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Report to the Chairmen, Committee on Commerce, Science, and Transportation, U.S. Senate, and the Committee on Commerce, House of Representatives

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CONSUMER PRODUCT SAFETY COMMISSION

Better Data Needed to Help Identify and Analyze Potential Hazards

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The Honorable John McCain
Chairman, Committee on Commerce,
Science, and Transportation
United States Senate

The Honorable Thomas J. Bliley, Jr.
Chairman, Committee on Commerce
House of Representatives

Every year, children are hurt while using playground equipment; users or spectators are injured when fireworks explode unexpectedly; and homeowners are cut while operating chain saws and lawn mowers. Created to protect consumers from "unreasonable risk of injury," the U.S. Consumer Product Safety Commission (CPSC) oversees these and about 15,000 other consumer products ranging from kitchen appliances and children's toys to hot tubs and garage door openers. With a budget of about $42.5 million, CPSC carries out its mission by (1) enforcing federal consumer product regulations (by recalling products from store shelves, for example) and (2) conducting projects to address products with potential hazards not covered by existing regulations.[1] These projects may result in CPSC issuing new regulations concerning specific products, assisting in the development of voluntary industry standards, or providing information to consumers about how to use the products safely.

Contending that the agency is ineffectively allocating its resources, CPSC's critics have voiced dissatisfaction with the selection of certain agency projects and have questioned the validity of CPSC's risk assessment and cost-benefit analyses supporting those projects. In addition, congressional and interest group critics have questioned the agency's procedures for ensuring the accuracy of manufacturer-specific information before releasing it to the public,

contending that such releases can mar the reputation of responsible corporate citizens.

In light of these concerns, you asked us to review CPSC's project selection, use of cost-benefit analysis and risk assessment, and information release procedures. Specifically, this report (1) identifies the criteria CPSC uses to

[1]Projects vary widely in scope, and CPSC has no standard definition of what constitutes a project. For our review, we defined a "project" as work CPSC conducted on any specific consumer product that was associated with a potential hazard or hazards not covered by existing regulation.

select projects and reviews the information it relies upon in making these choices, (2) assesses the information CPSC draws on to perform risk assessment and cost-benefit analyses and evaluates the agency's methodology for conducting cost-benefit analyses, and (3) describes CPSC's procedures for releasing manufacturer-specific information to the public and reports whether evidence exists that CPSC violated its statutory requirements concerning the release of such information.

To address these objectives, we reviewed internal CPSC documents, relevant legislation and regulations, and the literature on cost-benefit analysis and on consumer product safety issues. We interviewed CPSC commissioners and staff, four former commissioners, consumer advocates, industry representatives, and outside experts to obtain their perspectives on CPSC's work. We identified CPSC projects by compiling from various agency documents a list of 115 potential product hazards examined by the agency from January 1990 to September 30, 1996, and we reviewed available agency documentation on each of these projects. We examined the agency's internal databases to obtain project information and to assess the agency's information on product hazards. In reviewing CPSC's cost-benefit analyses, we consulted with experts to develop objective criteria that reflected elements commonly used in the evaluation of cost-benefit analyses. These evaluation questions were designed to elicit whether CPSC conducted comprehensive analyses and reported them in sufficient detail. However, they do not make up a complete measure of the quality of a cost-benefit analysis; for example, our evaluation assessed whether these elements were included but not how well they were measured or incorporated. We reviewed CPSC's internal procedures concerning information clearance and release, and we examined relevant legal cases in this area. For more detailed information on our scope and methodology, see appendix I.

Results in Brief

Although CPSC has established criteria to help select new projects, with the agency's current data these criteria can be measured only imprecisely, if at all. The criteria for selecting projects include the number of product-related injuries, chronic illnesses, and deaths. However, although CPSC has described itself as "data driven," its information on product-related injuries and deaths is often sketchy. For example, because the agency's measure of injuries generally includes only hospital emergency room reports, CPSC has an incomplete picture of injuries. Similarly, CPSC's data on product-related deaths understate the total number of deaths and are available to the agency only with a 2-year time

lag. In addition, CPSC does not maintain a comprehensive list or description of either its past or ongoing projects. This makes it more difficult not only for agency management to monitor current projects but also for staff and commissioners to assess and prioritize the need for new projects in different hazard areas. As a result, CPSC has insufficient data on both internal agency efforts and external product hazards to assess the impact and cost of each project, either when it is selected or after it has been implemented.

To help evaluate alternative methods of addressing potential hazards, CPSC may perform a risk assessment to estimate the likelihood of injury associated with a hazard or conduct a cost-benefit analysis to assess the potential effects of a proposed regulation. Although CPSC does not complete either a risk assessment or cost-benefit analysis for every project, the agency conducts these analyses more often than it is required to by law. Nevertheless, CPSC's data are often insufficient to support a thorough application of these analytical techniques—a problem that frequently arises in doing both risk assessment and cost-benefit analysis. To evaluate relative risks, it is usually necessary to have information on how many consumers use the product—information that CPSC frequently does not have. In addition, risk assessment of consumer products requires measurement of the number of harmful incidents. CPSC's imprecise and incomplete death and injury data make risk assessment and cost-benefit analysis at best less reliable and at worst impossible to do. Furthermore, the cost-benefit analyses conducted by CPSC between 1990 and 1996 were often not comprehensive, and the reports on these analyses were not sufficiently detailed. For example, experts generally agree that sensitivity analysis—a technique that enables the reader to determine which assumptions, data limitations, or parameters are most important to the conclusions—should be incorporated in cost-benefit analyses. Most of CPSC's cost-benefit analyses did not include such information. We are making recommendations to the Chairman of CPSC to improve the agency's project selection and cost-benefit analyses.

CPSC has established procedures to implement statutory requirements concerning the release of manufacturer-specific information. When releasing information to the public that identifies a specific manufacturer—for example, in a safety alert or recall notice—CPSC is required to verify the information and allow the manufacturer an opportunity to comment. Evidence from the industry and from legal cases suggests that CPSC has met its statutory requirements in this area. Individuals within CPSC, as well as some industry representatives and

consumer groups, expressed dissatisfaction with the requirements of this law. Some of these individuals have proposed statutory changes that range from reducing to expanding the current requirements.

Background

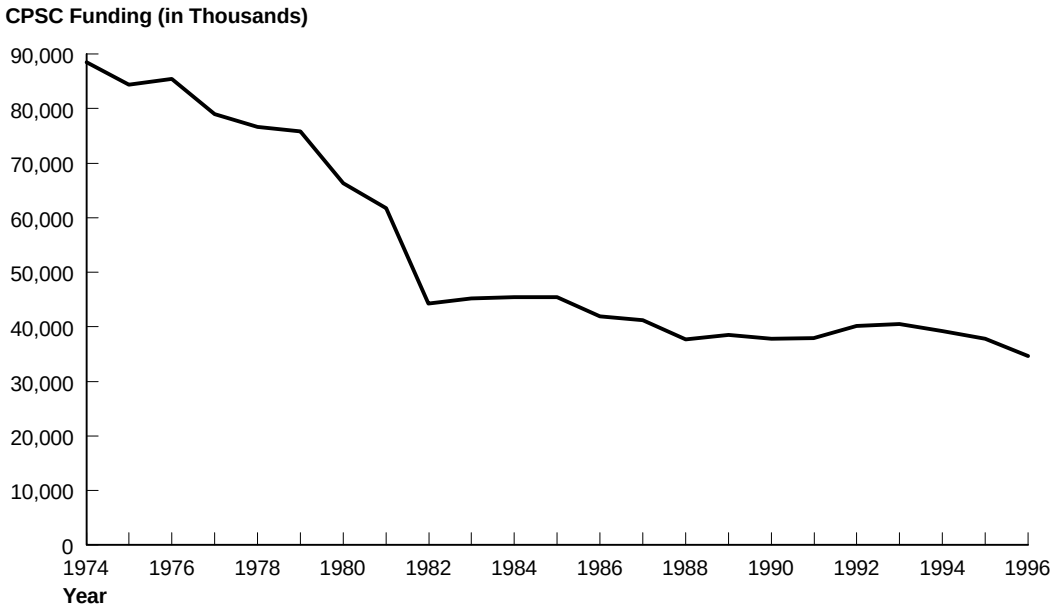
CPSC was created in 1972 under the Consumer Product Safety Act (P.L. 92-573) to regulate consumer products that pose an unreasonable risk of injury, to assist consumers in using products safely, and to promote research and investigation into product-related deaths, injuries, and illnesses. CPSC currently has three commissioners, who are responsible for establishing agency policy.[2] One of these commissioners is designated the chairman; the chairman directs all the executive and administrative functions of the agency.

The Consumer Product Safety Act consolidated federal safety regulatory activity relating to consumer products within CPSC. As a result, in addition to its responsibilities for protecting against product hazards in general, CPSC also administers four laws that authorize various performance standards for specific consumer products. These laws are the Flammable Fabrics Act (June 3, 1953, c.164), which authorizes flammability standards for clothing, upholstery, and other fabrics; the Federal Hazardous Substances Act (P.L. 86-613), which authorizes the regulation of substances that are toxic, corrosive, combustible, or otherwise hazardous; the Poison Prevention Packaging Act of 1970 (P.L. 91-601), which authorizes requirements for child-resistant packaging for certain drugs and other household substances; and the Refrigerator Safety Act of 1956 (Aug. 2, 1956, c.890), which establishes safety standards for household refrigerators.

In fiscal year 1997, CPSC carries out this broad mission with a budget of about $42.5 million and a full-time-equivalent staff of 480. As figure 1 shows, after adjusting for inflation, the agency's budget has decreased by about 60 percent since 1974. Similarly, CPSC's current staffing level represents 43 percent fewer positions as compared with the agency's 1974 staff.

[2]The Consumer Product Safety Act provides for the appointment of five commissioners by the President of the United States for staggered 7-year terms. However, since 1986, no more than three commissioners have served at one time.

Figure 1: CPSC Funding, in Inflation-Adjusted Dollars, 1974-96



Notes: Budget figures were obtained from CPSC. The 1993 budget figure excludes a special appropriation for office space relocation. Budget figures were adjusted for inflation using the Gross Domestic Product deflator for federal nondefense spending, with 1992 as the base year.

CPSC uses a number of regulatory and nonregulatory tools to reduce injuries and deaths associated with consumer products. Under several of the acts that it administers, CPSC has the authority to issue regulations that establish performance or labeling standards for consumer products. For example, in 1993, CPSC issued regulations under the Consumer Product Safety Act requiring disposable cigarette lighters to be child-resistant. If CPSC determines that there is no feasible standard that would sufficiently address the danger, CPSC may issue regulations to ban the manufacture and distribution of the product. In addition, under the Consumer Product Safety Act, if a product violates a safety regulation or presents a "substantial hazard," CPSC may order a product recall, in which the item is removed from store shelves and consumers are alerted to return the item

for repair, replacement, or refund.[3] CPSC can also impose civil penalties for violations of federal safety standards.

Although CPSC has these broad regulatory powers, much of the agency's efforts are carried out using nonregulatory methods. In addition to federally mandated product safety standards, many consumer products are covered by voluntary standards. These voluntary standards, which are often established by private standard-setting groups, do not have the force of law. However, many voluntary standards are widely accepted by industry.[4] The 1981 amendments to the Consumer Product Safety Act require CPSC to defer to a voluntary standard—rather than issue a mandatory regulation—if CPSC determines that the voluntary standard adequately addresses the hazard and that there is likely to be substantial compliance with the voluntary standard. As a result, voluntary standards development is an important tool in CPSC's hazard-reduction efforts. For example, in 1996 CPSC helped a private group develop a voluntary standard to address the risk of children getting their heads stuck between the slats of toddler beds, and in 1995 CPSC assisted a standard-setting group in upgrading safety standards to prevent fires associated with Christmas tree lights.

CPSC also addresses product hazards by providing information to consumers on safety practices that can help prevent product-related accidents. For example, to encourage consumers to use electricity safely—and particularly to promote the use of ground fault circuit interrupters—CPSC conducted a far-reaching publicity campaign that included radio public service announcements, messages printed on carryout bags for hardware stores, a joint press conference with industry representatives, presentations on television's Home Shopping Network, and promotional letters to real estate and home inspection associations. In addition to its own active efforts to disseminate information, CPSC provides considerable amounts of information in response to requests from the public. Like other federal agencies, CPSC must comply with the Freedom of Information Act (FOIA) when responding to requests from the public for information. A notable feature of FOIA is its presumption in favor of disclosure: any person has the right to inspect and copy any government

[3]In practice, CPSC rarely uses its regulatory power to order a recall, but works cooperatively with manufacturers to carry out recalls.

[4]Voluntary standards may benefit manufacturers by giving consumers added confidence in a product, providing some degree of protection from product liability, and allowing manufacturers to benefit from the safety expertise developed by voluntary standards groups. In addition, although federal law does not compel manufacturers to comply with voluntary standards, state or local regulations may incorporate some voluntary standards regarding consumer products, and some retailers prefer to carry only those goods that comply with the applicable voluntary standards.

records unless the documents requested fall within one of the exemptions to the act (for example, disclosure of trade secrets). FOIA requests may come to CPSC from regulated industries, the press, consumer groups, or individuals. During calendar year 1995, CPSC responded to 16,424 formal requests made under FOIA.

CPSC's resource base and extensive jurisdiction require the agency to select among potential product hazards. New initiatives may come to CPSC in several ways. First, any person may file a petition asking CPSC to issue, amend, or revoke a regulation. Petitions, which can be as simple as a letter or as formal and detailed as a legal brief, have come to CPSC from doctors and nurses, consumers and advocacy groups, and industry representatives. CPSC may grant or deny a petition either in full or in part. Even when CPSC denies a petition and declines to issue a regulation, it may still begin a project to address the hazard by promoting a voluntary standard or conducting a consumer education campaign. For example, a project on heat tapes (heated wraps for exposed pipes) originated with a petition from a concerned consumer. CPSC denied the petition for a mandatory standard, but conducted a research study and review of the existing voluntary standard for heat tapes.

Second, CPSC receives some product hazard projects from the Congress. The Congress may require CPSC to study a wide-ranging product area. For example, the Consumer Product Safety Improvement Act of 1990 resulted in a large body of work on products affecting indoor air quality, including wood stoves, kerosene heaters, and carpets. The Congress may also direct CPSC to impose a specific regulation, such as when it directed CPSC to require additional labeling on toys intended for children aged 3 to 6 warning parents of possible choking hazards when the toy is used by children under age 3.[5]

Finally, CPSC commissioners and agency staff may initiate projects or suggest areas to address. CPSC gathers death and injury information to help identify potential product hazards and also obtains input from the public. The agency maintains a toll-free hot line and an Internet site that the public can use to notify agency staff of a possible product hazard. In addition, CPSC holds public meetings to get input on possible hazards to address and on which hazards should receive priority. For example, CPSC increased its efforts to remove drawstrings from children's clothing after receiving a letter from a woman whose daughter was strangled when her jacket string caught on a playground slide.

[5]This mandate was imposed in the Child Safety Protection Act (P.L. 103-267, June 16, 1994).

The selection of projects to address new product hazards takes place at different levels of the agency throughout the year. For a petition, the commissioners decide whether the product hazard warrants further agency involvement, and the commissioners vote on whether to grant or deny the petition. If a project is believed to have a high potential for regulatory action or involve a substantial amount of agency resources, the commissioners decide whether to pursue it. Projects of this caliber are often noted in the agency's annual budget and operating plan, which must also be approved by commissioner vote.[6] Staff request a decision on such a project by preparing a briefing package about the product hazard for the commissioners, who vote to begin the regulatory process, take some other action, or terminate the project. Agency staff generally may decide to initiate projects that are unlikely to result in regulation, and no briefing package is sent to the commissioners for a vote.[7] (Of the 115 CPSC projects we identified, 80 (70 percent) were detailed in briefing packages.)

The scope of the agency's projects varies greatly, and CPSC has no standard definition of what constitutes a project. A project might cover general product areas, such as fire hazards, or address only a specific product, like cigarette lighters. A project might require undertaking an extensive research study or providing technical assistance to a group that is developing a voluntary standard.

CPSC Has Limited Information Available to Assist in Project Selection

The bulk of CPSC's workload is made up of projects selected by the agency rather than by the Congress. CPSC has established criteria to help in project selection, such as the numbers of deaths and injuries associated with a product. However, CPSC is unable to accurately measure these criteria because its data on potential hazards are incomplete. In addition, CPSC does not maintain systematic information on past and ongoing projects, which makes it difficult to assess and prioritize the need for new projects in different hazard areas. The lack of comprehensive data on individual product hazards and on agency initiatives raises questions about CPSC's ability to evaluate its own effectiveness—which it is now required to do under the Government Performance and Results Act of 1993 (the Results Act).

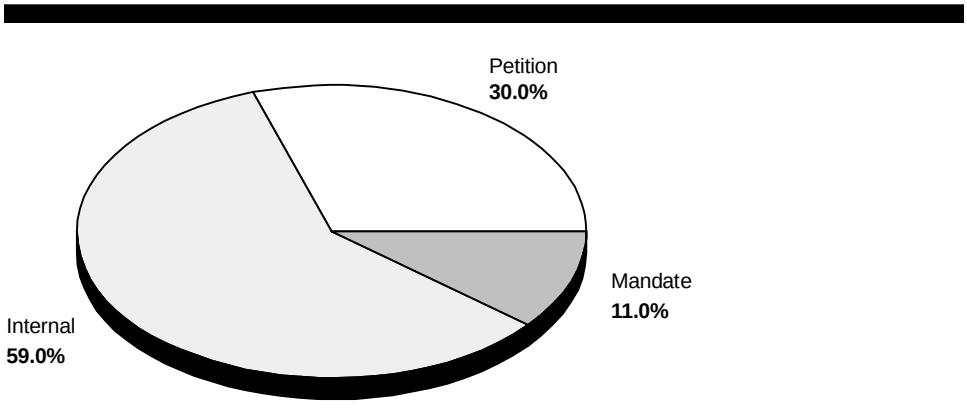
[6]Commission votes are also taken in several other instances, such as initiating a regulation, the use of the agency logo by outside groups, and the application of civil penalties.

[7]For more information about the agency's organization and structure, see app. II.

Agency Has Considerable Discretion in Project Selection

CPSC has wide latitude over which potential product hazards it targets for regulatory and nonregulatory action. Although it has little or no discretion over projects mandated by the Congress, CPSC can choose to accept or reject suggestions that are submitted by petition or proposed by the agency staff. As shown in figure 2, 59 percent of CPSC projects were initiated by CPSC, 30 percent originated from a petition, and about 11 percent resulted from congressional mandates. Of the 115 projects the agency worked on from January 1, 1990, to September 30, 1996, 97 (about 90 percent) were chosen by the agency.[8] Data were unavailable to assess the extent to which staff suggestions for projects were accepted or rejected. Of the petitions filed with CPSC between January 1, 1990, and September 30, 1996, 60 percent resulted in projects (32 percent by granting the petition in whole or in part, and 27 percent by denying the petition to establish a mandatory regulation but creating a nonregulatory project). In 27 percent of cases, CPSC decided that no action was needed or that existing actions or standards were sufficient to address the issue raised by the petition. In the remaining cases, a decision is still pending or the petition was withdrawn before a decision was rendered.

Figure 2: Origination of CPSC Projects, January 1, 1990-September 30, 1996



CPSC Project Selection Criteria Open to Differences in Emphasis and Interpretation

CPSC has established criteria for setting agency priorities and selecting potential hazards to address. These criteria, which are incorporated in agency regulations, include the following:

- the frequency of injuries and deaths resulting from the hazard;
- the severity of the injuries resulting from the hazard;

[8]For a listing of these 115 projects, see app. III.

- addressability—that is, the extent to which the hazard is likely to be reduced through CPSC action—agency regulations note that the cause of the hazard should be analyzed to help determine the extent to which injuries can reasonably be expected to be reduced or eliminated through CPSC action;
- the number of chronic illnesses and future injuries predicted to result from the hazard;
- preliminary estimates of the costs and benefits to society resulting from CPSC action;
- unforeseen nature of the risk—that is, the degree to which consumers are aware of the hazard and its consequences;
- vulnerability of the population at risk—whether some individuals (such as children) may be less able to recognize or escape from potential hazards and therefore may require a relatively higher degree of protection;
- probability of exposure to the product hazard—that is, how many consumers are exposed to the potential hazard, or how likely a typical consumer is to be exposed to the hazard; and
- other—additional criteria to be considered at the discretion of CPSC.

Vulnerable Populations, Numbers of Deaths and Injuries, and Causality Emphasized Over Other Selection Criteria

CPSC's regulations allow for considerable freedom in applying these criteria; commissioners and staff can base their project selections on what they perceive as the most important factors. For example, the regulations do not specify whether any criterion should be given more weight than the others, nor must all criteria be applied to every potential project. Indeed, our interviews with present and former commissioners and our review of CPSC briefing packages revealed a pattern in which three criteria—the numbers of deaths and injuries, the causality of injuries, and the vulnerability of the population at risk—were more strongly emphasized than the others. In addition, each of the commissioners we interviewed identified some criteria as being more important than others for project selection. For example, one commissioner indicated that the number of deaths and injuries was most important, while another commissioner included awareness of the hazard in a list of several criteria she believed were most important. However, there was considerable agreement among the commissioners about the importance of several criteria. The commissioners cited two criteria—vulnerability of population and number of deaths and injuries—as especially important for project selection. In addition, several—but not all—commissioners emphasized causality of injuries. None of the other criteria was emphasized by more than one or two commissioners.

Because the commissioners use their judgment in applying these criteria, there is no systematic checklist or scoring system that would enable us to determine which factors were considered most important for a particular product. However, information related to some or all of these criteria is sometimes contained in briefing packages and other documents. Our review of CPSC project documentation showed that information on vulnerable populations and the numbers of deaths and injuries associated with the product was likely to be compiled at some time during the project, but information associated with other criteria was less likely to be documented. For example, of the 115 projects we reviewed, death and injury information was available in 97 cases. However, only 26 cases included information on exposure to the hazard, a less-emphasized criterion.

Although data were insufficient to compare the universe of possible projects with the ones selected by CPSC, the characteristics of CPSC projects appear generally consistent with the stronger emphasis on death and injury data and on vulnerable populations expressed by the current and former commissioners. For example, while 76 of the 115 projects we examined were directed at least partially at a vulnerable population group, only 13 projects mentioned chronic illness. However, although the number of deaths and injuries associated with product hazards was almost always available in project documentation, there was no pattern of only those projects with high numbers of injuries or deaths being selected. Of the 97 projects that had death and injury statistics, 19 showed fewer than 50 injuries and/or deaths associated with the product. The estimated number of annual injuries associated with product hazards ranged from 1 to 162,100 (for baseball injuries), and the estimated number of deaths associated with product hazards ranged from zero to a high of 3,600 annually (for smoke detectors). This wide range is consistent with CPSC staff's statement that there is no threshold for the number of deaths and injuries that would require acceptance or rejection of a project.

