*

(1) any estimate, analysis, statement, description or report prepared under this Act, and any compliance or noncompliance with the provisions of this Act, and any determination concerning the applicability of the provisions of this Act shall not be subject to judicial review; and

(2) no provision of this Act shall be construed to create any right or benefit, substantive or procedural, enforceable by any person in any administrative or judicial action.



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Office of the Assistant Attorney General

Washington, D.C. 20530

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NO. OF PAGES: ~~2~~ ² (INCLUDING COVER PAGE) FAX 219-7147

TO: ② Gary Guzy ③ Seth Harris ④ Elena Kagan

TELEPHONE NO.: 219-6197 456-7901

FAX NO.: 260-3684 219-9216 456-1647

FROM: Bess Osenbaugh

DATE: 2/8/96

MESSAGE:

Here's an additional page. I have received no comments on the ~~extra~~ materials circulated to you about 2:00 today.

Mike Fitzpatrick advises we can bring paper to meeting tomorrow at 1:00. Please call before 11:30 if possible!

Thanks.

Bess

Definitions

Sec. 621(1) the term 'benefit' means the reasonably identifiable significant favorable effects, quantifiable and nonquantifiable, including social, health, environmental, economic, safety, distributive impacts, and equity that are expected to result directly or indirectly from implementation of, or compliance with a rule or an alternative to a rule.

COMMENT: The added language is contained in the Executive Order. Its inclusion will assure that the agency can consider non-economic factors, such as equity, and can also consider the distribution of benefits and costs among various groups, such as poorer neighborhoods, small business, etc.

Sec. 621(2) [Add same underlined language]

Sec. 621(3) the term 'cost-benefit analysis' means an evaluation of the costs and benefits of a rule, quantified to the extent feasible and appropriate and otherwise qualitatively described, that is prepared in accordance with the requirements of this subchapter at the level of detail appropriate and practicable for reasoned decision making on the matter involved, taking into consideration the significance of the decision and any need for expedition. In doing a cost-benefit analysis, the agency shall/may consider incentives for innovation, consistency, predictability, the costs of enforcement and compliance (to the government, regulated entities, and the public), flexibility, distributive impacts, and equity.

COMMENT: The underlined language is contained in the section of the Executive Order addressing the design of a regulation in the most cost-effective manner. Sec. b(5).

THE WHITE HOUSE

WASHINGTON

February 9, 1996

MEMORANDUM FOR SALLY KATZEN

FROM: ELENA KAGAN *EK*
SUBJECT: SUPERMANDATE LANGUAGE

You asked me to look at, and discuss with some agency counsel, section (e) in the decisional criteria language we reviewed yesterday. That section currently reads:

Nothing in this chapter shall be construed to override any statutory requirement, including health, safety, and environmental requirements.

One concern about this language focuses on the term "override." Although this term is not completely clear, it suggests that only the most direct and blatant kind of statutory conflict will allow an agency to depart from the decisional criteria. In order to avoid this construction, the word "override" could be replaced with the phrase "override, modify, or otherwise affect."

Another concern about the language focuses on the term "statutory requirement." This language might be taken to refer only to clear statutory (even textual) directives, and to exclude agency interpretations of more open-ended statutory provisions. In order to avoid the harshest possible construction, the language could be amended to refer to any "statutory requirement" -- or even any "statutory provision" -- "as reasonably interpreted by the agency."

If both concerns above are addressed, the resulting section would look something like this:

Nothing in this chapter shall be construed to override, modify, or otherwise affect any statutory provision [requirement], including a health, safety, or environmental provision [requirement], as reasonably interpreted by the agency.

Agency counsel mostly agreed that if these or similar changes are made, it would become unnecessary (perhaps even detrimental) to include a provision specifically directing the agency how to proceed in the event of a conflict between the decisional criteria and the statute authorizing the rule. (One such provision, suggested by Sen. Chafee, states that "if . . . the agency cannot comply as a matter of law both with a requirement of this section and any requirement of the statute authorizing the rule, such requirement of this section shall not

apply to the rule.") Inclusion of such a provision, however, remains a conceivable option for ensuring that the decisional criteria do not trump existing legal standards.

cc: Michael Fitzpatrick

SUPERMANDATE LANGUAGE

Section (e) in the decisional criteria section of the Levin draft currently reads:

Nothing in this chapter shall be construed to override any statutory requirement, including health, safety, and environmental requirements.

One concern about this language focuses on the term "override." Although this term is not completely clear, it suggests that only the most direct and blatant kind of statutory conflict will allow an agency to depart from the decisional criteria. In order to avoid this construction, the word "override" could be replaced with the phrase "override, modify, or otherwise affect."

Another concern about the language focuses on the term "statutory requirement." This language might be taken to refer only to clear statutory (even textual) directives, and to exclude agency interpretations of more open-ended statutory provisions. In order to avoid the harshest possible construction, the language could be amended to refer to any "statutory requirement" -- or even any "statutory provision" -- "as reasonably interpreted by the agency."

If both concerns above are addressed, the resulting section would look something like this:

Nothing in this chapter shall be construed to override, modify, or otherwise affect any statutory provision [requirement], including a health, safety, or environmental provision [requirement], as reasonably interpreted by the agency.

If these or similar changes are made, it would seem unnecessary (perhaps even detrimental) to include a provision specifically directing the agency how to proceed in the event of a conflict between the decisional criteria and the statute authorizing the rule. (One such provision, suggested by Sen. Chafee, states that "if . . . the agency cannot comply as a matter of law both with a requirement of this section and any requirement of the statute authorizing the rule, such requirement of this section shall not apply to the rule.") Inclusion of such a provision, however, remains a conceivable option for ensuring that the decisional criteria do not trump existing legal standards.

Supermandate issue

- 1) - can't to say "evolve, modify or otherwise affect"?
- 2) ^{provision of} statute, as necessarily interpreted by the agency?
- 3) Need to say when in conflict - so w/ subordinate statute?

flag intro language.

requirement of statute,

vs verbs in term of.

Amendment No. _____

Calendar No. _____

Purpose:

IN THE SENATE OF THE UNITED STATES—104th Cong., 1st Sess.

S. 343

To reform the regulatory process, and for other purposes.

Referred to the Committee on _____
and ordered to be printed

Ordered to lie on the table and to be printed

Amendment intended to be proposed by Mr. Chafee to amendment No. 1487
proposed by Mr. Dole

Viz:

- 1 On page 35, strike subsection 624(a) (lines 10 through 13) as modified by the Dole
- 2 Amendment No. 1496 and insert the following:
- 3 "(a) Construction with Other Laws.—The requirements of this section shall
- 4 supplement, and not supersede, any other decisional criteria otherwise provided by
- 5 law. If, with respect to any rule to be promulgated by a Federal agency, the
- 6 agency cannot comply as a matter of law both with a requirement of this section
- 7 and any requirement of the statute authorizing the rule, such requirement of this
- 8 section shall not apply to the rule."

- Over-ides (c)

MEMORANDUM

Date: September 25, 1995
From: Dave Hawkins
To: Interested Senate Offices
Subject: Latest Robb "Reg Reform" Proposal

We have looked at the latest package from Robb's office. It should be far from acceptable to responsible Senators.

- It moves essentially all the way back to Dole-Johnston on the key issues of decisional criteria and judicial review.
- It recreates unworkable overlapping petition processes.
- It restores the repeal of the Delaney clause.

Decisional Criteria

The proposal changes the August 4 Conrad-Robb proposal in two fundamentally adverse ways.

First, the proposal now imposes an unqualified "greater net benefits" or "less net costs" test on all major rules. The prior proposal excused agencies from making these findings where uncertainties prevented such a finding. Now the agency cannot issue the rule without making the finding and may only consider uncertainties as part of the finding. This will require the agency to prove the impossible, given the uncertainties, and will set up the rule for judicial reversal.

Second, the proposal restores the supermandate effect of Dole-Johnston, stripping away language that had been offered to Senator Chaffee and improved on by Conrad-Robb. The proposal strikes the following sentence that was in the "CONSTRUCTION WITH OTHER LAWS" subsection of the August 4 Conrad-Robb proposal: "If the requirements of this section are inconsistent with the relevant provisions of the statute, as reasonably interpreted by the agency, that authorize the promulgation of a rule subject to this subchapter, this section shall not apply to the rule."

The deleted sentence contained two important safeguards. First, it made clear that the underlying statute applied in case of a conflict. This rule of inapplicability would be eliminated. Second, the deleted sentence upheld existing judicial deference to agency interpretations of the many statutes that do not contain express prohibitions on consideration

of costs. Key statutes, such as the Clean Air Act, Clean Water Act, Occupational Health and Safety Act and others, have been interpreted by agencies and upheld by courts over the last 25 years to give primacy to health, safety and environment needs. By striking the sentence, the proposal would put at risk the 25 years of settled interpretations of these major environmental, health, and safety laws.

This result is not prevented by the addition of the "selected from among the reasonable alternatives" text in subsection (a). This new text is surplusage, since no rule would be legal if it were outside the range of reasonable alternatives. The definition of "reasonable alternatives" does not contain any safeguards making the decision rules inapplicable in case of conflict nor any language protecting reasonable agency interpretations of existing laws to limit cost considerations.

In sum, the new proposal creates decisional criteria that are much more difficult to pass and restores a supermandate that will weaken many existing laws.

Judicial Review

The new judicial review language returns to the across-the-board review approach of Dole-Johnston. Any failure to meet the myriad specific requirements of subchapter II or III can be grounds for overturning a rule. To avoid this result an agency would have to prove that its failure "did not materially affect the outcome" of its decision. This is a requirement to prove a negative - extremely difficult, if not impossible. To show that a deviation from the analytical specifics of S. 343 did not affect the outcome, the agency might have to redo the analysis after the court had identified the failure: this is the practical equivalent of overturning the rule. Thus, the new proposal restores S. 343's ability to tie up rules in court indefinitely.

