Risking America's Health and Safety

George Bush and the Task Force on Regulatory Relief

PUBLIC CITIZEN
October 1988

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The assistance of Robert Dreyfuss, Michael McCauley, Wm. Tod Cowen, Kathy Cashel, Rebecca Lemov, and Sandy Cunningham is gratefully acknowledged.

Copies may be purchased for $8.00 from Public Citizen, 2000 P Street, Suite 605, N.W., Washington, D.C. 20036.

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October 12, 1988

How much is a human life worth?

According to George Bush and the Task Force on Regulatory Relief, the answer is: not very much.

For instance, under Bush's direction, the U.S. Office of Management and Budget placed a price tag of $208,000 on a human being whose life is extinguished by cancer from asbestos. Bush and the OMB concluded that spending that much to save a life just wasn't worth it, and as a result they have refused since 1984 to approve a rule restricting or removing asbestos from the environment. Yet thousands of people die each year as a result of exposure to asbestos.

In only eight years, George Bush has undermined a system of health and safety standards that has taken America over 80 years to achieve. This report documents only a small portion of the carnage that has resulted from eliminating or obstructing many of these life-saving rules.

The record is brutal indeed. At least 40,000 deaths and one million injuries can be traced to the Administration's delay in requiring air bags and automatic safety belts in cars. Hundreds of thousands of infants were fed nutritionally deficient formula while Bush and the OMB delayed rules requiring testing of infant formula, and thousands of babies and young children suffered the serious and often-fatal Reye's Syndrome disease while the Administration stonewalled rules to place warning labels on aspirin products linked to Reye's in children.

The Bush Task Force's assault on our nation's health and safety standards is marked by a callous disregard for the value of human life and a shocking readiness to apply an accountant's spread sheet to rules that protect our lives and the lives of our children. It is time to set the record straight.

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SUMMARY

Throughout its seventeen-year history, Public Citizen has fought for a healthy workplace and environment, safe products, consumer rights in the marketplace, and corporate and government accountability. Since 1981, when George Bush assumed his role as head of President Reagan's Task Force on Regulatory Relief, the staff of Public Citizen has gone to court, to Congress, and to the American people in an effort to curtail the Reagan/Bush Administration's sweeping attempts to turn back the clock on a broad range of health and safety regulations.

In repeated battles, both alone and in conjunction with labor, health, and environmental organizations, Public Citizen has been the advocate of vulnerable constituencies -- children, workers, and ordinary citizens -- whose life and limb were put at risk by George Bush's headlong rush to deregulate health and safety standards at the behest of industries that sought to protect their own bottom line. This report is a partial record of of those efforts.

In selecting the cases presented here, the staff of Public Citizen chose only those regulatory decisions -- affecting thousands and sometimes millions of Americans -- for which George Bush can be held directly responsible, either because he was personally involved in the ultimate decision, or by virtue of his responsibility for the Office of Management and Budget's regulatory review functions. In each case, working through the staff of his Task Force and OMB, George Bush's deregulation philosophy has left its imprint directly on the lives of Americans and their children.

In some cases, that impact can be counted directly in terms of the lives that were sacrificed in the name of "regulatory relief." In others, it is only possible to identify a population jeopardized by poisons, unsafe products, and hazardous working conditions.

In some cases, there are documents, speeches, and court records that convey in black and white the pattern of Task Force interference that led to elimination and delay of important health and safety protections. In others, there are only accounts of secret meetings held by Bush or OMB with representatives of regulated industries seeking to do away with health or safety standards developed on the public record by government agencies entrusted by Congress to carry out the will of the people.

In some cases, the Bush Task Force was successful in granting an industry's request for the delay or elimination of vital standards. In others, it was blocked by a Congress that was unwilling to allow the dismantling of regulations needed to effectuate important statutory objectives. In still others, the courts intervened to require a stubborn Administration to act in accordance with the will of Congress rather than the interests of auto makers, oil companies, or drug manufacturers.

This report covers a wide range of health and safety issues. Some primarily affect children, such as testing requirements for infant formula; the delay of warnings about Reye's Syndrome, a serious and often fatal children's disease; and the Task Force's attempts to stop the reduction of lead in gasoline.

Some of the issues affect safety on the nation's highways -- where tens of thousands of people die and millions are injured each year. These include the Task Force's delay of requirements for airbags and automatic safety belts, the weakening of the bumper standard, and the failure to protect pedestrians.

Several of the case studies pertain to standards governing the workplace, including regulations requiring employers to inform workers about their exposure to hazardous chemicals, limits on the exposure of health care workers to the carcinogenic chemical ethylene oxide, and protections needed to reduce the risk of explosions in mills. Other examples include regulations affecting the environment, such as the phase-out of asbestos, and requirements for treating industrial sewage to reduce the levels of dangerous chemicals in drinking water.

Finally, several examples included here, such as tampon labeling, prescription drug inserts, tire grading, and labeling disclosures for processed meats, affect the public's ability to make informed decisions about the products they purchase which, in turn, can have a significant impact on their health and safety.

Sparked by the publication of such landmark books as Upton Sinclair's *The Jungle*, Rachel Carson's *Silent Spring*, and Ralph Nader's *Unsafe at Any Speed*, America, through its elected representatives and their delegates, has acted forcefully to develop a system of rules and regulations that protect our homes, our workplaces, our environment, and our marketplace, and ensure that those protections survive for the benefit of future generations. Too often, the public takes those protections for granted. Examination of just a portion of George Bush's record as the head of the Task Force on Regulatory Relief is powerful testimony of what can happen to these important protections if we do not hold the government accountable to its citizens.

INTRODUCTION

In his August 15, 1988, speech to the Republican Convention, President Reagan hailed George Bush's role in eliminating "many unnecessary regulations" as Bush's greatest service to the nation during his tenure as Vice President. Indeed, in his current campaign literature Bush proclaims that one of his "proudest accomplishments as Vice President has been to help eliminate needless government regulations that have stifled our economy, raised prices and cost jobs."

What both men are referring to is that under the Reagan Administration George Bush has chaired the President's "Task Force on Regulatory Relief," set up to carry out Reagan's campaign pledge to eliminate "unnecessary" and "excessive" government regulations. And, while George Bush has indeed been responsible for eliminating and delaying much federal regulation, the public has heard little about the effects that deregulation activity has had on health and safety. This report fills some of that void.

By looking at examples of actual regulations that were either eliminated or delayed under the Vice President's direction, the public can gauage for itself whether those regulations were "unnecessary" or "excessive." Public Citizen believes that these and many other examples show that George Bush has consistently placed the economic interests of the oil, drug, auto, chemical, and other industries above the health and safety of the nation.

The Administration's deregulation program has three primary components. First, regulatory decision-making has been centralized in the White House through the work of the Task Force and the Office of Management and Budget (OMB), by displacing the authority Congress gave to the expert agencies and to carry out the legislative intent of the laws. Second, the inner workings of the Task Force and OMB have been shrouded in secrecy in order to shield questionable off-the-record contacts with regulated companies and to allow the White House to exert tremendous political pressure on the agencies responsible for making the ultimate decisions. This secrecy, in turn, has significantly hampered the usual "checks" on an agency's abuse of power -- Congressional oversight and judicial review. Third, the scientific framework for regulatory decisions as articulated by Congress in dozens of laws has been largely replaced by OMB's highly subjective "cost-benefit" analysis. In the guise of more rigorous analysis, the Task Force and OMB, with its control over agency budgets, have actually subverted agency scientific and research capabilities as well.

CENTRALIZED POWER

On January 22, 1981, shortly after taking office, President Reagan announced the creation of his "Task Force on Regulatory Relief." He appointed Vice President Bush to head the Task Force and gave him the responsibility "to cut away the thicket of irrational and senseless regulations."

Barely a month later, on February 17, 1981, Mr. Bush announced that the President had issued Executive Order 12291, establishing the procedures under which the Task Force would carry out its mission to eliminate "unnecessary" regulations. Under the Executive Order, all Executive Branch agencies -- such as the Environmental Protection Agency, the Department of Labor, the Department of Health and Human Services, the Department of Transportation -- were, for the first time, prohibited from issuing either proposed or final regulations without prior approval from OMB. In order to obtain that approval, the agencies were required to demonstrate that the societal "benefits" of the proposed action outweighed its "costs," and that the least costly alternative had been selected, regardless of whether other choices would provide more benefits to the public.

On January 4, 1985, President Reagan issued another Executive Order -- No. 12498 -- designed to further centralize OMB's control over agency rulemaking. That Executive Order required agencies to notify OMB of all "regulatory policies, goals, and objectives" and "all significant regulatory actions underway or planned." Under the Order, agencies must obtain OMB approval even to collect information that might potentially lead to regulation at some future date. Executive Order 12498 was expressly intended to "complement" Executive Order 12291: agencies were instructed to adhere to the "cost-benefit" requirements of the previous Order and to abide by the regulatory "guidelines" of Bush's Task Force. This highly questionable displacement of agency decision-making authority by executive order was rejected by the Congress in the defeat of the Regulatory Reform legislation and is being challenged in the courts.

OMB derives its extraordinary power over agency rulemaking from yet a third source -- the Paperwork Reduction Act. That law, enacted in 1980 as a successor to the Federal Reports Act, was intended to give OMB the authority to coordinate the information collection activities of federal agencies -- in other words, to ensure that agencies are not unnecessarily burdening the public by imposing excessive government paperwork requirements

on the private sector. Although the Act specifically provides that it is not intended to give OMB any authority to formulate or change the "substantive policies and programs" of the agencies, the Task Force and OMB have used the law in connection with their authority under the two Executive Orders to prohibit agencies from collecting information that may expose health hazards and ultimately lead to stronger government regulation.

SECRECY AND INDUSTRY CONDUITS

What soon became apparent was that "cost-benefit" was nothing more than an excuse to justify the wholesale dismantling of important health and safety regulations through delaying, weakening, and eliminating those regulations, largely, if not exclusively, at the behest of the regulated industries.

In March, 1981, Bush sent a series of requests directly to corporations, soliciting lists of regulations that they found onerous and asking for specific proposals for changing them. In some cases, Bush made no effort to disguise the fact that he was responding to a particular industry's request by systematically eliminating or postponing several major regulations that the industry targeted as too "costly." Thus, on April 6, 1981, the Administration issued a report entitled "Actions To Help The U.S. Auto Industry," which credited Bush's Task Force with convincing the Environmental Protection Agency and the National Highway Traffic Safety Administration to "rescind, revise, or repropose" a total of 34 regulations, largely aimed at decreasing the startling number of deaths and injuries caused on the highways each year, and reducing air pollution caused by automobile exhaust.

C. Boyden Gray, who represented a number of America's largest industries in private practice before serving as legal counsel to Bush and his Task Force, was explicit in declaring his willingness to serve industry interests. In a speech before the Chamber of Commerce he explained his view of the role of the Task Force:

> If you go to the agency first, don't be too pessimistic if they can't solve the problem there. If they don't, that's what the Task Force is for. Two weeks ago [a group] showed up and I asked if they had a problem. They said they did, and we made a couple of phone calls and straightened it out, alerted the top people at the agency that there was a little hanky-panky going on at the bottom of the agency, and it was cleared up very rapidly -- so the system does work if you use it as a sort of an appeal. You can act as a double check on the agency that you might encounter problems with.

As a general rule however, OMB and the Task Force have not disclosed oral or written communications with regulated companies or even with agency officials. The secrecy surrounding their activities is in sharp contrast to the openness that is generally required of agencies who make regulatory decisions. Under the Administrative Procedure Act, agencies must allow all interested parties, including the public, to participate in rulemaking proceedings, and agency decisions must be made on the basis of the public record.

By contrast, OMB control is exerted behind closed doors, with no opportunity for public comment and no public record of the factors that influenced OMB's decisions. Thus, the OMB staff does not disclose contacts with private industry, allow the public to comment on industry submissions it has received, or even document its role in urging, pressuring, or directing an agency to take a particular regulatory action. As the House Committee on Energy and Commerce has explained, "since OMB's efforts in these rulemaking activities are largely clandestine and 'off the record,' its improper influence generally cannot be checked during the course of the rulemaking process or judicial review."

As the examples in this report show, Bush's Task Force and OMB have acted again and again as conduits for industry representatives whose views had already been rejected by the expert agencies designated by Congress to make often highly technical judgments.

JUDICIAL REVIEW

The examples also demonstrate that often the decisions made under pressure from the Task Force and OMB to eliminate, delay, or weaken regulations were subsequently overturned by either Congress or the courts. Thus, those rules were eventually put into effect, and the cost of Bush's regulatory review can be measured in the tremendous loss of life and health that resulted during the intervening years when those important regulations were delayed.

The fact that a court has reversed an agency's decision to eliminate or weaken a regulation is powerful proof of the unlawfulness of the agency's activities. On the other hand, the failure of a court to overturn an agency's rulemaking decision is not necessarily an indication that the choice made by the agency (or OMB) was correct. Under the traditional standards that apply to judicial review, it is extremely difficult to persuade a court to overturn an agency's regulatory decision. A court must uphold the agency unless its decision is "arbitrary, capricious, or not in accordance with law." In addition, unless the statute at issue leaves the agency absolutely no

discretion in the matter, courts must defer to an agency's interpretation of the law under which it operates. Therefore, unless the agency has acted in flagrant disregard of a clear statutory command, as long as it has some stated reason for the action that it has taken, the courts will generally not interfere with its decision. This is especially true in the District of Columbia Circuit, where many of these cases are brought and which is now dominated by Reagan appointed judges who believe that the judiciary should rarely disturb a decision of the Executive Branch.

"COSTS" VS. "BENEFITS"

At the heart of the regulatory process is the scientific and economic expertise that an agency applies to a particular problem. For example, the agency must identify and verify a hazard or potential risk, design complicated testing instruments and methodologies, formulate appropriate remedies, assist industries in complying with regulations, and construct and adapt regulatory programs that are cost-effective. The Task Force and OMB have undermined this important aspect of the process and replaced it with an overriding analytical fiction: cost/benefit analysis.

As applied by Bush and OMB, cost/benefit is nothing more than a means to a predetermined end. Indeed, although the initial approval form used by OMB under Executive Order 12291 required an agency to estimate the "costs" of the regulation to be reviewed, it did not even bother to ask the agency to estimate the benefits. Nor, for that matter, is there any mention at all of the benefits' side of the equation in any of the several "Progress Reports" that have been issued by Bush's Task Force.

The outcome of the "cost-benefit" calculation can be completely manipulated simply by deciding what counts as a "cost" and what is to be considered a "benefit." Moreover, the focus of OMB review is on the alleged cost savings to industry, based on highly subjective information furnished by the very industry with an economic interest in defeating the regulation at hand. On the other side of the ledger, information on benefits is difficult to obtain and virtually impossible to quantify. How much, for example, is a life worth? As one congressional committee concluded, cost/benefit analysis is "simply too primitive a tool." Indeed, the following two examples demonstrate that what constitutes "costs" and "benefits" is in the eye of the beholder.

One of the first regulations that Bush's Task Force targeted for review was a 1978 Department of Agriculture regulation requiring the meat industry to disclose on labels of processed meat, such as hot dogs, that the product contained a substance made from crushed bone. The meat industry had been unsuccessful in convincing the Carter Administration to change the regulation, but quickly seized upon Bush's solicitation of lists of unwanted regulations to identify the disclosure requirements as an "excessive" regulation that was costing the economy some $500 million annually. The industry's argument was that since consumers would not purchase products that they knew contained crushed bone, meat producers were throwing away or using for pet food the animal carcasses that it wished to pulverize for use in processed meats, and that this "waste" of an otherwise usable food source was costing the industry and the public $500 million each year.