Commissioners Interpret Some Selection Criteria Differently

Although the commissioners and former commissioners we interviewed generally agreed on the criteria they emphasized for project selection, they expressed very different views on how some of these criteria should be interpreted. For example, several commissioners viewed vulnerable populations as focusing on children, while others highlighted additional segments of the population that they considered vulnerable. One commissioner also listed low-income and poorly educated consumers as vulnerable populations, and another expressed concern that the elderly were especially vulnerable to injury from product hazards. Project

documentation focused on children more frequently than on other population segments thought to be at special risk. Many projects we examined contained no information in the documentation that indicated a particular population was being considered vulnerable. However, of the 76 projects for which information was available on special populations, 69 (91 percent) mentioned children.[9]

Industry observers, consumer advocates, current and former commissioners, and others expressed widely diverging views on how to apply causality of injuries in selecting projects. All seven commissioners we interviewed mentioned this as an important criterion, and several stressed causal factors. A major issue surrounding the application of causality is determining the appropriate level of protection the agency should provide when a product hazard results, at least in part, from consumer behavior. For example, a consumer advocate stated that regulatory action may be necessary whatever the cause of the incident if children who were incapable of protecting themselves get hurt. Similarly, another individual told us that CPSC should deal with potential hazards on the basis of the behavior that actually took place, not the behavior that might be expected or considered reasonable. However, other individuals asserted that CPSC should address only those hazards that result from products that are defective—that is, products that create a hazard even when used as intended by the manufacturer. Some industry representatives stated that it was inappropriate for CPSC to take action concerning a product if the product was "misused" by the consumer.

Complicating this debate is the difficulty of defining misuse of the product or negligence of the consumer. For example, the appropriate degree of parental supervision is frequently an issue with children's products. One of the agency's more controversial projects illustrates this point. CPSC staff conducted a project to investigate the deaths of children using baby bath seats or rings. In these incidents, infants slipped out of the seat and drowned in the bathtub when the parent or caregiver stepped out of the room and left the child unsupervised, despite warning signs on the seats not to leave children unattended. The Commission disagreed on the proper course of action, largely because of differing views on causality. In 1994, the staff recommended that the Commission issue an Advance Notice of Proposed Rulemaking (ANPR), the first step in the regulatory process. The staff argued (and one commissioner agreed) that some parents will leave a

[9]Many of these projects involved children's products, for which only children would be affected, such as cribs or baby walkers. Other projects dealt with products the general public would be exposed to but for which children would be more likely to receive injury, including mouthwashes with high concentrations of alcohol and automatic garage doors that could crush a child when they close.

young child alone in the bathtub regardless of a warning not to. However, in voting against issuing an ANPR, the other two commissioners stated that they believed regulation was not appropriate because the lack of supervision, not the product, caused the tragedies.

CPSC staff have also encountered other instances in which the behavior of consumers might be viewed as inappropriate. For example, the role of alcohol and drug use in accidents can also raise questions about the appropriate level of regulatory protection.[10] In addition, a 1991 CPSC study found that at least 33 percent of bicycle accidents involved behaviors such as performing stunts and going too fast. Similarly, a 1991 CPSC study of fires associated with heat tapes found that at least 38 percent of the heat tapes had been installed improperly. In each of these cases, no regulatory action was taken; in the case of bicycles, the staff did recommend increasing efforts to encourage consumers to take safety precautions such as using lights at night and wearing helmets.

Data Systems Provide Insufficient Information to Measure Selection Criteria, Monitor All Projects, or Evaluate Results

CPSC uses data from internal management systems and from external sources to assist in project selection. CPSC collects information on product-related deaths and injuries to provide information for project selection as well as to perform risk assessments and cost-benefit analyses. Furthermore, the agency maintains a computerized management information system (MIS) that contains information on some of its major activities and is used by the agency to develop its annual budget. Both these internal and external data are of limited value. The inadequacy of the information raises questions about CPSC's ability to make informed project selection decisions so that agency resources are being spent efficiently.

Significant Gaps Exist in CPSC's Data on Product-Related Injuries and Deaths

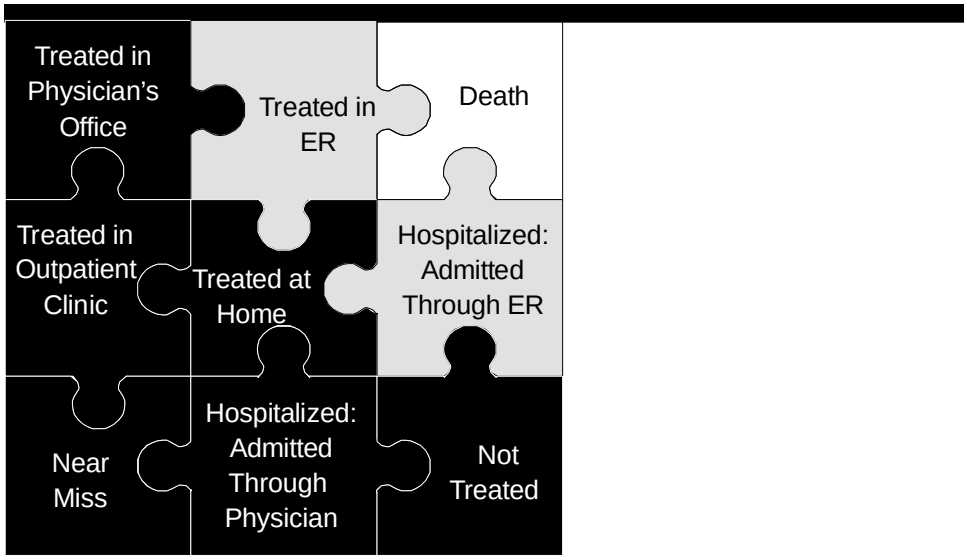
CPSC has developed a patchwork of independent data systems to provide information on deaths and injuries associated with consumer products. To obtain estimates of the number of injuries associated with specific consumer products, CPSC relies on its National Electronic Injury Surveillance System (NEISS). NEISS gathers information from the emergency room records of a nationally representative sample of 101 hospitals. CPSC also obtains information on fatalities by purchasing a selected group of death certificates from the states. It supplements this information with anecdotal reports from individual consumers and with data from private organizations such as fire-prevention groups and poison control centers.

[10]Alcohol and drug use contributed to an estimated 1.35 million injury-related visits to hospital emergency departments in 1992. See Cheryl R. Nelson and Barbara J. Stussman, "Alcohol- and Drug-Related Visits to Hospital Emergency Departments: 1992 National Hospital Ambulatory Medical Care Survey," Advance Data, No. 251 (Aug. 10, 1994).

Because neither NEISS nor death certificate data provide detailed information on hazard patterns or injury causes, CPSC investigates selected incidents to obtain more detailed information. In addition, CPSC sometimes uses mathematical modeling techniques or conducts special surveys to obtain information on product exposure. (For more information on CPSC's data sources, see app. V.)

CPSC's data give the agency only limited assistance in applying its project selection criteria. (These criteria, the measures used for each, and major data limitations are given in table 1.) CPSC's injury and death data allow the agency to piece together at best an incomplete view of the incidents that result from consumer product hazards. Product-related injuries may be treated in a variety of ways—in an emergency room, in a physician's office, or through an outpatient clinic, for example. As figure 3 illustrates, CPSC obtains systematic surveillance information only on deaths and on injuries treated in the emergency room; injuries treated in other settings (such as physicians' offices) are not represented in CPSC's surveillance data.

Figure 3: Types of Death and Injury Data Covered by CPSC's Systematic Surveillance Information



Note: Death data are considered partially included because CPSC obtains death certificates for selected causes of death. For the other sources of treatment, CPSC may obtain some anecdotal information from consumer reports or other sources (see app. V). The actual numbers of injuries treated in each setting is unknown.

A "near miss" refers to an incident in which a product-related injury nearly occurred but was narrowly averted. In its regulations that address priority-setting, CPSC states that such incidents can be as important as actual injuries in identifying potential hazards.

Table 1: CPSC Regulatory Priority-Setting Criteria and Systematic Information Available

Criterion	Measure used by CPSC	Major limitations
Number of deaths	Number of reported deaths where consumer product involvement can be inferred.	Incomplete because not all certificates are gathered and not all product-related incidents are coded.
Number of injuries	Estimated number of injuries involving consumer products treated in emergency rooms.	Generally omits injuries treated in other settings.
Severity of injuries	Estimated percentage of emergency-room-treated injuries requiring hospitalization.	Not representative of the severity of all injuries treated in all settings.
Chronic illnesses	Some limited information from emergency room diagnosis information.	Little systematic information.
Predicted future injuries	Prediction based on NEISS data.	Of questionable validity because of changes in medical care over time.
Vulnerable populations	Percentage of emergency-room-treated injuries or deaths involving children or the elderly.	Incomplete. Information available only on age, not on other vulnerable populations, such as persons with disabilities.
Exposure	Various measures, including sales, estimated products in use, and population.	Exposure surveys are time consuming and expensive; not done for all projects; done only after project is well under way.
Addressability/ causation	Judgment based on cause of incident, hazard pattern, and information on product design; investigations of selected incidents may be conducted to obtain this information.	Often impossible to make an informed judgment until project is well under way; investigations are time consuming and expensive.
Preliminary cost-benefit analysis	Results of analysis.	Quality data are frequently not available; limited accuracy in early stages of project.

CPSC staff identified the lack of data on injuries treated in physicians' offices and other settings as a key concern. Because CPSC's data sets reveal only a portion of the injury picture, the agency underestimates the total numbers of deaths and injuries associated with any given consumer product. The extent of this undercount is unknown. For example, researchers report widely varying estimates of the percentage of injuries that are treated in emergency rooms as opposed to other medical settings. For example, a 1991 study by researchers at RAND found that

approximately 65 percent of injuries were treated in the emergency room.[11] However, recent data indicate that the number of injury-related visits to physicians' offices alone were more than double the number of injury-related visits to the emergency room.[12] CPSC's estimates of product-related deaths are also undercounted, for two reasons. First, for budgetary reasons, the agency purchases only a subset of the total number of death certificates from states. Second, CPSC death counts include only those cases in which product involvement can be inferred from the information on the death certificate, and in some cases, product-related information is not recorded.

Even if a reliable figure was available to determine the exact percentage of product-related injuries that were treated in emergency rooms, this percentage would not necessarily apply to any specific type of product-related injury. For example, even if it was established that 40 percent of all product-related injuries were treated in emergency rooms, the percentage of bunk bed injuries treated in emergency rooms might be much larger or smaller. The setting in which injuries are treated depends on a wide array of factors that vary among individuals, across geographic regions, and among different types of injuries. Research indicates that African Americans are more likely to use the emergency room than Caucasians are.[13] Access to the emergency room or to a physician also depends on the type of medical insurance a person has. For example, health maintenance organizations (HMO) often place restrictions on reimbursement for emergency room care, and HMO membership as a percentage of the total population varies widely from state to state.[14] In addition, injuries that occur at night, when most physicians' offices are closed, may be more likely to be treated in the emergency room. As a result, it is unlikely that CPSC could approximate the number of injuries associated with a specific product by using data that apply to all consumer products as a group.

The incompleteness of CPSC's injury information also hampers its ability to reliably discern long-term trends in injuries, which is not only a criterion

[11]Deborah R. Hensler, and others, Compensation for Accidental Injuries in the United States (Santa Monica, Calif.: RAND, 1991).

[12]See Susan M. Schappert, "National Ambulatory Medical Care Survey: 1992 Summary," Advance Data No. 253 (Aug. 18, 1994), and Linda F. McCaig, "National Hospital Ambulatory Medical Care Survey: 1992 Emergency Department Summary," Advance Data, No. 245 (Mar. 2, 1994).

[13]See Linda F. McCaig, "National Hospital Ambulatory Medical Care Survey: 1992 Emergency Department Summary," p. 1.

[14]1996 figures from InterStudy show that while only 1.2 percent of individuals in Mississippi belonged to HMOs, 44.8 percent of individuals in Oregon were HMO members. See The InterStudy Competitive Edge: HMO Industry Report 6.2, InterStudy Publications (1996), p. 28.

for project selection but also an important factor for evaluating the success of CPSC's injury-reduction efforts and determining the need for follow-up actions. The relative sizes of the pieces of the injury puzzle in figure 3 are unknown but appear to change over time. For example, hospitalizations decreased by 5 percent on a per capita basis between 1982 and 1994, while between 1983 and 1993, hospital outpatient clinics saw a 53-percent increase in visits on a per capita basis.[15] As a result, it is impossible to determine whether any change in the number of emergency room visits represents a true change in injuries or a shift to other medical settings.[16]

According to CPSC staff, identifying chronic illnesses associated with consumer products is nearly impossible. CPSC staff stated that little is known about many chronic illness hazards that may be associated with potentially dangerous substances, and even less information is available about which consumer products may contain these substances. Chronic illnesses are especially likely to be underestimated in CPSC's NEISS data because they are underrepresented among emergency room visits and because product involvement is more difficult to ascertain. Similarly, consumer product involvement is very seldom recorded on death certificates in cases of chronic illnesses.

CPSC's surveillance data also give an incomplete picture of the severity of incidents. Although the data capture many relatively severe injuries—that is, those that result in death or require treatment in an emergency medical facility—data are missing for individuals who are admitted to the hospital through their physician rather than through the emergency room. Potentially less severe cases—for example, those treated in physicians' offices, walk-in medical centers, or hospital outpatient clinics—are not represented at all in CPSC's

systematic surveillance data systems, and consequently, CPSC has no data on some consumer product problems that may result in numerous but potentially less severe injuries.

Sketchy information about accident victims also limits CPSC's ability to assess which consumer product hazards have a disproportionate impact on vulnerable populations. NEISS and death certificates provide only the

[15]These figures were derived from data provided by the American Hospital Association.

[16]Precise estimates on the impact of changing treatment patterns are rare, and the impact may vary among local areas. However, one research team found that because of the growth in alternative facilities in their local area, emergency rooms handled about half of outpatient injury cases—down from a previous estimate of 75 percent. See Julian A. Waller, Joan M. Skelly, and John H. Davis, "Treated Injuries in Northern Vermont," Accident Analysis and Prevention, 27 (6) (1995), pp. 819-28.

age of the victim; no systematic or comprehensive information is available to determine whether a given hazard has a special impact on other vulnerable populations, such as persons with disabilities. A former commissioner told us that the lack of other demographic information such as race, income, and disability status made it difficult for her to know which subpopulations were predominantly affected by a particular hazard. Another commissioner echoed this concern, and said that such information would be useful in targeting public information campaigns on certain hazards to those groups that needed the information most.

CPSC staff identified the need for additional exposure data as a major concern. However, they also told us that obtaining information on exposure to products and establishing causation requires special efforts that can be time consuming and costly. Although CPSC's priority-setting criteria include exposure to the hazard, exposure data are generally not included in CPSC's ongoing data collection efforts. As a result, exposure is assessed either not at all or further along in the project, precluding the use of exposure as an effective criterion for project selection. Similarly, CPSC's emergency room and death certificate data provide little information on the circumstances surrounding the incident. As a result, CPSC staff perform follow-up investigations of selected incidents to obtain additional detail. These investigations may include detailed interviews with victims and/or witnesses, police or fire reports, photographs of the product and/or accident site, laboratory testing of the product, or recreations of the incident. As with exposure data, these investigations are not conducted for every project and are completed only after a project is well under way. Thus, assessment of causation at the project selection stage is unavoidably speculative.

Agency Project Management Information Incomplete or Unavailable

CPSC conducts a number of projects annually, but staff were unable to provide a comprehensive list of projects the agency had worked on in the 6-year period we examined. CPSC was also unable to verify the completeness of the project list we compiled from agency documents and interviews with staff. According to CPSC staff, internal management systems do not contain this information and such a list could be compiled only by relying on institutional memories of staff members who had been with the agency long enough to know which products the agency had addressed. Without systematic and comprehensive information on its past efforts, CPSC cannot assess whether some hazard areas have been overrepresented and whether agency resources might be more efficiently employed.

CPSC also lacks information on the characteristics of, resources used on, or outcomes of individual projects. CPSC's MIS tracks contract dollars and staff time by accounting codes that cover some specific projects and general categories, such as compliance work, which are composed of numerous activities. According to agency officials, CPSC's MIS generally cannot provide descriptive information on individual projects, such as when a project was started or concluded; the number of staff days used; what aspect of the product was addressed; whether the project originated from a petition, congressional mandate or other source; or what action was taken to address the hazard (mandatory standard, voluntary standard, or public information campaign, for example). In addition, CPSC staff told us that two separate projects involving the same or similar products at different times may be assigned the same MIS code. As a result, even if a project appears to be tracked in the MIS, reliable inferences cannot be drawn from MIS data.

CPSC Has Limited Ability to Evaluate Agency Impact

CPSC's limited data on deaths and injuries, combined with its lack of information on projects, reduce the agency's ability to evaluate the impact of its work, a process it is now required to undertake under recently passed legislation. The Results Act requires every federal agency to evaluate the effectiveness of its efforts starting in fiscal year 1999. The Results Act is aimed at increasing the investment return of tax dollars by improving agencies' performance. Under the Results Act, an agency is to set mission-related goals and measure progress toward these goals to evaluate agency impact. CPSC has preliminarily identified results-oriented goals in four areas: (1) reducing head injuries to children, (2) reducing deaths from fires, (3) reducing deaths from carbon monoxide poisoning, and (4) reducing deaths from electrocutions. However, the limitations in CPSC's injury and death data raise a question about how well CPSC will be able to evaluate the effectiveness of agency actions in these and other areas.

CPSC Uses COST-BENEFIT Analysis and Risk Assessment, but Improvements Are Needed in Data and Methodology

CPSC uses two analytical tools—risk assessment and cost-benefit analysis—to assist in making decisions on regulatory and nonregulatory methods to address potential hazards. Risk assessment involves estimating the likelihood of an adverse event (such as injury or death). For example, CPSC estimated that the risk of death from an accident involving an all-terrain vehicle (ATV) was about 1 death for every 10,000 ATVs in use in 1994. Cost-benefit analysis details and compares the expected effects of a proposed regulation or policy, including both the positive results (benefits) and the negative consequences (costs). Although cost-benefit

analysis may not be applicable to every decision and may not be the only factor appropriately considered in a decision, it can be a useful decision-making tool. The Congress requires CPSC to perform cost-benefit analysis before issuing certain regulations, and CPSC has conducted cost-benefit analysis for these regulations and in other situations in which it was not required. Although perfectly complete and accurate data are rarely available for any analysis, CPSC's data are frequently inadequate to support detailed, thorough, and careful risk assessment and cost-benefit analysis. In addition, CPSC's cost-benefit analyses are frequently not comprehensive, and the reports on these analyses are not sufficiently detailed. Improvements in the agency's methodology and in the quality of the underlying data are necessary to ensure the clarity and accuracy of CPSC's risk assessments and cost-benefit analyses.

CPSC Performs Cost-Benefit Analysis More Often Than Required by Law

Cost-benefit analysis can help decisionmakers by organizing and aggregating all the relevant information to clarify the nature of the trade-offs involved in a decision. Although cost-benefit analysis may not be appropriately used as the sole criterion for making a decision, a well-constructed cost-benefit analysis can highlight crucial factors, expose possible biases, and facilitate informed decisions even when it is impossible to measure all the potential effects of a specific regulatory proposal. The Congress has required CPSC to perform and publish a cost-benefit analysis when issuing a regulation (such as a mandatory standard or product ban) under the Consumer Product Safety Act. In addition, CPSC is also required to conduct cost-benefit analyses before issuing regulations under the authority of portions of the Federal Hazardous Substances Act (specified labeling provisions are exempt from this requirement) and the Flammable Fabrics Act.[17]

Because most of the agency's projects do not involve mandatory regulation, relatively few CPSC projects conducted between January 1, 1990, and September 30, 1996, were subject to these requirements. We identified 8 cost-benefit analyses that CPSC performed in accordance with these requirements, and an additional 21 analyses it conducted in situations in which it was not required. For example, CPSC performed cost-benefit analyses in eight instances in which it was considering issuing requirements for child-resistant packaging under the Poison Prevention

[17]As an independent agency, CPSC is not required to comply with Executive Order 12866, which requires federal agencies to perform a cost-benefit analysis and submit it to the Office of Management and Budget (OMB) for review whenever the agency issues a regulation that is economically significant.

Packaging Act, which does not require cost-benefit analysis.[18] CPSC frequently conducts cost-benefit analysis with respect to regulatory procedures, whether or not it is required to do so. However, a complete cost-benefit analysis is done less frequently for voluntary standards projects or information and education efforts, although some economic information may be generated to assist such projects. In addition to the complete cost-benefit analyses, we identified an additional 23 cases in which some information was provided on some economic benefits or costs.

Before issuing a mandatory regulation, CPSC is required to consider the degree and nature of the risk of injury the regulation is designed to eliminate or reduce. However, CPSC usually does not conduct a formal numerical risk assessment before issuing a regulation, and the law does not require it. We found 24 risk assessments conducted by CPSC between January 1, 1990, and September 30, 1996; only 4 of these were associated with regulatory action.

Agency Data Are Generally Insufficient to Support Thorough and Detailed Analysis

Both risk assessment and cost-benefit analysis require extensive data. Risk assessment requires information both on the adverse event and on exposure to the precipitating circumstances. For example, when CPSC performed a risk assessment on floor furnaces, the agency estimated the number of previous injuries associated with floor furnaces and the number of floor furnaces in use.[19] Similarly, when CPSC performed a risk assessment to examine the risk of contracting cancer from dioxin traces in common paper products, the agency used information from laboratory studies on dioxin's link to cancer and also incorporated data on exposure to paper products.[20] Because cost-benefit analysis includes a comprehensive delineation of the expected effects of a given proposal, a careful and thorough cost-benefit analysis will also be very data intensive and rich with detail.

CPSC's data systems are frequently unable to adequately meet the extensive demands for information posed by risk assessment and cost-benefit analysis. As a result, the agency's estimates of risks, costs, and benefits are

[18]For child-resistant packaging regulations, CPSC is legally required to consider only whether requiring child-resistant packaging is "technically feasible, practicable, and appropriate."

[19]CPSC found that the risk of injury associated with floor furnaces was small in terms of the number of incidents but relatively higher when considered in relation to the number of products in use.

[20]CPSC's study found that the risk from this type of dioxin exposure was negligible—at most, 5 cases per billion people exposed—and as a result no action was taken.

less accurate because they reflect the substantial limitations of the underlying data. Available information does not permit us to determine the potential impact of better data on the results of CPSC's cost-benefit analyses and risk assessments. Some of these data weaknesses tend to make product hazard risks seem larger, and other problems tend to make the same risks appear smaller. For example, because CPSC's data undercount the deaths and injuries associated with particular consumer products, estimates of risk—and the potential benefits of reducing that risk—appear smaller. However, CPSC's surveillance data provide information only on whether a product was involved in an accident, not on whether the product caused the accident. At least at the initial stages of a project, this can make the risks assessed by CPSC—and the benefits of reducing those risks—appear larger.