Petitions

The new proposal restores overlapping petition processes and creates an unworkable scheduling mechanism that could change with every year's appropriations bill.

Under the new proposal a major rule could be the subject of petition under both § 553(1) and under § 623. An agency could be forced to put (or keep) a rule on the § 623 schedule even if it had already granted a petition under § 553(1). The rule cannot be taken off the § 623 schedule until a notice of proposed rulemaking is issued under § 553(1). Thus, for several years a rule could be occupying a "slot" on the § 623 schedule (thus preventing scheduling another rule), even though it was expending resources to develop a proposal to respond to a § 553(1) petition.

While the August 4 proposal allowed the agency to extend deadlines when resources were

inadequate, the new proposal weakens that authority. First, in subsection(b)(3) the phrase "unless the agency reasonably determines the resources expected to be available ... prevent..." has been changed to "unless the resources expected to be available...prevent...." The deletion of the reference to the agency's reasonable determination means a court could strike down extensions even where the agency had reasonably determined that a resource shortage existed.

In addition, the new proposal would force an agency to disrupt an established 11 year schedule and replace it with a 5 year schedule, based on a single year's appropriations act. A funding rate sufficient for a 5 year completion path might be provided in year one but what happens if the next year's appropriations is not continued at that rate? As written, the new proposal might require the agency to complete its work in 5 years even though it lack the funds to do so.

Delaney Clause

The August 4 proposal would have deleted the repeal of the Delaney clause outright or have replaced it with a fast-track Congressional review. The new proposal is silent on Delaney, thus leaving the Dole-Johnston repeal intact. As we have said many times before, the repeal of the important Delaney provision is a special-interest fix that has no place in a regulatory reform bill.

1 “(d) NET BENEFITS AND COSTS.-- In an agency determination under subsection
2 (a)(3) or (b)(2), the use of the term “net” when referring to benefits or costs shall include the
3 considerations referred to in subsection (2) and subsection (3) in §621.”

4 “(e) CONSTRUCTION WITH OTHER LAWS.--The requirements of this section
5 shall supplement, and not supersede, any other decisional criteria otherwise provided by law.
6 Nothing in this section shall be construed to override or amend any statutory requirements,
7 including health, safety, and environmental requirements.”



U.S. Department of Justice

Environment and Natural Resources Division

Office of the Assistant Attorney General

Washington, D.C. 20530

CONFIRMATION NUMBER (202) 514-2701

FAX NUMBER (202) 514-0557

NO. OF PAGES: 2 (INCLUDING COVER PAGE)

TO: Gary Guzy Seth Harris Elena Kagan

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FROM: Bess Osenbaugh

DATE: 2/8/96

MESSAGE: Deliver immediately please.

PLEASE NOTIFY SENDER IMMEDIATELY IF YOU HAVE ANY PROBLEMS RECEIVING THESE PAGES.

623(a)(1)(B) -- Delete. ADD at end of 623(a)(1):

The agency shall explain why it selected the alternative in light of any cost-benefit analysis or risk assessment and other relevant factors.

[Alternative: revise 623(a)(1)(B):

achieve the benefits which is the objective of the rulemaking in a more cost-effective manner than the other reasonable alternatives evaluated by the agency, unless the agency provides a rational basis for selecting a different alternative;

Judicial Review -- delete sec. 624 and substitute:

No claim of noncompliance with this subchapter or subchapter III [or other subchapters?] shall be reviewed separate or apart from judicial review of the final agency action to which they relate.

Except as otherwise provided by law, the information contained in any cost-benefit analysis or risk assessment required under subchapter II or III may be considered by the court, to the extent relevant, solely for the purpose of determining whether the final agency action, based upon the entire record, is arbitrary, capricious, or an abuse of discretion [or not supported by substantial evidence...] The adequacy of compliance or the failure to comply with subchapter II or III shall not be grounds for remanding or invalidating a final agency action, unless the agency wholly omitted to perform a required cost benefit analysis or risk assessment.

ISSUES OF CONCERN

- Decisional Criteria/Supermandate -- ensure no supermandate and sufficient flexibility where scientific or other uncertainties exist.
- Judicial Review -- possibility that minor procedural misstep with cost or risk analysis could be ground for remand; any review should be restricted to final agency action based on the whole rulemaking record under existing standards.
- Petitions/Look-Back Review -- burdensome and overlapping processes would tie agencies in knots and waste increasingly scarce resources.
- Effective Date -- backdoor regulatory moratorium if applicable retroactively or Congressional review period extended.

* * * * *

- 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.
- Repeal of Delaney/TRI Restrictions -- significant substantive issues should not be resolved in what is a "process" bill.
- 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.

Cur draft

* Substitute the language of § 623 of S. 1001 for § 625 of S. 343¹, or

* Adopt the following revised judicial review language:

Strike line 15 of page 38 through line 7 on page 40, and insert in place thereof the following:

(a) REVIEW.--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 section.

(b) JURISDICTION.--(1) Subject to paragraph (2) and to any limitations on judicial review which are applicable to the final agency action, the court with jurisdiction to review the final agency action has jurisdiction to review claims of noncompliance with this subchapter or subchapter III.

(2) No claims of noncompliance with this subchapter or subchapter III shall be reviewed separate or apart from judicial review of the final agency action to which they relate.

(c) RECORD.--Any cost-benefit analysis or risk assessment required under this subchapter or subchapter III shall constitute part of the rulemaking record of the final agency action to which it pertains for the purpose of judicial review.

(d) STANDARD FOR REVIEW.--In any judicial review proceeding, the information contained in any cost-benefit analysis or risk assessment required under subchapter II or III may be considered by the court, to the extent relevant, as part of the administrative record solely for the purpose of determining whether the final agency action is arbitrary, capricious, or an abuse of discretion. The adequacy of compliance or the failure to comply with subchapter II or III shall not be grounds for remanding or invalidating a final agency action, unless the agency wholly omitted to perform a required cost benefit analysis or risk assessment.

¹ We have technical corrections to the S.1001 :

Proposed change to D-J judicial review.

(d) STANDARD FOR REVIEW. -- In any proceeding involving judicial review under section 706 or under the statute granting the rulemaking authority, failure to comply with this subchapter or subchapter III may not be considered by the court except for the purpose of determining, based on the rulemaking record as a whole, whether the final agency action is arbitrary or capricious or an abuse of discretion (or unsupported by substantial evidence where that standard is otherwise provided by law).

or

(d) STANDARD FOR REVIEW. -- In any proceeding involving judicial review under section 706 or under the statute granting the rulemaking authority, the information contained in any cost-benefit analysis or risk assessment required under subchapter II or III may be considered by the court as part of the administrative record solely for the purpose of determining whether the final agency action is arbitrary, capricious, or an abuse of discretion. The adequacy of compliance or the failure to comply with subchapter II or III shall not be grounds for remanding or invalidating a final agency action, unless the agency entirely failed to perform a required cost benefit analysis or risk assessment.

July 14, 1995

CONGRESSIONAL RECORD—SENATE

S 10061

Mr. GLENN submitted an amendment intended to be proposed by him to amendment No. 1487 proposed by Mr. DOLE to the bill, S. 343, supra; as follows:

On page 23, strike lines 20 through 23.

LEVIN AMENDMENT NO. 1662

(Ordered to lie on the table.)

Mr. LEVIN submitted an amendment intended to be proposed by him to amendment No. 1487 proposed by Mr. DOLE to the bill, S. 343, supra; as follows:

On page 39, strike lines 18 through line 7 on page 40.

DORGAN AMENDMENT NO. 1663

(Ordered to lie on the table.)

Mr. DORGAN submitted an amendment intended to be proposed by him to amendment No. 1487 proposed by Mr. DOLE to the bill, S. 343, supra; as follows:

On page 17, beginning on line 8, strike out "mergers, acquisitions."

BIDEN AMENDMENTS NOS. 1664-1665

(Ordered to lie on the table.)

Mr. BIDEN submitted two amendments intended to be proposed by him to amendment No. 1487 proposed by Mr. DOLE to the bill, S. 343, supra; as follows:

AMENDMENT No. 1664

On page 75, lines 24 through 26 delete "It shall be an affirmative defense in any enforcement action brought by an agency that" and insert "no civil or criminal penalty shall be imposed if".

AMENDMENT No. 1665

Delete from page 35 line 23 to page 37 line 18 and insert in lieu thereof the following:

*4624. Decisional criteria

"(a) CONSTRUCTION WITH OTHER LAWS.—The requirements of this section shall supplement, and not supersede, any other decisional criteria otherwise provided by law.

"(b) REQUIREMENTS.—Except as provided in subsection (c), no final major rule subject to this subchapter shall be promulgated unless the agency head publishes in the Federal Register a finding that—

"(1) the benefits from the rule justify the costs of the rule;

"(2) the rule employs to the extent practicable flexible reasonable alternatives of the type described in section 622(c)(2)(C)(iii); and

"(3)(A) the rule adopts a cost-effective choice among the reasonable alternatives that achieve the objectives of the statute; or

"(4) if a risk assessment is required by section 632—

"(A) the rule is likely to significantly reduce the human health, safety, and environmental risks to be addressed; or

"(B) if scientific, technical, or economic uncertainties or nonquantifiable benefits to health, safety, or the environment, preclude making the finding under subparagraph (A), promulgating the final rule is nevertheless justified for reasons stated in writing accompanying the rule and consistent with subchapter III.