By July 1981, the Department of Agriculture announced its intention to change the labeling requirements by eliminating the requirement that the meat industry dislose the presence of bone, and instead permitting manufacturers to state in the nutrient labeling that the product had added "calcium." This revision in the labeling rule became final a year later, and it is listed in George Bush's August 1982 "Progress Report" as an example of "major cost savings of completed regulatory reforms." The amount listed as an "annually recurring cost savings" to the public is $500 million. But surely this does not represent the cost of an "excessive" government regulation. Rather, it is the amount of money the meat industry was losing as a result of consumers not wishing to purchase processed meats that they knew contained crushed bone. We would call that a result of the "free enterprise system" -- a principle that George Bush and Ronald Reagan normally enthusiastically embrace as the reason government regulation is unnecessary.

Second, consider OMB's manipulation of the "benefits" side of the equation in its review of the Environmental Protection Agency's asbestos rule. In refusing to approve the EPA's decision to go forward with a proposed ban of certain asbestos products, OMB argued that the costs to industry far outweigh the potential benefits to society. However, in making its benefits calculation, OMB did not take into account any benefits to society other than the value of actual lives saved because of the prevention of deaths from asbestos-caused cancer. For example, as EPA's own final Regulatory Impact Analysis admitted, the cost-benefit analysis did not take into account any of the benefits associated with controlling asbestosis -- a serious lung disease -- such as a reduction in medical care expenses, increased productivity, and improvement in the quality of life. Nor did it take into account any of the secondary health effects on the families of workers who were exposed to asbestos.

Benefits were reduced further by the method used by OMB to quantify lives saved. OMB started by assigning a value of one million dollars for each life saved. Applying a "discounting" principle, it then reduced that value based on the number of years a person would be expected to live

before he or she actually died from cancer. Thus, OMB argued that since there is typically a 30- to 40-year lag time between the exposure to asbestos and the resulting death from cancer, a life saved 40 years from now is worth only a small percentage of the million dollars a life is worth today. Under this theory, OMB considered the present value of a life saved by the asbestos rule to be $208,000. As the congressional committee that investigated this matter concluded:

> OMB's theory of discounting human lives . . . leads to undervaluing the benefits of health and safety regulations, would thwart regulation of many toxic substances through the application of the cost-benefit criteria of Executive Order 12291, and would, therefore, fail to protect future generations from many serious chemical hazards.

What this report demonstrates is that the real issue at the core of the debate over George Bush's role as head of the Regulatory Task Force is one of priorities. While some may believe that a democratic society such as ours should make its highest priority the health and welfare of the nation and its children, George Bush has made it clear that the interests and profits of big business take precedent over these concerns. The public will have to decide whether to support Bush's regulatory relief activities, but it is at least entitled to know the real life consequences behind the rhetorical claims that he has eliminated so many "unnecessary" and "excessive" government regulations.

CASE EXAMPLES

ASPIRIN AND REYE'S SYNDROME

ISSUE

There is strong evidence of a link between the use of aspirin to treat chicken pox and flu and the development in children of Reye's Syndrome -- a relatively rare, but often fatal, disease.

Significance

According to a 1983 New England Journal of Medicine article, between 2200 and 4200 children develop Reye's Syndrome each year. The fatality rate is high - approximately 20-40 percent of those children die; a substantial percentage of those who survive suffer severe brain damage.

The Federal Food, Drug, and Cosmetic Act requires the label of a drug to contain "adequate warnings against use . . . by children where its use may be dangerous to health." In June 1982, after Public Citizen and the American Public Health Association had sued the Food and Drug Administration (FDA) for delaying a decision to require warning labels about Reye's Syndrome on aspirin, the Secretary of the Department of Health and Human Services (HHS) announced that the scientific evidence linking aspirin to the disease required that labels on aspirin products include a warning to ensure that parents would know not to give aspirin to their children with chicken pox or flu, without first consulting a doctor. Over the drug industry's strenuous objections, the Secretary directed the FDA to prepare a regulation that would require the necessary labeling.

Task Force Interference

In October 1982, while the proposed regulation was pending at OMB, a top OMB official held a secret meeting with several industry representatives, including the President of the Aspirin Foundation, and as a result stopped the labeling regulation from going forward. In November 1982, the Secretary of HHS formally withdrew the proposed regulations.

Impact on Health and Safety

Between June 4, 1982 when the Secretary of Health and Human Services first announced that warning labels were needed, and June 5, 1986, when such labels were finally required, approximately 3,000 children in this country developed Reye's Syndrome. (The dramatic decrease in the number of annual cases is attributed to the fact that as a result of the publicity and public education surrounding the issue, many parents stopped using aspirin to treat chicken pox and flu.) Of the 3000 cases, approximately one-third of the children died, and many of the surviving children suffered brain damage. Many of those deaths and injuries could have been prevented if parents had simply known that they should use something other than aspirin, such as acetaminophen (Tylenol) to treat their child's flu or chickenpox.

Final Outcome

In the face of a finding by the U.S. Court of Appeals that the record "strongly suggests that the pace of agency decision-making is unreasonably dilatory," the threat of mandatory legislation, and additional data from a Public Health Service study showing a strong link between the use of aspirin and the development of Reye's Syndrome, the government finally issued a regulation in March 1986, requiring aspirin manufacturers to include a warning about Reye's Syndrome in the labels of all over-the-counter and prescription aspirin products. The regulation became effective in June 1986.

CHRONOLOGY

November 1980: On the basis of four state epidemilogical studies, the Centers for Disease Control (CDC) concludes that there is a link between the use of aspirin for children with chicken pox or flu and the development of Reye's Syndrome.

November 1981: CDC concludes that the use of aspirin "should be avoided, when possible, for children with [chicken pox] and during presumed influenza outbreaks." The recommendations are immediately forwarded to the Commissioner of the Food and Drug Administration (FDA).

March 1982: The Public Citizen Health Research Group and the American Public Health Asssociation petition the FDA to require the labeling of all aspirin-containing products to warn about the association between aspirin and Reye's Syndrome.

May 1982: The Public Citizen Health Research Group and American Public Health Association sue the FDA for failing to require a warning label.

June 1982: The Secretary of the Department of Health and Human Services announces that he has concluded that there is a strong association between aspirin and Reye's Syndrome, and he directs the FDA to undertake an extensive public education campaign and to issue a warning label requirement for aspirin.

September 1982: The Secretary signs proposed regulations requiring a warning about Reye's Syndrome on all aspirin, and submits them to OMB, pursuant to Executive Order 12291.

October 1982: The President of the Aspirin Foundation and other industry representatives have a secret meeting with OMB official Jim Tozzi, at which they urge him to stop the labeling requirement, based on the same financial and scientific arguments that had already been rejected by HHS and FDA. Tozzi recommends to his boss, Christopher DeMuth, that the labeling requirement be stopped until there is more conclusive proof of the link. C. Boyden Gray, Counsel to the George Bush's Task Force on Regulatory Relief, also reviews the proposed regulation.

November 1982: Chris DeMuth tells Secretary Schweiker that the proposed regulations should be withdrawn.

November 18, 1982: Secretary Schweiker announces that he has decided to withdraw the labeling regulations, and to delay a final decision pending the results of a new government study.

July 1984: The United States Court of Appeals for the D.C. Circuit concludes that the record "strongly suggests that the pace of agency decision-making is unreasonably dilatory," that "[a]ll scientific evidence in the record points to a link between [aspirin] and Reye's Syndrome," and that the industry's role in the delay is particularly troubling "in that the pace of agency decision-making may jeopardize the lives of children." It directs the district court to scrutinize the agency's reasons for the delay.

December 1984: The results of the first phase of the new government study show that children with chicken pox or flu who are given aspirin are 12-25 times more likely to develop Reye's Syndrome than children with those diseases who are not given aspirin. The study also shows for the first time that teenagers are also at risk. On the basis of these findings, the Secretary of HHS asks the industry to include a warning label on a voluntary basis.

January 1985: Legislation requiring warning labels is introduced in the Senate.

March 7, 1986: The FDA issues temporary regulations requiring the warning label, effective June 5, 1986. On June 9, 1988, the labeling requirement is made permanent.

INFANT FORMULA

ISSUE

Commercially manufactured infant formula is often the sole source of nourishment for hundreds of thousands of infants during the first few months of their lives. Children who are fed nutritionally deficient formula are at risk of suffering severe mental or physical retardation, illness, or even death. A manufacturer can ensure that formula is safe and contains all necessary nutrients by simply testing each batch before it is released for sale to the public.

Significance

A disastrously deficient infant formula marketed in the late 1970's by Syntex Corporation affected thousands of children, hundreds of which were diagnosed with a serious chemical imbalance in their bodies. In response to this catastrophe, Congress passed the Infant Formula Act of 1980 which directed the Food and Drug Administration (FDA) to issue quality control regulations and testing requirements to ensure that all formula contains the essential nutrients at the appropriate levels for normal, healthy development. The FDA acted quickly to implement the law by proposing regulations that would have required the testing of each batch of formula before it left the factory to ensure that it contained the requisite nutrients.

Task Force Interference

OMB first delayed for fifteen months the issuance of any final regulations, during which time millions of cans and bottles of defective formula were released to the market. It then insisted on changes in the regulations that had originally been proposed by the FDA, on the basis of a "cost-benefit" analysis that was conducted by an individual who had for ten years been the quality control official for Mead Johnson — one of the largest manufacturers of infant formula — and who had authored Mead Johnson's objections to the FDA's proposed regulations, arguing that they were too costly to the industry. As a result of the changes in the regulations, testing of each batch of formula was no longer required. After several more batches of defective formula were released to the market, Congress passed emergency legislation in 1986 requiring the FDA to amend the regulations to require the necessary testing.

Impact on Health and Safety

Because of the fifteen month delay caused by OMB's "cost-benefit" review, 50,000 cans of the formula "Nursoy" entirely lacking in vitamin B-6 and 2.5 million cans and bottles of "SMA" with vitamin B-6 levels below those required by the Infant Formula Act were marketed. Although some of these defective products were eventually removed from the market, thousands of children were exposed to the defective formula; at least 90,000 cans of the defective formula were not located. A deficiency in vitamin B-6 can result in serious health effects, including convulsions and permanent brain damage. In addition, as a result of significant revisions in the regulations (as originally proposed by the Carter Administration), thousands of cans and bottles of defective formula have reached the market since the final regulations went into effect.

Final Outcome

In October 1986, declaring that "it's time to end FDA's policy of 'let the baby beware' and to institute the safeguards our children deserve," Senator Metzenbaum introduced special legislation that was immediately passed by Congress and directed the FDA to require manufacturers to perform the necessary testing to ensure that each can and bottle of formula released for sale to the public had all of the necessary nutrients at the appropriate levels.

CHRONOLOGY

1978: The Syntex Corporation markets two infant formulas that are deficient in chloride -- a life-sustaining nutrient. Thousands of infants are given the deficient formula and at least 200 are subsequently diagnosed as suffering from a potentially lethal and rare chemical imbalance in the blood (hypochloremic metabolic alkalosis) as a result. The extent of long-term injury to those exposed is unknown.

September 1980: Congress passes the Infant Formula Act of 1980, which requires that the composition of and manufacturing process for infant formula be regulated by the Food and Drug Administration (FDA). The Act makes it unlawful for any manufacturer to sell infant formula that does not contain specified amounts of 29 essential nutrients, and it requires the FDA to precribe "quality control" procedures, including testing requirements, to ensure that infant formulas contain all of the essential nutrients before they are released for sale to the public.

December 1980: The FDA publishes a proposed regulation specifying the quality control procedures that must be employed to ensure that infant formula is safe and contains all required nutrients at the appropriate levels, including testing requirements, and detailed record-keeping requirements.

March 1982: Wyeth Laboratories, a major manufacturer of infant formula has to recall two infant formulas that are deficient in the essential nutrient vitamin B-6. The FDA Commissioner testifies that "the proposed regulations would have, if followed by the firm, prevented the problem" because they would have prohibited Wyeth from shipping the formula. The Commissioner also testifies that the delay in issuing the final rule is due to the cost-benefit analysis that is required by OMB under Executive Order 12291.

April 1982: The FDA publishes a final rule which differs substantially from the proposed regulations. It establishes no detailed quality control procedures and does not require that the manufacturer test the final product to ensure that it contains all essential nutrients. Also, the rule fails to specify any records that the manufacturer must maintain to demonstrate that the formula contains all required nutrients. The sole justification for the change in the regulations is FDA's decision to adhere to the industry's desire for a rule that was "more cost effective and more flexible."

The "cost-benefit analysis" required by OMB was based principally on a report written by an individual who, for eight years prior to obtaining the contract to perform the analysis had been the quality control manager for Mead Johnson Co., one of the largest manufacturers of infant formula, and who had authored Mead Johnson's comments objecting to the proposed regulations on the ground that they were not "cost-effective."

December 1982: An organization representing the parents of children who had been injured by defective formula ("FORMULA") and Public Citizen file a lawsuit challenging the final regulations.

July - August 1983: Loma Linda, a manufacturer of infant formula, has to recall approximately 7200 cans of formula that is deficient in vitamin A -- one of the required nutrients that is essential for normal vision, skin and tooth formation.

September 1983: Another formula, "Naturlac," must be recalled because it is deficient in both copper and vitamin B-6.

September 1984: The district court judge (newly appointed by President Reagan) rules that the final regulations are not arbitrary and capricious, and therefore cannot be overturned. This decision is subsequently affirmed by the U.S. Court of Appeals which finds that the statute gives the FDA much discretion as to the kind of regulations it can require.

October 1986: Congress enacts legislation requiring the FDA to amend its regulations to require manufacturers to test each batch of formula before it is marketed to ensure that it contains all essential nutrients at the appropriate levels.

PATIENT PACKAGE INSERTS

ISSUE

In contrast to requirements for over-the-counter drugs and most consumer products that are dangerous, patients receive almost no written information about the risks of prescription drugs, including side effects. This information could easily be provided in an insert that is provided directly to the consumer, such as the package inserts that accompany the sale of oral contraceptives.

Significance

A 1980 Food and Drug Administration regulation would have required manufacturers of prescription drugs to include a "patient package insert" with their products, explaining, in lay language, information on the drug's common uses, instructions for proper use, when the drug should not be used, adverse effects, and potential safety hazards. The FDA concluded that consumers should be provided this information since the Federal Food, Drug and Cosmetic Act requires that the labeling of drugs provide consumers with "material facts with respect to consequences that may result from their use." The regulation established a three-year pilot program during which time manufacturers of ten widely-used drugs would be required to include PPIs with those drugs, including valium, darvon, and bendectin. Then FDA Commissioner Jere Goyan considered the PPI program to be his most important accomplishment at the FDA.

Task Force Interference

In February 1981 George Bush, at the request of several major drug companies, stopped the PPI program from going forward. One of the companies that lobbied Bush directly was the Eli Lilly Co., from whose Board of Directors Bush had recently resigned and in which he owned 1500 shares of stock, worth between $50,000 and $100,000.

Impact on Health and Safety

The ten classes of drugs that were to be covered by the PPI program represent over 300 individual drug products comprising approximately 16 percent of the 1.5 billion new prescriptions filled each year in this country. Therefore, since 1981, when the program would have become effective, hundreds of millions of prescriptions have been filled for these drugs, yet consumers have not been provided any information by the manufacturer about the side effects or other adverse consequences of the drugs. There are serious side effects associated with each of those drugs, including bendectin which was eventually withdrawn from the market because of concerns that it caused serious birth defects, valium, which is highly addictive, and clofibrate, which is used to treat high cholesterol and has been linked to an increased risk of cancer and gallbladder disease. For most of the drugs, there are much less dangerous alternative therapies.

Final Outcome

The PPI regulation was formally revoked in September 1982.

CHRONOLOGY

Late 1960's: The FDA requires patient labeling for a small number of drugs, including oral contraceptives.

March 1975: FDA is petitioned by a coalition of consumer organizations to require written warning information on labels of prescription drugs.

1975-1978: FDA holds a series of meetings, a symposium, and a public hearing to solicit views on the need for PPIs.

July 1979: FDA proposes regulations to implement patient package insert requirements for most prescription drugs. The proposal is based on an extensive administrative record, including a regulatory analysis of the economic consequences of the rule.