For risk assessment, CPSC must also obtain information on exposure to the hazard. For example, to assess the risk associated with aluminum ladders, CPSC obtained estimates of the number of ladders available for use and on the number of times each year the ladder was used. Obtaining exposure data presents special challenges for CPSC. Because the product definition that relates to a particular hazard is often relatively narrow, existing data sources frequently offer insufficient detail. For example, CPSC was unable to use Census sources to determine the number of saunas in the United States because saunas were included in a broader classification of products when government data were collected. In addition, CPSC staff told us that it is often difficult to find accurate information on the number of products that are in households and available for use.

CPSC sometimes responds to these challenges by using mathematical modeling techniques or easier-to-obtain proxy measures (such as population) to estimate product exposure. In addition, for a few large-scale projects, CPSC has incurred the substantial expenses necessary to conduct its own detailed exposure survey. For example, CPSC conducted a survey of households that asked detailed questions on matches and disposable cigarette lighters—the number purchased, where they are generally kept, how they are used, and other details. However, for the majority of the projects we reviewed, CPSC did not gather any data on exposure. Of the 80 projects we reviewed for which briefing packages were prepared, only 26 included information on exposure to the hazard, and CPSC's risk assessments were confined to 24 cases between 1990 and 1996—approximately 21 percent of all projects conducted over that time period.

CPSC Cost-Benefit Analyses Are Often Not Comprehensive and Not Reported in Sufficient Detail

The methodology used to conduct a cost-benefit analysis will frequently depend on the circumstances and the context of the analysis. For this reason, there is no complete set of standards for evaluating the quality of an individual cost-benefit analysis. However, the professional literature offers some guidance for analysts, and certain specific elements are frequently mentioned as essential for cost-benefit analysis. For example, because cost-benefit analysis is meant to be a complete delineation of the expected effects of a proposed action, all potential impacts (even those that cannot be quantified) should be discussed. To ensure that the reader is able to make an informed judgment, it is important to be explicit about the underlying data, methodology, and assumptions. Accordingly, the literature suggests that all methodological choices and assumptions should be detailed, all limitations pertaining to the data should be revealed, and measures of uncertainty should be provided to allow the reader to take into account the precision of the underlying data. Similarly, the literature calls for sensitivity analysis, which enables the reader to determine which assumptions, values, and parameters of the cost-benefit analysis are most important to the conclusions.

On the basis of our review of the cost-benefit literature, we developed a list of the elements that are frequently used in evaluating cost-benefit analysis. This list, and a description of all the factors we examined, is in appendix IV.[21] Although we compared each of these elements with each of CPSC's analyses, not all elements were applicable to each case. For example, in some cases, the circumstances indicated by a given element—such as reliance on statistical data—were not found, and those cases were treated as not applicable to that element. In addition, for some elements it was not always possible to determine whether CPSC's analysis was consistent with the element. For these reasons, and to emphasize those areas that we viewed as most critical, we reported only the evaluation results that relate to key elements, applied to the majority of CPSC's analyses, and for which a determination was possible in all or nearly all cases.

Our review of all the cost-benefit analyses that CPSC conducted between January 1, 1990, and October 31, 1996, showed that for many—but not all—elements, CPSC's analyses were not comprehensive and not reported in sufficient detail (see table 2). For example, CPSC provided descriptive information on proposals and also provided information on a variety of reasonable alternatives in almost 100 percent of cases. However, CPSC

[21]These elements are also similar to guidance OMB issued in January 1996 for preparing economic analyses of significant regulatory actions.

analyses generally did not provide measures of uncertainty for the underlying data. Estimates derived from samples are subject to sampling error, which can be especially large when the estimates are projected from relatively fewer cases. In only 17 percent of its analyses did CPSC provide any statistical information on the precision of the underlying estimates. Similarly, when estimates are based on a relatively small sample size, projections are generally not considered reliable. CPSC analysts cautioned the reader against making conclusions based on small sample data only 45 percent of the time. In addition, some of CPSC's data sets have a known upward or downward bias because of the way the data were constructed. For example, CPSC's estimates of deaths based on CPSC's death certificate database will be understated, and when estimates of incidents are based only on investigated or reported cases (such as cases reported to CPSC's hot line), two potential biases are likely to be introduced into the analysis: (1) the estimates are likely to be biased downward by nonreporting and (2) the incidents reported tend to be the more severe ones. In only 53 percent of applicable cases did CPSC's analysis inform the reader of known limitations inherent in the data being used for cost-benefit analysis.

Table 2: Evaluation of CPSC Analyses Shows Inconsistencies With Several Evaluation Elements

Evaluation element	Percentage of CPSC's analyses that were consistent with this element
Provided descriptive information about a well-defined proposal	98
Addressed multiple alternatives	95
Reported measures of precision for underlying data	17
Cautioned reader about making inferences from data with a small sample size	45
Reported known biases in underlying data	53
Provided any sensitivity analysis information	26
Included all important categories of benefits and costs	54
Considered "risk-risk" trade-offs[a]	49

[a]A "risk-risk" trade-off refers to an action to decrease a hazard's risk that unintentionally increases that or another risk.

We identified several other areas in which CPSC analyses could benefit from improvement. For example, researchers agree that sensitivity analysis—a technique that enables the reader to determine which assumptions, data limitations, or parameters are most important to the conclusions—should be incorporated in cost-benefit analyses. CPSC usually did not provide sensitivity analysis information. For example, agency

briefing packages did not include any information on how CPSC's injury cost estimates were derived or what factors were the largest components of injury costs. CPSC applies a statistical model to injury estimates to derive a figure for injury cost. The model that computed injury cost estimates accounts for a number of components, including medical costs, forgone wages, and pain and suffering. With only one exception, CPSC briefing packages provided only the total cost, without any information on the derivation of those costs or the individual components. In addition, CPSC provided only an average injury cost, not a range of injury cost estimates. For situations in which injuries differ in severity, or for projects in which severity is probably overstated or understated in the data, the reader would find such information useful.

Forty-six percent of CPSC analyses did not consider the full range of costs and benefits likely to result from regulation. For example, CPSC analysts frequently omitted mentioning intangible costs and/or benefits (costs or benefits that are difficult to quantify, such as loss of consumer enjoyment) or potential indirect effects (such as changes in the prices of related goods). In addition, CPSC frequently excluded risk-risk considerations from its evaluation of the costs and benefits of potential actions. Sometimes actions taken to reduce one risk can have the unintended effect of increasing that or another risk. Individuals may take more or fewer precautions in response to a change in a product's safety features, and this behavior can result in an increase in the risk the intervention was designed to mitigate. For example, in establishing a standard for child-resistant packaging that was also "senior-friendly," CPSC considered that because child-resistant medicine bottles can be difficult to open, a grandparent may leave the cap off the bottle, creating an even greater risk than would be the case with the original cap. Although CPSC considered such factors in some cases, only 49 percent of its analyses reflected potential risk-risk trade-offs.

CPSC has not established internal procedures that require analysts to conduct comprehensive analyses and report them in sufficient detail. For example, according to CPSC staff, the agency has little written guidance about what factors should be included in cost-benefit analyses, what methodology should be used to incorporate these factors, and how the results should be presented. Staff also told us that CPSC analyses are not generally subject to external peer review. Such reviews can serve as an important mechanism for enhancing the quality and credibility of the analyses that are used to help make key agency decisions.

CPSC Has Established Procedures for Complying With Statutory Requirements for Releasing Manufacturer-Specific Information

To help minimize the possibility that a product might be unfairly disparaged, in section 6(b) of the Consumer Product Safety Act the Congress imposed restrictions on the disclosure of manufacturer-specific information by CPSC.[22] Before CPSC can disclose any information that identifies a manufacturer,[23] the agency must

- take "reasonable steps" to verify the accuracy of the information and to ensure that disclosure is fair,
- notify the manufacturer that the information is subject to release, and
- provide the manufacturer with an opportunity to comment on the information.

If the manufacturer requests that its comments be included in CPSC's disclosure of the information, CPSC can release the information only if accompanied by the manufacturer's comments. If the manufacturer objects to the release even if its comments are included, it can challenge CPSC in U.S. district court to block disclosure. These restrictions on the release of information apply not only to information the agency issues on its own—such as a press release—but also to information disclosed in response to a request under FOIA. In addition, section 6(b) also requires CPSC to establish procedures to ensure that releases of information that reflect on the safety of a consumer product or class of products are accurate and not misleading, regardless of whether the information disclosed identifies a specific manufacturer.

CPSC has established procedures to implement these requirements, including requiring technical staff to "sign off" on information releases and notifying manufacturers. Evidence from several sources—industry sources, published legal decisions, and agency retractions—suggests that CPSC has complied with its statutory requirements. CPSC staff and commissioners, industry representatives, and consumer advocates expressed a wide variety of opinions on the effectiveness of these requirements, and some individuals favored specific changes.

[22]An exception to these restrictions is given if CPSC has declared that the product is an "imminent hazard" under section 12 of the Consumer Product Safety Act.

[23]These restrictions also apply even if the manufacturer is not named but the information would allow the reader to readily identify the manufacturer from the context. For example, if there is only one manufacturer of a product that is identified in the information, the information may be subject to restriction even if the manufacturer's name is not given.

CPSC Has Established Procedures for Verifying and Clearing Information for Release

Part of CPSC's mission is to provide the public with information to help individuals use consumer products safely. CPSC disseminates information through its own initiatives and also in response to requests from the public. For example, CPSC informs both consumers and businesses about product hazards through product recall notices, provision of information at trade shows and special events, and a telephone hot line and Internet site. In addition, CPSC responds to thousands of telephone and written requests for information each year.

CPSC's mission and its responsibility under FOIA require the agency to disseminate a great deal of information. However, because much of this information is about specific products or manufacturers, CPSC's information disclosure is often restricted under section 6(b). In its regulation implementing section 6(b), CPSC established several measures designed to ensure compliance with the statutory requirements. These measurers include obtaining written verification from consumers of the information they report to the agency, notifying manufacturers by certified mail when manufacturer-specific information is requested, and giving manufacturers the option of having their comments published along with any information being disclosed.

CPSC's procedures outline several steps to verify all information before it is released. For example, CPSC checks each report the agency receives from consumers about incidents involving potentially hazardous products to ensure that CPSC's records accurately reflect the consumer's version of the incident. Agency procedures require staff to send a written description of each incident back to the person who reported it with a request that he or she review it and state if any information needs to be corrected or supplemented.[24] The commission staff review each of these incident reports for discrepancies or any obvious inaccuracies. Once they have been checked and confirmed with the consumer, incident reports are made available to the public upon request. If the reports contain information that would identify a specific manufacturer, they are subject to 6(b) requirements regarding disclosure.

CPSC also investigates events surrounding selected product-related injuries or incidents. Investigation reports provide details about incident sequence, human behavior factors, and product involvement. The reports generally contain the consumer's version of what happened and the observations of witnesses, fire and police investigators, and others. Investigations may

[24]The cover letter that accompanies the incident report also asks recipients if they would like to have their names withheld if information about the incident is made public.

also include follow-up inspections at retail stores or service centers. However, neither investigations nor incident reports include the manufacturer's view of the incident. Its point of view may be expressed in comments it submits before the report is released. Like incident reports, investigation files are available to the public upon request and are subject to 6(b) requirements.

CPSC has issued clearance procedures to cover situations in which commissioners or staff initiate public disclosures—for example, when the Commission publishes the results of agency research. These procedures are intended to verify any information—oral or written—released by the Commission, regardless of whether the information identifies a manufacturer. Under CPSC's guidelines, each assistant or associate executive director whose area of responsibility is involved must review the information and indicate approval for the release in writing.[25] After all other review has been completed, the Office of the General Counsel must also review and approve the release. Press releases with respect to product recalls are written and issued jointly by CPSC and the affected manufacturer. In addition, CPSC's clearance procedures for press releases state that final clearance must be obtained from the Office of the Chairman of the Commission.[26] In addition, CPSC staff told us that the current chairman's policy of coordinating media inquiries through the Office of Public Affairs is intended to ensure that information provided is in compliance with section 6(b).

CPSC has also established procedures to implement the notification and comment provisions of section 6(b). Before CPSC releases information in response to an FOIA request, an information specialist determines whether a manufacturer could be readily identified. CPSC staff said that agency policy is to clearly and narrowly identify hazardous products (including by manufacturer) whenever possible, in order to prevent the person receiving the information from confusing safe products with unsafe products of the same type. However, if an information request is broad, like "all bicycle accidents," names of manufacturers are removed before the information is released, according to CPSC staff. If the requested information could identify a manufacturer, then staff review the information for appropriate exemptions (such as trade secrets), and delete portions as appropriate. The manufacturer is given 20 calendar days in which to review and

[25]For a description of CPSC's directorates, see app. II.

[26]An exception is made for those hazards considered by the Compliance staff as most serious, for which clearance must be obtained from a majority of the commissioners.

comment on a summary of the information CPSC plans to release.[27] Because CPSC often receives multiple requests for the same information, the agency informs manufacturers that it will not send them copies of subsequent requests for the same information unless specifically requested to do so. However, according to CPSC staff, more than 80 percent of the manufacturers that submit 6(b) comments routinely request such notification. In calendar year 1993 (the most recent year for which data were available), CPSC sent out 487 notices to manufacturers and received 154 responses (32 percent). Twenty-five manufacturers (5 percent) contested the accuracy of the information or claimed that the proposed disclosure would be unfair.

If a manufacturer fails to comment, the information can be released 30 days from the date CPSC notified the manufacturer. After taking the manufacturer's comments into account, CPSC may decide to disclose incident information despite the firm's objection if, for example, the comments lack specific information to support a claim of inaccuracy or a request for confidentiality. If CPSC chooses to disclose information over a manufacturer's objection, it must release the manufacturer's comments along with the other information, unless the manufacturer requests otherwise. In addition, if CPSC decides to release information and the manufacturer objects, the manufacturer has 10 working days to go to court and seek to enjoin CPSC from disclosing the information. Manufacturers have sued CPSC to prohibit disclosure of records only 11 times since the agency was founded, and CPSC was prohibited from releasing the information in 2 of these cases.[28]

Evidence Suggests That CPSC Complies With Legal Requirements Regarding the Release of Information

Information from three sources of evidence—industry, published legal cases, and data on retractions—suggest that CPSC complies with its statutory requirements concerning information release. Industry sources, even those otherwise critical of the agency, told us that CPSC generally does a good job of keeping proprietary information confidential as required by law. Our review of published legal decisions found no rulings that CPSC violated its statutory requirements concerning the release of information. Retractions by CPSC are also rare. If CPSC finds that it has disclosed inaccurate or misleading information that reflects adversely on any consumer product or class of consumer products or on any

[27]Since small companies may lack the technical ability to comment, CPSC staff told us that they will sometimes help small businesses to formulate their comments.

[28]Currently, Daisy Manufacturing, Inc. v. CPSC is on appeal, after a judge ruled in CPSC's favor in U.S. district court.

manufacturer, it must publish a retraction. Any retraction must be made in the same manner in which CPSC released the original information. According to CPSC, it has published only three such retractions. Two of these retractions, in 1984 and 1994, were made in response to requests from firms. A third retraction, in 1990, was issued after CPSC discovered that a report in its public reading room had mistakenly included inaccurate information.

Industry Observers, Consumer Groups, and Others Suggested Changes to 6(b) Requirements

Industry observers, CPSC staff, and consumer groups expressed a wide range of opinions on the effectiveness of section 6(b). In response to our inquiries, some CPSC commissioners and former commissioners said that these restrictions serve a useful purpose and should not be changed. However, CPSC's current chairman, industry and advocacy group representatives, and others expressed dissatisfaction with 6(b), and some of these suggested possible changes. Although these individuals raised issues about the extent of the protection afforded to manufacturers and the resources necessary to ensure compliance, we did not assess whether the specific suggestions were necessary or feasible.

CPSC's chairman, other CPSC officials, former commissioners, and the representative of a consumer advocacy group stated that compliance with 6(b) is costly for CPSC and delays the agency in getting information out to the public. Although CPSC has not estimated the cost of complying with 6(b), agency staff told us that it takes much more staff time to respond to FOIA requests that come under 6(b) than it does to respond to FOIA requests that do not involve company names. To reduce the burden of complying with these requirements, CPSC staff have suggested that the notification requirement that gives manufacturers 20 days in which to comment should apply only the first time an item is released. Some have suggested that instead of requiring CPSC to verify information from consumer complaints, the agency should be allowed to issue such information with an explicit disclaimer that CPSC has not taken a position on the validity of the consumer's report.

Instead of reducing CPSC's verification requirements, some industry representatives suggested expanding them. These manufacturers stated that before CPSC releases incident information, it should substantiate the information rather than relying on a consumer's testimony. Industry representatives stated—and CPSC staff confirmed—that many of the requests for CPSC information come from attorneys for plaintiffs in product liability suits. As a result, some industry representatives expressed

concern that unsubstantiated consumer complaints could be used against them in product liability litigation. They suggested that 6(b) should require CPSC to substantiate all incident reports by investigating them before they can be disclosed instead of merely checking with the consumer as it does now. However, CPSC officials told us that investigations—which are time consuming and costly—can be conducted only on a small proportion of specially selected cases because of limited resources.

Industry representatives also said that the current restrictions do not provide sufficient protection when information is released on product groups instead of on the products of an individual manufacturer. Several industry representatives expressed concern that producers of safer products may be unfairly maligned when CPSC releases information about a group of products, only some of which may be associated with a safety problem. According to some of these industry representatives, CPSC should extend protection to product groups similar to the safeguards manufacturers receive under 6(b).

Retailers' representatives also suggested specific changes to CPSC's information release requirements. They said that retailers do not receive timely notice of recalls because CPSC has interpreted the law to prohibit advance notification of retailers. Consequently, the retailers said that they sometimes receive notice of recalls at the same time as their customers and have no time to prepare. For example, when consumers come in with recalled products, the retailer may not yet know whether the manufacturer has agreed to replace the product, refund the purchase price, or provide some other remedy. Retailers' representatives suggested amending 6(b) to give 5 business days' advance notice to retailers before the public announcement of a recall. CPSC officials said that typically manufacturers are and should be the ones to contact the retailers and make all arrangements for a recall. Although they disagreed on the need for a statutory change, both CPSC staff and a major retailers' association said that they were trying to work out a more satisfactory arrangement.

Conclusions

CPSC's current data provide insufficient information to monitor ongoing projects and to determine whether potential projects adhere to the agency's selection criteria. Moreover, inadequate agency data often prevent CPSC from conducting risk assessments on projects, potentially limiting the agency's ability to target resources to the hazards presenting the greatest risks. The lack of sufficient data, combined with methodological problems, also makes CPSC's cost-benefit analyses less

useful than they could be. With more detailed information on both internal resources and external product hazards, CPSC would be better able to assure the Congress and taxpayers that its resources are expended wisely.

We identified several key areas where CPSC management could improve its collection and analysis of external data. For example, CPSC would be better able to make informed decisions on potential agency projects if it had additional statistically reliable and timely data in several areas, including (1) injuries treated outside of hospital emergency rooms; (2) exposure to consumer products and product-related hazards; (3) chronic illnesses related to consumer products; and (4) hazards that disproportionately affect certain vulnerable populations, such as low-income individuals and consumers with disabilities.

In addition, project selection and implementation could be improved if commissioners and staff had tracking information on CPSC projects, such as starting and ending dates, project origin, project costs (including staff days and contract costs), and agency actions taken to address the potential hazard. Such information could assist the commissioners in monitoring ongoing projects, targeting new efforts on the basis of previous work, and assessing the allocation of resources across current projects and among major hazard areas.

CPSC could also benefit from an improved methodology for cost-benefit analysis. A stronger methodological base for CPSC's cost-benefit analyses, including more complete documentation, would promote sound regulatory decision-making and could improve the quality of the input and comment CPSC receives during the regulatory process.

Without these improved data, CPSC will remain unable to accurately apply measurable criteria in choosing projects or to rigorously assess relative risks among potential hazards. Some of this necessary information—the need for more representative and complete injury and exposure data, for example—may require a significant investment of resources, so CPSC may need to prioritize these data needs. In doing so, is important for CPSC to draw on the insight of individuals outside the agency to ensure that all available alternatives for obtaining these data are explored. Some of the other information CPSC needs, however, could be compiled internally at relatively little additional cost and effort. For example, more detailed information on individual projects could be collected within the agency. Similarly, the methodological problems we identified in CPSC's cost-benefit analysis could be remedied without additional data.

Recommendations

We recommend that the Chairman of CPSC take the following actions:

- Improve the quality of CPSC's injury, death, and exposure data by consulting with experts both within and outside the agency to (1) prioritize CPSC's needs for additional statistically valid surveillance data on injuries and deaths related to consumer products and on exposure to consumer products and product-related hazards, (2) investigate the feasibility and cost of alternative means of obtaining these data, and (3) design data systems to collect and analyze this information.
- Direct agency staff to develop and implement a project management tracking system to compile information on current agency projects. For each project, such a system should include, at a minimum, a description of the hazard addressed, start and end dates, project origin, and major agency action resulting from it.
- Direct agency staff to develop and implement procedures to ensure that all cost-benefit analyses performed on behalf of CPSC are comprehensive and reported in sufficient detail, including providing measures of precision for underlying data, incorporating information on all important costs and benefits, and performing sensitivity analysis.

Agency Comments

We received two separate sets of comments from CPSC's commissioners—one from Chairman Brown and Commissioner Moore and one from Commissioner Gall. CPSC staff also submitted some technical comments, which we incorporated in the report as appropriate.

Chairman Brown and Commissioner Moore stated that they are considering our recommendations and that in some respects our recommendations parallel efforts already under way at the Commission. However, they disagreed with some of the specific findings of our report. They stated that CPSC's actions are based on solid injury and death estimates and that CPSC (1) employs sound economic analyses that are appropriate for the circumstances, (2) tracks projects to monitor the progress of its work, and (3) has been successful in dramatically reducing the threat to consumers from unsafe products. We concluded that CPSC's death and injury data are generally insufficient to support the agency's project selection process for two reasons: (1) CPSC has little or no data on several project selection criteria and (2) CPSC's data on its other project selection criteria exhibit significant gaps. Similarly, our finding that CPSC's cost-benefit analyses were not comprehensive and not reported in sufficient detail supports our conclusion that these analyses were less useful than they could have been in the agency's decision-making process.

Because CPSC's current management information system operates at a very high level of generality and (according to CPSC staff) does not produce consistent, reliable information, we recommend that the agency implement an improved tracking system that would provide enough information to monitor the projects selected and the resources spent for each hazard. We did not review whether CPSC's actions had been successful in reducing the number of injuries and deaths associated with consumer products. The full text of Chairman Brown and Commissioner Moore's detailed comments and our response are in appendix VI.

Commissioner Gall stated in her comments that she is looking forward to implementing many of the reforms we recommended. She also stated that she agrees with our conclusion that CPSC could improve the way it gathers information, including reassessing the need for injury data gathered outside of hospital emergency rooms. Commissioner Gall also agreed that CPSC needs an improved system to track ongoing activities or projects and that sensitivity analysis, measures of uncertainty, and risk-risk analysis should be incorporated into CPSC analyses. However, she also commented that additional GAO analysis of the implications of inadequate data could have been helpful. Unfortunately, available information does not permit us to determine the impact of better-quality data on the decisions made by CPSC. In addition, Commissioner Gall said that she believes the Compliance function of CPSC also warrants further review. Such a review is outside the scope of this report. Commissioner Gall's detailed comments and our response are in appendix VII.