"(c) ALTERNATIVE REQUIREMENTS.—If, applying the statutory requirements upon which the rule is based, a rule cannot satisfy

the criteria of subsection (b), the agency head may promulgate the rule if the agency head finds that—

"(1) the rule employs to the extent practicable flexible reasonable alternatives of the type described in section 622(c)(2)(C)(iii);

"(2)(A) the rule adopts a cost-effective choice among the reasonable alternatives that achieve the objectives of the statute; or

GLENN AMENDMENT NO. 1666

(Ordered to lie on the table.)

Mr. GLENN submitted an amendment intended to be proposed by him to amendment No. 1487 proposed by Mr. DOLE to the bill, S. 343, supra; as follows:

Delete from page 38, line 15 to page 39, line 17 and insert the following:

"(a) Compliance or noncompliance by a agency with the provisions of this subchapter and subchapter III shall not be subject to judicial review except in connection with review of a final agency rule and according to the provisions of this section.

"(b) Any determination by a designee of the President or the Director that a rule is, or is not, a major rule shall not be subject to judicial review in any manner.

"(c) The determination by an agency that a rule is, or is not, a major rule shall be set aside by a reviewing court only upon a clear and convincing showing that the determination is erroneous in light of the information available to the agency at the time the agency made the determination.

"(d) If the cost-benefit analysis or risk assessment required under this chapter has been wholly omitted for any major rule, a court shall vacate the rule and remand the case for further consideration. If an analysis or assessment has been performed, the court shall not review to determine whether the analysis or assessment conformed to the particular requirements of this chapter.

"(e) Any cost-benefit analysis or risk assessment prepared under this chapter shall not be subject to judicial consideration separate or apart from review of the agency action to which it relates. When an action for judicial review of an agency action is instituted, any analysis or assessment for such agency action shall constitute part of the whole administrative record of agency action for the purpose of judicial review of the agency action."

BOXER AMENDMENTS NOS. 1667-1678

(Ordered to lie on the table.)

Mrs. BOXER submitted 12 amendments intended to be proposed by her to amendment No. 1487 proposed by Mr. DOLE to the bill S. 343, supra; as follows:

AMENDMENT No. 1667

On page 96, insert between lines 20 and 21 the following new section:

SEC. . RULE OF CONSTRUCTION RELATING TO THE COMMUNITY RIGHT TO KNOW ACT.

Nothing in this Act (including any amendment made by this Act) shall be construed to revise, amend, weaken or delay in any way, the requirements or criteria under the Community Right to Know Act.

AMENDMENT No. 1668

On page 96, insert between lines 20 and 21 the following new section:

SEC. . RULE OF CONSTRUCTION RELATING TO THE CLEAN AIR ACT.

Nothing in this Act (including any amendment made by this Act) shall be construed to

revise, amend, weaken or delay in any way, the requirements or criteria under the Clean Air Act.

AMENDMENT No. 1669

In section 621(9)(B), strike clause (xii) and renumber accordingly.

AMENDMENT No. 1670

In section 621(9)(B), strike clause (xi) and renumber accordingly.

AMENDMENT No. 1671

In section 621(9)(B), strike clause (x) and renumber accordingly.

AMENDMENT No. 1672

In section 621(9)(B), strike clause (vi) and renumber accordingly.

AMENDMENT No. 1673

In section 621(9)(B), strike clause (iii) and renumber accordingly.

AMENDMENT No. 1674

In section 621(9)(B), strike clause (ii) and renumber accordingly.

AMENDMENT No. 1675

On page 25, between lines 22 and 23, insert the following:

"(g) EXEMPTION FOR RULE OR AGENCY ACTION RELATING TO THE SAFETY OF BLOOD SUPPLY.—None of the provisions of this subchapter or subchapter III shall apply to any rule or agency action intended to ensure the safety, efficacy, or availability of blood, blood products, or blood-derived products.

AMENDMENT No. 1676

On page 96, insert between lines 20 and 21 the following new section:

SEC. . RULE OF CONSTRUCTION RELATING TO THE SAFE DRINKING WATER ACT.

Nothing in this Act (including any amendment made by this Act) shall be construed to revise, amend, weaken, or delay in any way, the requirements or criteria under title XIV of the Public Health Service Act (42 U.S.C. 300f et seq.) (commonly known as the "Safe Drinking Water Act").

AMENDMENT No. 1677

On page 96, insert between lines 20 and 21 the following new section:

SEC. . RULE OF CONSTRUCTION RELATING TO THE COASTAL ZONE MANAGEMENT ACT OF 1972 AND THE OIL POLLUTION ACT OF 1990.

Nothing in this Act (including any amendment made by this Act) shall be construed to revise, amend, weaken, or delay in any way, the requirements or criteria under the Coastal Zone Management Act of 1972 (16 U.S.C. 1451 et seq.) and the Oil Pollution Act of 1990 (33 U.S.C. 2701 et seq.).

AMENDMENT No. 1678

At the end of section 621, add the following:

"(xiv) a rule or other action taken in connection with the safety of aviation."

CRAIG (AND HELFIN) AMENDMENT NO. 1679

(Ordered to lie on the table.)

Mr. CRAIG (for himself and Mr. HELFIN) submitted an amendment intended to be proposed by them to amendment No. 1487 proposed by Mr. DOLE to the bill S. 343, supra; as follows:

On page 96, between lines 20 and 21, insert the following:

**CHAFEE (AND LIEBERMAN)
AMENDMENT NO. 1592**

(Ordered to lie on the table.)

Mr. CHAFEE (for himself and Mr. LIEBERMAN) submitted an amendment intended to be proposed by them to amendment No. 1487 proposed by Mr. DOLE to the bill, S. 343, supra; as follows:

Beginning on page 38, line 14, strike all through page 40, line 7 (the proposed section 625 on jurisdiction and judicial review), and insert in lieu thereof the following:

SEC. 625. JUDICIAL REVIEW.

"(a) Compliance or noncompliance by an agency with the provisions of this subchapter and subchapter III shall not be subject to judicial review except in connection with review of a final agency rule and according to the provisions of this section.

"(b) Any determination by a designee of the President or the Director that a rule is, or is not, a major rule shall not be subject to judicial review in any manner.

"(c) The determination by an agency that a rule is, or is not, a major rule shall be set aside by a reviewing court only upon a clear and convincing showing that the determination is erroneous in light of the information available to the agency at the time the agency made the determination.

"(d) If the cost-benefit analysis or risk assessment required under this chapter has been wholly omitted for any major rule, a court shall vacate the rule and remand the case for further consideration. If an analysis or assessment has been performed, the court shall not review to determine whether the analysis or assessment conformed to the particular requirements of this chapter.

"(e) Any cost-benefit analysis or risk assessment prepared under this chapter shall not be subject to judicial consideration separate or apart from review of the agency action to which it relates. When an action for judicial review of an agency action is instituted, any analysis or assessment for such agency action shall constitute part of the whole administrative record of agency action for the purpose of judicial review of the agency action."

**CHAFEE AMENDMENTS NOS. 1593-
1595**

(Ordered to lie on the table.)

Mr. CHAFEE submitted three amendments intended to be proposed by him to amendment No. 1487 proposed by Mr. DOLE to the bill, S. 343, supra; as follows:

AMENDMENT NO. 1593

Amend section 621 of title 5, United States Code, as added by section 4(a) by inserting after paragraph (5), the following new paragraph:

"(6) The term 'major rule' does not include a rule that approves, in whole or in part, a plan or program adopted by a State that provides for the implementation, maintenance, or enforcement of Federal standards or requirements."

AMENDMENT NO. 1594

On page 36, beginning at line 11, strike all through line 21 (the proposed paragraph (4) on reducing risks).

Beginning on page 37, line 19, strike all through page 38, line 5 (the proposed paragraph (3) on reducing risks).

AMENDMENT NO. 1595

On page 25, after line 6, insert the following new paragraph:

"(3) No numerical estimate of benefits prepared pursuant to this subchapter shall in any way discount the value of benefits expected to be experienced in the future."

CHAFEE AMENDMENT NO. 1596

(Ordered to lie on the table.)

Mr. CHAFEE submitted an amendment intended to be proposed by him to amendment No. 1487 proposed by Mr. DOLE to the bill, S. 343, supra; as follows:

Beginning on page 35, line 9, strike all through page 38, line 13 (the proposed section 624 on decisional criteria) and insert in lieu thereof the following:

"SECTION 624. DECISIONAL CRITERIA.

"(a) CONSTRUCTION WITH OTHER LAWS.—If, with respect to any action to be taken by a Federal agency, it is not possible for the agency to comply both with the provisions of this section and the provisions of other law, the provisions of this section shall not apply to the action.

"(b) REQUIREMENTS.—Except as provided in subsection (c), no final major rule subject to this subchapter shall be promulgated unless the agency head publishes in the Federal Register a finding that—

"(1) the benefits from the rule justify the costs of the rule;

"(2) the rule employs to the extent practicable flexible reasonable alternatives of the type described in section 622(c)(2)(iii); and

"(3)(A) there is no other reasonable alternative that provides equal or greater benefits at less cost; or

"(B) if scientific, technical, or economic uncertainties or nonquantifiable benefits to health, safety, or the environment identified by the agency in the rulemaking record make a more costly alternative that achieves the objectives of the statute appropriate and in the public interest and the agency provides an explanation of those considerations, the rule adopts the least cost alternative of the reasonable alternatives necessary to take into account such uncertainties or benefits.

"(c) ALTERNATIVE REQUIREMENTS.—If an agency head has a nondiscretionary duty to promulgate a rule that cannot satisfy one or more of the criteria established by subsection (b), the agency head shall promulgate the rule ensuring that the remaining criteria of subsection (b) are satisfied.

