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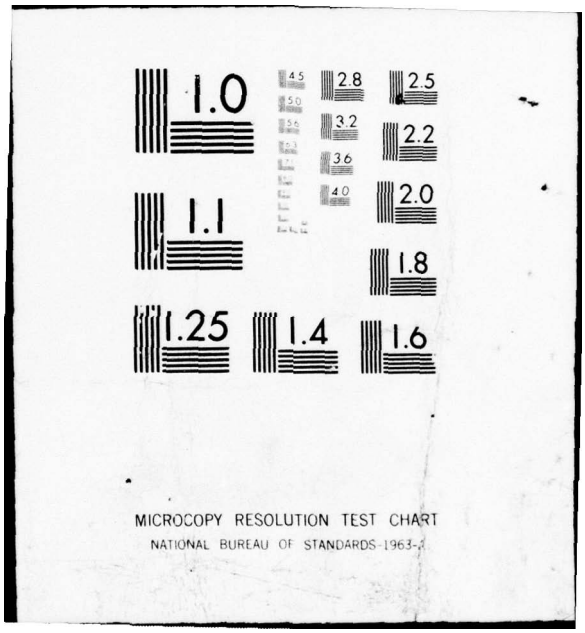
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A Review of the Role of Health Sciences in the Consumer Product Safety Commission

Bureau of Biomedical Sciences (CPSC) Review Committee

Committee on Toxicology

Assembly of Life Sciences

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The Bureau of Biomedical Sciences (CPSC) Review Committee was appointed to conduct an in-depth review of the activities of the Bureau of Biomedical Sciences to determine its role in fulfilling the mission of the CPSC, to review its current research programs, and to recommend a course of action for future research or any specific changes that would be beneficial to the Commission. During the course of the committee's deliberations, the CPSC underwent a reorganization that in June 1977 eliminated the Bureau as a specific entity and incorporated its functions under a new directorate. The committee was advised that the reorganizational change should be considered in determining the role of Health Sciences, now part of the Directorate for Engineering and Sciences. Recommendations are made for this purpose.

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(6) A REVIEW OF THE ROLE OF HEALTH SCIENCES
IN THE
CONSUMER PRODUCT SAFETY COMMISSION.

A Report Prepared by the
Bureau of Biomedical Sciences (CPSC) Review Committee

(15) N00014-75-C-0718

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National Research Council

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NOTICE

The project that is the subject of this report was approved by the Governing Board of the National Research Council, whose members are drawn from the Councils of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine. The members of the Committee responsible for the report were chosen for their special competences and with regard for appropriate balance.

This report has been reviewed by a group other than the authors according to procedures approved by a Report Review Committee consisting of members of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine.

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The Committee wishes to acknowledge with thanks the cooperation of the staff of the Consumer Product Safety Commission, as it made the tasks much easier. The support of the Advisory Center on Toxicology is gratefully acknowledged.

BUREAU OF BIOMEDICAL SCIENCES (CPSC) REVIEW COMMITTEE

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Dr. Robert A. Scala
Exxon Corporation

Dr. Ralph G. Smith
University of Michigan

Dr. Jack A. Winstead, Staff Officer
Advisory Center on Toxicology

Dr. Robert M. Hehir, Project Officer
Consumer Product Safety Commission

Since the inception of the Consumer Product Safety Commission (CPSC) in 1972 (Public Law 92-573, 1972), the role of the Bureau of Biomedical Sciences within the Commission has been questioned. At the request of the CPSC, the National Research Council appointed a committee to conduct an in-depth review of the activities of the Bureau of Biomedical Sciences to determine its role in fulfilling the mission of the CPSC, to review its current research programs, and to recommend a course of action for future research or any specific changes that would be beneficial to the Commission.

During the course of the committee's deliberations, the CPSC underwent a reorganization that in June 1977 eliminated the Bureau of Biomedical Sciences as a specific entity and incorporated its functions under a new directorate. The committee was advised that, although the Bureau, as such, no longer existed, the reorganizational change should be considered in determining the role of Health Sciences, now part of the Directorate for Engineering and Science.

BACKGROUND

The Consumer Product Safety Commission (CPSC) was established by passage of the Consumer Product Safety Act (Public Law 92-573; 15 U.S.C. 2051) on October 27, 1972, and began operation on May 14, 1973. It consists of five Commissioners appointed by the President of the United States, with the advice and consent of the Senate. One Commissioner is designated by the President as Chairman. The Chairman holds his office as long as he remains a Commissioner in the agency and may be removed by the President only for neglect of duty or malfeasance in office.