As agreed with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days after its issue date. At that time, we will send copies to the commissioners of the Consumer Product Safety Commission and make copies available to others upon request.

If you or your staff have any questions about this report, please contact me at (202) 512-7014. Major contributors are listed in appendix VIII.

Carlotta C. Joyner
Director, Education
and Employment Issues

Contents

Abbreviations

AAPCC	American Association of Poison Control Centers
ANPR	Advance Notice of Proposed Rulemaking
ATV	all-terrain vehicle
CO	carbon monoxide
CPSC	Consumer Product Safety Commission
FOIA	Freedon of Information Act
HMO	health maintenance organization
IPII	Injury or Potential Injury Incident
LP	liquified petroleum
MECAP	Medical Examiners' and Coroners' Alert Program
MIS	management information system
NEISS	National Electronic Injury Surveillance System
NFIRS	National Fire Reporting System
NFPA	National Fire Protection Association
OMB	Office of Management and Budget

Scope and Methodology

This report provides information on project selection, analytical research, and information release procedures at the Consumer Product Safety Commission (CPSC), which we gathered from a variety of sources inside and outside the agency. For example, we interviewed current CPSC staff, including analysts and line managers, to obtain information about CPSC's data and procedures. We also interviewed the three current CPSC commissioners and four former commissioners. In addition, we interviewed representatives of manufacturers, retailers, trade associations, consumer groups, and academic and other experts to obtain their perspectives on CPSC's activities. We reviewed the legislation governing CPSC's activities and the associated regulations. We also reviewed statements by public and private organizations and the academic research literature dealing with consumer protection issues and the technical literature on cost-benefit analysis and risk assessment.

We gathered extensive information from CPSC documents. We reviewed every agency budget request, operating plan, mid-year review, and regulatory agenda from 1990 to 1996. We reviewed all CPSC's annual reports from fiscal years 1986 to 1996. We also obtained all CPSC Federal Register notices from January 1993 to May 1996 and selected Federal Register notices from January 1990 to December 1992. We reviewed all CPSC press releases from September 1992 to February 1996. We also reviewed 644 CPSC briefing packages prepared from January 1, 1990, to September 30, 1996, including all briefing packages that concerned a specific, identifiable potential product hazard under consideration for regulatory, voluntary, or information-gathering activities. We excluded matters exclusively related to compliance with and enforcement of existing standards, civil penalties, and internal management issues as well as other items not related to a specific potential product hazard. In addition, we reviewed other agency documents, including information-clearing procedures, documentation of data systems, consumer education materials, internal memorandums and correspondence, and selected documents downloaded from CPSC's Internet site.

In describing CPSC's project selection, we drew on our interviews with commissioners, former commissioners, and agency staff, and we reviewed the project selection criteria in CPSC's regulations. Although we described the criteria used by the agency, we did not make judgments about the merit of individual criteria or about whether any criterion was appropriately applied in any specific case. We compiled a list of agency projects on the basis of the documents we reviewed. We included not only major regulatory efforts but also smaller-scale projects. We gathered

information on the characteristics of these projects; for example, we obtained information on how the projects originated, what action CPSC took, and (for most) how many deaths and injuries were associated with the hazard. CPSC officials examined our list and provided some information that was not readily available in agency documents. However, because CPSC's internal data management system does not track agency projects, neither we nor CPSC were able to verify the accuracy and comprehensiveness of this information. We also reviewed agency documentation and the technical literature and interviewed outside experts to obtain information on CPSC's data-gathering systems.

To examine CPSC's cost benefit analysis, we reviewed the technical literature and developed a set of objective evaluation questions to elicit descriptions of and to evaluate the analytical work. These evaluation questions were designed to indicate only whether CPSC's cost benefit analyses were consistent with elements that are commonly used to evaluate whether cost-benefit analyses are comprehensive and reported in sufficient detail. Our review did not assess whether CPSC's analyses were the best that could be done on any particular topic. We reviewed these evaluation questions with two leading experts in the field of risk assessment and cost-benefit analysis: Professor John Mendeloff of the University of Pittsburgh and Professor John Graham of Harvard University. Then we examined all CPSC's cost-benefit analyses from January 1990 through September 1996 to see how they measured up against these evaluation questions. In making these assessments, we reviewed all the information available to the commissioners in the written record; that is, we did not confine our analysis to the portion of the briefing packages that dealt explicitly with cost-benefit analysis or risk assessment, and we examined all the briefing packages that pertained to that particular project. Although we evaluated CPSC's cost-benefit analyses using a wide-ranging set of evaluation questions, we reported results of our analysis only for those questions where: (1) the question was applicable to the majority of the CPSC analyses we reviewed; and (2) we were able to make a determination of whether the analyses were consistent with the evaluation question in applicable cases.

To review CPSC's information release process, we reviewed internal agency procedures, discussed the information release requirements with agency officials and industry representatives, and reviewed the relevant legal cases. We provided information on CPSC's information release procedures but did not audit whether CPSC complied with these procedures in releasing information. Instead, we relied on other sources—industry

sources, published legal decisions, and retractions—to assess whether this readily available evidence suggested that CPSC had violated its statutory requirements in releasing manufacturer-specific information.

Our review was conducted between August 1996 and May 1997 in accordance with generally accepted government auditing standards.

Agency Organization and Structure

The Consumer Product Safety Act (P.L. 92-573) provides for the appointment of five commissioners by the President of the United States for staggered 7-year terms. Not more than three of the commissioners may be affiliated with the same political party. The President appoints the commissioners, subject to Senate confirmation. However, the President cannot directly overrule an agency decision or fire a commissioner for making an unpopular decision. Since 1986, there have been no more than three commissioners at one time. In fulfilling the provisions of the government in the Sunshine Act (P.L. 94-409),[29] in general, commissioners must open to the public any meeting held for the purpose of disposing of CPSC business—that is, if any two of the three commissioners want to discuss agency business, generally public notice must first be given. On a daily basis, communication among CPSC offices takes place at the staff level.

The chairman, the principal executive officer of the Commission, directs all executive and administrative functions of the agency. The chairman oversees the appointment and supervision of all agency personnel except those employed in the immediate offices of other commissioners. CPSC annually elects a vice chairman to act in the absence or disability of the chairman or in case of a vacancy in the office of chairman.

As figure II.1 shows, six offices report directly to the chairman:

- the Office of the Secretary manages the agency's records, publishes CPSC's public meetings calendar, and administers the requirements of the Freedom of Information Act;
- the Office of Congressional Relations serves as CPSC's liaison with the Congress;
- the Office of General Counsel provides advice and counsel to the agency on legal matters;
- the Office of the Inspector General is an independent office that undertakes activities to prevent and detect waste, fraud, and abuse; and
- the Office of Equal Opportunity and Minority Enterprise monitors compliance with equal opportunity employment laws.

The agency's executive director, who is appointed by and reports directly to the chairman, is responsible for overseeing the day-to-day management of the agency. The executive director's office also houses the agency's small business ombudsman, who acts as a liaison to small businesses,

[29]The purpose of the Sunshine Act is to provide the public with information regarding the decision making processes of the federal government while protecting both the rights of individuals and the ability of the government to carry out its responsibilities.

providing technical assistance concerning CPSC programs and regulations, among other things.

The executive director has line authority over nine operating directorates:

- The Office of Compliance is responsible for compliance with and administrative enforcement of CPSC regulations, including product standards. The office initiates investigations on safety hazards of products already in the consumer marketplace or being offered for import. It negotiates and subsequently monitors corrective action plans designed to give public notice of hazards and recall defective or noncomplying products.
- The Office of Hazard Identification and Reduction manages many of CPSC's activities that involve identifying, examining, and remedying new product hazards. The office's responsibilities include collecting and analyzing data to identify hazards and hazard patterns, carrying out CPSC's regulatory and voluntary standards development projects, and coordinating international activities related to consumer product safety. Serving in various groups under the director of hazard identification and reduction are the epidemiologists and statisticians, who provide information on particular products; engineers and human factors specialists, who help develop design remedies for product hazards; and economists, who provide market information and perform cost-benefit analysis on commission projects.
- The Office of Information and Public Affairs is CPSC's touchstone with consumers and the media. It prepares and publishes brochures, booklets, fact sheets, and safety alerts providing safety information to consumers on products used in the home environment. The Office of Information and Public Affairs also handles requests from the media for information and access to CPSC staff and prepares press releases announcing CPSC actions or decisions.
- The Office of Information Services manages the agency's toll-free hot line, Internet, and fax-on-demand services. Within the Office of Information Services, CPSC's Information Clearinghouse provides summary information on product-related injuries in response to requests from the public.[30]
- The Office of the Budget is responsible for overseeing the development of CPSC's budget.
- The Office of Human Resources Management provides support to the agency in recruitment and placement, position classification, training, and other personnel areas.

[30]If such a request can not be filled without identifying the manufacturer, however, the request is sent to the freedom of information officer for processing.

- The Office of Planning and Evaluation assists with long-term planning efforts and manages and ensures agency compliance with paperwork reduction regulations. In addition, the Office of Planning and Evaluation is currently preparing for the implementation of the Government Performance and Results Act (the Results Act) and reviewing the effectiveness of the agency's outreach efforts.
- The Directorate for Field Operations coordinates the activities of CPSC's 128 field staff located in 38 cities across the country. CPSC field staff carry out a wide range of agency activities, including conducting investigations of injury incidents; acting as liaisons with state and local organizations; working with the local press to support consumer education campaigns; and inspecting manufacturers, importers, distributors, and retailers to ensure compliance with safety regulations and standards. To complement the efforts of the field staff at the local level, CPSC contracts some product safety work to state and local entities; commissions state and local officials to function as officials of CPSC for the purpose of conducting investigations, inspections, recalls, and sample collections; and transmits information on CPSC programs and activities to states.
- The Directorate for Administration is responsible for executing general administrative policies.

Figure II.1: CPSC Organization Chart

CPSC Projects, 1990-96

CPSC has addressed many different product hazards. We identified 115 projects the agency worked on between January 1, 1990, and September 30, 1996. Because CPSC does not maintain a list of projects it has worked on or any project characteristics, such as project origin or result, we used various agency documents, such as budget requests, annual operating plans, regulatory agendas, and project briefing documents, to compile our list.

We attempted to determine how each project came to the attention of the agency, for example, through a petition, congressional direction, or internal initiation. This was not always clear. For example, in three cases, a petition was submitted and subsequently denied, but the issue was later mandated by the Congress as a project the agency must address. For example, a petition concerning the safety of bicycle helmets submitted in 1990 was denied. In 1994, the Congress passed the Children's Bicycle Helmet Safety Act of 1994, which requires CPSC to establish a mandatory standard. We counted such projects as originating through the Congress. In other cases, we categorized projects on the basis of information in CPSC documents.

We also attempted to identify the most significant action that resulted from the agency's efforts. Some projects were ongoing for several years and involved more than one agency action, such as information campaigns conducted in conjunction with voluntary standards efforts. For example, agency work on carbon monoxide (CO) detectors resulted in a voluntary standard in 1992, a "CO Awareness Week" information campaign in 1994, and public hearings on the issue in 1996. In cases such as these, we attempted to identify the activity with the greatest long-lasting impact; usually this was a voluntary or mandatory standard. Also, projects classified as "voluntary standard activity" include those for which a new voluntary standard was created, an existing voluntary standard was revised, or staff are currently participating in voluntary standard activities.

In addition, we identified whether a risk assessment or cost-benefit analysis was completed for a given project, using CPSC briefing packages. We defined a formal risk assessment to include only those cases for which a numerical estimate of unit risk was calculated; we defined a complete cost-benefit analysis to include those projects for which both economic costs and benefits were explicitly compared, even if quantitative estimates were not made for all economic factors considered. Some risk-related or economic information was provided for many of the projects for which no formal, complete risk assessment or cost-benefit analysis was performed.

Table III.1: CPSC Projects, 1990-96

	Origin		
Product	**Initiated by the Congress**	**Petition**	**Initiated by agency**
Fire/gas codes and standards			
Camping heaters			x
Carbon monoxide detectors			x
Children's sleep-wear flammability		x	
Cigarette lighters		x	
Cigarette safety	x		
Elderly sleepwear flammability			x
Fire safety devices			x
Fireworks, fuse-burn time		x[c]	
Fireworks, large and small reloadable shell			x
Fireworks, multiple tube mine and shell			x
Flexible gas connectors			x
Floor furnaces		x	
Fuel gas detectors			x
Gas control valves, automatic			x
Gas furnaces			x
Gas grills, 20-lb. systems			x
Gas systems, over-pressurization		x	
Heaters, unvented gas space heaters			x
Liquified petroleum (LP) gas odorant fade			x
Mattress/bedding fires			x
Multipurpose lighters		x	
Range/oven fires			x
Smoke detectors			x
Upholstered furniture		x	
Water heaters			x
Sports and Recreation			
All-terrain vehicles (ATV)			x
Baseball injuries[g]			x
Baseball bases			x

Agency action					Analytical efforts	
Ban	Mandatory standard	Voluntary standard activity[a]	Information and education	Other[b]	Cost-benefit analysis done	Risk assessment done
		x				
		x				
x				x		
	x				x	x
				x		
				x		
				x		
	x				x	
x					x	x
	x				x	
		x				
				x		x
				x		
		x				
		x				
		x				
	x					
		x				
		x				
				x		
				x[d]	x	
				x		
		x				
		x[e]				
		x			x	
				x[f]		x
				x		
		x				

(continued)

Product	Origin		
	Initiated by the Congress	Petition	Initiated by agency
Baseball, chest protectors for young batters			x
Baseball, face-guards on helmets	x		
Baseball, safety baseballs (soft)			x
Bicycles			x
Bicycle reflectors			x
Bicycle/recreation helmets	x[h]		
In-line skates			x
Model rocket motors		x	
Pools, barriers for swimming pools and spas			x
Pools, diving injuries			x
Pools, swimming pool covers		x	
Saunas		x	
Soccer injuries			x
Soccer goals			x
Spas and hot tubs		x	
Electrical/power codes and standards			
Garage door openers	x		
Go-carts			x
Hair dryers		x	
Heaters, portable electric		x	
Heat tapes		x	
Holiday lights			x
Home electrical system fires			x
Ladders, portable aluminum		x	
Lamps, portable			x
Microwave ovens			x
Mowers, riding			x
Mowers, walk-behind			x
Receptacle outlets			x
Shock protection devices (GFCI)			x

Agency action					Analytical efforts	
Ban	Mandatory standard	Voluntary standard activity[a]	Information and education	Other[b]	Cost-benefit analysis done	Risk assessment done
		x				
	x			x	x	
		x				
			x			x
				x		
	x					x
				x		
				x		
		x				
		x				
		x				
		x				
				x		
		x				
		x				x
	x				x[i]	
		x				
		x				
				x		
				x	x	
		x				
		x				
				x	x	x
		x				
		x				
		x			x	x
				x		
		x				
		x				x

(continued)

Product	Origin		
	Initiated by the Congress	Petition	Initiated by agency
Thermoplastics in electrical products			x
Children's products			
Baby bath seats			x
Baby walkers		x	
Bean bag chairs			x
Bunk beds		x	
Child restraints on grocery carts		x	
Choking hazards—balloons, balls, marbles, x small figures, pom-poms			
Clacker balls		x	
Crib corner post extensions		x	
Cribs, nonfull size			x
Crib toys		x	
Drawstrings on children's clothing			x
Electronic video games		x	
5-gallon buckets			x
Furniture tipover			x
High chairs			x
Infant cushions			x
Infant suffocation			x
Lead in paint			x
Playground equipment, home		x	
Playground equipment, public			x
Playground equipment, soft			x
Playground surfacing			x
Play yards			x
Strollers			x
Toddler beds			x
Window blind cords			x
Window guards			x
Chemical/poison prevention			

Agency action					Analytical efforts	
Ban	Mandatory standard	Voluntary standard activity[a]	Information and education	Other[b]	Cost-benefit analysis done	Risk assessment done
				x		
			x			
		x[d]			x	x
		x				
		x				
			x		x	x
x				x		
	x				x	
		x				x
		x				
		x				
		x				
	x				x	
		x				x
		x				
		x				
x					x	
			x			
				x		
		x			x	x
		x				x[j]
		x				
		x				
		x				
		x				
		x				
		x				
		x				

(continued)

Product	Origin		
	Initiated by the Congress	Petition	Initiated by agency
Acetone in 1-gallon containers		x[k]	
Architectural glazing		x	
Art materials	x		
Charcoal labeling		x	
Child-resistant, adult-friendly packaging of drugs			x
Child-resistant packaging of certain dietary products with iron powders		x	
Child-resistant packaging of dibucaine			x
Child-resistant packaging of ibuprofen			x
Child-resistant packaging of drugs with loperamide			x
Child-resistant packaging of glue removers with acetonitrile		x[l]	
Child-resistant packaging of hair wave neutralizers		x[l]	
Child-resistant packaging of lidocaine			x
Child-resistant packaging of mouthwashes with ethanol		x	
Child-resistant packaging of naproxen			x
Child-resistant packaging of spot remover with naptha		x[m]	
Coal- and woodburning stove emissions	x		
Dichlorobenzene			x
Dioxin in paper products			x
Exemption to child-resistant packaging of mouthwashes with ethanol	x		
Indoor air quality	x		
Indoor air quality—carpet emissions x			

Agency action					Analytical efforts	
Ban	Mandatory standard	Voluntary standard activity[a]	Information and education	Other[b]	Cost-benefit analysis done	Risk assessment done
				x		
				x	x	
	x					
	x				x	x
	x				x	
	x					
	x				x	
	x				x	
	x				x	
	x				x	
	x				x	
	x				x	
	x				x	
	x					
				x		
				x		x
				x		x
				x		x
			x			
				x		
		x			x	

(continued)

Product	Origin		
	Initiated by the Congress	Petition	Initiated by agency
Indoor air quality—formaldehyde in pressed x wood products			
Indoor air quality—glycol ethers x			
Indoor air quality—heating, ventilation, and x air-conditioning systems			
Indoor air quality—kerosene heaters x			
Indoor air quality—portable x room humidifiers			
Lead poisoning abatement			x
Methylene chloride in paint strippers		x	
Sulfuric acid drain cleaners		x	
Other			
Waterbeds		x	
Total 115	**13**	**34**	**68**

Agency action					Analytical efforts	
Ban	Mandatory standard	Voluntary standard activity[a]	Information and education	Other[b]	Cost-benefit analysis done	Risk assessment done
	x					
			x			
			x			
	x					
	x					
		x				
				x		x
				x		
		x				x
2	**21**	**55**	**5**	**32**	**29**	**24**

[a]"Voluntary standard activity" includes efforts in which agency staff participated in the development of a new voluntary standard or revision of an existing voluntary standard. This participation included regularly attending meetings of a standards development group; taking an active part in discussions; and providing research or other support, information and education programs, and administrative assistance.

[b]"Other" includes projects that were completed with no agency action, terminated, currently in process or pending, or completed with a study or report.

[c]Two petitions were submitted for fuse-burn time. The first, submitted in 1991, was denied. The second, submitted in 1996, resulted in a change to an existing mandatory standard.

[d]CPSC published an Advance Notice of Proposed Rulemaking (ANPR). This is the first step toward enacting a mandatory standard.

[e]CPSC published an ANPR in 1994, which is the first step toward enacting a mandatory standard. The ANPR also solicited offers to develop or modify a voluntary standard. During fiscal year 1996, CPSC worked with an industry group on voluntary standards development.

[f]CPSC has worked with states to develop state ATV legislation.

[g]The baseball injuries project started in the 1980s and resulted in a special report on baseball injuries and protective equipment. The projects—baseball bases, chest protectors, faceguards on helmets, and safety baseballs—all grew out of this umbrella project and, as such, are counted separately.

[h]A petition was also submitted in 1990. The Congress mandated this project in the Children's Bicycle Helmet Safety Act of 1994. Project origin is counted as congressionally initiated.

[i]The cost-benefit analysis for garage door openers applied to the labeling and record-keeping requirements only, not to the provisions of the safety standard.

[j]The risk assessment for playground equipment examined the hazard associated with exposure to arsenic from wooden equipment. The risk assessment concluded that the risk was small. Most of CPSC's efforts concerning playground equipment are related to injuries from falls or impacts of equipment and are not related to chemical exposure.

[k]Petition, submitted in 1995, was withdrawn.

[l]One petition was submitted in 1988 by the American Association of Poison Control Centers requesting CPSC to require child-resistant packaging both for household glue removers containing acetonitrile and home cold wave permanent neutralizers containing sodium bromate or potassium bromate.

[m]Petition, submitted in 1991, was withdrawn.

A Review of the Literature on COST-BENEFIT Analysis

Cost-benefit analysis can be described as an analytical technique that details the expected positive and negative effects of a given policy proposal (expected benefits and costs). To construct this framework, researchers approach a policy question needing considerable information about the potential remedy. Because cost-benefit analysis requires an inclusive approach to evaluating a proposal's impact, the proposal itself must be well defined, and some information must be known about its impact. Once the expected benefits and costs of the proposal are thoroughly identified and delineated, the next step is to place a value on each benefit or cost. Frequently, these expected costs and benefits are expressed in numerical or monetary terms to facilitate a comparison of the aggregate costs and benefits. If all relevant factors can be translated into monetary terms, the decision rule suggested by this proceeding is to accept the proposal if its aggregate benefits exceed its aggregate costs.[31]

Although at first the concept behind cost-benefit analysis seems relatively straightforward, the application of cost-benefit analysis is not. The practical difficulties associated with measuring effects, quantifying results, and accounting for uncertainty (to name only a few issues) can create a gap between the way cost-benefit analysis is described in theory and the way it is implemented in practice. For this reason, experts generally agree that analysts should be comprehensive in including all important factors and be explicit in their description of the underlying data, methodology, and assumptions.

This appendix describes many of the major methodological issues that often arise in cost-benefit analysis and outlines specific elements that are frequently used to evaluate cost-benefit analyses. The methodology used to conduct a cost-benefit analysis frequently varies depending on the circumstances and the context of the analysis. For this reason, there is no complete set of standards for evaluating the quality of an individual cost-benefit analysis. However, the professional literature offers some guidance for analysts, and certain specific elements are frequently used to determine whether a given analysis meets a minimum threshold of comprehensiveness and openness. These elements are necessary, but not sufficient, for a quality analysis.

[31]Variations of cost-benefit analysis include cost-effectiveness analysis, which relates the costs and outcomes of alternative methods to achieve the same desired goal. For example, one cost-effectiveness analysis compared the cost per case detected for different methods of treating the same medical condition. Because only cost-benefit analysis is relevant to CPSC's activities, related techniques are not considered here. For more information on these and other related analytical tools, see Michael F. Drummond, Greg L. Stoddart, and George W. Torrance, Methods for the Economic Evaluation of Health Care Programmes (New York: Oxford University Press, 1996).