"(d) PUBLICATION OF THE REASONS FOR NON-COMPLIANCE.—If an agency promulgates a rule to which subsection (c) applies, the agency head shall prepare a written explanation of why the agency is required to promulgate a rule that does not satisfy the criteria of subsection (b) and shall transmit the explanation with the final cost-benefit analysis to Congress when the final rule is promulgated."

**STEVENS AMENDMENTS NOS. 1597-
1603**

(Order to lie on the table.)

Mr. STEVENS submitted seven amendments intended to be proposed by him to amendment No. 1487 proposed by Mr. DOLE to the bill, S. 343, supra; as follows:

AMENDMENT NO. 1597

On page 19, strike lines 5 through 7 and insert in lieu thereof the following:

"78aaa et seq.:

"(xii) a rule that involves the international trade laws of the United States;

"(xiii) a rule intended to implement section 354 of the Public Health Service Act (42

U.S.C. 263b) (as added by Section 2 . . . of the Water Quality Standards Act of 1992);"

"(xiv) a rule that allocates resources or promotes competition among industry sectors, such as a rule to establish catch limits pursuant to the Magnuson Fishery Conservation and Management Act (16 U.S.C. 1801 et seq.) or to require interconnection among common carriers pursuant to the Communications Act of 1934 (47 U.S.C. 151 et seq.); or

"(xv) a rule that involves hunting under the Migratory Bird Treaty Act (16 U.S.C. 703 et seq.).

AMENDMENT NO. 1598

On page 19, beginning on line 16, strike all through page 20, line 6, and insert in lieu thereof the following:

"(1) whether the rule is or is not a major rule within the meaning of section 621(5)(A)(i) or 621(5)(C), or has been designated a major rule under section 621(5); and

"(2) if the agency determines that the rule is a major rule, whether the rule requires or does not require the preparation of a risk assessment under section 632(a).

"(b) DESIGNATION.—(1) If an agency has determined that a rule is not a major rule within the meaning of section 621(5)(A)(i) or 621(5)(C), the President may determine that the rule is a major rule or designate"

AMENDMENT NO. 1599

On page 20, beginning on line 23, strike all through page 21, line 4, and insert in lieu thereof the following:

"(B)(i) When the President has published a determination or designation that a rule is a major rule after the publication of the notice of proposed rulemaking for the rule, the agency shall promptly issue and place in the rulemaking file an initial cost-benefit analysis for the rule and shall publish in the Federal Register a summary of such analysis."

AMENDMENT NO. 1600

On page 14, strike lines 3 through 17 and insert in lieu thereof the following:

"(5) the term 'major rule' means—

"(A) a rule or set of closely related rules that the agency proposing the rule or the President determines is likely to have a gross annual effect on the economy of \$100,000,000 or more in reasonably quantifiable increased costs (and this limit may be adjusted periodically by the Director, at the Director's sole discretion, to account for inflation);

"(B) a rule that is otherwise designated a major rule by the President (and designation or failure to designate under this clause shall not be subject to judicial review); or

"(C) any rule or set of closely related rules, not determined to be a major rule pursuant to subparagraph (A) or (B), that the agency proposing the rule determines will have a significant economic impact on a substantial number of small businesses, pursuant to subchapter I;

"(6) the term 'market-based mechanism' means—

AMENDMENT NO. 1601

On page 3, line 7, strike "dures," and insert in lieu thereof "dures established by law or practice for the internal procurement or administrative functions of that agency"

AMENDMENT NO. 1602

On page 12, beginning with "(1)" on line 13, strike all through "(2)" on line 18.

AMENDMENT NO. 1603

On page 48, line 7, strike "this subchapter," and insert in lieu thereof "this

DRAFT**GOOD RULES/RULES LIKED BY INDUSTRY****U.S COAST GUARD**

USCG's regulatory program has both "local" and "national" components. The local component includes periodic and emergency regulations affecting commercial and recreational customers that are regularly updated as changing conditions warrant. These include bridge regulations and access to local waterways. Regulatory choices include temporary regulations, emergency rules and deviations to evaluate changes suggested by customers. This flexibility could be seriously impeded by additional oversight and analysis requirements. These local rules currently include changes, both temporary and permanent, that support and are responsive to local and small businesses, such as temporary rules for marine events (Memorial Day, July 4, Olympics, America's Cup

Offshore Supply Vessels

In conjunction with industry, USCG developed standards specifically designed for these vessels. The industry was unhappy because the vessels were regulated under small passenger vessels rules that were outdated and made little sense. IFR published 11/16/95.

Recreational Inflatable Personal Flotation Devices

Users want more comfortable PFDs. Safety will improve if the devices are made more comfortable and more people actually wear them.

Small Passenger Vessels

USCG updated these rules to make them more streamlined, tiered to vessel size, and relevant to modern vessels. Industry wanted the changes.

Facsimile Filing Of Instruments

USCG has consolidated many regional offices into one; to maintain ease of filing for the public, the Coast Guard is therefore allowing ownership and lien documents by fax.

Routine And Frequent Rules

The USCG frequently issues numerous routine traffic management and safety regulations to address local or temporary problems. These include local rules on aids to navigation (move buoy if sand bar shifts), anchorages, safety fairways and traffic separation schemes (around drill platforms), drawbridge operations, inland and international navigation, and regattas and marine parades. Most of

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these are popular; for example, the USCG issued the temporary rules that protected the America's Cup competition.

MARITIME ADMINISTRATION

Obligation Guarantees for Eligible Export Vessels and Shipyard Modernization and Improvement

In response to the Shipyard Act, MARAD issued a final rule in September 1994 expanding the scope of projects eligible for obligation guarantees under its Title XI Program to include vessels constructed for export and documented under foreign law, and for the statutory mandated modernization and improvement of U.S. shipyards. Title XI authorizes DOT to guarantee the repayment of loans issued for the purpose of financing construction, reconstruction, or reconditioning of vessels built in U.S. shipyards. Traditionally, Title XI guarantees were available solely to U.S.-owned and registered vessels. This rule is part of a National Shipbuilding Initiative to preserve shipbuilding capability for national security and to aid in the transition of the U.S. shipbuilding industry from military to commercial projects. It also provides an economic stimulus to U.S. shipyards and U.S. maritime industry suppliers by increasing the number of construction and reconstruction projects and supporting approximately 9,720 jobs (many of which otherwise might be lost) in the shipyard and supplier industries.

A NPRM was published on April 26, 1995, with respect to overall Title XI program administration. It is intended to shorten significantly the time MARAD takes for processing applications for loan guarantees and reduce the economic burden on applicants, while complying with MARAD's need to protect the Government's financial interests. This rulemaking applies to all Title XI projects, including export vessels and shipyard modernization and improvement. This streamlining will encourage worthy business interests to make application for loan guarantees with reasonable terms and conditions.

Cargo Preference U.S.-Flag Vessel: Fair and Reasonable Rates

Two cargo preference rulemakings relate to the calculation of fair and reasonable rates for the carriage of bulk cargoes. An ANPRM was published on April 19, 1995, requesting comments on a new methodology of calculating such rates for bulk and packaged preference cargoes that would be fair to all carriers, would lower the shipping costs to the Government, and would encourage more efficient vessels in the trade. Operators of bulk vessels should appreciate the opportunity to have an early role in restructuring the methodology for calculation fair and reasonable rates. An NPRM published on April 26, 1995, would expand the procedures for the calculation of fair and reasonable guideline rates for certain preference cargoes carried in U.S.-flag liner vessels to cover bagged or packaged agricultural commodities in parcels of 5,000 tons and greater.

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Cargo Preference U.S.-Flag Vessels; Available U.S.-Flag Commercial Vessels

On May 9, 1995, MARAD published a final rule that, for a one-season trial period, will permit agricultural product cargoes destined for foreign countries to count toward meeting cargo preference requirements if they are moved from Great Lakes ports by foreign feeder vessels through the St Lawrence Seaway and transferred to U.S.-flag vessels for the ocean portion of the voyage. This rule allows U.S. ports on the Great Lakes to compete again for agricultural commodity preference cargoes since direct U.S.-flag commercial ocean-going service to foreign countries from the Great Lakes ports has disappeared in recent years. This rulemaking is welcomed by the Great Lakes port and port-related business interests, growers of midwest grain, grain elevators and grain marketing concerns. MARAD is considering extending this interpretation for an additional five seasons.

FEDERAL AVIATION ADMINISTRATION

Commuter Aircraft Rule

Last December, the Federal Aviation Administration issued the final rule in its proceeding to upgrade the safety standards for commuter aircraft. This rule makes the requirements for scheduled aircraft with 10 or more seats much more comparable to those that apply to large airline aircraft. Passengers will be able to fly with greater confidence and the aviation industry has widely supported this rule.

Harmonization of Certification Standards (4 rules)

These four related rulemakings on small aircraft certification deal with powerplants, flight operations, systems and equipment, and airframes. They are part of an ongoing effort to harmonize FAA standards with those of the European Joint Airworthiness Authorities (JAA). By avoiding unnecessary duplication in airworthiness certification, the harmonization initiative holds the potential for enormous savings to the industry. Overall, one industry source has estimated the potential value of harmonization at \$1 billion.

Ground Deicing Procedures

Following a dramatic crash of an aircraft that had not been properly de-iced prior to takeoff, the FAA issued a rule based on the government-industry consensus reached at a public meeting. The rule allowed airlines to develop company-by-company operational programs, subject to FAA approval, specifying the kinds of fluids to be used for deicing, limitations on takeoff times in various conditions, and similar matters. No large aircraft has had a ground-based icing accident since the new procedures were adopted.