September - December 1980: FDA publishes final regulations establishing a three-year pilot program during which PPIs will be required to be included with ten widely-used drug categories comprising approximately 16 percent of all new prescriptions filled each year in the United States. The drugs include:

- ◊ ampicillins (antibiotics such as penicillin)
- ◊ benzodiazepines (valium)
- ◊ cimetidine (for treatment of ulcers)
- ◊ clofibrate (used to treat high cholesterol and linked to an increased risk of cancer and gallbladder disease)
- ◊ digoxin (for treatment of heart disease)
- ◊ methoxsalen (for treatment of skin diseases such as psoriasis)
- ◊ propoxyphene (darvon)
- ◊ phenytoin (for the treatment of epilepsy)
- ◊ thiazides (diuretics used for high blood pressure)
- ◊ bendectin (used to treat morning sickness, withdrawn from market in 1983 because of association with birth defects)

In support of the final rule, the FDA prepares a detailed regulatory analysis which concludes that the savings to be realized by a reduction in the excessive or inappropriate use of drugs and adverse drug reactions would greatly exceed the cost of the pilot program. FDA Commissioner Jere Goyan later states that he considered the PPI regulation to be his most important accomplishment at the FDA.

January - February 1981: The pharmaceutical industry undertakes a concerted effort to convince the new Reagan Administration to stop the PPI regulation. William S. Apple, president of the American Pharmaceutical Association, and Robert J. Bolger, President of the National Association of Chain Drug Stores, write a joint letter to OMB Director David Stockman urging him to stop the program on the ground that it is inflationary.

February 18, 1981: Attorney C. Joseph Stetler writes George Bush, on behalf of several drug companies -- including Eli Lilly from whose Board of Directors Bush had recently resigned and in which Bush owned 1500 shares of stock -- urging him to stop the PPI regulation on the ground that it will cost the industry in excess of $100 million annually, and thus should not be issued.

February 20, 1981: The FDA informs the industry's trade press that the PPI regulations will be suspended.

April 1981: The FDA announces that the PPI regulations have been suspended for an indefinite period of time pending further review of "the cost, necessity and utility of FDA's patient package insert program."

December 1981: Bush Task Force "progress report" lists the elimination of the PPI program as a "major regulatory reform."

February 1982: The FDA proposes elimination of the PPI regulation on the ground that its benefits do not outweigh its costs.

September 1982: The PPI regulation is formally revoked.

TOXIC SHOCK SYNDROME

ISSUE

Toxic shock syndrome -- a serious and sometimes fatal disease -- has been linked to the use of high absorbent tampons. The risk can be greatly reduced if women are provided meaningful information about the absorbency rates of tampons so that they can avoid buying those with the highest absorbency.

Significance

Since 1981 when the FDA was first informed of the association between the use of high absorbency tampons and toxic shock syndrome (TSS), there have been approximately 1600 reported cases of TSS, including 36 deaths. The reported cases are only a fraction of the total number of actual cases. A disproportionate number of the deaths were by women using higher-absorbency tampons who were unaware of the increased risks associated with those products. The Food and Drug Administration (FDA) has been studying the problem since 1981; however, current regulations do not require manufacturers to use the same absorbency terminology, and as a result one company's "super" is actually less absorbent than another company's "regular."

Task Force Interference

Following the deregulation rush by the Task Force, FDA refuses for five years to issue an effective tampon absorbency disclosure rule. After FDA finally moved in 1987, OMB delayed for another fifteen months the FDA's issuance of a proposed rule that would require tampon manufacturers to use a standardized system to disclose the absorbency rates on tampons. This system would allow women to compare products and avoid using high absorbency brands, thereby reducing their risk of suffering TSS. The proposal, which was finally issued in September 1988 after Public Citizen brought a lawsuit against the FDA and OMB, will have to be approved by OMB again before it can be made final.

Impact on Health and Safety

Millions of women are still at risk of developing TSS because they have been denied essential information about the absorbency rates of tampons.

Final Outcome

In September 1988, the FDA finally issued a proposed regulation that would require a uniform disclosure of tampon absorbency. However, the regulation must go through several layers of agency review, including additional OMB review, before it becomes final.

CHRONOLOGY

1981: A tri-state study demonstrates an association between high aborbency tampons and toxic shock syndrome (TSS).

April 1981: The Food and Drug Administration (FDA) concludes that users of high-absorbency tampons have a greater risk of contracting TSS than users of low-absorbency tampons.

1982: The federal government's Institute of Medicine issues a report recommending that women minimize their use of high-absorbency tampons.

June 1982: The FDA issues a regulation requiring tampon manufacturers to include information about TSS on tampon packaging or in a package insert, including the statement that advises women to use tampons with the minimal absorbency needed to control menstrual flow. However, the regulation does not require manufacturers to use standardized absorbency terminology or to disclose relative absorbency of one tampon in relation to other brands. Therefore, women cannot accurately identify which tampons provide the lowest absorbency.

July 1982: Public Citizen petitions the FDA to establish a test method for determining absorbency and a uniform nomenclature for disclosing absorbency on tampon labels.

September 1982 - April 1983: The FDA appoints a special "task force" to establish "voluntary" standards to address tampon absorbency testing and labeling.

April 1984: The FDA concludes that the test methodology accepted by the task force will measure tampon absorbency with reasonable accuracy, but the task force informs the FDA that it cannot agree on uniform labeling to disclose absorbency.

July 1984: The FDA concludes that "a labeling regulation is necessary to assure that consumers can make meaningful interbrand comparisons with respect to absorbency," and states that it will "develop a proposed absorbency test and labeling requirement as rapidly as possible."

June 1987: The FDA finally drafts regulations that would require the disclosure of absorbency rates on tampons and sends the proposal to the Office of Management and Budget for its cost-benefit review.

August 1987: Another government study confirms the association between increased tampon absorbency and enhanced risk of toxic shock syndrome.

April 1988: FDA Commissioner Frank Young tells lawyers for Public Citizen that the tampon regulation is being held up by OMB review.

June 1988: Public Citizen files a lawsuit in federal district court against the FDA, the Department of Health and Human Services, and OMB, challenging the delay in issuing the tampon regulation.

September 1988: The FDA issues a proposed rule that would require uniform absorbency labeling.

COLOR ADDITIVES

ISSUE

Color additives are widely used in foods, drugs, and cosmetics. Their use is prohibited by law if studies show that they cause cancer in animals or humans.

Significance

Color additives have no nutritional or therapeutic value -- they simply add color to the product to enhance its appeal to the consumer. In 1960, Congress passed the Color Additive Amendments to the Federal Food and Drug Act, requiring manufacturers of color additives to prove that they are "safe" in order to use them. Under the "Delaney Clause," any color additive shown to cause cancer in either animals or humans is automatically considered "unsafe" and must therefore be banned from the market.

In the early 1980's, the Food and Drug Administration (FDA) concluded that studies showed that several dyes -- Red Nos. 3, 8, 9, 19 and Orange 17 cause cancer in animals, and that, under the Delaney Clause, they must be removed from the market.

Task Force Interference

At the request of the color additive industry, in March 1983, C. Boyden Gray, counsel to the Task Force and OMB officials pressured the FDA to reverse its position and allow the carcinogenic dyes to remain on the market.

Impact on Health and Safety

The most significant of the carcinogenic dyes that was permitted to stay on the market is Red No. 3 -- widely used in foods principally eaten by children, such as candy, desserts and baked goods (it is also used in maraschino cherries). It has been been shown to cause thyroid cancer in animals, and may pose a particular risk to pregnant women. Red No. 3 is also used in cosmetics and externally applied drugs. Although the FDA is now allowing the continued use of the additive under a different theory, during the time that it has been permitted to stay on the market under OMB's theory that there is a "de minimis" exception to the Delaney Clause, hundreds of thousands of children are being exposed to the dye in various foods, and other segments of the population are being exposed to the dye in foods, drugs, and cosmetics. The other dyes that were allowed to remain on the market as a result of the agency's application of OMB's theory, Red No. 19, Orange 17, Red Nos. 8 and 9 have been widely used in cosmetics (e.g., lipstick, shampoo) and in drugs.

Final Outcome

In October 1987, in an opinion written by a Reagan-appointed judge, the U.S. Court of Appeals ruled that the theory under which OMB pressured the FDA to allow carcinogenic color additives to stay on the market is illegal. As a result of that ruling, Red Nos. 8, 9, and 19 and Orange No. 17 have all been banned from the market. However, the FDA is now relying on a new industry argument for allowing the continued use of Red No. 3; that theory has not yet been challenged in court.

CHRONOLOGY

February 1983: The Food and Drug Administration (FDA) decides that animal studies prove that the color additive Red No. 19 causes cancer in animals, and that it must be banned from the market under the Delaney Clause of the Federal Food, Drug, and Cosmetic Act. The color additive industry, represented by the Cosmetic Toiletry and Fragrance Association (CTFA), pressures the FDA to allow the dyes to stay on the market through the application of a "de minimis" policy -- i.e., on the theory that the number of people who will die from cancer is small. The FDA refuses, stating that the law does not permit such an exemption.

March 1983: CTFA writes the Secretary of HHS, C. Boyden Gray, Counsel to Vice President Bush, and Jim Tozzi, Deputy Administrator of OMB's Office of Information and Regulatory Affairs, opposing the FDA Commissioner's recommendation to ban Red No. 19. As a Congressional Committee later concludes, "from this point on, OMB [takes] up industry's case against FDA."

CTFA later meets with Boyden Gray and Jim Tozzi in the first of several contacts concerning HHS' regulation of the carcinogenic color additives. OMB official Christopher DeMuth meets with FDA's Chief Counsel and challenges the decision to ban the dye.

April 1983: Jim Tozzi holds an "interagency" meeting between representatives of OMB, HHS and FDA to discuss CTFA's "de minimis" theory and informs the group that he "intend[s] to pursue the issue of a government-wide application of the 'de minimis' theory." Jim Tozzi writes HHS Secretary Margaret Heckler, urging her to adopt a de minimis exception. Christopher DeMuth and Boyden Gray hold a meeting with Commissioner Hayes and the FDA Chief Counsel to convince them to reverse their decision. Meanwhile, HHS delays approving the FDA's decision to ban Red 19.

March 1984: Acting FDA Commissioner informs Secretary Heckler that four additional dyes -- Red Nos. 3, 8, 9 and Orange 17 -- have been shown to cause cancer in animals and must be banned.

November 1984: Dr. Sanford Miller, Director of FDA's Center for Food Safety, sends a memo to the Commissioner refuting each of the industry's arguments for a "de minimis" theory and explaining that the industry's calculation of the risk of cancer posed by the dyes "could be hundreds or even thousands of times too low."

June 3, 1985: The House Committee on Government Operations issues a report unanimously condemning HHS for its failure to remove the carcinogenic dyes from the market.

June 1985 - August 1986: FDA Commissioner Frank Young delays a final decision, during which time the dyes remain on the market.

August 7, 1986: Commissioner Young issues a final rule approving Red No. 19 and Orange 17. Although reiterating his conclusion that the dyes cause cancer in animals and that under a "literal application of the Delaney Clause" they would be prohibited from the market, he nonetheless, for the first time in the 26 year history of the Delaney Clause, accepts the argument that he can leave the dyes on the market under a "de minimis" exception. The new policy is also relied on to allow the continued use of Red Nos 3, 8 and 9.

October 23, 1987: In a case brought by Public Citizen, Reagan appointee Stephen F. Williams rules for the U.S. Court of Appeals that the "de minimis" theory is unlawful. As a result, Red Nos. 8,9, and 19 and Orange No. 17 are banned from the market. However, Red No. 3 remains on the market under a new FDA theory which has not yet been challenged in Court.

HAZARDS COMMUNICATIONS RULE

(WORKERS' RIGHT TO KNOW)

ISSUE

Millions of workers are exposed to hazardous chemicals in the workplace. Without knowing the identities of these chemicals, workers cannot protect themselves, ensure that their employers take protective measures, or recognize and associate symptoms of occupationally caused diseases and deaths. The solution is to provide workers with a list of the chemicals to which they are normally exposed with a description of the known hazards, and to label chemicals used in the workplace.

Significance

In January, 1981, the Occupational Safety and Health Administration (OSHA) published a proposed regulation that would have required manufacturers to inform their employees about the hazards associated with appproximately 32,000 chemicals. In addition, the rule would have required that non-manufacturing employees have access to information on hazards through labeling requirements imposed on the manufacturers and importers of chemicals.

Task Force Interference

The Task Force convinced the Secretary of Labor to withdraw the hazards communication regulations on the ground that they were too costly to employers who would have been responsible for ensuring that their employees were informed about the hazardous chemicals. After OSHA later decided to go forward with a regulation, OMB delayed issuance of the rule and then insisted on changes that resulted in two-thirds of the workforce, including workers in the construction industry, from being deprived of the protections of the rule.

Impact on Health and Safety

As a result of the Task Force's repeated interference, issuance of a hazards communication regulation for any segment of the workforce was delayed 2 1/2 years, and a hazards communication regulation for the non-manufacturing segment -- including hospital, construction, and agricultural workers -- was delayed almost seven years. During that time, according to statistics from the National Institute of Occupational Safety and Health, 65 to 70 million workers were denied critical information about the identities of dangerous chemicals in their workplaces, were prevented from identifying symptoms of illness associated with such hazards, and were prevented from taking steps to avoid or limit such exposure or see that their employers take such steps. In addition, physicians who treat those employees were denied important information that would shed light on the causes and prevention of chemical-related illnesses and death.

Final Outcome

As a result of three lawsuits brought by Public Citizen and several unions, in August 1988 a United States Court of Appeals ordered OSHA to issue a hazards communication rule covering employees in all occupations covered by the Occupational Safety and Health Act. In doing so, the Court ruled that OMB's interference was illegal, declaring that "OMB cannot in the guise of reducing paperwork substitute its judgment for that of the agency having substantive rulemaking responsibility."

CHRONOLOGY

January 1981: OSHA publishes a notice of proposed rulemaking that would require all manufacturers covered by the Occupational Safety and Health Act to inform their employees about the hazards associated with some 32,000 chemicals. In addition, the proposal would require that non-manufacturing employees be informed of hazards through comprehensive labeling requirements imposed on manufacturers and importers of chemicals.

February 1981: The Secretary of Labor, at the request of Bush's Task Force, withdraws the proposal in order to consider "regulatory alternatives."

November 1983: OSHA issues a final rule requiring manufacturers and importers of hazardous chemicals to include a label on each container which identifies the chemical and contains appropriate hazard warnings. Manufacturers and importers must also prepare a "material safety data sheet" (MSDS) which contains the names of the chemical compounds and information necessary for safe use of the product. Each MSDS must be provided to employers, who must then make the sheet available for employee inspection and provide employees with information and training on hazardous chemicals in their work area. The final rule covers only workers in the manufacturing sector, thereby failing to protect two-thirds of the nation's workforce, including workers in the hospital, construction, and agricultural sectors.

May 1985: In response to a lawsuit by the United Steelworkers of American and Public Citizen, the United States Court of Appeals for the Third Circuit strikes down the rule and directs the Secretary to apply the rule to non-manufacturing sectors unless he can demonstrate that to do so is not feasible.

November 1985 - May, 1987: OSHA delays issuing the rule.

May 1987: The Court of Appeals finds that in delaying issuance of a hazards communications rule covering non-manufacturing employers, OSHA has violated the Court's previous ruling, and directs the agency to issue a final decision.

August 1987: OSHA finally issues the expanded hazards communication rule, applying the standard to employers in all sectors, including the requirement that employers make available for employee inspection material safety data sheets furnished by the manufacturers of hazardous chemicals used in their work areas. The final rule adds the requirement that at multi-employer worksites employers exchange MSDSs, and make them available to the employees either through each of the employers at the worksite, or through a central location. The purpose of this provision is to ensure that workers in one trade at a multi-employer site, for example a construction site where there are carpenters, plumbers, and electricians, are informed about and protected from hazardous substances used by another trade at the same jobsite. The final rule is scheduled to go into effect on May 23, 1988.