From the extensive cost-benefit literature, we developed objective evaluation questions to evaluate cost-benefit analyses performed by CPSC. These evaluation questions are summarized in table IV.1. Although these evaluation questions are not a comprehensive measure of the quality of an analysis, they were designed to reflect whether an analysis is comprehensive and reported in sufficient detail. We applied these questions to each of CPSC's analyses, but not all evaluation questions were applicable to each case. In addition, for some questions it was not always possible to determine whether CPSC's analysis complied with the particular element reflected in the question. For these reasons, and to emphasize those areas that we considered as most critical, we reported only the evaluation results that related to key elements and that applied to the majority of CPSC's analyses; these eight are shown in bold in table IV.1.

Table IV.1: Frequently Used Elements of Evaluation of Cost-Benefit Analysis

Number	Evaluation question
Evaluating potential courses of action	
1	**Was descriptive information given about well-defined alternative courses of action?**
2	**Was more than one alternative course of action considered in the analysis?**
3	Was evidence given to support the degree to which the proposal was assumed to mitigate the problem?
Considering all important factors for analysis	
4	**Were all important categories of potential costs and benefits included in the analysis?** (For example, did the analysis include [where applicable] intangible benefits and costs, health and safety benefits, costs of compliance, upfront costs, price changes, and changes in consumer surplus?)
5	Were the effects of intangible costs and benefits detailed explicitly, even if they could not be quantified? (For example, did the analysis include [where applicable] consumer utility?)
6	Did the analysis show how the existence of intangible costs or benefits could affect the conclusions?
7a	Were possible indirect effects discussed? (For example, did the analysis include [where applicable] price changes of related goods or likely changes in market concentration?)
7b	If indirect effects were measured quantitatively, were the calculations and assumptions behind this measurement discussed in detail?
7c	If indirect effects were measured qualitatively, did the analysis show how the existence of these factors could affect the conclusions?
Considering interdependent factors	
8	Were possible issues of standing identified?
9	Was an incremental (marginal) analysis of costs and benefits performed?

(continued)

Number	Evaluation question
10	Were major policy interdependencies identified? (For example, did the analysis discuss the implications if another agency also had jurisdiction over the product, or if the proposal could create a conflict with existing government policy?)
Considering distribution issues	
11	Did the analysis make clear the distribution of gains and losses? (For example, who would pay the costs and who would get the benefits of the proposal?)
12a	Was the impact of distribution of gains and losses assessed? (For example, would the proposal be likely to have a greater adverse impact on small businesses, potentially leading to increased market concentration?)
12b	Were distributional weights employed in the analysis?
12c	If weights were used, was information provided about the basis for those weights?
13a	Is the standard assumption that relative market prices are insensitive to the policy change likely to hold in this case—that is, are there likely to be few or no macroeconomic effects?
13b	If no, was this impact discussed or considered in the analysis?
Considering risk-risk factors and potential offsetting behaviors	
14	**Were risk-risk or offsetting behavior concerns identified and considered in the analysis?**
Using the willingness-to-pay approach to value risk reduction	
15	Were willingness-to-pay measures used to value reductions in the risk of death or injury?
16	Is the numerical value of a statistical life used in this analysis consistent with the literature?
17	Is the numerical value of a reduction in the chance of injury consistent with the literature?
Discounting future costs and benefits	
18a	Are costs and benefits that occur at different points discounted for differences in timing?
18b	Does the discount rate or rates used include the suggested rate by the Office of Management and Budget?
18c	Does the discount rate or rates used include the Treasury bill rate for the time horizon of the analysis?
18d	Does the discount rate or rates used include a lower “social” discount rate?
Considering data issues	
19a	Where applicable, were the implications of unverified or unverifiable data provided by an interested party identified and discussed?
19b	Where applicable, were the implications of uncertainty surrounding a dose-response model identified and discussed?
19c	Where applicable, were the implications of uncertainty surrounding crossspecies extrapolation identified and discussed?

(continued)

Number	Evaluation question
19d	Where applicable, were the implications of the use of data relying on investigated or reported cases identified and discussed?
19e	Where applicable, were the implications of survival bias in the underlying data identified and discussed?
19f	**Where applicable, were the implications of small sample sizes identified and discussed?**
19g	**Where applicable, were the implications of other known biases in the underlying data identified and discussed?**
20	**If the underlying data were derived from a statistical sample, were appropriate measures of precision provided?**
Performing sensitivity analysis	
21a	**Was sensitivity analysis performed on any parameter in the analysis?**
21b	Was sensitivity analysis performed on the value of a statistical life?
21c	Was sensitivity analysis performed on the value of injury reduction?
21d	Was sensitivity analysis performed on the discount rate?
21e	Was sensitivity analysis performed on the precision of the underlying data?
21f	Was sensitivity analysis performed on other important parameters?

Note: We reported results for questions that are in bold. We viewed these measures as especially important, and they applied to the majority of CPSC analyses and a determination could be made for these questions in each case.

Background

As an organizing framework, cost-benefit analysis can help a decisionmaker to organize and aggregate all the relevant information in a way that can clarify the nature of the trade-offs involved in a decision. At the same time, by providing a framework to convert dissimilar effects to a common measurement, cost-benefit analysis can allow this information to be weighed and aggregated to help make a decision. A well-constructed cost-benefit analysis can highlight crucial factors, expose possible biases, and perhaps expand the openness of the decision-making process by clarifying the factors on which the decision was based—whether these factors are purely economic criteria or include other social factors. A key advantage of carefully built cost-benefit analysis is that it promotes explicit rather than implicit decision-making, even when it is impossible to monetize or even quantify all the potential effects of a given regulatory proposal.

Despite the value of this analytical tool, in some situations using cost-benefit analysis as the sole basis for decision-making may be

inappropriate. For example, alternatives that would eliminate basic human rights or dramatically increase income inequality may be viewed as morally unacceptable. Similarly, when uncertainty about possible effects is so pervasive that attempting to identify potential costs and benefits would amount to nothing more than uninformed speculation, cost-benefit analysis probably has little to offer.[32] In addition, for minor decisions it may not be necessary to employ a rigorous, time- and resource-consuming decision-making process, and a less detailed cost-benefit analysis—or none at all—may be more appropriate. Virtually all observers agree that the appropriate role for cost-benefit analysis—sole decision-making rule, input into decision-making, or not done at all—will depend on the context in which the particular decision is being considered.

To some individuals, application of an abstract analytical technique such as cost-benefit analysis is especially unpalatable in certain situations. For example, the idea of applying a value to "saving life" may be distasteful, because we regard our own lives as "priceless" or of infinite value. However, although our lives may be priceless, avoiding risks often means forgoing time, convenience, enjoyment, or other opportunities—all of which do have a price. Thus, policy interventions that can affect life expectancy pose an unavoidable problem—to refuse to consider the value of potentially lifesaving interventions is to implicitly value them at zero, and to consider any potentially lifesaving activity as infinitely valuable implies that individuals would never take any action that involves risk (driving a car, for example). The literature on cost-benefit analysis makes a key distinction in this area. For ethical reasons, most practitioners consider it inappropriate to use cost-benefit analysis to evaluate alternatives that would (with certainty) affect the life expectancy of a given, known individual. But government policy does not usually involve making such decisions. Instead, policy questions typically center on actions that may bring about small changes in the statistical life expectancy of anonymous members of a large group. For example, when CPSC considered imposing a mandatory regulation on large, multiple-tube fireworks, the agency estimated that such a standard could reduce the number of individuals that die in related accidents by one anonymous

[32]However, one should use caution in assuming that this situation applies. Sometimes the conclusions of a cost-benefit analysis can be quite robust even in the face of substantial uncertainty. For example, a recent analysis of the benefits and costs of reducing emissions of acrylonitrile concluded that imposing strict standards on acrylonitrile emissions fails reasonable cost-benefit tests, despite as much as a threefold factor of uncertainty in acrylonitrile emissions, additional uncertainty in the amount of exposure to acrylonitrile, and a probable but unmeasurable upward bias in the estimate of cancer risk. (See John A. Haigh, David Harrison, Jr., and Albert L. Nichols, "Benefit-Cost Analysis of Environmental Regulation: Case Studies of Hazardous Air Pollution," ch. 1 in The Moral Dimensions of Public Policy Choice: Beyond the Market Paradigm, eds., John Martin Gilroy and Maurice Wade (Pittsburgh, Pa.: University of Pittsburgh Press, 1992), pp. 15-57.

consumer over a 3-year period. On a daily basis, each of us makes such trade-offs between perfect safety and other things we value, such as the convenience of driving a car or the excitement of skiing down a mountain. Such assessments, which place a value on reductions in risk, are viewed as appropriate, whereas valuing a given person's life may be viewed as less reasonable.

Similarly, a decision to surrender basic rights—such as liberty—may be unacceptable on moral grounds, and so cost-benefit analysis might not be applicable in a situation involving such rights. In addition, some individuals object to cost-benefit analysis in circumstances in which other species may be affected adversely. For example, one individual objected to a proposal that would allow increased pollution in a particular river because the proposal would adversely affect the fish and other species in the river. Cost-benefit analysis would probably be unable to address this objection because there is no accepted method to place a value on the losses suffered by the fish.

Conceptual, Analytical, and Technical Issues Arise When Applying COST-BENEFIT Analysis

Over the past 3 decades, a substantial economic literature has explored the conceptual, analytical, and technical issues posed by the application of cost-benefit analysis. From this literature, generally accepted standards of professional practice have emerged that cover a wide range of research methods. As one experienced researcher has said, "Good studies follow procedures that are in accord with economic theory for estimating benefits and costs, provide a clear statement of all assumptions, point out uncertainties where they exist, and suggest realistic margins of error."[33] Even when undertaken by careful and competent researchers, cost-benefit analysis can sometimes be difficult to interpret, especially when uncertainty is substantial and information is incomplete.

Conceptual Issues in Cost-Benefit Analysis

Some of the issues underlying the application of cost-benefit analysis are conceptual, and the researcher may make a different judgment in different circumstances. With respect to these issues, being complete and explicit is important—the consensus in the literature is that while there may be no single method for dealing with these issues that is universally appropriate, the researcher must be clear and direct in detailing how the issue was addressed in the context of the analysis.

[33]See Eban Goodstein, "Benefit-Cost Analysis at the EPA," The Journal of Socio-Economics, 24 (2) (1995), pp. 375-89.

Intangible or Unquantifiable Factors Can Pose Dilemmas for Researchers

Ideally, a cost-benefit analysis involves translating each impact into a common measurement (such as dollars) for comparison. However, some effects may be difficult or impossible to measure or quantify. For example, a researcher evaluating an alternative outpatient mental health treatment program realized that the greater independence afforded by the outpatient program could create increased anxiety—or, alternatively, higher self-esteem—for some participants. However, these intangible effects would be very difficult to measure and even more difficult to quantify.[34] Some individuals have criticized certain individual practitioners of cost-benefit analysis for ignoring or de-emphasizing aspects of proposed changes that cannot be easily quantified. Although it is necessary for such effects to be described and emphasized appropriately, the existence of such intangibles does not necessarily limit the value of the analysis. For example, in the discussion of mental health programs, the researchers found that patients in the experimental program experienced higher satisfaction and reported having a greater number of social relationships. These qualitative benefits were important to the analysis even though they could not be valued in dollars. In addition, if it can be shown explicitly that the value of the intangibles would be unlikely to change the conclusion, then cost-benefit analysis has played a valuable role by considering intangible effects explicitly, even if it is not possible to consider them quantitatively. (We addressed this issue in questions 5 and 6 of table IV.1.)

Measuring Indirect and Secondary Costs and Benefits Can Be Difficult

Researchers must also decide whether or not to include indirect or secondary effects that may result from the proposal. For example, a change in tax rules may not only have an initial, direct effect on individuals' income but may also create a secondary ripple (or "multiplier") effect on the economy as a whole. Similarly, a medical treatment that prolongs life can be expected to have a secondary effect on health care costs as individuals live longer.

A researcher who wants to include such secondary impacts will frequently find a measurement challenge, because determining the magnitude (or perhaps even the existence) of many secondary effects involves answering a "what if?" type of question, and frequently without relevant historical experience. For example, individuals who receive improved treatment for hypertension may contract more prolonged or costly illnesses in the future.[35] Any attempt to measure the impact of these indirect future costs

[34]See Burton A. Weisbrod, "Benefit-Cost Analysis of a Controlled Experiment: Treating the Mentally Ill," Journal of Human Resources, 16 (4) (1981), pp. 523-48.

[35]For an example of such an analysis, see W.B. Stason and M.C. Weinstein, "Allocation of Resources to Manage Hypertension," The New England Journal of Medicine, 296 (13) (1977), pp. 732-39.

would require the researcher to predict the future health status and health care costs of the patient group in the event that the treatment had or had not been available. In addition, the existence of some secondary effects is dependent on one or more key assumptions. For example, an economic multiplier effect is generally thought to take place only in an economy operating below its productive capacity. A researcher who wants to include such an effect must thus determine whether or not this assumption holds, and then decide how large an effect should be included.

Secondary impacts may be considered part of the cost-benefit analysis or extraneous to it. The proper choice in each circumstance probably depends on the likelihood that the secondary effects in fact exist, their probable importance, and the ability to measure them. However, like intangible effects, potential secondary or indirect effects should be detailed even if they are not included quantitatively. Furthermore, should such effects be included, the assumptions underlying their existence and measurement must be revealed explicitly to allow the reader to make an informed judgment. (We addressed this issue in question 7 of table IV.1.)

Issues of "standing" May Require Clarification of the Scope of the Analysis

In some circumstances, it may be difficult to define the point of view from which the cost-benefit analysis is calculated—that is, who has "standing," or whose costs and benefits should be included in the analysis. For most cost-benefit calculations involving government policy, the analysis is appropriately done at the level of "society" (rather than, for example, considering only the impact on individuals in a particular state or locality), so that a wide range of implications is considered. However, in some circumstances, it is important to make the point of view explicit. For example, when policy effects may cross national boundaries, "society" may be best defined on a broader basis. If the cost-benefit analysis is considering policies to reduce acid rain, for example, considering the effects of acid rain and pollution reduction on the Canadians who share U.S. weather patterns may be important. Similarly, analysts may wish to consider the impact of product regulation on foreign producers as well as on U.S. consumers.

Even when the unit of analysis is clear, occasionally some members of that unit are not afforded standing under cost-benefit analysis. For example, suppose that a particular policy proposal is likely to result in a decrease in property crime. If a thief steals a television, and both the victim and the thief are given standing, then the gain to the thief could offset the loss to the victim in a cost-benefit accounting. "Society," however, is clearly worse off. Unless we try to measure the psychological and sociological

costs of crime, it may make more sense not to afford the thief standing in the cost-benefit analysis. Such issues arise infrequently but should be made clear if they could affect the interpretation of the analysis. (We addressed this issue in question 8 of table IV.1.)

Taking the Status Quo as Baseline, Cost-Benefit Analysis Should Account for Relevant Factors and Constraints

Some cost-benefit analyses have been criticized for excluding relevant factors on what appears to be an ad hoc basis. Without including such factors, or providing an explicit justification for excluding them, a researcher limits the value of the analysis. However, while it is important to consider a variety of alternative actions, it is equally crucial to adopt a realistic view of the possible alternatives. For example, political and agency realities often place meaningful constraints on options available for consideration. If these constraints are not incorporated into the analysis, the results could be "pie in the sky" recommendations that would be of little use of the decisionmaker. (We addressed these issues in questions 1, 2, 4, and 10 of table IV.1.)

Similarly, it is important that cost-benefit analysis be conducted in a way that evaluates the change in aggregate costs and benefits, with current conditions serving as a baseline. For the properties of economic efficiency to hold, cost-benefit analysis must take what economists call a marginal or incremental approach—that is, it must consider only the changes that would result from the proposed intervention. For example, a proposal to renovate a museum should be evaluated, for cost-benefit purposes, on the basis of the incremental cost of the renovation, not on the basis of the original cost of constructing the entire museum. (We addressed this issue in question 9 of table IV.1.)

Issues of Distribution May Be Considered Within or Outside the Cost-Benefit Context

By definition, cost-benefit analysis is a method for considering the aggregate effects of a given proposal. If the aggregate expected benefits of the proposal exceed the aggregate expected costs, the proposal is said to pass the cost-benefit test. This does not necessarily mean that adopting the proposal would improve the condition of each individual; instead, it implies only that when the expected gains and losses to all individuals are added up, the total expected gains exceed the total expected losses.[36]

[36]Economists make a distinction between events that lead to a "Pareto improvement" and those that lead only to a "potential Pareto improvement." If a change leads to a Pareto improvement, then as a result of the change no individual will be worse off, and at least one individual will be better off. However, if a change leads to a "potential Pareto improvement," then the aggregate gains exceed the aggregate losses, but some individuals will gain and others will lose. In this situation, it would be theoretically possible for the "winners" to compensate the "losers" and leave no individual worse off than before if redistribution itself is costless.

By adding up individual gains and losses to determine the effect on society as a whole, cost-benefit analysis implicitly assumes that each individual's gains or losses should be valued equally with any other individual's gains or losses. As a result, cost-benefit analysis is "neutral" with respect to the distribution of gains and losses. To put it another way, the "fairness" of how gains and losses are distributed is generally not included in the calculations underlying a cost-benefit analysis.

Sometimes a decisionmaker might want to address such issues of fairness. For example, if a proposal would involve redistributing income, the loss of one dollar to a wealthy person may be viewed as less consequential than the gain of one dollar to a poor person.[37] In order to address such an issue, the researcher or decisionmaker can consider issues of distribution inside or outside the cost-benefit context. One method of examining such issues might be to analyze the distributional impact of a proposal separately, and consider fairness issues—along with the cost-benefit calculation—as another factor in the decision-making process. Under these circumstances, if the proposal is viewed as having negative distributional consequences, and it would be costly or difficult to redistribute the gains and losses, then the proposal might be rejected even though it would otherwise meet a cost-benefit test.

Occasionally a researcher who wants to consider distributional issues explicitly chooses to incorporate distributional consequences into the mathematics of the cost-benefit calculation. Instead of simply adding up the costs and benefits accruing to each individual, the researcher uses a mathematical formula that applies different weights to different individuals. These weights could be based on a number of factors, depending on the characteristics of the "fairness" issues being addressed. For example, if the proposal would affect income directly, weights could be based on income (with greater weight being applied to gains in income experienced by low-income individuals). Weights could also be based on other circumstances; for example, greater weight could be placed on vulnerable populations or on future generations. Similarly, if a change was proposed in a given program, greater weight could be applied to the

[37]There is some limited ground in utilitarian economic theory for this assumption. Economic theory states that individuals will generally, at some point, experience "diminishing marginal utility of income"—that is, receiving one additional dollar of income brings less additional satisfaction (or "utility") as the individual becomes wealthier. However, the amount of satisfaction deriving from any good or service, including income, cannot be compared across individuals. As a result, while economic theory suggests that it is plausible that at some point giving one dollar to a rich person produces less total "utility" than giving one dollar to a poor person, economic theory also tells us that it is generally not possible to measure the circumstances under which this assumption might (or might not) be correct.

smaller number of program participants (who would be more significantly affected) than the rest of society (who would be affected only indirectly). A weighting scheme would be most helpful to decisionmakers and outside observers, however, if the formula was detailed explicitly and the analysis was accompanied by a sensitivity analysis, so the effect of the distributional weights was clear to the reader. (We addressed these issues in questions 11 and 12 of table IV.1.)

Implementation Issues in Cost-Benefit Analysis

While a number of conceptual issues arise in cost-benefit analysis for which the appropriate answer depends on circumstances, there are also a number of methodological or implementation issues about which there is widespread agreement. For example, years of debate on the appropriate valuation method for risk reduction have largely been resolved in the favor of "willingness to pay" measures, and the importance of sensitivity analysis is generally recognized. While the choice of discount rate has long been a subject of controversy, with some practitioners arguing for the use of market rates and others advocating a lower "social" discount rate, the literature generally recognizes the value of multiple rates. Finally, there is virtually universal agreement on the importance of reliable data and careful risk measurement to cost-benefit analysis.

Costs and Benefits Should Be Adjusted for Differences in Timing

Frequently, the various consequences of the proposal under discussion will differ in when they occur. For example, changing the labeling requirements on bags of charcoal could reduce carbon monoxide deaths years later and also result in an immediate, one-time increase in industry costs. As individuals and as a society, we generally prefer to have dollars or resources now than at some time in the future because we can benefit from them in the interim. In addition, if we acquire $1 next year instead of today, we give up the opportunity to invest that dollar and earn interest on our investment. As a result, it is generally agreed that future dollar cost and benefit streams should be reduced or "discounted" to reflect differences in timing.

The rate at which this adjustment is made is usually done on a case-by-case basis. Many analysts choose to use the market rate of interest—for example, the rate payable on government bonds with a time horizon comparable to the analysis. Some researchers have argued that the discount rate should be set somewhat higher because, presumably, economic growth will leave future generations better off. Others have advocated using a "social" discount rate, which is generally lower than the market rate, on the grounds that society's interest in the welfare of future

generations implies that the discount rate for all of society should be lower than the rates chosen by individuals. Experts on cost-benefit analysis generally encourage researchers to use multiple rates—both to assess the sensitivity of the results to the chosen discount rate and to facilitate comparison across studies. (We addressed issues of discounting in question 18 of table IV.1.)

Comparability With Other Analyses Could Influence Selection of Parameters

Ideally, proponents of extensive cost-benefit analysis would like to be able to order and prioritize regulatory interventions across agencies. A potential mechanism for this type of coordination is provided in Executive Order 12866, which requires agencies to submit to the Office of Management and Budget (OMB) cost-benefit analyses for regulations with an estimated impact on the economy of $100 million or more.[38] OMB has suggested or prescribed certain rules (such as a presentation format and/or a specific discount rate) to facilitate comparability across agencies and to help promote quality analyses.[39] While a common set of assumptions or parameters may facilitate comparability by a central government authority, so that priorities may be set across as well as within agencies, some of these assumptions may fit the circumstances of the given analyses less well. For example, a given discount rate may be more appropriate for one project (for which the benefits and costs are spread out over a long period) than another (with costs and benefits spread over a shorter period). Therefore, there may be a tension between making an analysis comparable to others and customizing it to fit a unique situation. (We addressed these issues in questions 10 and 18 of table IV.1.)

Potential Future Price Changes Can Add Uncertainty to Analysis

Typically, cost-benefit analysis assumes that the intervention considered has only a small or negligible effect on relative prices throughout the economy. Generally, this assumption makes sense; however, for major changes (such as a big change in tax law) the assumption is clearly inappropriate. In these cases, it is much harder to put a value on the potential impact of the proposed change. For example, a large cut in the capital gains tax could affect a wide range of investment behavior, and may even affect how much some individuals choose to work and how much they are paid. A researcher trying to place a value on the potential consequences of a capital gains tax cut might introduce an error by valuing changes in productivity using the wage rates that prevailed before the cut, because, in reality, once the new policy has been implemented, wages rates might change. In such a situation, it is especially important for

[38]CPSC, as an independent agency, is not required to follow these procedures.