DRAFT**Advance Qualification Program**

This rule allows airlines, with FAA approval, to use alternative methods for training and certifying crewmembers, dispatchers and other personnel. This rule thus allows a carrier to tailor training to its particular needs and operational circumstances, and it encourages innovation in the development of training strategies. Moreover, AQP improves flightcrew performance; some of the current specific training requirements would otherwise inhibit the use of modern training technologies.

NATIONAL HIGHWAY TRAFFIC SAFETY ADMINISTRATION**Heavy Vehicle Antilock Brake Systems (ABS)**

In March 1995, NHTSA published a final rule to require heavy vehicles to be equipped with ABS to improve the directional stability and control of these vehicles during braking. To address earlier concerns about ABS reliability and durability, the agency sponsored a carefully documented study of ABS equipped vehicles. The agency estimated that the rule would prevent 320 to 506 fatalities each year. The cost per "equivalent fatality" is \$242,000 to \$563,000.

Automatic Restraints

In July 1984, NHTSA published a final rule that required automatic protection systems in passenger cars. This rule was issued before NHTSA started calculating the cost per "equivalent fatality." NHTSA estimated that lives saved ranged from 520 to 9,110 annually, depending on the type of automatic restraint installed. It also estimated total annual costs, exclusive of insurance or other savings, to be between \$510 million and \$3.64 billion. In March 1991, NHTSA published a final rule to extend the automatic crash protection requirements to light trucks. That extension was based in large measure on the experience with automatic protection in passenger cars. The agency estimated that the rule would prevent 2,016 to 2,378 fatalities each year. The cost per "equivalent fatality" is about \$600,000. One method of occupant restraint, air bags, was so effective that Congress required the installation of air bags in passenger cars, light trucks, and multipurpose vehicles beginning in model year 1997. NHTSA estimated that the rule would prevent 1,964-3,670 fatalities each year. The cost per "equivalent fatality" is \$690,000-1,180,000.

OFFICE OF THE SECRETARY**Airline Service Quality Performance Reports**

In response to a large number of complaints about airline delays, this regulation requires major air carriers to file on-time service reports with the Department of

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Transportation. The Department compiles this information and makes it available to the public. Airlines regularly use this information in their advertising and otherwise to gain a competitive advantage. Consumers and the media have avidly followed the on-time reports. Without imposing any substantive requirements on carriers, this rule has established a dynamic that uses the competitive forces of the marketplace to improve service.

RESEARCH AND SPECIAL PROGRAMS ADMINISTRATION

Hazardous Materials Placarding

Most people have seen tank trucks and tractor-trailers cruising along highways with colorful signs on them indicating the kinds of cargoes they are carrying. These square-on-point signs are hazardous materials placards required by the Department's hazardous materials regulations. The placards enable transportation workers and emergency response personnel to identify what hazardous materials are present, what precautions to take, and what steps to take in response to fires, spills, and other accidents, wherever the accident may happen.

Harmonization of Domestic and International Hazardous Materials Rules

Over the past several years, the Department has transformed its hazardous materials rules, which are necessary to establish a uniform U.S. system for the safe transportation of hazardous materials, so that they are consistent with international standards used by our trading partners. This effort both protects the safety of hazardous materials transportation in the United States -- wherever the shipments originate -- and reduces the cost of transportation, since it makes it unnecessary for shippers and carriers to contend with separate domestic and foreign regulatory schemes. This harmonization facilitates international trade in the chemicals industry, in which the U.S. enjoys a positive annual trade balance of about \$18 billion.

Odorization of Natural Gas Distribution Pipelines

Most people think they know what natural gas smells like and know to contact the gas company when they smell a lot of it. However, what most don't realize is that natural gas is odorless. DOT/RSPA's pipeline safety regulations require that pipeline companies mark the gas in distribution lines with distinctive odorant. As a result, people now identify the odorant, a mercaptan compound, as the "smell of gas."

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NHTSA

Seat Belts: Lap and shoulder belts have been required for passenger cars since 1968. Beginning in 1973, integral lap/shoulder belts were required. The same requirements were extended to light trucks a few years later. Seat belts are well accepted by the industry and the public and have had a great safety impact. For example, in 1994, 9,175 lives were saved because of seat belt usage. The numbers of lives saved has been going up over the last few years as greater numbers of people have been buckling up.

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CPSC STAFF DRAFT
March 1, 1996

EXAMPLES OF PROBLEMS WITH THE PROPOSED
SUBSTITUTE TO H.R. 994 (DISCUSSION DRAFT 2/28/96)¹

The proposed substitute to H.R. 994 (Discussion Draft 2/28/96) offered by Congressman Hyde and Clinger fails to correct the numerous problems with the bill. The proposed substitute suffers most of the same flaws as other versions of this bill. The examples discussed below demonstrate some of the most significant problems and how the bill could harm public safety, waste resources, and undermine legitimate industry interests.

Example: Refrigerator Safety Act

The CPSC's regulations under the Refrigerator Safety Act show how the bill could cause agencies to engage in a senseless dance of regulating, relaxing, and re-regulating -- at a potentially high cost in terms of resources and lives. 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 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

¹ The views expressed in this paper do not necessarily reflect those of the commissioners.

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review -- and the paltry \$25 processing fee ensure a flood of petitions (see §§ 204(c)(1) and (2)(D)). 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 (§ 204(b)(1)). 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

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

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(potentially every one) and the short deadlines for review virtually guarantees that some rules will be "suspend[ed]" simply because agencies run out of time. See § 211(d)(3). 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.

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. See § 238(b). 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

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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.

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 rules, industry would still have to label toys according to the statute -- without the practical

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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" (§ 207(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 a rule that fails rigid cost-benefit tests even if its repeal would provide an unfair advantage to unscrupulous companies.

Example: Small Parts Regulation

The potential problems that the possible termination of rules would create is increased for long-standing rules upon which industry has come to rely. One of the Commission's most

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STAFF DRAFT

CPSC Regulations That Have Saved Lives

1. Toy Safety. Under CPSC's small parts regulation, toys and other products intended for children under 3 years old are prohibited from having small pieces that a child could choke on. Before the regulation, approximately 12 choking deaths related to such small parts were reported annually; now there are virtually none. This is one of CPSC's most important rules and is fundamental to ensuring that children's play does not turn into disaster.

2. Child-Resistant Cigarette Lighters. The Commission issued a safety standard in 1993 that established requirements to make disposable cigarette lighters child-resistant. Fires started by children under age 5 have caused an estimated annual average of 150 deaths, approximately 1,100 injuries and nearly \$70 million in property damage. This rule, which was supported by industry, saves lives. The Commission found that the rule could save between 83 and 105 children's lives per year and would bring potential net benefits of \$115 million annually.

3. Poison Prevention Safety Closures. CPSC's requirements for child-resistant packaging for products like aspirin or turpentine have saved over 700 lives. Such safety packages protect children from accidental poisonings. CPSC just recently approved revisions to the adult test under which child-resistant packaging is evaluated. These changes will increase the use of child-resistant packaging by making it easier for adults to use properly. Many adults find child-resistant packaging difficult to open, and they leave the caps off, fail to properly close them, or transfer the bottle's contents to a non-child-resistant container. By making these packages easier for adults to use, accidental and tragic poisonings will be further reduced.

4. Ban of Infant Bean Bag Cushions. On June 23, 1992, the Commission issued a rule banning infant cushions filled with foam plastic beads. These cushions (commonly called "bean bag cushions or pillows") were intended for children under one year of age. When the Commission issued its rule, it had reports of 35 infant deaths involving this product. The deaths apparently occurred when a pocket was created in the cushion that would trap the infant's exhaled carbon dioxide which the infant would then rebreathe. With CPSC's rule, these infant cushions are no longer on the market to claim young lives.

5. Child-Resistant Packaging for Mouthwash. Just this year, CPSC issued a rule requiring child-resistant packaging for mouthwash that contains more than 3 grams of ethanol (alcohol). Young children, who find the color and sweetness of mouthwash appealing, have been seriously injured or died from accidentally ingesting mouthwash containing ethanol. Three deaths of children under age 5 have been reported. The American Association of

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Poison Control Centers had 10,193 reports of mouthwash ingestions by children under 6 years of age between 1987 and 1991. The mouthwash regulation is but one example of the life-saving poison prevention rules CPSC has issued.

5. Fireworks Requirements. The Commission has several regulations concerning the safety of Class C fireworks, the type normally purchased by consumers for non-professional use. These fireworks regulations help to keep families' Fourth of July celebrations from becoming tragedies. The Commission has banned some particularly dangerous devices like cherry bombs and M-80s. Fireworks devices that are allowed must meet certain performance requirements, such as the amount of time a fuse must burn before the device ignites. Additional regulations specify warning labels that fireworks must display to apprise consumers of potential hazards and include instructions for use.

7. Safe Cribs. CPSC's crib requirements ensure that a baby's crib provides a safe sleeping environment, not nightmares. This is crucial since parents and caregivers must be able to leave a child unattended in a crib. These regulations require, for example, that crib components like slats are separated by a safe distance so that an infant could not become trapped between the slats and strangle. In addition, the crib's hardware must not be accessible to the child or present the possibility of injuring the child.

8. Flammable Children's Sleepwear. Under CPSC's regulations, children's sleepwear must meet flammability standards to reduce the tragic incidence of deaths and injuries when a child's sleepwear catches on fire. Over the 20 years that these regulations have been in place, the number of burn deaths and injuries to children associated with ignition of clothing have substantially declined.