The Commissioners were first apointed to serve terms of three, four, five, six, and seven years, the term of each being designated by the President at the time of nomination. Each of the successors is appointed for a term of seven years. No more than three of the Commissioners may be affiliated with the same political party.

The Chairman of the Commission is its principal executive officer and exercises all of the executive and administrative functions of the Commission, including appointment and supervision of personnel, distribution of business among personnel and administrative units of the Commission, and the use and expenditure of funds. The purposes of the Consumer Product Safety Act are:

1. To protect the public against unreasonable risks of injury associated with consumer products

2. To assist consumers in evaluating the comparative safety of consumer products

3. To develop uniform safety standards for consumer products and to minimize conflicting state and local regulations

4. To promote research and investigation into the causes and prevention of product-related deaths, illnesses, and injuries

A "consumer product" means "any article or component part thereof which is produced or distributed for use in or around a permanent or temporary household or residence, a school, in recreation, or otherwise, or for the personal use, consumption or enjoyment of a consumer in or around a permanent or temporary household or residence, a school, in recreation, or otherwise." Excluded from jurisdiction of the Act are such products as tobacco and tobacco products, motor vehicles, economic poisons, aircraft, boats, drugs, devices, cosmetics, and food, as defined under specific acts of Congress. See Sec. 3(a) (1) of the Consumer Product Safety Act. It should be noted that use of products in the workplace is also excluded from jurisdiction.

The Act requires the Commission to (1) maintain an Injury Information Clearinghouse to investigate, analyze, and disseminate injury data and information relating to the cause and prevention of death, injury and illness associated with consumer products; and (2) conduct such continuing studies and investigations of deaths, injuries, diseases, other health impairments, and economic losses resulting from accidents involving consumer products as it deems necessary.

The Act permits the Commission to (1) conduct research, studies and investigations on the safety of consumer products and on improving the safety of such products; (2) test consumer products and develop product safety test methods and testing devices; and (3) offer training in product safety investigation and test methods, and assist public and private organizations, administratively and technically, in the development of safety standards and test methods. The Commission may make grants or enter into contracts for the conduct of the above functions with any person, including a governmental entity.

Inclusive Acts

The Consumer Product Safety Act transferred to the Commission the responsibility for implementing the following four existing laws:

- The Flammable Fabrics Act, as amended (15 U.S.C. 1191)
- The Federal Hazardous Substances Act, as amended (15 U.S.C. 1261)
- The Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471)
- The Refrigerator Safety Act of 1956 (15 U.S.C. 1211)

The Commission's authority is derived from the Consumer Product Safety Act and the above named four other laws.

Purpose of each law

Consumer Product Safety Act. To protect the public against unreasonable risk of injury associated with consumer products.

Flammable Fabrics Act. To prohibit the introduction or movement in interstate commerce of articles of wearing apparel and fabrics which are so highly flammable as to be dangerous when worn by individuals.

Federal Hazardous Substances Act. To regulate the interstate distribution and sale of packages of hazardous substances intended or suitable for household use.

Poison Prevention Packaging Act. To provide for special packaging to protect children from serious injury or serious illness resulting from handling, using, or ingesting household substances.

Refrigerator Safety Act. To prohibit the transportation in interstate commerce of any household refrigerator manufactured after August 2, 1956, unless it is equipped with a device, enabling the door to be opened from the inside in conformance with standards prescribed in the Act.

ORGANIZATION OF THE CONSUMER PRODUCT SAFETY COMMISSION

In 1973, the Consumer Product Safety Commission was composed of five Commissioners with eight supporting offices. In addition, there were eight offices, six bureaus, and 13 field stations, all reporting directly to an Executive Director, who in turn reported to the Chairman of the Commission. (Appendix, page 1)

On November 16, 1976, the Chairman of the Commission issued an order (0130.1 CHG1) revising the organizational structure and functions assigned to the primary organizational components. It established an Office of Strategic Planning and an Office of Program Planning and Evaluation, responsible to the Chairman of the Commission. The Offices of Medical Director, Project Management, and Standards Coordination and Appraisal were assigned to the Office of the Executive Director. This reorganization also established six Associate Executive Directors (AED), one each for Hazard Identification and Strategy Analysis, Engineering and Science, Compliance and Enforcement, Communications, Field Operations, and Administration. The Bureaus and remaining offices were assigned to one of the six primary organizational components. The Bureaus of Epidemiology and of Economic Analysis were assigned to the Associate Executive Director for Hazard Evaluation and Strategy Analysis; the Bureaus of Biomedical Science and Engineering Science to the Associate Executive