[39]The evaluation factors we examined parallel OMB's suggestions; in some areas, we have operationalized these concepts to create more specific and objective evaluation questions.

the researcher to point out the potential mismeasurement, and (if feasible) try to model its effect. (We addressed these issues in question 13 of table IV.1.)

Researchers Recognize the Importance of Sensitivity Analysis to Inform the Reader

Every cost-benefit analysis will include some level of uncertainty or imprecision, or reflect a methodological choice that not everyone will necessarily agree with. Careful analysts will identify critical sources of uncertainty or controversy, and revise or test the analysis quantitatively or qualitatively to identify how or whether these areas affect the conclusions reached. If large variations in measurement or assumption do not alter the conclusions, then the researcher and the decisionmaker can have greater confidence in the original results. However, if the conclusions of the analysis can change depending on methodological choices or variable measurement, then the researcher may want to try to improve the measurement of the original variables. If this is not possible, then the analysis may be of more limited value—an implication the decisionmaker would need to know. (We addressed these issues in question 21 of table IV.1.)

Reliable Underlying Data Crucial to Reliable Cost-Benefit Analysis

Despite the importance of sensitivity analysis, even the most careful and elaborate sensitivity analysis often cannot sufficiently compensate for poor underlying data. Obviously, if key variables are defined poorly or measured imprecisely, the quality of the cost-benefit analysis will suffer. Because many variables used in research are measured from surveys or samples, sampling error may be unavoidable. The researcher can use a sensitivity analysis to test the potential for sampling error to affect the conclusions; however, if the survey instrument itself is flawed, the results may be unreliable even beyond the degree indicated by sampling error. Similarly, researchers may face a difficult problem when key data (such as the cost of compliance) are provided for the analysis by an interested party (such as the industry). If the interested party provides the data, that party may have an incentive to provide biased, inaccurate, or misleading information. In such cases, it is important to try to verify the data to the extent possible; if not, the researcher needs to at least note the source of the underlying information and allow the reader to make an informed judgment about the reliability of the final analysis. (We addressed potential data issues in questions 19 and 20 of table IV.1.)

Measuring and Valuing Risk Reduction Under Cost-Benefit Analysis

Frequently, the benefits of a particular proposal involve a reduction in risk of injury or death. In these situations, the quality of the cost-benefit analysis will also depend substantially on the estimates of the proposal's

impact on these risks. However, it is often difficult to accurately measure and value risk reduction. A number of issues arise, including the effect of the proposal on the level of risk (especially when individual behavior is a factor in determining the size of the risk) and measuring individuals' willingness to take risks in exchange for rewards.

Considerable Uncertainty Often Surrounds Risk Measurement and Risk Assessment

Measuring the effect of a proposal on the level of risk can be especially difficult. Generally, it is not realistic to assume that any regulatory intervention will reduce the risk level to zero—removing an environmental carcinogen, for example, will probably reduce the number of cancer deaths, but is unlikely to eliminate cancer entirely. Considerable uncertainty may be inevitable when extrapolating a dose-response model. Sometimes large doses of a potentially dangerous substance, given over a short period of time, are used to predict the results of long-term exposure. When the model moves across species—for example, predicting cases of cancer in humans based on experiments with laboratory animals—another source of uncertainty is introduced.

Measurement problems in the underlying data can make it hard to predict future risk from epidemiological data as well. For example, when longitudinal data are used, there may arise a "survival bias" in that the analysis could be biased if it excludes individuals who die or otherwise move out of the data set. Similarly, when some cases go unreported, the data may understate the size and/or overstate the severity of the hazard. For rare hazards, limited variation in the epidemiological data can make measurement and prediction of risk more difficult. In addition, some data may be known to produce biased estimates (because of exclusions or potential double-counting, for example). Data problems such as these (and the statistical or analytical methods used to deal with them) should be pointed out to the reader to increase the opportunity for informed judgment. (We addressed these issues in questions 3 and 19 of table IV.1.)

Risk-Risk Trade-Offs and Individuals' Behavioral Responses to Policy Changes Can Affect the Level of Risk

Sometimes actions taken to reduce one risk can have the unintended effect of increasing that or another risk. For example, unforeseen consequences arose in the 1970s when CPSC issued regulations requiring children's sleepwear to meet flammability standards. Manufacturers used a chemical called Tris to meet these standards, but later it was discovered that Tris posed a cancer risk. Changes in individual behavior can also create uncertainty in predicting the level of risk because valuations of costs and benefits of a proposed action are often based on historical behavior. For example, valuations of a proposed new highway may be based on the number of individuals currently traveling the route, their

commuting times, and other factors. However, once the new highway is built, some people may make extra trips in the area (shopping in different stores, for example) than they did before. Some people who had driven at off-hours to avoid congestion on the old road may now travel at peak hours on the new one. Similarly, changes in public policy may cause individuals or firms to change the technology they use, the amount of time they spend at leisure or at work, or the amount they invest in innovation.

A special type of behavioral change—often referred to as "offsetting behavior"—occurs when individuals change the amount of precautions they take in response to a change in policy. For example, having an air bag in the car or being required to wear a motorcycle helmet might make some drivers feel safer, so they exercise less caution on the road. Sometimes this offsetting behavior can result in an increase in the risk the intervention was designed to mitigate. For example, because child-resistant medicine bottles can be difficult to open, a grandparent may leave the cap off the bottle, creating an even greater risk than would be posed with a non-child-resistent cap. If such changes in consumer behavior are foreseeable, the analysis will be improved if the researcher points out such possibilities, and it will be even more useful if reasonable attempts can be made to measure the impact. (We addressed these factors in question 14 of table IV.1.)

Willingness-To-Pay Measures Viewed as Appropriate for Valuing Risk but Require Careful Estimation

Measuring the benefit of risk reduction requires placing a value on avoiding death and/or injury. Several approaches are available for this task, but two have been used in cost-benefit analysis: (1) the "human capital" approach, in which death or injury is valued at the market value of the lost production it causes plus the medical costs expended and (2) the "willingness-to-pay" approach, which attempts to measure directly individuals' willingness to pay for reducing the risk of death or injury.[40] In early cost-benefit analysis, the human capital approach was used, largely because lost wages and medical costs were relatively easy to measure. However, this approach is not preferred today because of a number of shortcomings. First, if this approach were taken literally to apply to individuals, then persons who do not produce output in the marketplace—such as the elderly or homemakers—are not valued—an assumption that is clearly ethically and economically inappropriate. In addition, the human capital approach is unable to take into account costs to the individual of death or injury such as pain and suffering. Also, it is difficult to apply an "average" value based on human capital calculations

[40]This terminology has been borrowed from W.K. Viscusi in "The Valuation of Risks to Life and Health," in Benefits Assessment: The State of the Art, eds., Judith D. Bentkover, Vincent T. Covello, and Jeryl Mumpower (Dordrecht, Holland: Reidel Publishing Company, 1986), pp. 193-210.

to a statistically anonymous member of a large group. Finally, we are all more valuable than the sum of what we produce, and these amounts could not be included in a human-capital-based formulation. Thus, human capital measurements are generally viewed as a lower boundary on the value of avoiding death and injury, and are less preferred than the more recent willingness-to-pay measures.

In part because of dissatisfaction with human capital measures as used in cost-benefit analysis, and facilitated by newly available large micro-level data sets, economists measure the benefits of reducing death or injury by calculating the consumer's willingness to pay for small reductions in the probability of injury or death. These calculations have been done several ways. Some approaches attempt to glean willingness-to-pay measures from observed behavior in the marketplace. For example, one approach examines pay differentials for jobs with different risks. Another approach looks at the payoff to consumers who purchase safety devices, such as smoke detectors and air bags in automobiles. These measures have the advantage of being based on actual observed behavior in the marketplace rather than on an artificial experimental situation. However, the validity of such measures is based on the questionable assumption that workers and consumers are sufficiently knowledgeable about the risks they face and potential of different occupations or safety devices to alleviate those risks. For many purposes, practitioners of cost-benefit analysis can select an appropriate value from the range of research already done in this field without performing the actual analysis themselves. However, for other analyses, especially those involving unique risk-taking situations, it may be wiser to gather new data to construct an estimate that is based on circumstances as close as possible to those being studied.

Another common method for valuing risks is known as contingent valuation, in which such values are elicited by observing responses or behavior on a survey or in a controlled experiment. For example, researchers surveyed individual shoppers on how much of a premium they would be willing to pay for pesticide-free grapefruit.[41] These methods have the advantage of being able to provide information on areas that cannot be addressed with market data. However, this characteristic could also be a weakness—the very artificiality of the situation could make the consumer make a less deliberate choice or could limit the usefulness of applying this measure to other situations. This method does entail some technical requirements—for example, it may be useful to perform statistical tests on

[41]Jean C. Buzzby, Richard C. Ready, and Jerry R. Skees, "Contingent Valuation in Food Policy Analysis: A Case Study of a Pesticide-Residue Risk Reduction," Journal of Agricultural and Applied Economics, 27 (2) (Dec. 1995), pp. 613-25.

the distributional assumptions when constructing contingent valuation measures. (We addressed these issues in questions 15 through 17 of table IV.1.)

Death, Injury, and Incident Data Sources Used by CPSC

In order to target its resources and analyze the costs and benefits of projects or potential projects, CPSC must obtain data on injuries and deaths related to particular product hazards. CPSC relies on a patchwork of independent data systems to address this need. However, not only does each of these data sources have its own internal limitations, but together CPSC's data sources present an incomplete—and potentially distorted—picture of consumer-product-related injuries and deaths. The implications of this lack of data range from reducing CPSC's ability to apply regulatory project selection criteria to limiting the agency's ability to estimate the impact of its regulatory actions.

CPSC Relies Heavily on Hospital Emergency Room Reports to Obtain Estimates of Injuries

NEISS System

CPSC obtains most of its injury information from its National Electronic Injury Surveillance System (NEISS), which gathers information from hospital emergency room records. NEISS provides national estimates about the number and severity of emergency-room-treated injuries associated with, although not necessarily caused by, consumer products in the United States. To accomplish this, a stratified probability sample of hospitals is drawn that is representative of all hospitals with emergency departments in the United States and its territories.[42] CPSC constructs national estimates of the number of injuries associated with individual consumer products on the basis of reports from this sample of 101 hospitals.

NEISS data result from information abstracted from hospital emergency room records by coders trained by CPSC staff. The data are coded and entered, at each site, into a personal computer programmed for this purpose. The software checks the data entries for consistency. The data collections are linked nightly to a CPSC permanent central database. Data about product-related injuries are available to CPSC staff within 72 hours after the accident for most of the injuries reported. These daily inputs are reviewed by CPSC staff for quality and for identifying possible emerging

[42]The hospitals are sampled from a universe in which each hospital has at least six beds and provides 24-hour emergency service.

hazards. The timeliness of the data also allows staff to observe seasonal or episodic variations. For example, during a 30-day period surrounding the Fourth of July in 1990, CPSC gathered extra data through NEISS for a special study on injuries involving fireworks.

The unit of analysis for NEISS is the injured person. Other key characteristics coded include the date of treatment, age and gender of patient, injury diagnosis, body part affected, disposition of case, product involved, and accident location. In addition, important details about the injury and the injured person are provided in NEISS. For example, the address and phone number of the injured person is included, permitting follow-up investigations about the nature and cause of the injury. There are about 900 product codes, ranging from abrasive cleaners to youth chairs, which the coders use to specify the product involved.[43] Consumer products are coded to allow for a great deal of specificity in the estimates. For example, a "hand saw" would be differentiated from a "portable circular power saw," and a "bicycle-mounted baby carrier" would be specified differently from a "backpack baby carrier." However, NEISS' coding system that describes the diagnosis of the primary injury and the body part injured is not overly specific, and because it is unique it cannot be directly compared with similar data from other databases.

Despite the extent of valuable information provided by NEISS, this system also has significant limitations. One important consideration relates to the nature and size of the NEISS sample design. NEISS, throughout its history, has been designed so that only national—not state, local, or regional—estimates can be made. Thus, NEISS cannot detect interregional or interstate differences, and may also be limited in its ability to identify emerging product hazard patterns that are focused in specific states or regions.

A limitation in the NEISS data for which CPSC has received criticism is the lack of information that would assist in assessing causality—that is, information that would establish (or provide a starting point to establishing) whether the product in question caused the accident or merely was involved in the accident. NEISS contains neither "N" codes—which describe the nature of the injury—nor "E" codes—which help explain how the injury happened. E codes briefly describe the circumstances of the accident that produced the injury. For example, E codes could help distinguish among falls that occurred on stairs, from a

[43]Customarily excluded from NEISS are injury data involving automobiles and motorcycles, trains, boats, planes, firearms, food, illegal drugs, pesticides, cosmetics, medical devices, assaults and suicide attempts, and occupational injuries.

ladder, or off a roof. NEISS' short narrative section sometimes contains this type of information, but NEISS does not generally provide much information on the circumstances surrounding the product's involvement.

Other Sources of Data on Injuries

CPSC augments the NEISS injury reports with other sources of anecdotal information. For example, CPSC maintains an Injury or Potential Injury Incident (IPII) database of reports the agency receives about injuries or incidents involving consumer products. These reports come from a variety of sources, including news clips; consumer complaints, including calls to CPSC's hot line; and public reports of product liability suits. Although the IPII can provide only anecdotal information, this database sometimes contains more detailed information than can be found in NEISS. For example, IPII records can contain specific information about the product involved—such as the manufacturer and date of purchase—that are generally not found in NEISS. The IPII also serves as a source for cases to investigate. This is particularly important for hazards for which NEISS provides relatively few cases.

CPSC has also purchased data on poisonings in the form of the American Association of Poison Control Centers (AAPCC) database. This database is composed of reports from approximately 65 poison control centers throughout the country.[44] Reports from the AAPCC database contain such information as the number of phone calls received by participating centers concerning possible ingestion of a product and the number of individuals who reported experiencing symptoms related to the ingestion. But these reports contain little other information—for example, they do not show how much of the poison was ingested.

Although NEISS provides some information on fire-related injuries, CPSC obtains additional data on fires from the National Fire Protection Association (NFPA) and the U.S. Fire Administration. NFPA, a private organization, conducts an annual survey of fire departments that is designed to make statistically valid national estimates of the total number of fires experienced nationally each year. However, the NFPA survey does not collect much detailed information about the characteristics of individual fires. To augment the NFPA information, CPSC relies on the more detailed information provided in the National Fire Reporting System

[44]The number of poison control centers reporting cases to the AAPCC database varied over the years, ranging from 47 centers in 1984 to 67 in 1996.

(NFIRS), which is compiled by the U.S. Fire Administration.[45] NFIRS data can provide information on the ages of the victim or victims, and the type of dwelling (apartment versus single-family home, for example). However, these data are available only with a long lag; a CPSC official we interviewed in October 1996 told us that the most recent data he had available at that time was from 1993.

CPSC Obtains Most of Its Fatality Information From Selected Death Certificates

CPSC obtains the majority of its information on fatalities from purchasing death certificates from the states and culling information from them to determine which deaths were related to consumer products. (Like the NEISS emergency room reports, the death certificates establish only involvement—not causality—of a consumer product.) CPSC does not purchase the complete annual set of death certificates from each state; instead, the agency buys death certificates according to selected E codes.[46] CPSC purchases about 8,000 death certificates annually; of these, approximately 50 percent will be related to a consumer product. Over the years, in response to declining budgets, CPSC has reduced even further the number of E codes for which it purchases certificates. Death certificates include the date, place, cause of death, age, gender, race, and residence of the deceased.

Although death certificates cannot indicate whether the consumer product was "at fault" in a death, they do provide some information on the underlying circumstances. For example, the E code would specify that a person was killed in an accident caused by electric current. Of course, the quality of the data depends on the care with which causation is determined and reported. It is likely that this differs from locality to locality as well as among individual doctors. However, there are some objective indications that the quality of reporting causes of death has been improving; for example, the proportion of cases that are categorized under

[45]Although NFIRS is a large dataset, it does not capture data uniformly across states. CPSC generally assumes that NFIRS data accurately depict the distribution of characteristics across fires, and then applies the NFIRS proportions to the NFPA data to approximate these characteristics on a national level.

[46]According to agency officials, the major categories of E codes the agency does not purchase involve falls (which infrequently involve consumer products) and fires (for which the agency relies on other sources). This means that fall-related deaths associated with consumer products—such as falls from playground equipment—will be undercounted. In 1995, CPSC conducted a pilot in which it purchased a complete set of E codes from one state to determine whether it should change its mix of E codes. CPSC decided that the set it was buying was still the best choice given the budget for death certificate data.

ill-defined conditions has been falling.[47] Although death certificates do not constitute a sample of known probability or a complete count of fatalities, and thus statistically reliable estimates cannot be made, the geographic information contained in death certificates may help to identify state and regional patterns as well as those that are national in scope.

However, death certificate data also have substantial limitations. First, there is an extensive lag—usually 2 years—before data become available. Therefore, death certificates are not very useful in timely identifying emerging hazards. Furthermore, a number of factors contribute to obtaining rather sketchy causal information. For example, details are quite limited, which inhibit determining the degree to which a consumer product was involved in the death, let alone whether the product was defective or hazardous. Certificates are frequently completed without the benefit of autopsy information to establish the precise cause of death, either because an autopsy was not performed or because the certificate was filled out before the autopsy took place. There is substantial variation in coding practices and the level of detail available from state to state.[48] The information available about the injured individual is very limited, and the number of cases for most categories is very small; such data therefore limit the kinds and amount of analyses CPSC can perform and the conclusions it can draw.

CPSC augments its death certificate data with other sources where possible. For example, CPSC has instituted a Medical Examiners' and Coroners' Alert Project (MECAP), to provide more timely fatality information that lends itself to follow-up investigations. CPSC has engaged some 100 coroners and medical examiners from across the country to report potential product-related hazards. This project produces about 2,000 reports annually, and CPSC staff credit the coroners' reports with alerting them to a suffocation hazard concerning infant cushions, which eventually led CPSC to recall existing products and ban future production. In addition to the MECAP data, CPSC also records some reports of fatalities in the IPII, NEISS, and NFIRS databases.

[47]See National Center for Health Statistics, Advance Report of Final Mortality Statistics for 1994, 45 (3) (Sept. 30, 1996), p. 74.

[48]For more information on this variation, see New England Journal of Medicine, Vol. 313 (1985), pp. 1285-86, and U.S. Department of Health and Human Services, Morbidity and Mortality Weekly Report, Vol. 37 (1988), pp. 191-4.

CPSC Investigates Selected Incidents to Obtain Detailed Information About the Causes of Deaths and Injuries

In order to effectively target resources, identify hazard patterns, and determine the appropriate remedy for particular product hazards, CPSC needs detailed analyses of the causes of reported incidents. CPSC's data sets generally do not provide such information. The NEISS data do not include E codes (standardized, if brief and incomplete, descriptions of incident circumstances), nor do they include detailed information about how the incident happened. Some information may be provided in the short, free-text comment area of the NEISS report, but generally few such details are recorded. Death certificates do include E codes, but product involvement is often difficult to ascertain.

As a result, CPSC staff perform follow-up investigations on selected cases to develop additional information about each incident. Some of these investigations are conducted entirely by telephone, while others are conducted at the accident site. These investigations may include detailed interviews with victims and/or witnesses, police or fire reports, photographs of the product and/or the accident site, laboratory testing of the product involved, or re-creations of the incidents. For example, in 1996 CPSC staff investigated an incident in which a baby's leg was scratched as it was caught between the slats of her crib. As part of the on-site investigation, the CPSC investigator interviewed the child's mother, examined the child, examined and photographed the crib, and interviewed staff at the store where the crib was purchased.

The CPSC staff we interviewed told us that investigations, particularly on-site investigations, were an important source of information on established projects. The additional detail these investigations gathered helps determine causality and identify hazard patterns, leading analysts to the appropriate remedies. For example, investigations revealed that very few bicycle accidents were related to mechanical problems, and as a result, CPSC staff decided not to recommend any changes to existing bicycle standards. In addition, investigations may provide key evidence to help identify and correct compliance problems. For example, the investigator who reviewed the crib incident found that the crib in question appeared to violate several mandatory safety standards.

CPSC Uses Modeling Techniques and Special Surveys to Estimate Exposure Information

In order to produce a numerical risk assessment, CPSC must have some information on the extent to which individuals are exposed to a particular product hazard. Exposure information can take many different forms, and the best measure of exposure will depend on the characteristics of the particular product hazard. For example, one measure of exposure might be the number of products in use, while another measure might be the number of hours a person spends using the product, and another measure might take into account the intensity with which a product is used. If a product is for one-time use only and is usually used soon after it is sold (such as fireworks), number of products sold might be a reasonable proxy for exposure. However, when a product is more durable, and used for a longer period, and often "handed down" to another user, such as a baby high chair, it would probably be more reasonable to base estimates of exposure on the number of products in use. In cases where the potential hazard is especially ubiquitous (like air pollution, for example), population measures (the number living near the source or the number of children under 5, for example) may be reasonable. For some hazards, it may be important to account for the intensity of use. For example, the probability of developing cancer from exposure to a wood stove may depend on how often the stove is used, how large a space it heats, and how many times the stove door is opened to add wood. Similarly, bicycles could be used very frequently and very intensely (every day in urban traffic) or infrequently and not intensely (once a season on the bike path in the park); thus, a good exposure measure would take such factors into account.

CPSC does not conduct a formal, numerical risk assessment for each project it undertakes. Of the 115 CPSC projects we reviewed, only 24 included a numerical assessment of risk. CPSC most frequently relied on estimates of products in use to provide the exposure information for its risk assessments. In 65 percent of the cases where an epidemiological risk assessment was performed, CPSC based its exposure measure on an estimate of the number of products in use.[49] In an additional 5 percent, CPSC obtained information on the actual number of products in use. In 30 percent of cases, CPSC used a population-based measure, and in 10 percent of cases, CPSC used a sales measure.[50] We did not evaluate whether the exposure measure CPSC chose was appropriate for each case.

CPSC conducted special surveys on bicycles and on cigarette lighters and matches, for instance, to develop exposure information. The survey

[49]About half of these estimates of products in use were derived from modeling and about half from special surveys.

[50]Percentages do not total 100 because in two cases CPSC used more than one measure of exposure.

questions were designed to obtain information on the number of products in the home, the intensity of use, the characteristics of the households using the product, and the usual patterns of use. For example, the bicycle survey included questions on the number of hours spent biking, the ages, education, and income of household members, whether riding was done most often on streets, sidewalks, or bike paths, and whether riders used helmets.

Where special surveys are not practical—because of time, resource, or other limitations—CPSC sometimes uses mathematical modeling techniques to estimate the number of products in use. These models can take sales information and information on the life of the product to estimate the number of units in use. For example, CPSC used such a model to estimate how many of the portable heaters made before a 1991 revision to a voluntary standard were still in use.