9. Power Mowers. In 1979 CPSC published a performance standard for walk-behind power lawn mowers, which were implicated in 77,000 injuries that were occurring each year from contact with the moving blades. The standard, which went into effect in 1982, requires that the blade on rotary powered lawn mowers stop within three seconds of the release of the lawn mower handle. A 1994 CPSC study found that walk-behind lawn mower injuries declined by about 40% between 1983, the year after the standard went into effect, and 1993. This reduction saves society about \$200 million (1993 dollars) annually.

10. Automatic Residential Garage Door Opening Equipment.

In accordance with the provisions of the Consumer Product Safety Improvement Act of 1990, in December 1992, the CPSC established a safety standard for the opening equipment of automatic residential garage doors. Since 1982, the CPSC had received

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reports of 54 children between the ages of 2 and 14 who had died after becoming entrapped under such garage doors. The rule requires that equipment manufactured after January 1, 1993, contain features to minimize the likelihood that a child would be trapped and killed by a garage door.

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SBA'S BUSINESS LOAN PROGRAM REGULATION

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SBA expands access to capital by providing credit, through thousands of financial intermediaries, to small businesses unable to obtain loans to start-up or expand. Traditionally, small firms have faced serious problems obtaining long-term loans in the private credit marketplace. SBA has taken substantial steps in the last three years to ensure that its loan guarantee programs help the maximum number of small businesses at minimum cost.

All of the rules governing SBA's non-disaster business loan programs have been consolidated in one Part of the Code of Federal Regulations. These programs include the general business loan program ("7(a) loans"), its microloan demonstration program, and its development company program, which is designed specifically to provide asset-based financing for acquiring land, buildings, machinery and equipment. A final rule revising this Part was published on January 31 and became effective March 1.

In fiscal year 1995, SBA provided 56,000 7(a) loans amounting to \$7.8 billion. Thus far in fiscal year 1996, we have served almost 16,000 small businesses with loans totaling just under \$2.5 billion. The 504 program served 4,500 customers in fiscal year 1995 at a volume of 1.6 billion, and this fiscal year over 2,000 loans have been approved totaling over \$700 million. It is worth noting how healthy SBA 7(a) loan portfolio is today. The default rate stands at 1.3 percent, which compares favorably to rates of private sector lending community.

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

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RE: REQUEST FROM BOB GUIDOS 2/29/96**CFSAN Regulations that are good for business:**

Seafood HACCP Rule - ensures 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. Consumer confidence in the quality and safety of U.S. seafood is vital to the health of our U.S. fishing industry and to the many industries dependent on that industry.

Bottled Water Standards - ensure that bottled water is free from pesticides, heavy metals and other contaminants. These regulations have the strong support of the bottle water industry, alleviate consumer confusion, and create parity with municipal water standards.

CFSAN Regulations that are good for public health:

Folic Acid - has been shown to reduce the risk of certain birth defects. Recent proposals to modify food standards, approval of a health claim, and amendment of the folic acid food additive regulations will ensure that folic acid is more abundant in the food supply.

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.

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

March 1, 1996

NOTE TO: Bob Guidos, Office of Legislative Affairs**Subject:** Examples of Medical Device Program Rules That Benefit Consumers and Industry

Dr. Burlington has asked me to pull together the information you requested yesterday in anticipation of Monday's House floor action on regulatory reform.

FDA Rules Benefitting Consumers

- **Medical Device Reporting** - On December 11, 1995, FDA issued final regulations requiring hospitals, nursing homes and health care facilities to report patient deaths and serious injuries and illnesses connected with the use of medical devices. Previously, only device manufacturers had to report adverse incidents of this type. By expanding this reporting coverage, FDA's surveillance capability has been significantly strengthened, which in turn will enable the agency to pinpoint and correct device problems more quickly, thereby preventing additional patient morbidity and mortality.
- **Mammography Quality Standards Assurance** - On Dec. 21, 1993, FDA published interim final regulations to insure higher quality of mammography performed on the over 20 million women who undergo this procedure annually. The rule sets minimum requirements for the training and qualifications for personnel who perform breast x-ray examinations, maintain the equipment and clinically interpret the results. In addition, FDA's rules ensure that mammography equipment perform properly and that radiation exposures are kept to the lowest levels possible, commensurate with the needs of the procedure.
- **Medical Device Wires** - In July 1995, FDA published a proposed rule setting a new performance standard for electrical wires that connect patients to medical devices such as those used to monitor breathing, heart rate and brain waves. This action was the result of instances where children and adults were seriously burned and electrocuted due to the design of the wires, also referred to as cables and leads. The FDA standard had two effects. It divided medical devices that use these cables and leads into 2 categories, depending on their risk. Devices whose cables resemble power cords, and thus are more likely to be involved in accidents, will be required to have

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Mr. Bob Guidos - Page 2

a protected lead. Devices less likely to be involved in such accidents, will be required to meet the agency's standard within three years.

- Hearing Aids - In November 1993, FDA published an ANPR designed to ensure that hearing-impaired Americans receive clear and reliable information in order to make well-informed purchasing decisions as they relate to this product. This action was the end result of an FDA review of advertising, promotion and labeling practices of the hearing aid industry. The agency discovered that for many products, companies were making unsubstantiated claims, which was misleading consumers about the performance of the products and creating unrealistic expectations. And in nearly all cases, promotional and labeling material failed to disclose product risks and benefits. This rule set forth a process in which the agency will approve claims made for these products and establish the clinical proof necessary to substantiate claims other than the general claim of improving hearing.

Rules Benefitting Industry

- 510(k) Exemptions - In December 1994 and again in January 1996, the agency published two separate regulations that, together, exempts some 270 categories of class I and certain class II devices from premarket notification. These de-regulatory actions have relieved manufacturers of low-risk products from the time and cost burdens of submitting 510(k)s to FDA and deferring marketing until agency clearance has been granted.
- Product Reclassification - In May 1995 and earlier this year, the agency promulgated rules to reclassify cochlear implants (devices to aid the profoundly deaf) and YAG lasers, respectively, from class III to class II. These de-regulatory actions, which are based on accumulated experience with both devices that provide reasonable assurance of their safety and effectiveness characteristics, relieve manufacturers from the requirement of submitting premarket approval applications and conducting the requisite supporting research.
- Third-Party Review of Devices - Within the next week, FDA will announce in the Federal Register its ~~intent to embark upon~~ a pilot program to use third parties to review marketing applications for some medical devices. This alternate form of review will be employed for low and moderate risk devices for which FDA does not require clinical data of safety and effectiveness, about 1500 per year. FDA will retain final clearance authority, but this allowance for external review,

Mr. Bob Guidos, OLA - Page 3

may hasten the review process and get medical devices to patients and physicians more quickly.

- **Revamped IDE Process** - On September 19, 1995, FDA and the Health Care Financing Administration jointly published a final rule allowing for expanded Medicare payment coverage for investigational devices. This reform by FDA, which entails a triaging of incoming Investigational Device Exemption (IDE) applications, is designed to permit Federal reimbursement based more on product risk and, in practical terms, authorizes payment for newer generations of existing technologies whose safety and effectiveness have previously been established. Under the modified structure, innovative devices for which no baseline safety and effectiveness information exists, will be non-reimbursable. The net effects of this process change are that generations of pre-existing devices will now be eligible for HCFA reimbursement, thus expanding Medicare beneficiaries' access to newer technology and enabling device manufacturers and clinical trial sponsors to maintain investigational device studies in the U.S.


Bob Eccleston

Attachment

cc: Ms. Thompson
Dr. Burlington
Mr. Levitt

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PAYMENT UPDATES TO HOSPITALS COULD BE DELAYED

ISSUE: Since the inception of Medicare, hospital providers have been reimbursed for the services they render to beneficiaries. In 1983, Congress established a prospective payment system (PPS) for the operating costs of acute hospital inpatient stays under Medicare. Under this system, payments are made at a predetermined, specific rate for each hospital discharge. By law, the Department is required to make annual updates to this payment formula to ensure that PPS rates keep pace with inflation and other changes to the health care system which affect hospital costs. The annual PPS Rule also includes other programmatic changes to the PPS system to improve its accuracy and to ensure that it provides incentives for the delivery of appropriate care.

AGENCY RESPONSIBILITY AND ACTION: The Secretary is required by law to make various updates to the PPS methodology and reimbursement rates to reflect changes in costs and implement new Congressional policies. For example, each year the Department must update hospital payment rates to account for inflation. (Based on the most recent forecasts, the standardized amounts for all PPS hospitals will be increased 1.5 percent.) As another example, the statute requires the Secretary to update periodically the hospital wage index with the most recent data available. The Department carries out these Congressionally-mandated changes to the PPS system through a rule published in the Federal Register. Accompanying each rule is an extensive impact analysis.

As the mechanism by which the Department reimburses hospital providers, the annual PPS regulation is a crucial process for ensuring that appropriate adjustments are made to payment rates. The hospital community has a keen interest in the prompt issuance of the PPS regulation as a means of carrying out Congressional policy changes.

IMPACT OF H.R. 994 SUBSTITUTE: Federal law (section 1886(e) of the Social Security Act) requires the Department to publish a proposed PPS rule by May 1 of each year and a final rule by September 1 of each year. Preparing the rule is a labor-intensive and complicated process, requiring many players and external data inputs which are available at established times of the year. For example, revised annual wage data are not available until the end of March; Medicare Geographic Classification Review Board decisions (incorporated into the wage index) and MedPAR data (used to recalibrate DRG rates) are not available until April. Once the proposed rule is published, the public comment requirements of the APA apply. In short, the Health Care Financing Administration (HCFA) devotes nearly an entire year to prepare for the next iteration of the PPS rule. The cost-benefit analysis mandated by H.R. 994 (substitute) (which does not supplant the required impact analysis) would require HCFA to consider the cost and benefits of each minor and major calibration change to the rule and all alternatives. This imposed burden would require hundreds of additional person-hours and could add months to the process of preparing the annual PPS regulation. Providers who rely on the PPS regulation for updated payments would experience considerable delays in receiving their updated payments.