Director for Engineering and Sciences; the Bureau of Compliance and the Office of Product Defect Identification to the Associate Executive Director for Compliance and Enforcement; the Office of Field Coordination and the 13 field offices to the Associate Executive Director for Field Operations; and the Bureau of Information and Education to the Associate Executive Director for Communications. While this brought about a marked reduction in the number of offices and bureaus reporting directly to the Executive Director, it also resulted in a relative reduction in rank for all of the technical bureaus. (Appendix, page 2)

On June 1, 1977, a further reorganization eliminated the Bureaus and placed their functions in one of five Directorates. The former Bureau of Biomedical Sciences now operates under a Deputy Associate Executive Director (DAED) for Health Sciences, and the former Bureau of Engineering under a Deputy Associate Executive Director for Engineering Sciences. Both report to the Associate Executive Director (AED) for Engineering and Science. The former Bureaus of Economic Analysis and of Epidemiology now operate under the Deputy Associate Executive Directors for Economics and for Epidemiology who report to the Associate Executive Director for Hazard Identification and Analysis. Similar changes were made for the other functional units. The Office of the Medical Director was eliminated and its functions placed under the Office of Strategic Planning. The reorganization also established an Office of Program Management with a Director and seven program managers reporting to the Executive Director. (Appendix, pages 3, 4)

ROLE OF HEALTH SCIENCES IN THE CONSUMER PRODUCT SAFETY COMMISSION

No unit within the Consumer Product Safety Commission has a greater responsibility for protecting human health than the Division of Toxicology and Medicine. This does not mean to say that mechanical injuries are less important, but injuries from substances about which little is known may have more far-reaching consequences.

Following are the views of the committee concerning the role of the Health Sciences Directorate within the CPSC.

The Health Sciences Directorate Should Develop a Surveillance Program on Potentially Hazardous Consumer Products to Support Compliance Action.

To function effectively, the Health Sciences Directorate should have ready access to as much information as possible on a wide variety of chemicals. The reason is twofold. First, data must be collected and evaluated on toxicity of chemicals used in household products. Second, data on composition of household products is necessary in order to evaluate those products that contain potentially hazardous materials.

The CPSC has addressed the problem of product composition by establishing and maintaining a computer data base consisting of both proprietary and nonproprietary information on some 15,000 consumer products. It collects and summarizes data on the toxicological properties of selected chemicals or classes of chemicals. Information on other chemicals is also obtained from various data bases such as MEDLINE, TOXLINE, and CHEMLINE. Other sources of data include the National Electronic Information Surveillance System (NEISS) and the Clearinghouse on Mutagens and Carcinogens.

The Committee believes that heavy reliance on computerized data bases should be avoided because these bases cover only recent literature, thereby omitting information on many chemicals present in household products that have not been the subject of recent investigations. A more extensive in-house compilation of the world's literature on potentially toxic ingredients of consumer product formulations should be a high-priority component of the total information storage and retrieval system.

The Interagency Chemical Data Policy Committee, working under the Office of Management and Budget and the Council on Environmental Quality have the task of surveying the kinds of data in various systems of government agencies, of developing mutually compatible storage and retrieval systems, of handling data with varying degrees of confidentiality, and of developing uniform chemical nomenclature. The committee fully endorses this activity and recommends full participation by the CPSC. However, it is not likely that such activities will adequately address the full spectrum of CPSC's data requirements. Therefore, the Health Sciences Directorate should supplement its national data bases with specialized data collections dealing with specific mission requirements so that the potential hazards from chemicals in household products can be evaluated in a timely manner.

The interagency agreement between the Consumer Product Safety Commission and the Environmental Protection Agency (EPA) requiring CPSC to provide both proprietary and nonproprietary data to the EPA is to be applauded. The committee recommends, however, that there be reciprocity between the two regulatory agencies in the exchange of data on chemicals used in household products over which the CPSC exercises control.

The National Electronic Surveillance System is a rudimentary epidemiological system in which hospitals report acute conditions associated with consumer products. If the product proves defective or contains a highly toxic substance, corrective action can be taken in an attempt to prevent future accidents. It would be helpful if this system could be expanded to include data on the incidence of acute effects related to consumer products that are not now being reported by hospitals. The Health Sciences Directorate of the CPSC does not have trained epidemiologists on its staff and these are needed for an effective surveillance system.