CPSC Obtains Some Information Under Reporting Requirements for Manufacturers and Other Businesses

CPSC may also receive information about potential product hazards through industry reporting requirements. Although this information is used mostly for identifying and addressing compliance problems, it may also help identify new hazards. Companies are legally obligated to report to CPSC information they receive that indicates a consumer product they distribute is potentially hazardous. Under section 15 of the Consumer Product Safety Act, manufacturers (including importers), distributors, and retailers of consumer products must notify CPSC if they obtain information that a product (1) fails to comply with a consumer product safety regulation or a voluntary consumer product safety standard, (2) contains a defect that could create a substantial product hazard, or (3) creates an unreasonable risk of serious injury or death.

In addition to these reporting requirements, manufacturers and importers of a consumer product must report to CPSC if (1) a particular model of a consumer product is the subject of at least three civil actions that have been filed in federal or state court, (2) each suit alleges the involvement of that model in death or grievous bodily injury, and (3) within a specified 2-year period at least three of the actions resulted in a final settlement involving the manufacturer or importer or in a judgment for the plaintiff. Manufacturers must file a report within 30 days after the settlement or judgment in the third such civil action.

CPSC may receive requests for information that firms have reported to it under section 15 requirements. The law limits CPSC's disclosure of any

information identifying a manufacturer and further limits CPSC's release of information that firms have provided under these requirements. Reports on civil lawsuits may not be publicly disclosed by CPSC or subpoenaed or otherwise obtained from CPSC through discovery in any civil action or administrative procedure.

Comments From the Chairman and Commissioner Moore, Consumer Product Safety Commission, and GAO'S Evaluation

Note: GAO comments supplementing those in the report text appear at the end of this appendix.

U.S. CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, D.C. 20207

July 24, 1997

BY HAND

Ms. Carlotta C. Joyner
Director, Education and Employment Issues
General Accounting Office
441 G Street, NW
Washington, DC 20548

Dear Ms. Joyner:

The enclosed memorandum presents the comments of the U.S. Consumer Product Safety Commission on the draft GAO report entitled "Improved Data Needed to Better Identify and Analyze Potential Product Hazards."[1]

The draft report makes recommendations on CPSC's data collection, use of cost-benefit analysis and tracking of projects. We are reviewing these recommendations thoroughly; in some respects, they parallel efforts already under way at the Commission. Although we welcome GAO's recommendations, several of the draft report's assertions reflect basic misunderstandings about how CPSC operates. In the memorandum we address those assertions.

Our comments show that the Commission's use of an interrelated network of data collection systems ensures that our actions are based on solid injury and death estimates; that we employ sound economic analyses that are appropriate to the circumstances, including cost-benefit analysis; and that we track projects in a variety of ways to monitor the progress of our work. Finally, we will illustrate our success in dramatically reducing the threat to Americans from unsafe consumer products. Our comments are organized into the following four sections:

I. How the Commission Collects and Uses Data
II. How the Commission Uses Economic Analysis
III. How the Commission Tracks Projects
IV. How the Commission Selects Projects
V. How the Commission Has Succeeded in Reducing Deaths and Injuries.

[1] Commissioner Gall does not join these comments.

Ms. Carlotta C. Joyner
July 24, 1997

Page 2

CPSC is one of the best bargains in government. Our achievements are particularly impressive because they have come so inexpensively. The Commission's budget now is less than 60% -- in real dollars -- of its size at the Commission's inception. Not only are we providing safety; we are doing it on a shoestring.

None of this means that there is no room for improvement or that the Commission cannot find ways of doing its job even better, especially with more resources. In fact, the Commission has worked very effectively in recent years to improve its operations and to focus on achieving results. We look forward to determining how the GAO recommendations can help us continue to make progress in these directions. But the fundamentals at the Commission are sound. CPSC will build upon its past successes to continue reducing injuries and deaths in the future.

Thank you for providing us the opportunity to comment on the draft report.

Sincerely yours,

Ann Brown
Chairman

Thomas H. Moore
Commissioner

Enclosure

cc: Hon. John McCain
Hon. Ernest F. Hollings
Hon. Thomas J. Bliley, Jr.
Hon. John D. Dingell

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

MEMORANDUM

DATE: July 24, 1997

TO : General Accounting Office

FROM : United States Consumer Product Safety Commission

SUBJECT: GAO Draft Report Entitled "Consumer Product Safety Commission: Improved Data Needed to Better Identify and Analyze Potential Product Hazards"

This memorandum presents the comments of the U.S. Consumer Product Safety Commission (the "Commission" or "CPSC") on the draft report of the General Accounting Office entitled "Improved Data Needed to Better Identify and Analyze Potential Product Hazards" (the "Draft Report").[1]

The Draft Report makes three recommendations: first, that the Commission consult with experts to improve its injury, death and exposure data; second, that the Commission employ the cost-benefit methodology set forth in the Draft Report; and, third, that the Commission track projects better. Draft Report, p. 37. We are reviewing the GAO recommendations thoroughly; in some respects, they parallel efforts already underway at the Commission.

GAO is widely and properly recognized for the importance of its work. Its investigators spent a great deal of time on this particular project, reviewing Commission documents and interviewing our personnel in a thoroughly professional manner. This project was an entirely cooperative effort between GAO and our staff.

However, the Draft Report makes assertions about CPSC's existing data collection systems, economic analyses, and project selection and tracking procedures that reflect certain fundamental misunderstandings about how CPSC operates. Some aspects of the Draft Report do not seem entirely realistic and overlook the remarkable reduction that our Nation has witnessed in consumer product-related deaths and injuries over the past quarter century.

We have organized our comments into five sections. Part I clarifies how we collect and use data. Part II responds to the

[1] Commissioner Gall does not join these comments.

Draft Report's critique of the Commission's economic analyses. Part III summarizes our project tracking system. Part IV discusses our project selection criteria. Part V concludes by providing a few examples of how the Commission is fulfilling its mandate to protect American consumers from unsafe products. Under separate cover, our staff is sending GAO technical corrections to the Draft Report.

I. HOW THE COMMISSION COLLECTS AND USES DATA

CPSC'S mission is to prevent deaths and injuries associated with consumer products. To carry out this mission, the Commission has perhaps the most extensive consumer product injury data collection systems in the world. Our data does not include every death and injury associated with every consumer product, nor is this necessary. The Commission uses a variety of data sources to identify potential product hazards and to assess whether action would reduce those hazards in a cost-effective way. When making these determinations, we recognize the limitations of each data source, and we use the data accordingly. Although there is merit in GAO's recommendation to consult with experts to improve our data (which we already do), we believe that the extensive data now available to us provides ample support for the Commission's regulatory, enforcement and other decisions.

Our injury data systems are widely accepted and used. For example, several other countries (Japan, Australia, United Kingdom) have developed systems that are modeled after the Commission's National Electronic Injury Surveillance System ("NEISS"). Many of our sister Federal agencies use NEISS data. This year, CPSC is collecting data on air bag injuries for the National Highway Traffic Safety Administration, firearm injuries for the Centers for Disease Control, and work-related injuries for the National Institute for Occupational Safety and Health.

The Draft Report recommends that we consult with experts about how our data sources could be expanded. The Commission has done so since its inception. Experts from other government agencies, from universities and research organizations and from foreign countries have studied CPSC's data systems. Their consensus has been that the CPSC systems are worthy of emulation.[2] Our data-collection activities are strengthened when

[2] The nationally recognized experts who have reviewed and/or provided guidance in the development of the CPSC data system include Dr Lee Annest, CDC; Dr. Jerry Blondell, EPA; Dr. Harvey Meislin, University of Arizona; Michael Rand, Department of Justice; Dr. Rich Schieber, CDC; Dr. Gary Smith, Ohio State University; Dr. Nancy Stout, NIOSH; Joseph Waksberg,

we consult with experts and organizations outside CPSC. We will continue to do so.

A. The Commission Uses an Interrelated Network of Data.

The Draft Report asserts that the Commission uses a "patchwork" of data systems, which incorrectly implies a certain haphazard quality to our data systems. Draft Report, p. 15. In fact, our systems are an interrelated network, providing us with a range of data that we examine as a whole before making decisions.

See comment 1.

The centerpiece of our data systems is NEISS. However, no single national data set could provide all the injury or death data necessary to support CPSC's broad mandate. Therefore, CPSC uses additional data sources. For example, we use data from the American Association of Poison Control Centers' large data base for important detail about poisoning hazards; for fire hazards, we use data from the National Fire Incident Reporting System operated by the United States Fire Administration and from surveys conducted by the National Fire Protection Association. Other sources, including consumer complaints, news clips, physician reports, fire and police department reports, litigation reports, and other government referrals, provide important input to CPSC.[3]

The Commission has recognized from its inception that hospital emergency department systems do not treat all injuries. In the 1970s, CPSC added a product-related supplement to the National Health Interview Survey conducted by the National Center for Health Statistics ("NCHS"). Since then, we have explored repeating this supplement with staff at NCHS. However, the extremely expensive household survey covers so few product-related injuries from its approximately 40,000 participating households that NCHS advised CPSC that repeating the product-related injury supplement would not be cost effective.

In the 1980s, we conducted pilot studies of physician office injuries and of ambulatory care clinic injuries. These studies provided information on the available injury data at these sites and its cost. The Commission concluded that formal surveillance systems in these areas would not be cost-effective because of the

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Westat; and Dr. Gordon Smith, Johns Hopkins University.

[3] We object to Figure 3. It is extremely misleading because it incorrectly implies that the Commission does not collect or use any information covering the sources referred to as "not covered." It also incorrectly implies that an equal number of injuries are treated in each setting.

See comment 2.

small volume of useful data at most of these sites and the high costs of setting up formal systems. Approximately five percent of the cases in the ambulatory care clinics were consumer-product related. This compared to approximately 15 percent in the typical hospital emergency department, which also treats many more patients.

Now, in the 1990s, the Commission is updating the computer model it uses to assess the extent and costs of injuries and their distribution across treatment venues. As discussed below (at note 4 and accompanying text), we are updating this model to reflect changes in our Nation's healthcare delivery system.

We will remain alert to opportunities for expanding our data sources in a cost-effective way.

B. NEISS Provides Extensive Injury Data.

The core of the Commission's injury data collection activities is NEISS. However, it appears that GAO misunderstood how we use this data, believing that we rely on it for certain purposes when we do not.

1. NEISS Estimates Are Statistically Sound.

NEISS consists of 101 hospital emergency departments that report to us each day regarding injuries associated with a consumer product. These hospitals provide the statistical sample on which we base our national injury estimates of hospital emergency department treated injuries.

The Draft Report points out that not all injuries are treated in hospital emergency rooms. Draft Report, pp. 15, 16. We have long recognized this. See 16 CFR § 1009.8(c)(1). This does not undermine Commission action; rather, it means that the basis for our action may be even stronger than it appears. If the number of emergency room injuries justifies a response, additional injuries treated elsewhere justify that response all the more.

We have deliberately concentrated resources on a statistically representative sample of hospital emergency departments for two reasons:

- Injuries treated in hospital emergency departments represent the more serious incidents to identify and investigate.
- We can obtain information about these injuries in a timely manner at a relatively low cost because large

numbers of incidents are identified at a limited number of sites.

The Draft Report asserts that the Commission's NEISS (and death certificate data) provide little information about the injury incident itself. Draft Report, p. 20. This is true, but irrelevant. No national surveillance system will provide this detail. However, CPSC receives causation information from the in-depth injury investigations that our field investigators conduct. We conduct about 3,000 investigations each year. (Almost 1,000 of these are conducted each year at the site of the incident, at a cost of over $1,000 for each investigation.) These investigations provide detail about causation. When a proper sample of NEISS cases is investigated for a particular time period, we can use the resulting information to make national estimates about causation. In many cases, we learn about injury incidents through reports that industry is required by law to provide to us. (The Draft Report did not examine this data source.) These reports often contain information about causation.

See comment 3.

See comment 4.

2. The Commission Does Not Assume That Its NEISS Data Is Perfectly Representative, Nor Is It Necessary That the Data Be So.

In its critique of the Commission's NEISS data, the Draft Report asserts that the percentage of persons seeking treatment in a hospital emergency room may vary by injury. Draft Report, p. 17. This statement is true, but comes as no surprise to CPSC, which has never assumed to the contrary.

The CPSC uses a model that reflects results from the National Health Interview Survey ("NHIS") to estimate the percentage of victims for each type of injury treated in hospital emergency departments. This model then allows staff to make estimates of the total number of injuries and the cost of these injuries for any specific hazard.[4] The Commission occasionally uses this model to help select projects; more importantly, it plays a very important part in the assessment of the costs and benefits of Commission action.

See comment 5.

[4] The model considers the distribution of injuries for the hazard, calculates the numbers of each type of injury treated outside emergency departments and sums the results across all injury types. This model is being updated to reflect changes in recent data from HIS. The Commission expects to make periodic updates to account for future changes in medical care delivery patterns.

5

CPSC has responded to the shifting patterns in the delivery of emergency medical care in several ways. For example, we monitor the total number of hospital emergency visits. (Estimates of the total number of these visits is available from several sources including the American Hospital Association, SMG Marketing Group, NCHS and by extrapolation from the NEISS sample.) We also use the results of the NHIS mentioned earlier, which provide data on the number of victims treated in a variety of settings, including hospital emergency departments, physician offices and ambulatory care centers. Tracking of this type is sufficient to assure the adequacy of our data, as we use it. We agree with GAO that developments in the emergency medical care system may well be pertinent to our activities, and we will continue to monitor those developments.

See comment 6.

3. The Commission Does Not Rely on NEISS for Reports of Chronic Illnesses.

The Draft Report asserts that NEISS underrepresents chronic illnesses because they are not generally treated in hospital emergency departments. Draft Report, pp. 18-19. Even if true, this is irrelevant, for the Commission does not rely on NEISS for reports of such illnesses.

See comment 7.

There is no data source that specifically identifies chronic illnesses associated with particular consumer products. Estimating the number of victims of chronic illnesses (such as those that occur with chemical exposures) requires a different approach from estimating the number of victims of acute conditions. It can be difficult (and sometimes impossible) to estimate how many chronic injuries and deaths are related to consumer products. This is not because of any data "gaps," but rather because the adverse health effects and symptoms of chronic illnesses are often subtle and difficult to diagnose, develop slowly over a long period of time, or resemble those associated with other causes. Most importantly, identifying chronic illnesses that can be attributed to a single consumer product is extremely difficult, if not impossible. Identifying a possible chronic hazard depends mostly on determining what consumer products contain a chemical known or suspected to cause chronic illnesses.

The Commission will continue to investigate and consider additional surveillance methods that will identify victims of chronic illnesses related to chemical exposures from consumer products.

6

See comment 8.

C. Death Certificate Data Is Not Used for National Estimates.

The Draft Report asserts that the Commission's death data is incomplete. Draft Report, p. 15. However, the Commission does not use a count of death certificates as an estimate of the number of deaths associated with a particular hazard. Nevertheless, death certificates help us assess the mortality experience for specific hazards. The Commission obtains several different levels of information on deaths, depending on the type of hazard and the resources available for the analysis. In general, the Commission combines the death reports it receives from all its data sources to produce an unduplicated count of the number of deaths known to the Commission for a specific hazard. The best death estimates are made by combining CPSC data on individual deaths from different sources and then using a statistical technique called "capture-recapture."

The Draft Report asserts that our data on product-related deaths are "available to the agency only with a 2 year time lag." Draft Report, p. 3. This statement is misleading. We receive nearly 60% of death data within one year; it is only the slowest data that arrives within the two-year period mentioned. Moreover, CPSC has partially compensated in recent years for this delay by developing the medical examiner and coroner reporting system whereby individual medical examiners and coroners call CPSC immediately to report product-related deaths.

D. The Commission Collects Substantial Information About Injury Victims and Generally Understands the Impact of Particular Injuries on Vulnerable Populations.

See comment 3.

The Draft Report asserts that the Commission collects too little information about injury victims, and thus we have a limited ability to determine which hazards are disproportionately impacting vulnerable populations. Draft Report, p. 19. We do not agree. CPSC has excellent data on hazards affecting certain vulnerable populations, including children and the elderly. Data on hazards disproportionately affecting other vulnerable populations are generally available after follow-up investigations. In view of the many thousands of injuries that occur each year, we obviously cannot investigate each injury in depth. However, as noted above, we do conduct about 3,000 investigations each year. These investigation reports permit us to determine whether the injury victims are in a vulnerable population. In addition, the consumer product in question often indicates the population affected. For example, unsafe cribs

endanger babies; small toy parts endanger small children; and so forth.

II. HOW THE COMMISSION USES ECONOMIC ANALYSES

The Draft Report makes two assertions regarding the Commission's cost-benefit analyses: first, that the analyses are incomplete due to so-called data "gaps"; second, that the Commission does not consistently follow "generally-accepted professional practices" for performing cost-benefit analyses. Draft Report, pp. 25-28. Part I of these comments discussed the GAO critique of the Commission's so-called data "gaps." This Part focuses on GAO's second critique.

The CPSC was one of the first Federal regulatory agencies to use cost-benefit analyses in its regulatory activities. Our long history with such analyses has taught us that there is no single mechanistic approach appropriate to every economic analysis. Furthermore, although CPSC staff provides various economic information to the Commission for different activities, most of the time this information is not intended to be a formal cost-benefit analysis, nor is it required to be so. Therefore, it is not appropriate to judge these economic discussions by the criteria that GAO has set forth for formal cost-benefit analyses.

A. The Commission Has Been a Leader in Evaluating the Relationship Between Costs and Benefits Before Taking Action.

The Commission has pioneered research into, and application of, cost-benefit analysis. For example, in 1976, the Commission began the construction of an injury cost model that is unique to Federal regulatory agencies. This model provides comprehensive injury cost data and is based upon, but not limited to, the NEISS data discussed above. Similarly, the Commission was one of the first Federal agencies to introduce "value of life" estimates in cost-benefit analysis. Many sources have recognized the cost-effectiveness of our rules. See, e.g., Newsweek (Feb. 11, 1980) (Murray Weidenbaum, later Chairman of the Council of Economic Advisors under President Reagan); R. Hahn, Regulatory Reform, What Do the Government's Numbers Tell Us? in "Risks, Costs, and Lives Saved" (R. Hahn ed.; Oxford University Press, 1996); S. Breyer, "Breaking the Vicious Circle", Table 5 (Harvard University Press, 1993); T. Tengs, et al., "Five-Hundred Life-Saving Interventions and Their Cost-Effectiveness" (draft dated 1994).

See comment 9.

B. There Is No Single Mold for a Cost-Benefit Analysis.

The Draft Report acknowledges that "the methodology used to conduct a cost-benefit analysis may vary depending on the circumstances and the context of the analysis." Draft Report, p. 25. GAO nevertheless attempted to derive its own particular methodology based on professional literature. It then measured various Commission economic analyses by this standard.

We do not believe that a single set of criteria apply to every economic analysis. As OMB has observed (in providing guidance for Executive Order 12866, which requires certain cost-benefit analyses), "[T]his document is not in the form of a mechanistic blueprint, for a good [economic analysis] cannot be written to a formula. Competent professional judgment is indispensable for the preparation of a high-quality analysis. Different regulations may call for very different emphasis in analysis." Economic Analysis of Federal Regulations Under Executive Order 12866, p.2 (Jan. 11, 1996).

The criteria that the Commission staff apply to a particular economic analysis depend on the nature of the hazard, the level of information required, the regulatory or enforcement action contemplated, and other factors. This flexibility is consistent with good professional practice. Most importantly, it is consistent with our governing statutes, which do not prescribe a particular methodology for the assessment of the relationship between the costs and benefits of a particular Commission action. However, we recognize that the principles of transparency and full disclosure are important in presenting cost-benefit analyses, and we will endeavor to ensure that these principles are satisfied.

C. Not Every Presentation of Economic Information Is a Cost-Benefit Analysis.

Not only may cost-benefit analyses vary according to the circumstances, but many of our staff's presentations of economic data are not formal cost-benefit analyses. The staff provides a wide range of information about the economic impacts of various possible Commission actions. It would not be appropriate to judge each such presentation by the criteria that GAO has identified as appropriate for formal cost-benefit analyses.

The Commissioners expect a wide range of descriptive and analytic economic information. For example, the staff prepares market reports on various products. Such market profiles contain a great deal of economic information, but they are not cost-benefit analyses. Similarly, what we call "regulatory analyses"

9

also contain information on costs and benefits. They are detailed analyses of the effect a regulation may have on cost, price, competition, utility, normal business practices, international trade, small businesses, and the like. However, not all regulatory analyses are intended to be full-blown cost-benefit analyses.

The Draft Report asserts that Commission staff prepared a cost-benefit analysis for 29 projects between January 1, 1990 and September 30, 1996, but that the analysis was required by law in only eight instances. Draft Report, p. 23. The Draft Report then measured the analyses in those 29 projects by the GAO-derived methodology. This is a questionable approach because the projects differed from each other and were at different stages of development when the various economic memos were written. Seldom was staff's purpose the preparation of a formal cost-benefit analysis, nor was such a formal approach required.

See comment 10.

We note that the Draft Report did not separately "grade" the eight instances in which we were required by law to conduct a cost-benefit analysis. Instead, the Draft Report lumps all 29 projects together. We have examined those eight projects and our staff believes that in virtually every case we either evaluated the criteria that GAO has identified as important (as we understand the criteria), or they were not pertinent for some reason unique to the project.

Our future presentations of economic analyses will contain additional analytical detail where appropriate and useful, and we appreciate GAO's recommendation in this regard. However, in most cases, cost-benefit analyses required by statute will continue to be more detailed than other presentations of economic information.

III. HOW THE COMMISSION TRACKS PROJECTS

The Draft Report asserts that "project selection and implementation could potentially be improved if Commissioners and staff had access to tracking information on CPSC projects, such as starting and ending dates, project origin, project costs (including staff days and contract costs) and agency actions taken to address the potential hazard." Draft Report, p. 36. Unfortunately, the Draft Report paints only a partial picture of how the Commission tracks projects.

See comment 11.

CPSC's Management Information System tracks employee time and contract costs for each project. In addition, the Commissioners exercise their oversight of agency activities through periodic briefings and reviews with staff that occur monthly, weekly, and sometimes even daily. The Commission does not keep detailed tracking reports of activities that do not rise

to the "project" level. Although we will consider GAO's recommendations to institute an improved tracking system, we are not convinced that tracking at the level of detail suggested would be cost-effective.

The Draft Report fails to mention the numerous ways that the Commission monitors its current projects and may leave the inaccurate impression that no project tracking occurs now. In fact, we have several tracking systems in place, including the following:

- o The employee time and contract costs of each approved project are recorded in our Management Information System and distributed to CPSC administrators and office directors and are available to the Commissioners.

- o Each of the major functional areas has project management systems in place. For example, the Office of Hazard Identification and Reduction conducts quarterly reviews of major project milestones. The Office of Compliance has monthly meetings with the Commissioners to review all its activities. The Integrated Field System tracks projects for the field staff in their support of Compliance, Consumer Information and Hazard Identification and Analysis programs.

- o Projects are reviewed at various stages of the budget process, including the preparation of the annual budgets to OMB and the Congress, the initial operating plan, and at a mid-year review. The staff regularly briefs individual Commissioners informally. The current budget documents make it clear to the Commissioners how resources are allocated among hazards.