September 1987: OSHA submits the final rule to OMB for approval.

October 1987: OMB rejects the requirement that MSDSs be exchanged by employers at multi-employer worksites, and it "disapproves" the entire rule until its objections to that provision are addressed.

August 1988: The U.S. Court of Appeals for the Third Circuit rules that OMB has no authority to interfere with OSHA's determination that employers at multi-employer worksites should be required to exchange their MSDSs in order to increase workplace awareness of hazards, and thereby enable workers to avoid injury, illness, or death. The Court directs OSHA to implement the final hazards communication rule, including the MSDS exchange provision.

ETHYLENE OXIDE

ISSUE

Ethylene oxide is a widely used chemical that has been linked to cancer, chromosome damage, and spontaneous abortions. Exposure to the chemical can be greatly reduced, principally by increasing ventilation in the workplace.

Significance

Tens of thousands of health care workers are at risk of exposure to ethylene oxide, used as a sterilant in hospitals, in the manufacturing of medical devices, as a fumigant for spices and agricultural products, and as an intermediate in chemical manufacturing.

The Occupational Safety and Health Act requires the Occupational Safety and Health Administration (OSHA) to issue workplace standards that "most adequately assure, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard . . . for the period of his working life." After being ordered by a federal appeals court to issue an emergency standard for ethylene oxide as a result of a lawsuit brought by the Public Citizen Health Research Group and several labor unions, in April 1983 OSHA finally issued a proposed rule that would have set both a permanent and short-term exposure limit for ethylene oxide.

Task Force Interference

OMB delayed the issuance of any regulation, and then insisted that OSHA eliminate the part of the ethylene oxide regulation that would have set a short-term exposure limit, despite OSHA's own expert scientific conclusion as well as the conclusion of the National Institute for Occupational Safety and Health that chromosome damage and spontaneous abortions occur at low short-term exposures of the chemical.

Impact on Health and Safety

Between 1981 when the OSHA staff originally wanted to issue a new standard for exposure to ethylene oxide, and June 1988 when the final rule, including the short-term exposure level provision, finally became effective, approximately 75,000 workers in health care facilities in this country were exposed each year to ethylene oxide. Calculations show that at least 115 of those workers are likely to die of ethylene oxide-induced cancers as a result of OSHA's failure to lower the standard for permanent exposure and to impose a short term exposure standard. The number of illnesses and spontaneous abortions that will be caused by OMB's interference with the rulemaking proceeding are not known.

Final Outcome

After being ordered to do so twice by the U.S. Court of Appeals for the District of Columbia Circuit, which held that failure to issue a short-term exposure limit for ethylene oxide "may well expose OSHA to liability for contempt," OSHA issued a final rule on April 6, 1988, setting a short-term exposure level for ethylene oxide at 5 parts per million over a period of 15 minutes. The rule became effective on June 6, 1988.

CHRONOLOGY

1979: Environmental Protection Agency's Carcinogen Assessment Group issues its findings concerning various studies on EtO and concludes that it is mutagenic (causes genetic damage) and may also be linked to an increased incidence of leukemia in exposed workers.

1981: The National Institute for Occupational Safety and Health issues a report concluding that EtO must be regarded in the workplace as a potential occupational carcinogen.

January 1983: A federal district court orders OSHA to issue the standard in response to a lawsuit brought by the Public Citizen Health Research Group and the American Federation of State, County and Municipal Employees, and several other unions, when OSHA had failed to respond to their petition for an emergency temporary exposure standard.

April 1983: OSHA issues a proposed rule which includes a permanent exposure level and a short-term exposure level (STEL) ranging between 5 to 50 ppm for 30 minutes or less.

June 14, 1984: OSHA is prepared to issue a final rule which, in addition to a permanent exposure level, includes a requirement for a 10 ppm 15-minute STEL and contains a lengthy discussion of the scientific evidence showing that chromosome damage and spontaneous abortions occur at low short-term exposures of EtO.

June 14, 1984: Christopher DeMuth, OMB's Administrator for Information and Regulatory Affairs, sends a letter to the Department of Labor, complaining about the STEL provision and urging its elimination, stating that OMB has concluded that the rule is inconsistent with the cost/benefit policies of Executive Order 12291.

June 15, 1984: OSHA issues the final rule, but eliminates the STEL provision along with the discussion of chromosome damage and spontaneous abortions caused by low short-term exposure.

August 1984: The district court judge calls the handling of the EtO regulation "atrocious," and orders the agency to complete the ongoing proceeding by December 17, 1984.

September 1984: The National Institute of Occupational Safety and Health (NIOSH) urges OSHA to issue a STEL requirement, stating that "OMB's concern regarding inclusion of a short term exposure limit in the ethylene oxide standard appears to conflict with the substantial scientific evidence collected by OSHA." The National Institute of Environmental Health Sciences ("NIEHS") also urges OSHA to adopt a STEL. Most significantly, OSHA's own EtO team, including all of the scientists, health professionals, and even the lawyer who worked on the standard, sign a memorandum stating that "no new significant information has been provided by parties opposing adoption of a STEL for EtO as a result of the extended rulemaking," and urging the agency to reinstate the STEL requirement.

December 1984: Despite the unanimous recommendation of its own scientific staff and the recommendations of the two government scientific agencies asked to reconsider the need for a STEL (NIOSH and NIEHS), OSHA decides to "go along with OMB's reservations and not to promulgate a STEL." OSHA Staff Memorandum (December 19, 1984).

July 1986: The U.S. Court of Appeals for the District of Columbia Circuit rules that OSHA has acted unlawfully by failing to include a STEL provision in the final ethylene oxide regulation and remands the matter to the agency for development of a standard that includes a STEL.

July 1986 - July 1987: Under the direction of OMB, OSHA continues to delay issuing a final regulation with a STEL.

July 1987: In response to a follow-up lawsuit by the Public Citizen Health Research Group, the Court of Appeals holds that OSHA's target date of March 1988 for issuance of a final rule was at the "very lip of the abyss of unreasonable delay" and warns the agency that any delay beyond that date will expose the agency to liability for contempt.

April 1988: OSHA issues a final rule setting a STEL for ethylene oxide of 5 parts per million over a period of 15 minutes, effective June 6, 1988.

GRAIN DUST

ISSUE

The accumulation of grain dust in grain handling facilities, including grain elevators and mills, exposes workers to the serious risk of explosions and fires. The problem can be greatly alleviated by simply requiring employers in such facilities to clean up the dust when it accumulates in dangerous levels.

Significance

Grain dust explosions are a serious problem for both grain elevators (where grain is stored during movement and processing) and mills (*e.g.*,feed, flour, rice). Each year over 2200 fires occur in grain handling facilities. In 1977 alone, 13 inspectors of the U.S. Department of Agriculture were killed in a grain explosion; during an eight day period in December 1977 five explosions caused 59 deaths and injuries to workers; a high rate of explosions continued in 1978-80, and there has been no reduction in the rate of deaths and injuries in recent years. A principal source of these explosions and fires is grain dust accumulation. Tens of thousands of workers are exposed to this risk each year, since all types of grain elevators and mills accumulate grain dust at high levels. In 1980, the Occupational Safety and Health Administration (OSHA) began rulemaking to limit the amount of permissible grain dust accumulation in grain elevators and mills.

Task Force Interference

After having secret meetings with the trade associations representing the industries opposed to the rule, OMB delayed for five years the issuance of any rule that would limit the permissible amount of grain dust, and then significantly weakened the standard that had been proposed by OSHA, by insisting that the regulation exempt mills and allow grain elevator operators to choose their own method for reducing the problem. Although OSHA concluded that the potential for fires and explosions was the same in grain mills as in grain elevators and also concluded that mill workers face a significant risk of death and injury from this problem, it nevertheless bowed to pressure from OMB, and exempted mills from the standard altogether.

Impact on Health and Safety

As a result of the changes in the regulations, tens of thousands of mill workers will continue to be exposed to the risk of death and injury from grain dust explosions and fires. Additional weakening of the standard as it relates to grain elevators jeopardizes the health of those workers as well.

Final Outcome

The grain dust standard was finally issued in December 1987. It is presently being challenged in court by several unions, including the AFL-CIO and the Oil, Chemical and Atomic Workers.

CHRONOLOGY

Late 1970's: A series of explosions and fires in grain dust facilities focuses national attention on the serious risk posed by grain dust. A number of government agencies, including the National Institute for Occupational Safety and Health, the Department of Agriculture, the National Academy of Sciences, and OSHA began studying the causes of grain dust explosions and fires to determine whether effective preventive measures could be implemented.

February 1980: OSHA requests comments and information on health and safety hazards in grain handling facilities and announces its intention to promulgate a grain elevator and mill safety standard.

July 1982: The government's National Academy of Sciences issues a report singling out grain dust reduction in elevators and mills as the most critical factor in preventing explosions. It recommends that OSHA impose a strict standard to ensure that dust levels are kept below 1/64 inch throughout the facility.

Late 1982: OSHA drafts a proposed standard requiring grain elevators and mills to remove grain dust accumulations at or exceeding 1/8 inch. The draft is cleared by the Department of Labor and submitted to OMB for approval. Shortly thereafter, OMB officials meet with representatives of both the American Feed Manufacturers Association and the National Grain and Feed Association who strenuously oppose the standard on cost grounds.

February - March 1983: OMB takes the position that "dust control is cost-ineffective and therefore should be eliminated entirely." As a fall-back position, it suggests substituting a broadly written performance standard that would require employers to reduce grain dust accumulations but would not set a specified limit on acceptable accumulation levels. In addition, OMB advocates exempting mills altogether from the standard.

Summer 1983: OSHA rejects OMB's objections, explaining that the 1/8 inch standard is necessary to protect the safety of workers and that it is cost-effective, and insisting that mills must be subject to the standard. While OSHA and OMB battle over the contents and scope of the standard, issuance of a proposed regulation continues to be delayed.

January 1984: The proposed standard is finally issued but is vastly different from the draft that OSHA submitted to OMB: it includes a broad performance standard, as requested by industry, and, for the first time suggests exempting mills.

December 30, 1987: After another three years of delay, the final regulation is issued, largely in accord with the expressed concerns of OMB and industry (and demonstrably at odds with what OSHA stated was needed in 1983). It is a broad performance standard, allowing employers to select the means for reducing dust accumulations. Mills are not covered, and grain elevators must clean dust only in "priority areas" (i.e., those near an ignition source) whenever grain dust accumulations exceed 1/8 inch, but not in other areas of the plant, where no limit is set.

April 1988: Several unions, including the Food & Allied Service Trades Department, AFL-CIO, and the Oil, Chemical & Atomic Workers sue OSHA over the standard. The case is pending.

COMMERCIAL DIVING STANDARDS

ISSUE

Commercial diving, such as diving at off-shore oil rigs, is the most dangerous of any profession within the jurisdiction of a federal agency. It is ten times as dangerous as coal mining, according to government and industry data.

Significance

The commercial diving standard issued by the Occupational Safety and Health Administration (OSHA) sets minimum safety standards for professional divers who are often at risk of death and injury. The standard affects divers who "suit up," dive as deep as several hundred feet, go through various decompression stages, and depend on external life support systems at the water's surface. Intended as minimum standards on which to build, the rule is similar in large degree to the industry's voluntary consensus standards which preceded the Federal standard.

Task Force Interference

In 1981 the OSHA standard was targeted by the Task Force for review and possible rescission. An OSHA official claimed that the White House, responding to business complaints, identified the standard as a "classic case of over-regulation." On April 24, 1981, Task Force Counsel C. Boyden Gray had an off-the-record meeting with the Associated Diving Contractors, the President of Taylor Diving and Salvage Company, and the Director of Federal Relations of Brown and Root Construction, to discuss changes in the standard. Gray's financial disclosure statement revealed that a few days after assuming his post as Counsel to the Vice President and the Task Force, he sold substantial holdings ($50,000 to $100,000) in Halliburton, Inc., of which both Taylor Diving and Salvage, and Brown and Root Construction, are subsidiaries.

Impact on Health and Safety

In 1975 two divers died of decompression sickness due to the diving contractor's failure to have a decompression chamber available at the dive site. These and other avoidable deaths prompted the Carpenter's Union to petition OSHA in June of 1976 for an emergency temporary standard regulating diving. It argued that the need for the standard was imperative. A significant portion of the approximately 3000 commercial divers suffer from permanent neurological disability and from "bone rot" caused by lesions on the bone shaft or near the joints as the result of inadequate decompression. With a rate of lost workday illness at sixty times that of the interindustry rate, diving is clearly a dangerous business. Yet instead of extending protections to include vitally-needed decompression standards, the Task Force recommended review and rescission of the existing standard.

Final Outcome

After a congressional committee investigated Task Force and OMB actions concerning the diving standard, it found that "to lessen the protections afforded commercial divers on the basis of a meeting between industry representatives and the Counsel to the Task Force [Boyden Gray] is just short of outrageous." As a result of this congressional pressure, OSHA amended the standard to provide much needed protections for divers.

CHRONOLOGY

August 1975: The United Brotherhood of Carpenters and Joiners of America files a petition with OSHA for an Emergency Temporary Standard in the wake of industry non-compliance with the voluntary consensus standards which many contractors claimed to be following.

June 1976: After hearings and post-hearing comments, OSHA proposes an Emergency Temporary Standard for commercial diving, finding that "these factors-- the diver's exposure to the unique hazards of undersea activity, isolation from aid in the event of an accident or injury, the complex nature of the protective system and the slight tolerance for error which exists in the operaton of that system-- all combine to create a situation in which the potential for serious or fatal injury is great. The factors creating the potential are present in few if any other regulation."

July 1977: OSHA promulgates a final rule on minimum safety standards for commercial diving. The rule mandates, among other things, periodic medical examinations, inspection and certification of equipment, and decompression chambers in certain instances.

April 1981: Private meetings take place between Task Force Counsel C. Boyden Gray, and the Associated Diving Contractors, the President of Taylor Diving and Salvage Company, and the Director of Federal Relations of Brown and Root Construction, the companies involved in the commercial diving business.

August 1981: George Bush announces the targeting of the OSHA Commercial Diving Standard for review, citing as the impetus comments of businesses, although there are no written records revealed in Task Force files of such comments.

March 1982: Congressional hearings are held to investigate OMB and Task Force interference in targeting the diving standard for revision. A subsequent report by the House of Representatives Committee on Government Operations finds that efforts by OMB and the Task Force to lessen the protections for commercial divers at the request of industry are "just short of outrageous." It also finds that OMB has disregarded due process and requirements for public rulemaking.

April 1982: As a result of the Congressional pressure, OSHA strengthens the commercial diving standard by adding crucial decompression and treatment requirements.

VIDEO DISPLAY TERMINALS

ISSUE

With widespread use of computers and word processors, there has been increasing evidence that prolonged exposure to video display terminals may cause adverse reproductive effects, including miscarriages and birth defects. In order to determine the existence and extent of the hazard so that the potential dangers can be reduced or eliminated, meaningful scientific data concerning the suspected link must first be collected.

Significance

Approximately 17 million Americans work at video display terminals, the vast majority of them are female. It has been estimated that by 1990, 40 million workers in the U.S. will make their living by using VDTs. Since 1980, scientists have been concerned that there may be a link between prolonged exposure to VDTs and negative pregnancy outcomes, including spontaneous abortions, stillbirths, premature births, birth defects, neonatal death and infant respiratory disease.

The National Institute of Occupational Safety and Health ("NIOSH") is authorized by law to investigate working conditions to determine whether there is scientific evidence linking particular working conditions to adverse effects on health. The results of such investigations are often relied on by the Occupational Safety and Health Administration in deciding whether workplace standards should be imposed in order to reduce the hazard. Since 1982, NIOSH has proposed doing a comprehensive study of the telecommunications industry to determine whether VDTs cause infertility and birth defects.