HOW DOE'S NUCLEAR SAFETY REGULATIONS WOULD BE AFFECTED BY THE HYDE-CLINGER SUBSTITUTE TO H.R. 994

The Department of Energy has proposed regulations to establish nuclear safety requirements for DOE nuclear facilities, and to protect the public and the environment from nuclear, radiological, and chemical hazards posed by those facilities. DOE currently imposes those requirements through directives made applicable to DOE contractors through the terms of their contracts. DOE is proposing the new regulations in order to identify the basic requirements important for nuclear safety and radiation protection, and to restate those requirements in terms of performance standards, instead of command-and-control orders. The new regulations will strengthen nuclear safety and radiation protection, while also providing for a partnership between DOE and its contractors to ensure safe management of nuclear facilities through a more efficient use of resources and greater accountability and flexibility of the contractors in achieving performance objectives.

The "administrative review" provisions of the Hyde-Clinger substitute would impose a series of inflexible, resource-intensive requirements that would hinder DOE's efforts to improve its nuclear safety regulations. More specifically:

- The bill would establish a rigid schedule for agency review of covered rules, and would require an agency to issue a notice of proposed rulemaking even if it determines after its review to continue a regulation without change.
- The bill provides that each part in the C.F.R. shall be treated as one rule. Because DOE's nuclear safety management regulations will all be included in one part of the C.F.R., that provision could include within the scope of a single covered rule virtually all individual DOE rules essential to nuclear safety at its facilities. In addition, the bill requires review and rulemaking of any covered "rule," and "rule" is defined broadly to include "any agency statement, including agency guidance documents, which are designed to implement, interpret, or prescribe law or policy or to describe the procedure or practices of an agency". DOE would be required to engage in repeated review and rulemaking on safety guidance documents that merely interpret regulations, but which are essential to the safety of nuclear facilities and the public.
- The bill would authorize courts to suspend the effectiveness of nuclear safety regulations, even though the suspension of those regulations would expose the public and the environment to catastrophic health and safety risks from nuclear accidents.
- The bill would discourage an agency from undertaking a comprehensive review and significant revision of a covered rule more frequently than required by the bill. This provision could impede DOE's current efforts to streamline and improve its nuclear safety regulations.

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U.S. DEPARTMENT OF AGRICULTURE - FOOD SAFETY AND INSPECTION
SERVICE

Comments on H.R. 994, Title II

- o FSIS is committed to a comprehensive review and revision of all of its regulations as a part of its strategy to improve the agency's effectiveness and efficiency in accomplishing its food safety mission.
- o Adoption of H.R. 994 would be a barrier to accomplishing the agency's objectives in a logical way.
- o Under the bill's definition of a "rule", FSIS may be required to treat all poultry product regulations (almost 200 pages in the CFR) as one "rule" and the meat regulations as 26 different rules.
 - o The result: FSIS could not, for example, review the requirements for slaughter operations--both meat and poultry--in one rulemaking.
- o Once FSIS has revised its regulations, requiring it to review the regulations again in 7 years would divert agency resources from implementing its programs to protect public health and safety.
- o FSIS's regulatory review will (among other things) seek to replace command-and-control regulations with standards that provide industry with flexibility in how they comply with public protection standards. FSIS expects that this will result in a greater use of guidance materials (e.g., examples of different methods that industry may use to comply with regulatory requirements).
- o Even under the current regulations, the bill would reduce FSIS's ability to respond to changing circumstances because it appears that under the rule FSIS may have to undertake notice and comment rulemaking for guidance materials. For example, FSIS issued guidance on using steam pasteurization (a process supported by industry) to reduce pathogens on beef carcasses.
- o Because FSIS administers an inspection program through an 8000-person inspection force, it is essential to consistent and equitable enforcement that the agency be able to provide timely guidance and respond to changing conditions.
- o Limiting agency reviews between the comprehensive reviews required by H.R. 994 could create problems for FSIS. For example, if the agency decided to "continue" a "rule" without changes in 1996 and a new health hazard emerged in 2001, FSIS might not be able to conduct a rulemaking to consider whether to modify its regulations to address changed circumstances.

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OUTER CONTINENTAL SHELF

Important ongoing activities on the Outer Continental Shelf could be disrupted by a review under this bill and interruption of regulations and policies applicable to the OCS. Industry generally supports OCS regulations since they have been tailored to be performance based, they incorporate industry standards, and enhance those standards through public review and Department acceptance. They facilitate planning and orders to contractors. They also help to control marginal operators that might cut corners and impact the reputation of the industry. Review and changes that might be occasioned by this bill could disrupt the operation of an ongoing program that has been carefully worked out over time between the Department and the industry.

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H.R. 1022 COULD SLOW EFFORTS TO PROTECT PEOPLE'S PROPERTY FROM SUBSIDENCE DUE TO DEEP MINING

ISSUE: Thousands of citizens from coalfields throughout the country fought to include protection for their homes and water supplies in the National Energy Policy Act which Congress passed in 1992. This law is the only protection citizens have from subsidence caused by deep mining which can crack the foundations of homes, pollute drinking water from wells, ruin crops, and displace entire families.

AGENCY AUTHORITY AND ACTION: These citizens depend upon the Office of Surface Mining to ~~issue~~ a subsidence rule, ~~expected to be approved very shortly~~, which will protect their families and homes.

implement 994

issued last year

IMPACT OF H.R. 1022: If the terms of H.R. 1022 were applied to this rulemaking, the ~~process~~ *implementation* for issuance of the rule could be ~~stretched out by nine months or more~~. This does not account for any additional delays that are likely to be caused by litigation and by additional opportunities for judicial review to test conformity with the standards of this legislation. This would considerably delay implementing protection for these people. ~~Until the subsidence rule is issued,~~ Coal operators will continue to be uncertain about their obligations to replace water and repair homes. The Office of Surface Mining took great care to ensure that this rule was designed so as not to place additional regulatory burdens on the coal industry.

implementation

rendered uncertain or impeded by the existence of any review initiated under this bill.

Draft document for discussion purposes only.

GLACIER BAY NATIONAL PARK VESSEL REGULATIONS

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11/29/94
ISSUE: The National Park Service has proposed regulations that would authorize increased traffic by cruise ships in Glacier Bay National Park in Alaska. ~~S-343~~ could hinder implementation of these regulations and make it impossible for the Service to respond quickly to changes in response to wildlife needs or visitor demand.

AGENCY RESPONSIBILITY AND ACTION: The National Park Service (NPS) is required to manage National Park units to "conserve the scenery and the natural and historic objects and the wild life therein and to provide for the enjoyment of the same in such manner and by such means as will leave them unimpaired for the enjoyment of future generations." Glacier Bay National Park is an exceedingly popular tourist destination, given its spectacular resources and abundant wildlife. In this proposed regulation, NPS is endeavoring to accommodate additional cruise ship traffic, while protecting endangered and other sensitive wildlife and the Park experience. The proposed rule would allow a 72% increase in annual cruise ship visitation in the Park during certain seasons, while maintaining a daily limit on the number of ships allowed in the Park.

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IMPACT OF ~~S-343~~: DOI's obligation to balance the need to protect Park resources with the need to provide access to those resources to Park visitors does not lend itself well to the one-size-fits-all, cancer-oriented risk assessment methodologies detailed in ~~S-343~~. While the Park Service based its proposal on sound scientific data (a National Marine Fisheries Service biological opinion) indicating that negative effects of this increased ship traffic on the Park's endangered humpback whale population would be minimal, it is essential to monitor the whales and other wildlife in the Park to determine whether the negative affects turn out to be greater than expected. This regulation will be revisited as necessary, taking into account the latest available scientific data. Adding in layers of irrelevant risk assessment steps, in an area where risk assessment methodologies and parameters are not exact or well-defined, would so complicate and delay this regulation as to make it impossible to respond quickly to changes in wildlife behavior and to visitor demands.

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CONSENSUS STANDARDS FOR SAN FRANCISCO BAY DELTA

^{HR 944}
ISSUE: ~~S. 343~~ would permit the re-opening of EPA's just-completed, consensus-based rule establishing water quality standards for the San Francisco Bay Delta. Late last year, EPA, in cooperation with other federal agencies, ended 20 years of indecision and bitter wrangling by issuing these standards, which were developed with extensive involvement of the State of California and the affected agricultural, municipal, and environmental communities. ~~S. 343~~ would require EPA to reexamine this landmark decision in response to a petition for reconsideration under S. 343's cost-benefit and risk assessment criteria.

AGENCY RESPONSIBILITY AND ACTION: Section 303 of the Clean Water Act requires EPA to set standards for water quality when EPA determines that a state's standards fail to protect the beneficial uses of state waters. EPA issued the Bay Delta standards in December, 1994 to restore the quality of the degraded Bay Delta ecosystem and provide certainty for all water users. The standards addressed permissible salinity levels and established protective biological indicators. The standards provide certainty to agricultural and municipal communities, thus allowing long range planning for water usage without the continued threat of immediate crisis. The rule was a critical component of the Federal effort to cooperatively put an end to the economic hardship experienced by the agricultural community in loss of land value and inability to obtain financing for crop production. The municipal authorities can reassure the bond markets that they know what water capacity is available. They can now build reservoirs, plan canals, plan urban growth and development, and decide what water reusage they need to provide to the public.