Much of the information that GAO reviewed pertained to low-level activities that required little time each year and would not be considered a project by the Commission's budget and operating plan. Nevertheless, we take seriously GAO's recommendation of a refined tracking system. In fact, we are exploring ways to refine project tracking as part of our efforts under the Government Performance and Results Act. Thus far, we have reviewed several sub-project level tracking systems used at the Commission. Modifications to these systems are being developed that will allow the Commission to measure performance by our strategic goals. These modifications include classifying our projects and sub-projects by hazard area and tracking the time and resources expended for activities within each hazard area. Additionally, activities for which we have customer

service standards, such as the Hotline, Clearinghouse, and State Partners program, already have systems in place to track how well we are meeting these standards.

CPSC has also included items in its 1998 budget request to Congress that would help improve our project tracking systems. For example, we are seeking funding for a new accounting system that could accommodate a tracking system on the sub-project level. Our current system is over 25 years old and cannot accommodate the kind of sub-project tracking that the GAO has suggested. In addition, CPSC has requested funding to integrate our databases (both historical and current), which would facilitate a one-stop tracking system.

IV. HOW THE COMMISSION SELECTS PROJECTS

See comment 12.

The Draft Report identified the Commission's criteria for setting priorities, but may leave the impression that GAO's interviewees randomly selected these criteria based on personal whim. Draft Report, p. 10. In fact, for 20 years, our regulations have set forth seven specific criteria for consideration in project selection. These are (i) frequency and severity of injuries; (ii) causality of injuries; (iii) chronic illness and future injuries; (iv) cost and benefit of CPSC action; (v) unforeseen nature of risk; (vi) vulnerability of the population at risk; and (vii) probability of exposure to harm. See 16 C.F.R. Sec. 1009.8. Additional criteria may also be pertinent in a particular case. Id.

However, we have never embraced a mechanistic project selection process. Instead, our regulation recognizes that:

> [I]ncontrovertible data related to the criteria identified ... may be difficult to locate or develop on a timely basis. Therefore, the Commission may not require extensive documentation on each and every criterion before making a decision. In addition, the Commission emphasizes that the order of listing of the criteria ... is not intended to indicate either the order in which they are to be considered or their relative importance. The Commission will consider all the criteria to the extent feasible in each case, and as interactively or jointly as possible.

Id. (emphasis added).

This decisionmaking process reflects the real world, where staff resources, funds and time may not exist to perfect every nuance of the analysis, especially when unsafe products threaten consumer safety. Once evidence sufficient to support Commission

action is available, we must turn from further study of the problem to solving it.

CPSC has three Commissioners, each a political appointee, each representing a different point along the spectrum where facts and policy merge. That our Commissioners look at the pertinent factors somewhat differently, with some emphasizing one factor and others another, is exactly what Congress intended when it set up this multi-member Commission. This is not a sign of confusion or institutional vacillation, but rather of strength, as the wisdom and experiences of three independent Commissioners meld into a final agency decision.

V. HOW THE COMMISSION HAS SUCCEEDED IN REDUCING DEATHS AND INJURIES

By the only relevant measure -- how well it fulfills its statutory mission -- the Commission earns high marks. Congress has directed the Commission to protect the public against unreasonable risks of injury associated with consumer products; to provide safety information to consumers; and to promote research into product-related deaths and injuries. See Consumer Product Safety Act, § 2(b), 15 U.S.C. § 2051(b). In fulfilling this mission, the Commission uses both sound data and the critical element of human judgment. Congress wisely contemplated this process by giving the Commission power to assemble data, but also creating a bipartisan commission of five (now three) members. The CPSC's record reflects the effectiveness of this arrangement. In the past 25 years, the Commission has reduced hazards to consumers from lawn mowers, cribs, children's toys, clothing, furniture, cigarette lighters, bicycles, household appliances, and a host of other products.

A few specific "success stories" illustrate the point:

Cigarette lighters

The CPSC safety standard requiring cigarette lighters to be child-resistant became effective in 1994. We anticipate that it will prevent up to 100 deaths, several hundred injuries and millions of dollars in property damage each year. Beginning in fiscal year 1998, the Commission will begin a project to formally evaluate the effectiveness of the standard.

Poisonings

CPSC's actions requiring child-resistant packaging (under the Poison Prevention Packaging Act) have saved the lives of over 700 young children from accidental poisonings by prescription drugs and aspirin.

Cribs

Crib safety standards have reduced annual deaths by over 80% since 1973 when it was estimated that up to 200 infants died primarily from suffocation or strangulation in full-size cribs. That number has been reduced to about 50 crib-related deaths per year. CPSC continues to work to lower that number further by educating consumers on the hazards of older cribs and the importance of using cribs that meet current safety standards.

Infant suffocation

CPSC research in the past few years provided the first direct evidence that infants sleeping on their stomachs on top of soft bedding were at risk of suffocation and death. CPSC estimated that this hidden hazard contributed to as many as 1800 infant deaths a year -- most diagnosed as sudden infant death syndrome. CPSC publicized the hazard of soft bedding and joined with other public health groups in the "Back-to-Sleep" campaign to advise parents to place children to sleep on their backs.

Drawstrings on children's clothing

In an outstanding example of achieving speedy results through voluntary cooperation with industry, CPSC and children's clothing manufacturers cooperated to eliminate a specific strangulation hazard for young children. In April 1994, CPSC informed the industry that drawstrings at the hoods and necks of jackets, coats and sweatshirts were responsible for strangulations when they caught on playground equipment and other items. Within four months, makers of most of the 20 million children's garments manufactured annually in this country agreed to replace drawstrings with alternative closures such as hooks, buttons, snaps and Velcro. CPSC issued voluntary guidelines to alert the public to remove drawstrings and to advise manufacturers how to eliminate the hazard.

Members of Congress have acknowledged our successes. Earlier this year, Senator Richard Bryan described the Commission as "one of the taxpaying public's best bargains in government." Cong. Rec. (Jan. 30, 1997; S851). Congressman Rodney Frelinghuysen described the Commission's new child-proof cap rule as "a rare example of how Government can work with industry -- instead of against them -- on regulations that will improve safety." Cong. Rec. (June 16, 1995; H6048). Recently, Congressman David Hobson remarked, "We have worked very closely with this Agency. I think it is an example of where we can do things together, and you can do them without heavy rules and regulations by getting people together . . . . [W]e have learned a lot from what the Consumer Product Safety Commission has done . . . ." Hearings Before Subcommittee on VA, HUD, and

Independent Agencies, p. 552 (May 7, 1997). Senator Carl Levin has commended the Commission's drawstring initiative (mentioned above) and applauded Chairman Brown "for bringing a human face to Government by reaching out personally . . . and working voluntarily with industry to solve this problem." Cong. Rec. (Oct. 26, 1995).

Ordinary American consumers also have encouraged us with a steady stream of compliments sent through our award-winning Hotline and website. Comments like:

"Keep up the good work, just one life saved is worth it."

"The information you offer is priceless to folks with kids."

"Your information possibly prevented me from having a potential fire . . . . Keep up the good work!"

"The most conscientious parent can easily overlook dangers that exist in even the most innocent looking product. I have bookmarked this site and will be returning often. Thank you again . . . for your website that is a definite educational tool for the public."

"Thanks for helping me recognize a life-threatening situation from carbon monoxide."

"One of the most hassle-free experiences I have ever had in dealing with a government agency!"

CPSC's achievements are particularly impressive because they have come so inexpensively -- and never more so than today. The Commission's budget now is less than 60% -- in real dollars -- of its size at the Commission's inception. Draft Report, Fig. 1. Not only are we providing safety, we are doing it on a shoestring.

None of this means that there is no room for improvement or that the Commission cannot find ways of doing its job even better. We look forward to determining which GAO recommendations will help us do so. But the fundamentals at the Commission are sound. The Commission's past successes provide assurance of its continued effectiveness.

15

The following are GAO's comments on Chairman Brown and Commissioner Moore's letter dated July 24, 1997.

GAO Comments

1. As we discuss in the report, CPSC relies on a number of different sources for injury incident data. (Descriptive information on all CPSC's data sources is provided in app. V.) However, only one source—the NEISS system—is capable of providing statistically reliable, representative information, and the NEISS system covers only those injuries treated in hospital emergency rooms. Although CPSC obtains information from other sources, these data are anecdotal and thus their usefulness is very limited in estimating injury prevalence. As a result, we have recommended that CPSC consult with experts both inside and outside the agency to prioritize its additional data needs and to explore the feasibility of options for obtaining these data. Changes over the past decade in the health care market, including the growth of ambulatory care, changes in reimbursement procedures, and improved health services research have the potential to make such additional data collection more feasible and less costly than it was a decade ago when some of these assessments were last made.

2. Figure 3 correctly states that CPSC does not obtain systematic surveillance data on injuries treated outside the emergency room. In the text of the report, we state that the number of injuries treated in each setting is unknown. We added a similar statement to the figure to emphasize this point.

3. In several places in their comments, Chairman Brown and Commissioner Moore refer to CPSC's investigations of selected incidents to obtain more information. We discussed these investigations in our report. We believe that these investigations provide valuable information on causation, characteristics of accident victims, and hazard patterns, and we agree that some information gleaned from investigations is not obtainable from surveillance data. However, according to CPSC staff, this information is available to the agency only after a project is well under way, not at the initial stage of project selection. As a result, CPSC has little information on these important factors to assist in project selection, and evaluation of these criteria at the project selection stage is thus unavoidably speculative.

4. Descriptive information on this source of information was provided on in appendix V.

5. For reasons we discussed in the report, relying on aggregate data (data not specific to a particular consumer product) to address the limitations of CPSC's surveillance data is problematic. In addition, in the briefing packages we reviewed, the estimates of injury incidents usually referred only to NEISS cases and were not extended with modeling techniques; because these techniques were used so infrequently for this purpose, we did not assess their application in this report.

6. In referring to the agency's monitoring of other aggregated sources of injury data, Chairman Brown and Commissioner Moore state that "Tracking of this type is sufficient to assure the adequacy of our data, as we use it." We disagree. Examining trend information from other sources (without a rigorous application to CPSC's own specific needs) is not sufficient to compensate for (or even measure the magnitude of) the limitations of CPSC's injury surveillance data.

7. We believe this comment may reflect a misunderstanding of our point. We do not mean to suggest that CPSC incorrectly relies on NEISS to provide information on chronic illnesses. Rather, we are pointing out that CPSC has virtually no systematic data on chronic illnesses. As we stated in the report, on page 20, we agree with Chairman Brown and Commissioner Moore (and with the CPSC staff we interviewed) that such data are often difficult to obtain. However, chronic illness is listed as a criterion for CPSC project selection, and CPSC has little information to assist in applying this criterion. Accordingly, we are pleased with the statement by Brown and Moore that CPSC will consider additional surveillance methods to obtain more information on chronic illnesses.

8. We acknowledge in the report that CPSC uses other sources to supplement its death certificate data. However, our interviews with CPSC staff and our review of agency documents confirmed that death certificates are the most important source of death data for CPSC. In the briefing packages we reviewed, 80 percent of the calculations for numbers of deaths were based in whole or in large part on death certificate data, and death certificates were the sole source of death information in 36 percent of all CPSC briefing packages (a far greater percentage than for any other single source). Death data were usually reported in CPSC briefing packages with a lag of 2 or more years, especially when death certificates were the sole source of data.

9. We agree with Chairman Brown and Commissioner Moore that there is no single mold or perfect set of criteria for evaluating a cost-benefit

analysis, and we have revised the report to further emphasize this point. We believe that Chairman Brown and Commissioner Moore may have misunderstood the purpose of our evaluation questions. We did not "derive a particular methodology" for cost-benefit analysis, nor do we mean to suggest that CPSC should follow some "formula" for conducting analyses that does not leave room for competent professional judgment. However, to say that there is no perfect "formula" for cost-benefit analysis does not imply that all methodological choices are equally consistent with rigorous and comprehensive professional work. Although no litmus test exists for a "good" analysis, the professional literature offers some basic, minimum elements that are commonly used in evaluating cost-benefit analyses. These elements, which are based on the principles of transparency and completeness, are generally considered necessary, although not sufficient, for a good analysis. Although flexibility may be sometimes necessary in the assumptions or models underlying a cost-benefit analysis, the elements we used—including full disclosure of data limitations, sensitivity analysis, and incorporating all important costs and benefits—are appropriate to a wide range of situations.

10. Chairman Brown and Commissioner Moore are correct in stating that we evaluated 29 CPSC cost-benefit analyses that were completed between January 1, 1990, and September 30, 1996. We identified these 29 analyses as complete on the basis of CPSC's statements—specifically, we considered a cost-benefit analysis to be complete only if an explicit comparison was made between aggregate costs and benefits. In addition, although the analyses may have been prepared at different stages of the project, we based our review on all available documentation on the project, and we reported results only for the evaluation questions that applied to the majority of cases and for which a clear determination could be made. We did not report results separately for the eight regulatory analyses that were required by law, because there were relatively few of these. However, we found no substantial differences between these 8 and the remaining 21 in terms of how they performed, compared with commonly used elements of evaluation of cost-benefit analysis. Therefore, we are confident that our results present an accurate assessment of CPSC's cost-benefit analyses, and we recommend that the agency implement changes to ensure that its analyses are comprehensive and reported in sufficient detail.

11. We believe that, as now constructed, CPSC's method for tracking projects operates at too high a level of generality and provides too little information to give a comprehensive, accurate picture of the agency's activities either at a given point or over a longer period. CPSC staff told us,

and our review of agency documentation confirmed, that the Management Information System (MIS) usually tracks most agency activities only at a very general level. For example, CPSC's 1996 year-end MIS report lists some specific projects such as "upholstered furniture" and "range fires," but most projects are accounted for under either broad umbrella codes such as "sports and recreation" or "children's projects," or under activity codes such as "investigations," "product safety assessment," or "emerging problems." In addition, CPSC staff told us that reliable inferences on resources spent cannot be drawn from MIS data because of limitations in the computer system and because no consistent rule exists about how staff time in different directorates is recorded to project codes. As a result, CPSC staff were unable to generate a comprehensive list of projects or to provide accurate information about resources allocated to those projects. We recommend an improved tracking system that would provide enough information to monitor the projects selected and resources spent for each specific consumer product hazard. We believe that as CPSC develops its planned accounting system, it should attempt to make it as compatible as practicable with the recommended tracking system. Nevertheless, we believe that whether or not it implements its planned accounting system, CPSC can and should improve its ability to track projects.

12. Our interviews with present and former commissioners revealed a pattern by which certain of CPSC's regulatory criteria have historically been given greater emphasis in CPSC's project selection process. Our objective was to describe the process as it was related to us; we have not taken a position on whether this process is appropriate. We have added a statement to our methodology section to emphasize this point.

Comments From Commissioner Gall, Consumer Product Safety Commission, and GAO'S Evaluation

Note: GAO comments supplementing those in the report text appear at the end of this appendix.

U.S. CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, D.C. 20207

Office of Commissioner Gall

July 23, 1997

Carlotta C. Joyner
Director, Education and Employment Issues
Health, Education, and Human Services Division
U.S. General Accounting Office
Washington, D.C. 20548

Dear Ms. Joyner:

I have read with considerable interest the draft General Accounting Office (GAO) report on the Consumer Product Safety Commission (Draft Report) and would like to respond to your invitation to submit my views on it. I will deal with specific items of the Draft Report in separate sections of this comment letter. I first wish, however, to commend the GAO for the thorough, professional approach that the Draft Report takes to the Consumer Product Safety Commission (CPSC or Commission). Although I may not agree with all of the conclusions reached by the GAO, I appreciate the time and effort by the GAO reviewers in carrying out their congressional mandate. In all of my conversations with the Commission staff, I heard no comments other than those commending the professional, conscientious attitude taken by the GAO reviewers and the ease of working with them. I believe that the GAO review will be a useful document for Commissioners and Commission staff in assessing how the Commission can improve those operations.

See comment 1.

Comments

1. Selection of Projects

I agree with the GAO reviewers' conclusion that this process is too ad hoc and is not subject to systematic initial risk assessment, cost-benefit analysis, or vulnerability assessment. I think that better allocation of resources at this stage in the product safety process would yield greater overall product safety results, and prevent the chasing of "targets of opportunity." I also agree with the observation that the Commission needs an improved system to track the projects or activities that are ongoing, so that Commissioners have a better sense of what Commission staff are doing over and above the activities approved in the Commission's yearly Operating Plan. With an up-to-date tracking system, Commission staff can better

organize their limited resources. Finally, I agree that the concept of "vulnerable populations" needs better explanation. Some observers conclude that persons with disabilities are automatically vulnerable to product safety problems. I firmly believe, however, that not all persons with disabilities ought to be classified as a vulnerable population needing special Commission action for protection.

2. Information Gathering Mechanisms

I agree that the Commission could improve the way that it gathers information. The National Electronic Injury Surveillance System (NEISS) is a state-of-the-art system of injury information collection, which has served as a model for other nations with similar systems. Its utility is demonstrated by the fact that data collected by it are used by other government agencies, including the Center for Disease Control's National Center for Injury Prevention and Control, and the National Institute for Occupational Safety and Health and the National Highway Traffic Safety Administration. This utility can always be improved, however, and I believe that the Commission staff should reassess the decision to confine NEISS to hospital emergency rooms. This reassessment should be conducted in light of trends that: (1) indicate increasing numbers of injuries are being treated in settings other than emergency rooms; and (2) the types of injuries treated in emergency rooms may not be representative of the types of injuries occurring in the general population. This review should be conducted with the recognition that in a nation of approximately 270 million inhabitants and a population of approximately 15,000 consumer products, no system of information gathering will ever produce better than a best estimate.

I also agree that exposure data is very important in Commission and Commission staff assessments of the magnitude of hazards posed by particular products. It is, however, usually difficult, time-consuming and expensive to collect. Full-blown exposure surveys should be limited to projects of sufficient magnitude to justify them. For less important projects, the staff should develop less costly but still useful measures of exposure by use of appropriate surrogates, such as sales or estimated populations of specific projects.

3. Types of Analysis Conducted

I agree that sensitivity analyses should be conducted on important variables in Commission staff work, and that these analyses should be disclosed whenever staff communicates with Commissioners, with the regulated community, or with the public. Similarly, the statistical errors of estimates should be provided whenever the Commission staff is not reporting an actual number based on measured or reported incidents. Too often, specific numbers are assumed by readers to be actual numbers, rather than numbers based on some type of estimate from a sample population. I also concur that risk-risk analysis needs to be conducted on certain types of Commission projects, particularly where the hazard is complex and closely associated with consumer behavior. The hazard posed by air bags to children in the front seat of automobiles is a good example where alleviating one hazard may increase the risk of another. The Commission should profit by this example and perform risk-risk analyses when possible.

4. Compliance with Section 6(b) of the Consumer Product Safety Act

I was pleased to note that GAO found that the Commission and its staff complied with Section 6(b) of the Consumer Product Safety Act. Section 6(b) strikes an importance balance between the public's justified right to know about hazardous products, and the right of the manufacturers of consumer products to comment on information and even to block the release of misleading information. The public is not well served by the release of raw data that may be readily misunderstood because of undue emphasis placed on particular risks, rather than a more thorough understanding of how those risks relate to others.

Criticisms

See comment 2.

1. Data Gathering

My single most critical observation of the Draft Report is that it notes that there are deficiencies of data gathering and information analysis on the part of the Commission and its staff, but does not analyze the importance of these deficiencies. The GAO reviewers examined over 600 briefing packages. Not all of the consumer product safety problems covered by these briefing packages were worthy of equal data gathering and analytical effort. For example, where Commission staff are working cooperatively with industry and consumer groups to modify an already-existing voluntary standard, only a minimum amount of data gathering and analysis may be justified: the problem and proposed solutions are usually well understood by the participants and further definition may be duplicative of work already done. In other cases, such as where the Commission proposes to impose major new regulations on hitherto unregulated products, a great deal of both data gathering and analysis is absolutely essential to ensure that the Commission arrives at a justified solution.

See comment 3.

The resource implications also need to be considered in any decision to undertake new data collection. The Commission can always hope for additional resources from Congress, but in the event that such resources are not forthcoming, the Commission needs to consider how it should reallocate resources to collect additional data while still fulfilling its other vital functions. The Commission almost always does the best that it can with the tools available to it. The better the tools that we are able to provide to the staff, the better the Commission is able to protect consumers and to work with industry.

2. Compliance

My other critical observation is that the Draft Report deals only in passing with the Compliance function carried on by the Commission. Consumer product safety regulations are far from self-enforcing and the Commission expends considerable resources each year in intercepting products that fail to meet such standards, or otherwise constitute substantial product hazards, and in seeking recalls of such products. Both the resources devoted to those efforts, and the analyses required in conducting them, are deserving of GAO consideration in any review of Commission operations.

Conclusion

The Draft Report is a reasoned and useful document for the Commission to use to improve its already successful operations and to remedy deficiencies where they exist. I look forward to working with my fellow Commissioners, the Commission staff, and the authorizing and appropriating committees of Congress to analyze and implement many of the reforms suggested by the Draft Report.

Sincerely,

Mary Sheila Gall
Vice Chairman and Commissioner
U.S. Consumer Product Safety
Commission

cc: The Honorable Thomas J. Bliley
Chairman
House Committee on Commerce

The Honorable John D. Dingell
Ranking Democratic Member
House Committee on Commerce

The Honorable John McCain
Chairman
Senate Committee on Commerce, Science and Transportation

The Honorable Ernest F. Hollings
Ranking Democratic Member
Senate Committee on Commerce, Science and Transportation

The following are GAO's comments on Commissioner Gall's letter dated July 23, 1997.

GAO Comments

1. Our interviews with present and former commissioners revealed a pattern by which certain of CPSC's regulatory criteria have historically been given greater emphasis in CPSC's project selection process. Our objective was to describe the process as it was related to us; we have not taken a position on whether this process is appropriate. We have added a statement to our methodology section to emphasize this point.

2. Commissioner Gall states that we did not analyze the relative importance of the deficiencies we found in CPSC's data and methodology. However, as we stated in the report, available information does not permit us to determine the impact of better-quality data on the decisions CPSC made. The limitations we found in CPSC's data have a variety of potentially conflicting impacts, precluding us from determining exactly how the results of the analysis might change if improved data were available. For example, because CPSC's injury estimates are often confined to injuries treated in hospital emergency rooms, CPSC's estimates will generally understate the actual number of injuries associated with a consumer product. However, CPSC's systematic injury and death data can generally tell only whether a product was involved in an accident—not whether the product caused or contributed to the accident. As a result, this can make the risks assessed by CPSC appear larger than they might actually be. Similarly, we cannot determine how improved exposure data would change the relative importance of the risks assessed by CPSC. We agree with Commissioner Gall that not all projects will merit the same level of data or analysis. However, our review of CPSC raises questions about the agency's ability to obtain and analyze data necessary to support rigorous analysis of important agency projects.

3. We agree with Commissioner Gall that resource considerations should enter into CPSC's decisions to undertake new data collection. For this reason, we recommended an overall feasibility study for CPSC to prioritize among its data needs and investigate new options for obtaining additional information.

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