Task Force Interference

Since November, 1985 OMB has refused to allow NIOSH to conduct the study it believes is necessary to determine the extent of adverse health effects caused by the radiation from VDTs. After delaying the study for several years, at the request of the telecommunications industry, including Bell South — a major employer of VDT workers — OMB finally allowed NIOSH to conduct a study, but insisted on changes in the methodology that are guaranteed to undermine the results and thereby forestall any government regulation to reduce VDT exposure.

Impact on Health and Safety

OMB's changes in the study will prevent the government from collecting meaningful data on whether there is a causal link between the use of VDTs and adverse reproductive effects. As a result, tens of millions of Americans who work at VDTs will be deprived of information upon which to make decisions about whether to remain at their jobs. In addition, the government will lack crucial information needed to decide whether changes in the workplace are needed to eliminate or reduce any adverse health effects of VDTs.

Final Outcome

NIOSH completed the data collection for the modified study in June, 1988. The projected completion date for the final study is sometime in the Spring of 1989. NIOSH scientists say that OMB's revisions guarantee that the study will be of limited value in assessing the link between VDTs and adverse reproductive effects, and that the study will be vulnerable to attack by the industry on the grounds that it does not take into consideration stress and former reproductive history as factors affecting the ability of female workers to conceive and deliver normal babies — the very factors that would have been accounted for by the questions that OMB insisted be removed from the questionnaire on "cost" grounds.

CHRONOLOGY

1980 - 1986: Scientists identify 12 clusters of negative pregnancy outcomes among VDT operators in the United States and Canada. Many of these occur in the telecommunications industry where employees (typically women) sit in front of VDTs all day long. For example, during an 18 month period between 1980 and 1981, three out of three pregnancies of women employed by Pacific Northwest Bell at a facility in Renton, Washington had adverse outcomes. One woman gave birth to a mongoloid child, another's child was born with an open spine, and the remaining woman's child was stillborn. During 1983 six miscarriages out of a total of 15 pregnancies occurred among women employed by Southern Bell in one of its work locations in Atlanta, Georgia.

1982 - 1984: The National Institute of Occupational Safety and Health ("NIOSH") initiates a feasibility assessment of whether a VDT reproductive study could be conducted and what populations are appropriate for the study.

May 1984: NIOSH contacts the telecommunications industry, including AT&T, BellSouth, and others, indicating its intent to conduct a study and asking for demographic information about their VDT workers.

September 1985: NIOSH finishes plans for the study and requests OMB clearance to begin.

November 1985: BellSouth urges OMB to disapprove the study, claiming that the proposed plans are deficient.

December 1985: OMB disapproves the study on the same grounds urged by BellSouth. At the suggestion of OMB, a meeting is held between BellSouth and NIOSH staff to discuss BellSouth's concerns with the protocol.

January - May 1986: NIOSH revises certain aspects of the study in response to BellSouth's concerns; revised protocol goes through agency clearance procedures.

May 1986: NIOSH sends revised protocol to OMB for approval.

June 1986: OMB approves the study conditioned upon NIOSH removing from the questionnaire questions on lifestyle practices, such as use of contraceptives, workplace and personal stress, smoking practices and alcohol use. Although NIOSH takes the position that it must be able to ask workers these questions in order to obtain reliable information as to whether there is a causal link between VDT use and adverse reproductive effects, OMB, repeating the complaints of the telecommunications industry, states that these questions are irrelevant to the study and therefore have no "practical utility" and will add unnecessary costs to the study. Despite the strong objections of NIOSH scientists, and having no other recourse other than foregoing the study altogether, NIOSH agrees to revise the protocol.

July 1987: NIOSH finally begins the data collection for the study. The reason it takes a full year after the protocol was approved for data collection to begin is that OMB would not authorize NIOSH to go into the workplace to gather employee personnel records during the time that OMB had disapproved the protocol. Therefore, NIOSH had to wait until after the revisions demanded by OMB were made before it could even begin collecting the basic employee data needed for the study. (Typically, the data collection and protocol approval process are conducted simultaneously.)

June 1988: NIOSH completes the data collection for the study; final completion date is projected as spring, 1989.

AIR BAGS AND AUTOMATIC SAFETY BELTS

ISSUE

Tens of thousands of vehicle occupants are killed and injured each year in auto crashes, yet thousands could be spared by air bags and automatic belts (as required by federal safety standard 208). A few auto companies sold these safety systems beginning in 1974, but the industry continually fought to delay the standard.

Significance

Between 6,000 and 9,000 lives per year -- up to 20 percent of the 46,400 killed annually in highway crashes -- could be saved by standard 208, according to National Highway Traffic Safety Administration (NHTSA) estimates. In addition, 150,000 serious injuries could be prevented. These systems protect occupants in front and front angular crashes, the type that kills and injures about one-half of all vehicle occupants. An economic analysis prepared for the insurance industry found the cost to society for every year of delay of the standard was $2.4 billion.

Task Force Interference

General Motors wrote Jim Tozzi of OMB on January 29, 1981, "GM urges that the passive restraint requirements be eliminated...There is an immediate need to avoid the sharp economic impediment that these requirements...would place on the domestic car market's recovery."

The passive restraint standard, scheduled to become effective in October 1981, was postponed for one year on April 9 and revoked completely on October 29, 1981.

In concert with the auto industry, the Bush Task Force prepared an April 1981 program of "Actions to Help the U.S. Auto Industry," listing 34 safety and environmental standards or proposed standards for elimination or delay. The purpose of the program is to reduce "substantially the cost of producing a new car or truck," to "stimulate sales," to free up "capital needed for essential investments in new plant and equipment," and to improve "U.S. manufacturers' international competitive position." Automatic restraints were at the top of the list scheduled for recision to help the auto industry economically, a rationale not contemplated by the 1966 auto safety law.

Impact on Consumers

At least 40,000 deaths and one million injuries can be traced to the delay and cancellation of the passive restraint requirements. The cost to society is over $17 billion, based on past and future model cars manufactured without these vital safety features.

Final Outcome

Insurance and consumer groups challenged the revocation of the standard in court, resulting in a 9 to 0 decision by the U.S. Supreme Court in June 1983, ordering DOT to either better justify its arbitrary action or reissue the standard. The court noted that, "For nearly a decade, the automobile industry waged the regulatory equivalent of war against the airbag and lost -- the inflatable restraint was proven sufficiently effective."

Standard 208 was reissued in July 1984, to be fully effective in 1990 models (a six year delay). In response to subsequent industry petitions, the passenger side is delayed until 1993 models (a nine year delay.) The Administration tried further to undermine the standard by permitting it to be cancelled again if two-thirds of the public is covered by mandatory seatbelt use laws, but this effort failed after vigorous lobbying in state legislatures by insurance and consumer groups to enact use laws that prevent cancellation of the standard.

In 1990, as many as 50% of new cars could comply with the standard by installation of air bags (combined with shoulder/lap belts). The Administration claimed in the 1981 revocation that only 1% of the cars would contain air bags to meet the standard. By June 1988 Ford and Chrysler were advertising air bags in addition to Mercedes. Also, State Farm, Allstate, USAA and other insurers were offering premium discounts for automatic restraint equipped cars.

CHRONOLOGY

July 1969: NHTSA issues advance notice of rulemaking proposing to require installation of inflatable occupant restraints in 1972 models. The proposal is based on work by auto supplier Eaton, Yale and Town with Ford and other manufacturers.

May 1970: NHTSA issues proposed rule for 1973 models. In June, GM promises to install air bags on one million 1974 models.

November 1970: NHTSA issues inflatable restraint standard 208 for 1974 cars, vans and light trucks. Ford petitions for delay and substitute of seat belt ignition interlock system.

April 1971: Manufacturers (except GM) sue DOT; Henry Ford II and Lee Iacocca of Ford meet President Nixon to urge substitution of seat belt interlock.

October 1971: DOT, on instruction of White House staff, delays air bag standard until 1977 models and allows ignition interlock belts as an interim alternative.

December 1972: U.S. Court of Appeals orders revision of dummy test device but upholds NHTSA authority to require new technology such as air bags for safety standards.

August 1973: GM commences production of air-bag equipped cars but says it will make only 150,000 such models in 1974.

October 1974: Congress revokes ignition interlock requirement.

May 1976: GM states it is reconsidering its decision to eliminate air bags as optional equipment, but then stops manufacture.

March 1977: New Secretary of Transportation Adams proposes new automatic restraint standard (air bags or automatic belts) for 1981 models.

July 1977: Adams issues standard to phase-in over three years, beginning with large 1982 model cars, with all 1984 models to comply.

October 1977: Congress rejects resolutions to veto the automatic restraint standard.

December 1978: Auto companies hint they will use automatic belts, not air bags, in most cars to meet the standard, and several air bag manufacturers drop out of the business.

February 1979: U.S. Court of Appeals again upholds standard 208.

March 1980: Mercedes-Benz announces it will equip 1982 models with air bags on the driver side.

June 1980: GM cancels plans for optional air bags in 1982 models.

April 1981: The Bush Task Force and NHTSA delay automatic restraints for one year, just as it is to begin taking effect.

October 1981: NHTSA rescinds the entire standard for automatic restraints.

June 1982: U.S. Court of Appeals finds recission arbitrary and capricious.

June 1983: U.S. Supreme Court agrees and sends the standard back to NHTSA for reissuance or justification.

July 1984: NHTSA reissues the automatic restraint standard but permits it to be rescinded again if two-thirds of the population is covered with belt use laws meeting certain criteria by April 1989 (referred to as the "trap door").

September 1986: U.S. Court of Appeals holds insurance/consumer challenge to revised "trap door" standard is moot, but suggests state belt use laws do not meet NHTSA criteria for recission of the standard in 1989.

March 1987: NHTSA delays passenger side air bags until 1993 models.

BUMPERS

ISSUE

Motor vehicles are involved in millions of low-speed collisions every year that cause billions of dollars of damages. Until they were rolled back to 2 1/2 mph in 1982, Federal vehicle standards required that cars be equipped with bumpers that prevent all damage to any exterior part of the car and the bumper itself in collisions up to 5 mph into a wall or 10 mph into another car.

Significance

Since 1982, with bumpers required to protect only up to 2.5 mph, cars that previously would have had no damage in minor 5 mph accidents now suffer hundreds and as much as a thousand dollars in damages. Now cars also are more likely to be involved in accidents due to damage of safety equipment such as lights, latches and fuel systems. The 5 mph no-damage bumper standard was the most popular Federal vehicle safety standard ever issued, with over 90% of the American public strongly supporting the standard because it not only saved their cars from serious damage, but also it saved them from the tremendous inconvenience and cost of filing accident reports, getting repair estimates, being without their cars during repairs, and paying for repairs not covered by insurance.

Task Force Interference

On April 6, 1981, the Task Force announced that the NHTSA would relax the agency's 5 mph bumper standard following a January 28, 1981 General Motors letter to Jim Tozzi of OMB, stating that if the bumper standard were cut 2.5 mph, "GM car bumpers would realize an initial cost savings of $50 per unit." On April 9, NHTSA issued a notice of intent to relax the standard, citing the Task Force. NHTSA issued a notice of proposed rulemaking for a 2 1/2 mph bumper on October 1, 1981 to accomplish the Task Force's recommendation and relaxed the rule effective July 1, 1982.

Impact on Health and Safety

This standard saved consumer dollars as well as improving safety. During its 10-year useful life, the average car will have three low-speed collisions up to 5 mph that will cause $425 in damage. For the entire passenger car fleet, total damages in low-speed accidents are over $4 billion, which could be largely avoided if cars had 5 mph bumpers. Taking into account bumper costs, insurance saving, and accident costs, net savings to consumers for 5 mph no-damage bumpers over minimal 2.5 mph bumpers are more than $400 million annually. Cars without 5 mph bumpers have more damage to safety equipment such as lights, latches and fuel systems.

Final Outcome

Despite a legal challenge by insurance companies and consumer groups, the U.S. Court of Appeals for the District of Columbia upheld the rollback on January 8, 1985. Although NHTSA promised lower sticker prices and better gas mileage from cheaper and lighter 2.5 mph bumpers, the benefits never materialized and consumers still got stuck with high repair bills for low-speed accidents. Prior to the 1982 rollback, *Consumer Reports* stopped testing bumpers in 5 mph crashes because no cars suffered any damage. In 1986, *Consumer Reports* found the majority of cars it tested suffered from $146 to $1081 in damage in 5 mph crashes.

CHRONOLOGY

1967: NHTSA issues an advance notice of proposed rulemaking to require car bumpers that protect against damage to safety components in low-speed crashes.

1970: Florida is the first state to pass a bumper law. It prohibits damage in 10 mph barrier crashes for cars made after January 1, 1973.

1970: NHTSA issues a notice of proposed rulemaking to require passenger car bumpers that protect in 5 mph crashes. NHTSA standard would preempt various state laws being passed.

1971: NHTSA issues a rule on April 16, 1971 prohibiting any damage to safety-related equipment including lights, trunk and hood latches, and fuel systems in collisions up to 5 mph.

1972: Concerned about expensive accident repairs, Congess passes the Motor Vehicle Information and Cost Savings Act of 1972 "to reduce the economic loss resulting from damage to passenger motor vehicles involved in motor vehicle accidents."

1973: NHTSA issues notice of proposed rulemaking under the Cost Savings Act to require bumpers that protect against any damage of all components of a vehicle in 5 mph crashes.

1976: NHTSA issues standards prohibiting any damage whatsoever to any exterior part of a car (1979 models) and to the bumper itself (1980 models) in 5 mph front and rear impacts into a wall and 3 mph corner impacts.

1978: NHTSA refuses to relax the bumper standard in response to manufacturer petitions.

1979: At the request of Senator Robert Byrd (W.Va.), NHTSA reevaluates no-damage 5 mph bumpers and finds them cost-effective in saving consumers $400 millon annually.

1981: On October 1, in response to the Task Force, NHTSA proposes relaxing the 5 mph no-damage bumper standard to 2 1/2 mph.

1982: NHTSA issues a new bumper standard requiring only 2 1/2 mph protection in collisions.

PEDESTRIAN SAFETY

ISSUE

Thousands of pedestrians are killed and injured every year on urban streets at relatively low impact speeds. Cars can be designed to be forgiving and significantly reduce pedestrian injuries to speeds of 20 mph and below.

Significance

About 7500 pedestrians and cyclists are killed every year and 120,000 are injured. The elderly and youths under age 15 are over-represented in pedestrian casualties, accounting for more than 25 percent of the fatalities and 40 percent of the injuries. Pedestrians have a much higher probability of being injured than do occupants. Pedestrians are involved in 2 percent of highway crashes but account for 16-18 percent of fatalities. Ninety percent of pedestrian crash victims require medical treatment compared to 18 percent of other crash-involved road users.

A notice of proposed rulemaking in 1967 prohibiting decorative protrusions caused manufacturers to vigorously object, but persuaded them to discontinue use of rigid hood ornaments which are lethal to pedestrians. In January 1981, after years of research, NHTSA proposed a pedestrian safety standard to reduce lower-leg adult injuries as well as child head injuries.

Task Force Interference

In its April 6, 1981, report on "Actions to Help the U.S. Auto Industry," the Task Force listed as an item for further study the review of comments on NHTSA's January 1981 proposal. In GM's February 9, 1981, letter to David Stockman, director of OMB, the automaker stated that the proposed standard "will probably require costly redesign of bumpers with questionable real safety benefit."

NHTSA has taken no rulemaking action on pedestrian safety since 1981. In the regulatory calendar it lists possible publication of a proposed rule in July 1991 "if appropriate, based on results of injury benefits observed in research tests." New research is necessary in part according to NHTSA because the injury criteria proposed in the 1981 notice are "no longer appropriate for use with the new, lower profile front ends becoming the norm in the passenger fleet."