^{HR 944}
IMPACT OF S. 343: ~~The petition process of S. 343~~ would permit the reopening of this landmark decision and, notwithstanding the extensive involvement of all affected parties, could require EPA to use new decisional criteria to determine what standards should be set for the Bay Delta. EPA could be required to either revise the regulation or demonstrate that it satisfies the decisional criteria of S. 343. As a result, EPA would have to perform unnecessary, expensive and time consuming cost-benefit and risk analyses on a regulation that has just been adopted, ends years of costly disputes and delays, is based on an agreement of all affected parties, and gives the financial market critical new certainty about the availability of this vital asset -- water -- that is desperately needed by municipal and agricultural interests.

**ISSUE: INDIAN SELF DETERMINATION, INDIAN SELF-GOVERNANCE
(DEPT. OF INTERIOR/BUREAU OF INDIAN AFFAIRS)**

STATES AFFECTED: All

Rule: These regulations will implement amendments to the Indian Self-Determination and Educational Assistance Act and will be designed to enhance the capability of tribes to assume and operate Bureau of Indian Affairs and non-Bureau of Indian Affairs programs which are currently staffed and managed by federal agencies. These rules will allow tribes to contract for the management of activities and funding of federally run programs.

Beneficiary of the Rule: Tribes, the government, and all Americans. Tribal consultations in anticipation of negotiated rulemaking are underway ~~and will be completed~~ *near completion*

Impact of H.R. 450: *994* A moratorium *Review under the bill* could delay the removal of obstacles that make tribal assumption and operation of programs more difficult. These rules contemplate the downsizing and streamlining of Bureau of Indian Affairs processes, which could be delayed if H.R. 450 ~~passes~~ *994*. In addition, these regulations will offer the opportunity for non-Bureau of Indian Affairs agencies to streamline their operations by contracting with tribes for participation in the management or assuming the management of program activities.

Date: Regulations to be published in ~~1993~~ *April* after Tribal ~~consultation and negotiation~~ *comment period* are completed.

This long and difficult process that the Congress, by the recent enactment of Public Law 103-413, has attempted to accelerate and resolve.

OSHA

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OSHA has issued many regulations that reflect the most basic and recognized principles of safety and health. These common sense rules are universally acknowledged as being necessary: no benefit would be gained by engaging in lengthy and costly administrative reviews and new rulemaking on these regulations. An example is OSHA's rule prohibiting employers from locking fire doors that open to the outside of the building. The recent disaster in Hamlet, North Carolina, where 25 workers burned to death after an employer disregarded this rule, demonstrates in the most tragic way that this rule is vital to worker health and safety.

Another example of a rule that has provided common sense protection against a toxic substance that is both deadly and destructive to the quality of life of those exposed to it is OSHA's standard on dibromochloropropane (DBCP), an agricultural pesticide previously in widespread use. Despite strong evidence in animals of DBCP's cancer-causing and reproductive effects, workers in the manufacturing, formulating, and transportation sectors continued to be exposed to it. OSHA acted after a number of workers at a DBCP-formulating facility reported experiencing sterility and testicular effects, among other exposure-related health problems. Publication of the OSHA rule, which required employers to implement cost-effective controls to protect against these effects, put an end to these reproductive effects. OSHA's rule for DBCP, which is based on actual clinical effects substantiated by laboratory tests, does not need to be subjected to the elaborate and costly risk assessment and cost/benefit analyses that would be required by H.R. 994.

In 1990, OSHA issued a final rule relaxing the permissible exposure-limit for non-asbestiform tremolite, anthophyllite, and actinolite. In taking this action, OSHA relied on health effects and feasibility information in the record but did not perform a quantitative risk assessment. Under the administrative review and rulemaking procedures contained in Title II of H.R. 994, OSHA would be required to conduct detailed and costly risk assessments and economic analyses to support continuation of the less-stringent limit now in effect. Employers in the affected industries would be unable to plan for the future or project their capital expenditures during the 7-year period of administrative review and rulemaking required by Title II of H.R. 994.

Final Rule Concerning the Longshore and Harbor
Workers' Compensation Act

Pursuant to OWCP's commitment to streamline processes and implement cost savings, final regulations (published October 2, 1995, 60 FR 51346) revised the regulations implementing the Longshore and Harbor Workers' Compensation Act (LHWCA) to improve administration and clarify existing policy. Among the other changes implemented in this rule were two provisions eagerly sought by the industry: 1) formalization of the practice of using the Office of Workers' Compensation Programs (OWCP) fee schedule as the standard for determining what is a reasonable and customary medical charge where there is a dispute; and 2) eliminating the requirement that an employer with geographically different work sites within one compensation district have only one insurance carrier. The employer community expressed strong interest in these rules and would strongly object to seeing them repealed.

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PROTECTION FROM HARMFUL AIRBORNE CONTAMINANTS - VALUABLE GUIDANCE

ISSUE: Airborne contaminants are a serious concern to the millions of workers who face that threat in the workplace everyday. For these workers, it is crucial that the face and lung protection they wear effectively prevents transmission of cancer-causing contaminants like asbestos, and hundreds of other harmful fumes and chemicals which can cause serious lung diseases and chronic ailments. In professions ranging from health care workers and painters to fiberglass and aircraft workers, the workplace presents a special risk and respirators are used to ensure clean breathable air for employees; however, the wide ranging use of respirators to combat a diverse range of contaminants has led to some confusion as to which respirators best address a workers' needs on a particular job.

AGENCY RESPONSIBILITY AND ACTION: In order to assist employers in selecting those respirators that are most appropriate to the work being performed and in providing the medical surveillance necessary for workers who use respirators, the Occupational Safety and Health Administration developed guidelines linking the type of work to the type of respirator needed. These guidelines link the type of respirator needed to the particular airborne contaminants and exposure situations in a given workplace, providing employers and employees with sensible and efficient assistance in a technically complex area. This guidance has the potential to prevent many cases of cancer and other serious illnesses every year.

IMPACT OF H.R. 994: The comprehensive administrative review requirements under Title II would compel OSHA to compile stacks of paperwork for each individual use of respirators in each occupation for each of the various contaminants encountered by the millions of workers affected. The added time and manpower required to fulfill these requirements would cost OSHA a great deal more money than the Agency's current budget allows. And even with additional budgetary increases, issuance of these guidelines would be pushed back for years while the cumbersome paperwork was completed. These delays would seriously undermine OSHA's responsibility to assist employers in protecting the health and safety of their workers.

Draft document for discussion purposes only.

Regulations: Preventing Injury, Illness, and Saving Lives

Lead Poisoning: In 1978, OSHA issued a standard to protect workers from exposure to lead, a chemical that is absorbed into the body by breathing or ingesting it. The lead accumulates in the blood, organs and bones, and is slowly released over time, causing anemia, brain and nerve disorders, high blood pressure and reproductive problems. Just five years after OSHA's lead standard was issued, the number of workers in lead smelting and battery manufacturing with high levels of lead in their blood dropped by 66%, from 19,000 to 6,500.

"Brown Lung" Disease: In 1978, OSHA issued a standard to protect the nation's textile workers from "brown lung"—a crippling and sometimes fatal disease that reduces a person's pulmonary function and obstructs their ability to breathe. In 1978, there were an estimated 40,000 cases of "brown lung" (also called "byssinosis") but in 1985 the prevalence of the disease had declined to about 900 cases, or less than 1% of cotton textile workers. Moreover, there is evidence that complying with OSHA's cotton dust standard actually increased productivity in the textile industry. A 1980 article in *The Economist* reported that the tighter dust control measures required by OSHA's rule prompted firms to replace outdated machinery with newer, more-efficient systems.

Collapsed Trenches: In 1989, OSHA issued a revised standard to protect workers from accidents and injuries caused by collapsed trenches and cave-ins at excavation sites. During the four-year period beginning in 1987, an average of 46 workers were killed each year in such accidents, many of which were preventable. Although the number of workers killed in trenching and excavation accidents remains intolerably high, the number has declined by 35% since OSHA revised its trenching and excavation standard.

Exposure to HIV and Hepatitis B: In December 1991, OSHA issued a rule to protect those workers who are routinely exposed to blood or other infectious material from HIV, Hepatitis B and other bloodborne diseases. In 1990, there were at least 65 reported cases of HIV infection in healthcare workers related to on-the-job exposure. Based on data provided by the Centers for Disease Control (CDC), the number of actual cases of Hepatitis B in health care workers dropped by 77%, from 3100 cases in 1987 to 725 in 1993. (1993 was the first full year that employers were complying with, and OSHA was enforcing its bloodborne pathogens rule.)

Confined Spaces: In 1993, OSHA issued a rule to protect workers from the hazards created by working in confined spaces. From 1986 through 1990, an estimated 63 workers lost their lives and an additional 5,931 workers were seriously injured in confined space environments (which pose special dangers because their size or dimension create toxic, asphyxiating, or other life-threatening hazards.) Although the actual numbers are not yet in, OSHA estimated that 54 fatalities and 5,041 serious injuries would be prevented annually when employers comply with the confined space rule.

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Mine Explosions and Fires: MSHA's ventilation standards 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 133 miners.

Mine Roof-Falls: In 1988, MSHA issued a rule requiring the use of automated temporary roof support in underground coal mines. This equipment virtually eliminates the need for miners to install temporary roof support, such as timbers—a high-risk practice. From 1979 through 1988, 64 miners were killed installing temporary support. One miner has been killed since.

Black Lung Disease: MSHA's exposure limit for respirable coal mine dust protects miners from black lung, silicosis, and other disabling respiratory diseases. Since adoption of the dust standard in 1969, the prevalence of black lung has dropped by two-thirds.

Mine Cave-Ins: A 1972 rule requires cabs and canopies for underground coal mine equipment. The rule protects miners who are operating the equipment from cave-ins. Since the rule went into effect, there have been 282 documented cases in which miners were saved from being crushed.