Impact on Consumers

NHTSA research shows that many hundreds of fatalities and thousands of serious pedestrian injuries could be prevented each year, particularly in crashes of 20 mph and below. Research also shows that 85 percent of pedestrian crashes and 60 percent of pedestrian fatalities occur on urban streets at relatively low impact speeds (70 percent of pedestrian crashes have pre-impact braking). Research shows that it is very feasible to make cars much more forgiving with softer front ends, lowered underhood components, reduced stiffness in hoods and frontal structures, elimination of frontal protrusions and a lower impact surface below the bumper. This has been shown to be feasible by NHTSA Research Safety Vehicles and in some existing production models. The cost is small if these features are performance requirements for new production models.

The ultimate delay in final issuance of a pedestrian safety standard will be ten or more years, during which thousands of pedestrians will be unnecessarily injured.

Final Outcome

NHTSA continues to conduct analyses and research at a leisurely pace with little anticipation of any near term action on issuance of a safety standard.

CHRONOLOGY

October 14, 1967: NHTSA issues an advance notice of proposed rulemaking on exterior protrusions for all types of vehicles.

December 28, 1967: NHTSA issues a notice of proposed rulemaking prohibiting decorative or identifying protrusions. Major objections were voiced by manufacturers but they voluntarily discontinued use of rigid hood ornaments.

December 1969: A new notice of proposed rulemaking is developed but is never issued.

1973-1979: NHTSA research program establishes that pedestrian injury reduction is feasible with softer, energy-absorbing materials, and a compliance test device, methodology and injury criteria are developed.

January 22, 1981: NHTSA issues a proposed pedestrian standard for adult lower leg and child head protection.

1981-1988: No further rulemaking action occurs but further research is initiated and continued on pedestrian safety.

MAXIMUM SPEEDOMETER DISPLAY

ISSUE

An upper limit on speedometers of 85 mph as required by Federal vehicle safety standard 127 increases safety because it reduces "the temptation of immature drivers to test the top speed of their vehicles on public roads" and increases the readability of speedometers. The standard is simple to implement.

Significance

Nearly half (20,000 in 1987) of all fatalities occur on roads with speeds posted above 54 mph. Speed kills, and a disproportionate number of the victims are males under 25 years old, who are killed almost twice as frequently on the highway as any other population segment. The 85 mph display limit was aimed in large part at younger drivers likely to be influenced in their driving habits by cars with 120-140 mph speedometers.

Task Force Interference

In its April 6, 1981 report, "Actions to Help the U.S. Auto Industry," the Presidential Task Force on Regulatory Relief promises it "will give high priority to relief for the auto industry." The report supports elimination of the speedometer standard since "there appear to be no direct safety benefits to be gained from the regulation and... potential for significant consumer savings."

On May 7, 1981, the National Highway Traffic Safety Administration (NHTSA) suspended standard 127 for one year, and followed this action on October 22, 1981 with a proposal for permanent rescision. In its December 1981 Final Regulatory Evaluation, the agency stated that "in 1976, NHTSA estimated that the annual safety benefits from the speedometer provision would be a reduction of 175 fatal and 1900 injury accidents," mostly involving drivers under age 25. NHTSA said it could not "confirm" these numbers, thus opening the door for rescision of the standard under a strict cost/benefit test, even though the standard makes sense, was already implemented by industry, and some cost would be incurred to change the speedometer design.

Impact on Consumers

In its decision to rescind standard 127, Transportation officials dismissed the concerns for safety voiced by, among others, the Center for Auto Safety and Subaru. "Their objection[s] did not take into consideration the manufacturers' intent to continue equipping most vehicles with the same speedometers," explained the NHTSA in its Final Regulatory Evaluation of 1981. Implicit in the agency's reasoning was a prediction that the 85 mph limit would be rescinded in name only, since manufacturers would not alter speedometers. Despite these claims, many speedometers have been altered since 1981, often showing speeds of 120-140 mph.

Final Outcome

The rescision has remained in effect since the final rule was published on February 18, 1982. Many cars again have speedometers showing 120 to 140 mph, and manufacturers have revived the horsepower race with production of muscle cars and ads emphasizing speed.

CHRONOLOGY

February 22, 1974: NHTSA publishes a reuqest for comments on the question whether "there should be a rule concerning maximum speedometer indication and, if so, the most appropriate maximum indication," taking into account the current lower speed limits, the corresponding highway fatality reduction, driver convenience and the expected effectiveness of the rule.

Dec. 13, 1976: The NHTSA proposes a new safety standard 127 which would require that vehicles be equipped with speed and distance indicators, and that the speed indicator scale be limited to 85 mph. Two of the large four U.S. manufacturers said they intended to do this voluntarily.

March 16, 1978: Standard 127 is issued in final form.

May 7, 1981: NHTSA delays implementation of standard 127 for one year.

Oct. 22, 1981: Recission of standard 127 is proposed because the "rule is unlikely to yield significant safety benefits."

Feb. 18, 1982: Standard 127 is revoked, but to assist General Motors and Renault, who questioned whether recision would open the door for state regulation of speedometers, NHTSA claims that the states are preempted from regulating in this area even though the federal standard is revoked. This is contrary to the federal statute which requires preemption by a federal standard, but permits states to regulate in the absence of a federal standard. The NHTSA statement has no force or effect.

MOTOR VEHICLE FUEL ECONOMY STANDARDS (CAFE)

ISSUE

Relaxation of the statutory 27.5 mpg gas mileage standard increases gasoline consumption and air pollution, worsens the greenhouse effect, increases dependence on foreign oil, and exports small car production and American jobs abroad.

Significance

The motor vehicle fuel economy standards mandated in the 1975 Energy Policy and Conservation Act are the most significant energy conservation program in this country. According to the Department of Energy (DOE), the 1987 vehicle fleet consumed 2.35 million barrels per day less gasoline than it would have if the fleet had had the same fuel economy as in 1975 when the law was passed. Despite this energy saving, the U.S. is more dependent on imported oil now than in 1975.

Task Force Interference

On April 6, 1981, the Task Force announced that NHTSA would terminate its rulemaking to increase the 27.5 mpg CAFE standard for 1986 and later model years. Just three days later, NHTSA issued a notice of intent to this effect citing the Task Force and then ceased the rulemaking on April 16. In response to petitions from Ford and General Motors, NHTSA reduced CAFE standards for 1986-1988 to 26.0 mpg and 26.5 mpg for 1989 and has proposed 26.5 mpg for 1990. All the relaxations relied on analyses conducted under Executive Order 12291, which is administered by the OMB.

The Task Force also promised in April 1981 that NHTSA would substantially reduce the semi-annual reporting "of extremely complicated data on manufacturers' progress in meeting interim fuel economy standards leading to the statutory 1985 goal." The rationale used was that all manufacturers are now substantially exceeding such interim goals, making monitoring "unnecessary." Shortly thereafter the fuel economy reporting requirements were reduced. Predictably, within three years the large U.S. manufacturers were exceeding the standard, resulting in the agency and consumers having little information on which to base regulatory judgments.

Impact on Consumers

The original CAFE rulemaking killed by the Task Force would have raised gas mileage standards to at least 40.5 mpg by 1990 instead of the 26.5 mpg under the Task Force-caused relaxation. As a result of the Task Force's action, gasoline consumption from passenger cars alone will be 400,000 barrels per day, or 5.5 billion barrels more in 1990 than if NHTSA's rulemaking had not been rescinded. Consumption of this much additional gasoline results in 54 million more tons of carbon dioxide (CO_2) being emitted into the atmosphere, increasing the warming of the earth due to the insulating greenhouse effect of CO_2. Air pollution has also worsened due to the relaxation of CAFE standards. The increased gasoline use will result in 1990 in an additional 70,000 tons of reactive hydrocarbons nationally per year, with 1,000 tons in cities such as New York and San Francisco.

Before the Task Force began to relax CAFE standards, GM and Ford imported no small cars, because they needed to manufacture as many small cars as possible in the U.S. to meet the 27.5 mpg CAFE. In 1988, with the lower standards, they imported well over 500,000 small cars at a cost of 175,000 American jobs.

Final Outcome

The proposed increase to 40.5 mpg for CAFE by 1990 was rescinded; the 27.5 mpg CAFE standard was relaxed to 26.0 for 1986-1988 and 26.5 for 1989, with a relaxation to 26.5 pending for 1990.

CHRONOLOGY

1973-1974: Arab oil embargo leads to intense national debate on what to do about U.S. dependence on foreign oil.

1975: Congress passes the Energy Policy and Conservation Act with a mandatory fuel economy program to reduce U.S. vulnerability to foreign events by improving vehicle fuel efficiency by 100% over the 1974 level of 14 mpg to 27.5 mpg by 1985. Congress rejects a Ford Administration proposal to rely on market forces and voluntary efforts of auto makers to improve fuel efficiency.

1977: NHTSA issues a stepped-up CAFE schedule for 1981-1984 models.

1978: First CAFE standards of 18.0 mpg take effect.

1979: Ford and GM press NHTSA to relax standards, but after a major study NHTSA rejects their requests.

January 1981: NHTSA proposes increasing post-1985 CAFE standard to 40.5 mpg by 1990.

April 1981: Task Force announces decision to terminate rulemaking to increase post-1985 CAFE standards.

March 1985: NHTSA grants GM and Ford petitions to start rulemaking to reduce 1986 and later CAFE standards.

October 1985: NHTSA reduces 1986 CAFE standard from 27.5 to 26.0 mpg, even though Ford and GM cars exceed this standard; credits earned by exceeding standards can be used to offset penalties due from not meeting earlier standards.

January 1986: NHTSA initiates rulemaking to reduce 1987-1988 CAFE standards.

October 1986: Once again, NHTSA reduces the 27.5 mpg CAFE standard to 26.0 for 1987-1988.

August 1988: NHTSA initiates rulemaking to reduce 1989-1990 CAFE standards.

October 1988: Yet again, NHTSA reduces CAFE standards, from 27.5 mpg to 26.5 mpg for 1989 even though 1989 models are already rolling off production lines, and states that a decision on 1990 standards is to be made shortly.

TIRE QUALITY GRADING

ISSUE

Grading of tires for quality to assist consumers make an informed choice in purchasing tires is required by the 1966 auto safety statute.

Significance

There are wide variations among tires in terms of traction, treadwear, and heat resistance, but the manufacturers will not reveal this information unless required to by federal law because they believe they sell more tires based on brand name than with factual information about tire performance.

Task Force Interference

On April 6, 1981, in its report, "Actions to Help the U.S. Auto Industry," the Task Force states, "NHTSA is conducting an evaluation to determine whether meaningful consumer information is provided by this complicated grading system," and said a "substantial simplification" would be proposed.

In its February 9, 1981 letter to David Stockman, General Motors stated, "Although General Motors could possibly take steps to avoid the impact of the regulations advanced by this proposed rule, it objects in principle. It could impose an administrative burden on tire and auto manufacturers with little or no benefit to the consumer."

In its April report the Task Force admits the grading standard could be abused "by deliberate under-grading of tires [by manufacturers] to promote marketing of other models," but rather than tighten up the standards, it suggests simplification to enhance relevance, and to reduce testing costs, as well as "significant reporting and paperwork burdens."

On July 12, 1982 NHTSA proposed "suspension" of the treadwear grading requirement "to avoid dissemination of potentially misleading tire grading information to consumers, but also to minimize the imposition of unwarranted compliance costs on industry and consumers." In early 1981 NHTSA had stated that the treadwear characteristic appeared to be the most meaningful.

On February 7, 1983 NHTSA formally "suspended" the treadwear grading requirement.

Impact on Consumers

Tire quality is a critical issue for highway safety, as the Firestone 500 defect case revealed in 1978. At least 41 people were killed and 65 were seriously injured because the treadwear defectively separated from the tire. While precise savings cannot be assigned to grading requirements, they are designed to assist consumers to buy better and safer tires, an impossible task without independent grading standards.

Final Outcome

On August 17, 1983 Public Citizen petitioned the Court of Appeals to find NHTSA acted improperly, because "suspension" eliminated the most important part of the standard and because it ignored simple ways to improve test methods for less variability. On April 24, 1984 the D.C. Circuit Court of Appeals overruled the suspension as arbitrary, and concluded, "It is hard to imagine a more sorry performance of a Congressional mandate..."

On September 27, 1984 the Court found NHTSA in violation of its April mandate and ordered it to reinstate the treadwear requirements "forthwith." NHTSA finally issued a final rule for implementation on December 19, 1984 with the rule effective on various dates in 1985. NHTSA is still considering changes in test procedures to ensure that tire grades provide consumers with more accurate information, but has yet to make any proposal. The government's 1988 regulatory calendar lists December as the target date for proposal issuance.

CHRONOLOGY

September 1966: Enactment of the National Traffic and Motor Vehicle Safety Act of 1966 (signed into law by President Lyndon Johnson). Section 203 reads: "In order to assist the consumer to make an informed choice in the purchase of motor vehicle tires, within two years after enactment....the Secretary *shall* publish....a uniform quality grading system for motor vehicle tires." The committee report found a direct relationship to safety.

May 1968: NHTSA announces it is considering rulemaking on tire quality grading.

1971: NHTSA proposes and then withdraws grading standard for traction and treadwear.

March 1973: NHTSA published a revised proposal with traction and treadwear. NHTSA found on the basis of public comments that "consumers are most interested in evalutions of tread life, traction and high speed performance."

1974: The grading standard is published in final form in January, then revoked in May. Public Citizen sues NHTSA to require issuance of tire grading system standard, after which NHTSA proposes a revised grading system in compliance with the court order.

1975: In January, NHTSA publishes another proposal for tire quality grading. In May, the D.C. Circuit Court of Appeals in the Public Citizen case requires issuance of the standard, and NHTSA reinstates the grading system. B.F. Goodrich and other tire companies sue to overturn the standard.

1976: Court of Appeals for 6th Circuit upholds the standard with minor exceptions.

February 1977: Pursuant to court order NHTSA sets effective dates for bias ply and bias belted tires. It excludes radials because of a newly discovered problem.

1978: NHTSA revises and reissues regulations excluding radial tires from treadware requirements temporarily. Again, B.F. Goodrich and other tire companies challenge the revised standard. But the 6th Circuit Court of Appeals upholds the validity of the tire quality grading standard and rejects industry arguments.

February 1981: Letter from General Motors to David Stockman conveys industry objections to the standard.

April 1981: Task Force report on "Actions to Help the U.S. Auto Industry" states a revision of the grading system will be proposed.

July 1982: NHTSA proposes "suspension" of treadwear grading requirement.

August 1983: Public Citizen sues NHTSA for improperly suspending the grading requirement.

April 1984: D.C. Circuit Court of Appeals overrules the suspension as arbitrary and capricious.

September 1984: The Court found NHTSA in violation of its April mandate for its "dilatory schedule."

December 1984: NHTSA issues final rule to be effective between April and September 1985.

LEAD IN GASOLINE

ISSUE

Lead is extremely toxic to small children. It can have a devastating effect on the central nervous system, causing learning and emotional disabilities at low levels, and resulting in death at higher levels. Lead in gasoline is responsible for 90 percent of the lead in air. In addition, lead particles fall from the atmosphere and cling to dirt and grass. Lead is not a necessary ingredient in gasoline, and cannot be used in cars with catalytic converters.

Significance

In the mid-70's, the EPA undertook a regulatory program to reduce the amount of lead in gasoline by setting a limit on the amount of permissible lead in gasoline through a phasedown schedule. The phasedown for large refiners was put into effect immediately. The phasedown for small refiners — including those that refine up to 50,000 barrels of gasoline a day -- was to become effective in October 1982.

The EPA's program was clearly working: between 1976 and 1980, the amount of lead in gasoline was cut in half. At the same time, lead levels in the bloodstreams of children, measured across the country, were reduced by over a third. There was no question that the EPA's phasedown program was responsible for this dramatic reduction.

Task Force Interference

After being asked by refiners to eliminate the program to reduce lead, on the ground that it was too costly, George Bush announced in August 1981 that the regulations would be reconsidered. He called for "quick relief" for small refiners and possibly "relaxing or rescinding the entire lead phasedown rule." OMB officials then exerted "tremendous pressure" on the EPA to abolish the regulations and to increase the amount of lead small refiners could use in gasoline. Anne Gorsuch verbally granted a waiver from existing requirements to a small refiner, Thriftway, and in February 1982 proposed an indefinite suspension for all small refiners and possible repeal for large refiners.

Impact on Health and Safety

Lead is a major health hazard especially to children living in inner cities. According to one expert, the amount of lead in just one gallon of leaded gasoline -- 0.5 grams -- would be enough to kill a child if it were ingested. It is undisputed that the lead levels in childrens' bloodstreams were drastically reduced as a result of the EPA's lead phasedown regulations during 1976 - 80. Therefore, if the Task Force had been successful in eliminating the phasedown, the lead levels in children would have increased, and hundreds of thousands of children would have suffered serious health effects, including damage to their nervous systems. An unknown number of those children would have died from the lead exposure.

Final Outcome

As a result of tremendous pressure from Congress, the press, and the general public, OMB reversed itself in October 1982 and allowed the EPA to go forward with the lead phasedown. In August 1983, in a reversal, the Bush Task Force took credit for "accelerating the removal of lead from gasoline."

CHRONOLOGY

1976-1980: EPA's program to reduce lead in gasoline is successful: the amount of lead used in gasoline is cut in half. At the same time, levels of lead in the bloodstreams of children, measured across the country, are reduced by over a third.

May 1981 - March 1982: In response to George Bush's solicitation to industry of lists of regulations that should be revised, gas refiners ask for relief from the lead phasedown regulations. Subsequently, officials at EPA and OMB hold 46 private meetings with large and small gasoline refiners.

August 11, 1981: George Bush announces that the Task Force has ordered review of EPA's lead-in-gasoline regulations, calling for"quick relief" for small refiners and possibly "relaxing or rescinding the entire lead phasedown rule." (The regulations had specified two phasedown schedules: one for large refiners, which had already passed, and second for small refiners, which was to take effect on October 1, 1982.)

December 11, 1981: EPA Administrator Anne Gorsuch meets with officials from Thriftway, a small refiner in New Mexico seeking an exemption from the phasedown regulation. According to later sworn testimony from a lawyer for Thriftway before a Congressional Committee, Gorsuch verbally grants the waiver, reasoning that "EPA's phasedown regulations would probably be revised or perhaps even abolished during the course of upcoming rule making, in accordance with Vice President Bush's expressed intentions."

Fall-Winter 1981: According to later Congressional testimony from John Daniels, Anne Gorsuch's chief of staff, OMB officials placed "tremendous pressure" on the EPA to abolish the lead phasedown, allowing small refiners to increase the amount of lead in the gasoline they produce.

February 1982: Bowing to OMB pressure, EPA formally announces in a Federal Register notice a proposed indefinite suspension of the deadline for small refiners and consideration of relaxing or repealing the lead rule for large oil refiners as well.

April 1982: In a memo to the White House, Gorsuch admits that "there is strong medical evidence that lead in gasoline is an important contributor to lead levels in children, and that changes in gasoline lead levels may increase the number of children who have unsafe blood lead levels."

August, 1982: A Bush Task Force report states that the lead regulations are targeted for revision because they "create costly inefficiencies in gasoline refining markets."

August 3, 1982: Gorsuch reports to the White House that under the proposed revisions to the regulations, small refiners will be permitted to have a "higher lead level in their gasoline and as a result will not have to incur costs for the equipment which raises octane levels without lead."

October, 1982: After a tremendous public and Congressional outcry, the Administration announces a new lead phasedown regulation one week before the mid-term Congressional elections. Under the regulations, the permissible lead level is increased from 0.5 grams to 1.1 grams, but averaging of lead and unleaded gasoline to satisfy the restriction is no longer allowed.

ASBESTOS

ISSUE

Asbestos is a proven human carcinogen that causes lung cancer, mesothelioma (a cancer of the chest and abdominal lining), asbestosis (a serious lung disease), and other diseases. There is no recognized safe threshold level of exposure, and the substance is used in hundreds of consumer products. It is also a serious hazard in occupational settings such as mining, fiber processing, and asbestos installation. As the EPA itself told a Congressional Committee in 1984, exposure can be greatly reduced by eliminating many asbestos products and replacing them with readily available, competively-priced substitutes.

Significance

Asbestos fibers are released during the manufacture, processing, use, and disposal of asbestos products. They are colorless, odorless, often invisible, and indestructible, and can be carried on clothes and other materials and are also transported through the air. Persons are exposed not only at the time and place of release of asbestos fibers, but long after the release has occurred and far from the initial exposure site. In 1984 alone, about 240,000 metric tons of asbestos were used in this country.

In 1976 Congress enacted the Toxic Substances Control Act (TSCA) to give the Environmental Protection Agency (EPA) the authority to ban toxic substances that are found in products or environments typically regulated by other agencies, such as the Consumer Product Safety Commission (CPSC) and the Occupational Safety and Health Administration (OSHA), where the EPA determines that regulation by such agencies cannot prevent or reduce the chemical risk to a sufficient extent. One of the principal substances that Congress targeted for control was asbestos.

Task Force Interference

Since 1984, at the request of the industries that make and use asbestos products, OMB has delayed EPA's issuance of a rule that would phase out the use of asbestos products. In concluding that the benefits of EPA's asbestos rule did not outweigh its costs OMB decided that a life lost to cancer is worth only $208,000 -- a calculation that one Congressional Committee found "morally repugnant."

Impact on Health and Safety

According to the EPA, between 3,300 to 12,000 cancer cases occur each year in the United States as a result of past exposure to asbestos; almost all of these cancer cases are fatal. In addition, tens of thousands of people suffer from asbestosis, and other asbestos caused illnesses. Therefore, because of the delay caused by OMB's interference with EPA's issuance of an asbestos rule, millions of Americans were unnecessarily exposed to asbestos, and an unknown number of those people will die from lung cancer, mesotheliomas, other asbestos-related cancers, and asbestosis. In addition, an untold number of the exposed population will suffer from severe respiratory illnesses.

Final Outcome

In January 1986, the EPA finally issued a proposed asbestos rule, but a final rule has not yet been submitted to OMB for its approval.

CHRONOLOGY

1976: Congress enacts the Toxic Substances Control Act, authorizing EPA to ban toxic substances, including asbestos, when regulation by other agencies is inadequate to protect the public.

1979: EPA proposes issuing a series of rules to prohibit the manufacture, processing, and use of certain asbestos-containing products, and to limit the annual amount of asbestos produced and imported in the United States.

1981 - 1983: During the tenure of EPA Administrator Anne Gorsuch, the EPA's progress on the asbestos rule falters while the agency pursues "voluntary" action from representatives of the affected industries.

1983 - 1984: Several EPA officials conclude that the regulatory authority of OSHA and the Consumer Product Safety Commission is inadequate to protect workers, consumers, and the general public from the risks of asbestos-caused cancer and other diseases.

May - August 1984: EPA proposes regulation prohibiting the manufacture, processing, and selling of asbestos in cement piping and fittings, roofing and flooring felts, and floor tile. The agency concludes that these products expose the public to a known human carcinogen, they represent a significant proportion of all asbestos consumed in the U.S., and they can be replaced by readily available, competively-priced substitutes.

In addition, EPA issues a proposal to phase down remaining asbestos production and importation over a ten-year period, and to ban the manufacture, importation, processing, and sale of asbestos clothing.

May 1984 - October 1985: OMB has numerous secret contacts with industry representatives opposed to EPA's asbestos rules.

August - October 1984: OMB refuses to approve EPA's decision to issue the absestos regulations, and takes the position that the benefits do not exceed the costs. In calculating the benefits, OMB assigns a million dollar value to every life saved, but "discounts" this amount on the theory that since death from asbestos-caused cancer occurs long after the initial exposure to asbestos, each life saved is only worth a fraction of its present worth. Under OMB's calculations, avoidance of a cancer death 40 years in the future is presently worth approximately $208,000.

February 1985: EPA announces that it has decided to drop its regulation of asbestos and to refer the matter to OSHA and CPSC. A House of Representatives Congressional Oversight Committee initiates a formal investigation.

March 1985: In the face of the Congressional investigation, the EPA announces its intention to reconsider its decision, and the EPA's General Counsel subsequently concludes that EPA may go forward with an asbestos rule without deferring to OSHA and CPSC.

In response, OMB official Robert Bedell sends a letter to EPA officials directing them to refer the asbestos matter to OSHA and CPSC.

October 1985: The House Oversight Committee concludes that OMB has unlawfully interfered with the asbestos rule and that its "concept of discounting human life is morally repugnant."

January 1986: EPA issues a proposed rule to prohibit the manufacture, importation, and processing of asbestos in certain products and to phase out the use of asbestos in all other products over ten years.

September 1988: EPA's proposed asbestos regulation is still pending and a final rule must still be approved by OMB.

DUMPING TOXIC CHEMICALS IN SEWERS

ISSUE

One of the single largest sources of pollution in our rivers, lakes and harbors are toxic industrial chemicals dumped into sewers by factories across the country. Since few municipal waste water treatment plants have the capacity to remove these substances, they can ultimately end up in the water we drink.

Significance

Congress passed the Clean Water Act to ensure that industrial factories "pretreat" their waste to remove toxic chemicals before releasing the waste into local sewer systems. The amounts of toxic chemicals that are dumped into the public water system are staggering: in 1982 alone, 56 million pounds of toxic metals and 190 million pounds of toxic inorganics were dumped unto sewers across the country.

Task Force Interference

After receiving from private industry lists of regulations they wanted repealed, Vice President Bush immediately responded by directing the Environmental Protection Agency to suspend certain pretreatment regulations in the spring of 1981, pending "review" by the Task Force. The suspension was eventually declared unlawful by a U.S. Court of Appeals. The Chemical Manufacturers Association -- which strongly opposed the pretreatment regulations -- had been a client of C. Boyden Gray, counsel to both the Vice President and the Task Force.

Impact on Health and Safety

If the Court of Appeals had not ordered the retroactive reinstatement of the pretreatment regulations, millions of pounds of toxic chemicals would have continued to be dumped into the sewage system, including:

- ◊ cadmium, which causes kidney damage and chronic respiratory problems;
- ◊ lead, which damages the nervous system, especially in children;
- ◊ mercury, which causes brain damage and loss of hearing and vision;
- ◊ phenols, which are suspected carcinogens;
- ◊ phthalate esters, which may cause birth defects.

Final Outcome

The EPA was ordered to reinstate the pretreatment regulations in July 1982 by a U.S. Court of Appeals as a result of a lawsuit brought by the Natural Resources Defense Council. As a result, the regulations took effect as originally scheduled.

CHRONOLOGY

1972: Congress passes the Clean Water Act which requires the Administrator of the Environmental Protection Agency (EPA) to promulgate regulations requiring industries to pretreat waste by removing toxic pollutants before discharging the waste in publicly owned treatment works.

1978: EPA publishes general pretreatment regulations, requiring companies to remove toxic chemicals such as lead, mercury, chromium and cadmium from the waste water they dump into municipal sewer systems.

January 1981: EPA issues amendments to its pretreatment regulations and schedules the amendments to go into effect in March 1981. One of the amendments would require special measures to be taken by integrated electroplating facilities, *i.e.*, industries such as the auto industry, that combine highly toxic wastes from metal electroplating operations, including cyanide, cadmium, and lead, with other wastes. Some of the largest integrated electroplating facilities are operated by General Motors and Ford. The special requirements were to be implemented three years from the date the amendments became effective.

March 1981: In response to George Bush's request for lists of regulations that industry wants repealed or relaxed, the Chemical Manufactuers Association, which had previously been a client of C. Boyden Gray -- counsel to the Vice President and the Task Force -- identifies the pretreatment regulations, as does the auto industry. George Bush subsequently announces that the EPA's pretreatment amendments, including those covering integrated electroplating facilities, will be suspended, and the EPA formally announces the indefinite postponement of the amendments "pursuant to Executive Order 12291."

June 1981: The Natural Resources Defense Council brings a lawsuit challenging the indefinite suspension of the pretreatment regulations.

July 1982: The United States Court of Appeals for the Third Circuit rules that the EPA has acted unlawfully in postponing the regulations, and it orders their immediate reinstatement. As a result, the pretreatment requirements for the integrated eloctroplating facilities were permitted to take effect as originally scheduled.

CRUSHED BONE IN MEAT

ISSUE

Since 1976, the meat industry has increased its use of a substance made from crushed bone as an ingredient in processed meat such as hot dogs and bologna. These products are not only inferior in quality to competitive brands that contain more meat, but they also pose health problems for certain segments of the population which must avoid the additional lead and cholesterol that is added to the product with the inclusion of bone.

Significance

The Federal Meat Inspection Act prohibits the sale of any processed meat product "if its labeling is false or misleading in any particular," or if "any inferiority has been concealed in any manner." In 1976, the Department of Agriculture permitted the meat industry to begin using a substance in processed meat that was made from the pulverized bones of animals. That decision was declared unlawful by a federal court on the grounds that the agency had not determined whether the substance was harmful, and because it had not allowed the public an opportunity to comment on the matter.

In 1978, after determining that the substance would be safe if it were limited to 20 percent of the finished meat product, the USDA issued regulations allowing such use, but requiring the meat industry to label those products to disclose to consumers that they contained the substance and particularly to disclose the presence of bone. In 1979, the meat industry petitioned the USDA to delete the labeling requirements, arguing that consumers would not purchase meat products with such "negative labeling." The USDA denied the petition on the ground that the required labeling "provides information necessary for an informed choice."

Task Force Interference

In response to Bush's solicitation of regulations industry would like to see eliminated, the meat industry requested "regulatory relief" from the labeling requirements for processed meats. By July 31, 1981, the USDA -- at the request of the Task Force -- had proposed eliminating the requirement that manufacturers disclose in the labels of processed meat that the product contains a substance made from crushed bone along with a disclosure of the percentage of bone. The regulations became final in June 1982.

Impact on Consumers

As a result of the change in the labeling requirements for processed meat, consumers are unwittingly purchasing products that contain up to 20 percent of a substance made from crushed bone and bone marrow. For most consumers this means that they are paying money for an inferior meat product that they might otherwise not purchase. For some segments of the population, including children, pregnant women, and the elderly, the impact may be more substantial, since the bone added to the product brings with it added lead which the FDA has warned should be avoided by such individuals. In addition, meat products containing the crushed bone substance also have greatly increased levels of cholesterol, which is a particular problem for people who must restrict their cholesterol intake.

Final Outcome

In 1982 several consumer groups sued the USDA over the labeling regulations. In an opinion written by Reagan appointee Judge Antonin Scalia (subsequently appointed as a Justice to the Supreme Court), the U.S. Court of Appeals upheld the regulations, stating that "this is an area in which courts must give great deference to the Secretary's judgment." In September 1988, USDA proposed further weakening the labeling regulations in response to a request from the American Meat Institute.

CHRONOLOGY

April 1976: Earl Butz, Secretary of the Department of Agriculture (USDA) under President Gerald Ford, gives the meat industry permission to include in processed meats a substance made from crushed bone (called "mechanically deboned meat").

September 1976: In response to a lawsuit brought by consumer groups, a federal judge reverses the Secretary's decision on the ground that the agency has not adequately determined whether the substance is safe and because the agency failed to provide the public with an opportunity to comment on the matter.

1976 - 1978: As a result of the court's decision, the USDA does not allow the use of crushed bone in meat products.

1978: Having completed its safety analysis and after conducting an extensive rulemaking proceeding, the USDA issues new regulations. Finding that the name mechanically deboned meat "would be false or misleading to consumers in that the term 'deboned' would incorrectly represent that the product does not contain bone or bone marrow and the term 'meat' would incorrectly represent that the product consists solely of 'meat'," the USDA renames the crushed bone substance "mechanically separated meat product," and limits its use to no more than 20 percent of the meat portion of the product. It also requires that its presence be disclosed in the labels of the product, and that the label also disclose the percentage of bone that is present.

April 1979: The Pacific Coast Meat Association (PCMA) -- a trade association of meat packing and processing companies -- petitions the USDA to amend its regulations on the ground that the "negative labeling" effectively precludes the meat industry from selling certain meat products because consumers will not purchase products that they knew contain "mechanically separated beef product" and "bone."

May 1979: The USDA denies the meat industry's petition, noting that a substantial majority of consumers "were against even allowing the product in commerce," and concluding that "the current label provides information necessary for an informed choice."

February 1981: The PCMA, joined by the American Meat Institute -- a national association of meat packing and processing companies -- submits another petition to USDA, again asserting that the industry is effectively precluded from marketing the crushed bone substance because consumers will not buy meat products labeled in accordance with the labeling requirements.

March 1981: George Bush asks industries to send him lists of regulations that they would like to see repealed or changed.

June 1981: The meat labeling regulations are listed among the regulations being reconsidered at the request of the Task Force on Regulatory Relief.

July 31, 1981: USDA issues final regulations adopting virtually all of the labeling changes requested by industry, including the requirement that the label need not disclose the presence of the crushed bone substance or the percentage of bone on the front of the package. Instead of the bone disclosure, the industry is permitted to state in the nutrient labeling that the product contains added "calcium."

July 30, 1982: A coalition of consumer groups challenge the labeling revisions. In a decision by the U.S. Court of Appeals (authored by Reagan-appointee Judge Antonin Scalia and joined by Judges Robert Bork and Malcolm Wilkey) the regulations are upheld on the ground that "this is an area in which courts must give great deference to the Secretary's judgments."

July 1988: Stating that consumers still will not purchase products containing the crushed bone substance (now called "mechanically separated meat,") the American Meat Institute petitions USDA to change the labeling requirements to eliminate any mention of the substance in the list of ingredients where it constitutes up to 10 percent of the meat in the product.

September 1988: USDA proposes changing the labeling requirements in accordance with the suggestions made by the meat industry.

CUTTING BACK HEALTH AND SAFETY STATUTES

In its attempts to dismantle many health and safety regulations, the Bush Task Force on Regulatory Relief ran into a formidable impediment: the laws passed by the Congress of the United States. Many of those laws direct an agency to take a certain measure to protect the public's health, spell out the criteria to be applied, leave the agency very little discretion in making regulatory decisions, or set a specific deadline for completion of such action.

George Bush determined that to accomplish the Reagan/Bush deregulation goals to the fullest extent, the Administration would have to convince Congress to repeal or change many of these laws. Thus, in his first statement as Chairman of the Task Force, on January 22, 1981, Bush stated that his mission included the responsibility to "oversee the development of legislative proposals in response to Congressional timetables (e.g., the Clean Air Act amendments expire this year), and, more importantly, to codify the President's views on the appropriate role and objectives of regulatory agencies."

Indeed, in his talk to the Congress on February 18, 1981, on "America's New Beginning," President Reagan lamented that "not all of our regulatory problems can be resolved satisfactorily through more effective regulatory management and decisionmaking." Therefore, he promised the Administration "will examine all legislation that serves as the foundation for major regulatory programs." Four month later, George Bush announced that, "the Task Force and its staff are working actively with those in Congress to achieve legislative change in the regulatory area."

This effort to cut back regulatory statutes was vigorous, particularly in the early Reagan/Bush years, but it was not successful. The attempts to rescind the car emissions standards under the Clean Air Act finally backfired as the Congress learned about the conflicts of interest and unprofessional conduct of Anne Gorsuch and Rita Lavelle at EPA. The Consumer Product Safety Act was damaged -- but the agency was not abolished as David Stockman originally proposed. Likewise, Congress refused to amend the food safety laws administered by the Food and Drug Administration, rejecting Administration proposals to eliminate the Delaney Clause -- which outlaws known carcinogens in the food supply. The Superfund law was reauthorized over the Administration's objections and made even stronger in some respects, as was the Clean Water Act which Congress enacted over the President's veto.

Just as important, the Task Force's major legislative effort to codify the executive orders under which it operated and to permit even more intrusion into the regulatory process by the White House and OMB was unsuccessful. The so-called Regulatory Reform Act was defeated after a four-year battle, when a number of House committee chairmen, who oversee the regulatory agencies, recognized this end-run attempt to amend dozens of health and safety laws. They strongly opposed giving the decision-making authority of the expert government agencies to the political operatives in the White House.

CLEAN AIR ACT

Congress enacted the Clean Air Act in 1970, requiring the EPA to establish safe concentrations for seven major pollutants designed to protect both the public health and environment from these airborne hazards. Passage of the Act was prompted by a growing body of evidence suggesting that the lack of adequate pollution controls was contributing to incidences of respiratory infections, lung cancer, and heart disease. The American Lung Association now estimates that as much as $40 billion each year is spent on health care as a result of exposure to just a few air pollutants. The Congressional Research Service has estimated that air pollution damage to property and crops approaches $5 billion annually.

When the Clean Air Act was up for reauthorization in 1982, the President's Task Force, led by Vice President Bush, lobbied Congress to pass a much weaker version of the statute, which would have amounted to a virtual repeal of the Clean Air Act. Among the most troubling provisions of H.R. 5252, the Administration-supported bill, were measures that would have:

- ◊ doubled the allowable carbon monoxide and nitrogen oxide emissions for new automobiles;
- ◊ limited the EPA's ability to enforce emission standards on new automobiles by removing EPA's authority to tighten the assembly-line testing requirement and weakened the agency's authority to recall automobiles that failed to meet the standard;
- ◊ eliminated special clean air protections for 163 million acres of national parks, national monuments, wilderness areas, and national wildlife refuges;

◊ extended the deadline for urban compliance with all primary pollutant standards for six years from 1987 to 1993; and

◊ dropped the requirement that heavy trucks achieve emission standards;

◊ equivalent to normal-sized trucks and delayed tightening of heavy truck standards for a four year period.

In addition, the Administration-supported bill contained no provisions designed to control acid rain, despite a National Academy of Sciences report released at the time which characterized the continuation of sulfur and nitrogen oxides emissions at current levels as "extremely risky." One version of the bill even contained a provision that would have legitimized the illegal evasion of control requirements by allowing the construction of tall smokestacks, which contribute to the exportation of acid rain pollutants. H.R. 5252 was eventually defeated when it was considered by the full House Energy and Commerce Committee.

CONSUMER PRODUCT SAFETY COMMISSION

The Consumer Product Safety Commission (CPSC) was created in 1973 to issue product safety standards to protect consumers from unreasonable risks. As the Reagan Administration came into office in the winter of 1981, CPSC records indicated that the agency had successfully implemented standards that resulted in the prevention of considerable deaths and injuries. These included:

◊ preventing approximately 130 deaths and more than 90,000 injuries since the 1978 implementation of mandatory rules involving unstable refuse bins, dangerous toys, unvented gas space heaters and lawn mowers;

◊ preventing approximately 200 deaths and 125,000 injuries since the implementation of voluntary product standards involving bathtubs, playpens, strollers, and extension cords; and

◊ preventing one million injuries and 150 deaths through recall of hazardous products such as hair dryers, paint strippers and toys.

Despite this successful record, the Reagan Administration lobbied Congress to abolish the CPSC and shift its responsibilities to the Commerce Department -- the agency created to protect the economic interests of business. Congressional supporters of the CPSC argued that preserving the agency's continued independence was critical for preserving objective regulation. When the Reagan proposal was defeated by Congress, the Administration fought for and won a one-third reduction in the CPSC budget, as well as severe limitations on disclosure of information to the public about product hazards brought to the agency's attention by consumers and others.

These cutbacks resulted in closing down eight of the Commission's thirteen regional offices, and the dismissal of over 150 employees. As a result, the Commission delayed or abandoned taking action on a variety of product reviews including unsafe preschool playground equipment, rider lawnmowers, snowblowers, kerosene heaters, and light fixtures.

SUPERFUND

In 1980, Congress enacted the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) or "Superfund" statute, setting a priority on cleaning up the nation's growing number of toxic waste sites. Superfund provided the federal government with the resources and authority to respond to this environmental crisis, and established procedures to finance cleanup efforts through liability imposed on those industries responsible for creating the toxic wastes.

Under the Reagan Administration, the implementation and enforcement of key provisions of the Superfund statute has been sorely lacking. From 1980 to 1985, EPA devoted most of its cleanup efforts to land disposal techniques, despite the agency's own admission in 1981 that such strategies were infeasible and were likely aggravating the hazardous waste problem.

The Reagan Administration opposed reauthorization of the Superfund law in 1984. When that effort failed, it backed a weaker, under-funded version of the law. The bill called for a funding level of $5.3 billion over a five-year period, less than half of what most experts had concluded was necessary to meet EPA cleanup deadlines.

In addition, the Administration proposal would have:

◊ codified EPA's existing ad hoc, case-by-case cleanup standard, allowing EPA the full discretion to override existing health-based environmental statutes;

◊ doubled the financial burden on states, even though EPA had previously acknowledged that the inability of states to provide additional funds was slowing cleanup activity; and

◊ narrowed the scope of Superfund to exclude many existing and proposed sites from receiving assistance.

Reacting to EPA's failure to implement effective cleanup strategies, Congress amended Superfund in 1986, directing the agency to seek out long-term, permanent treatment solutions. Since that time, little progress has been made and EPA's lack of enforcement of key Superfund provisions continue to come under fire from Congress and the public.

In a major report released in 1988, the Office of Technology Assessment concluded that EPA's handling of the hazardous waste crisis has been ineffective and inefficient and that the program "is not working environmentally the way the law directs it to." This view is shared by the environmental community, which recently charged that the majority of the cleanup efforts made since Superfund was amended do not adhere to the statutory preference for permanently effective remedies. In addition, although required by law, EPA has yet to amend the National Contingency Plan for hazardous wastes, making its program consistent with the 1986 amendments to the statute.

Finally, since Congress created the program in 1986, EPA has failed to award a single Technical Assistance Grant -- money available to citizens living near Superfund sites to participate in the remedy selection process. These and other complaints about EPA's implementation of the law were raised in a September 1988 letter sent to EPA Administrator, Lee Thomas, by sixteen chairmen of congressional committees and subcommittees.

FOOD SAFETY LAWS

Congress enacted the Food Additive Amendment to the Federal Food, Drug and Cosmetic Act in 1958, and the Color Additive Amendments in 1960. Two core principles in these laws are the requirement that additives be evaluated on the basis of their safety without any consideration of their arguable benefits, and a ban on the approval of any carcinogenic additive.

Congress' rationale for both provisions was that unsafe food and color additives are generally interchangeable with safe additives. In other words, Congress determined that the public does not care whether soft drinks are colored with Red No. 2 or Red No. 40, and similarly that they are indifferent as to which of the many preservatives are used in a particular product. Therefore, Congress decided to be cautious and to eliminate unnecessary health risks from the food supply. This was accomplished by requiring that the producers of additives prove that they are safe before the FDA approves their use and by prohibiting the use of any additive that is shown to cause cancer in animals or humans (the Delaney clause).

Shortly after President Reagan took office, Senator Orrin Hatch -- at the urging of the food industry and the Administration -- introduced a bill that would have radically changed the regulation of food products and undermined the protection that those laws provide the American consumer. In October 1981, the Reagan-Bush Administration issued a working paper adopting the Hatch proposal. That proposal would have made the American food supply less safe by changing the current laws to:

◊ repeal the Delaney clauses which prohibit the intentional addition of carcinogens to foods;

◊ redefine the statutory term "safe" which could allow the introduction into the food supply of new chemicals that can cause serious injuries;

◊ allow the Food and Drug Administration (FDA) to leave food and color additives on the market even after substantial questions have been raised about the additives' safety, and then to "phase out" the additives over an additional five years;

◊ permit the FDA to allow new uses of additives before the safety of those uses has been evaluated;

◊ allow meat and poultry products too contaminated to be sold in the United States to be exported to foreign countries.

The Administration's proposal would also have redefined the safety standard of the statute to provide the FDA with almost unlimited discretion to approve unsafe additives. For example, it would have allowed the FDA to approve the use of a color additive that causes cancer in one in 100,000 persons per year on the ground that the risk to the public as a whole is not significant. However, such a decision could result in 2,000 additional cancers a year that are clearly avoidable, since the addition of a color to food is always unnecessary and is used simply to enhance the eye-appeal of the product. To date, Congress has rejected the Administration's proposals to weaken the food safety laws.

REGULATORY REFORM ACT

One month after assuming office in 1981, President Reagan signed Executive Order 12291, subjecting most new regulatory rules to a complex cost/benefit analysis overseen by the Office of Management and Budget

(OMB). While OMB went to great lengths to calculate the economic costs of regulation, benefit estimates were often nonexistent or at best imprecise, making these analyses largely subjective.

In the following years, Reagan made "regulatory reform" one of his top legislative priorities by pushing such measures as the Regulatory Reform Act. Among other things, this Administration-inspired proposal would have given the Executive Order the force of law so that subsequent presidents could not recind it without the approval of Congress through its law-making function. In addition, the Regulatory Reform Act would have:

- ◊ extended the Executive Order to independent agencies including the Consumer Product Safety Commission, the Securities and Exchange Commission, and the Federal Trade Commission;
- ◊ implemented 32 additional, cumbersome regulatory hurdles that agencies would have to clear before new rules could be adopted;
- ◊ required agencies to review all existing regulations, spending limited resources on evaluating past actions rather than acting on urgently needed new measures to protect the public;
- ◊ excluded the public from the decision-making process by giving OMB, which conducts its activities in extreme secrecy, unprecedented supervisory power over proposed regulations;
- ◊ imposed cost-benefit requirements on agencies responsible for implementing statutes that do not require benefits to outweigh costs.
- ◊ provided OMB with the statutory basis to circumvent Congressional intent and displace a regulatory agency's discretion.

A version of the proposal was passed in the Senate but never emerged from the House. House opposition to the bill was led by a number of committee chairmen who recognized that the practical effect of the legislation would have been to create a regulatory labyrinth, taking regulatory decision-making away from the expert agencies, vesting enormous power in the hands of the White House directly, and needlessly delaying action on measures designed to protect public health and safety.

PUBLIC CITIZEN

Who We Are and What We Do

Public Citizen is a nonprofit membership organization based in Washington, D.C., representing consumer interests through lobbying, litigation, research and publications. Since its founding by Ralph Nader in 1971, Public Citizen has fought for consumer rights in the marketplace, for safe products, for a healthy environment and workplace, for clean and safe energy sources, and for corporate and government accountability.

With a staff of 60, Public Citizen is active in every public policy forum: The Congress, the courts, government agencies, and the media. Public Citizen has forced the Food and Drug Administration to ban unsafe drugs and to remove food dyes with carcinogens from the market, persuaded the government to require employers to label dangerous chemicals in the workplace, and pushed Congress to pass the National Consumer Cooperative Bank law, the Superfund law and many other bills vital to citizens. Public Citizen has won 14 cases before the U.S. Supreme Court, including decisions to require disclosure of prescription drug price information, to remove minimum fees by attorneys in house settlements — saving consumers billions of dollars ever since — and many others.

Because many of these consumer issues are controversial, Public Citizen does not accept government or corporate grants. Support funding comes from individual contributions from citizens throughout the country and from the sale of publications.

Public Citizen fights for citizen interests through five divisions:

Congress Watch monitors legislation on Capitol Hill, documents campaign financing abuses, tracks House and Senate voting records, and lobbies for the public interest;

The Health Research Group fights for protection against unsafe foods, drugs, and workplaces, and for greater consumer control over personal health decisions;

The Litigation Group brings precedent-setting lawsuits on behalf of citizens against the government and large corporations to enforce rights and ensure justice under the law;

The Critical Mass Energy Project works for safe, efficient, and affordable energy; and

Buyers Up is a group-buying organization that enables individuals to become more knowledgeable consumers and to exercise their economic leverage in the marketplace.

For copies of "Risking America's Health and Safety" ($8.00) or for more information about Public Citizen, please write to:

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