While everyone is deeply concerned about the acute effects from exposure to potentially hazardous material, very little attention has been given to consumer products that may produce illness and death from chronic exposure to chemicals.

The surveillance systems now in use are not effective mechanisms for collecting such data. They do not identify users or exposed populations, and whether those populations are in fact exposed. A mechanism should be developed for detecting chronic effects in humans resulting from the use of certain substances, such as known carcinogens. Exposed populations should be identified in a prospective epidemiological investigation and disease and injury incidence measured in comparison to some nonexposed population. Retrospective epidemiological investigations should also be undertaken for rare diseases or injuries.

The Consumer Product Safety Commission should make every attempt to validate and support its actions through epidemiological investigations, particularly in cases of borderline decisions based on risk/benefit analyses. It should recruit trained epidemiologists, preferably with a medical background, and trained biostatisticians. Their role should be to design and maintain an ongoing program for the evaluation of consumer products as determinants of disease in humans and provide the epidemiological data needed to initiate and support compliance action. Epidemiological studies would provide the credibility needed for widespread acceptance of decisions made by the CPSC.

The Health Sciences Directorate Should be Responsible for Hazard Evaluation of Chemicals Leading to Compliance Action.

The Consumer Product Safety Commission must regulate the safety of a multitude of consumer products in which a single chemical or mixture of chemicals are major ingredients. The hazards to consumers exposed to such products are primarily linked to the kinds and amounts of these chemicals which may enter the human organism by oral ingestion, inhalation or percutaneous absorption, and the toxicological consequences of either acute or chronic exposure to the chemicals. Some persons making regulatory decisions on chemicals entering the environment often mistakenly believe that the terms "toxicity" and "hazard" are synonymous. This has in many instances resulted in severe curtailment or even removal of useful chemicals because the regulatory actions were based solely on the intrinsic toxicity with no regard to hazard assessment. In a report prepared by the Food Additives Committee of the National Academy of Sciences-National Research Council on "Problems in the Evaluation of Carcinogenic Hazard from Food Additives," (Cancer Research 21: 433, 1961) toxicity is defined as the capacity of a substance to produce injury while hazard is the probability that injury may result from the use of a substance in a proposed manner. Thus, hazard is not only a function of toxicity but depends upon many other factors among which are: assessment of usage patterns that result in human exposure; the intrinsic nature of the consumer product which governs the scope of toxic

hazard by whatever route of exposure; the relative dosages received by humans and the time periods over which they are exposed; the metabolic fate of these consumer chemicals in the body and the pharmacokinetics of their turnover in the human; and the occurrence of irreversibility or degrees of reversibility of the toxic actions of these chemicals on human tissues following acute or chronic exposures.

The measurement and interpretation of these complex factors in terms of hazard to human health are highly professional tasks to be performed by personnel fully trained in toxicology, medicine, and the epidemiological aspects of human exposure to chemicals. Such personnel are in short supply in the CPSC structure, especially at the levels of professionalism and experience required to assess human hazard. It is clear, therefore, that such personnel must be grouped into a cohesive unit in which the toxicological, medical and epidemiological talent can interact to produce a reliable hazard assessment function.

In the context of this analysis, it seems inappropriate that a hazard analysis function for chemicals in the new organizational structure of the Consumer Product Safety Commission should reside in the Division of Hazard Analysis under the Deputy Associate Executive Director for Epidemiology. Rather, since all of the medical and toxicological talent for assessment of health hazards from consumer chemicals is located in the Division of Toxicology and Medicine under the Deputy Associate Executive Director for Health Sciences, it is much more logical, and indeed imperative, to assign the chemical hazard assessment function to this structure, placing the responsibility where the appropriate skills are clustered.

The question might logically be raised as to whether the talent cluster in the CPSC for chemical hazard evaluation is of sufficient magnitude and scope of experience to handle the number of health hazard analyses required to make regulatory decisions for the exponentially growing number of consumer chemicals coming under suspicion each year. The committee is of the opinion that the present toxicological and medical talent is less than optimum for carrying out the workload in chemical hazard assessment. Two possible courses of action seem apparent. First, additional biomedical and toxicological talent could be recruited to meet the Commission's total needs. Second, recognition could be given to the fact that assessment of health hazards from chemicals is a function not unique to the Consumer Product Safety Commission. The Environmental Protection Agency and other regulatory agencies have substantial missions in sectors of the regulatory arena that involve surveillance of many classes of chemicals to which consumers are exposed. In recognition of this fact, it might be possible to construct a high-level group of professional personnel skilled in the most modern techniques for translating toxicological and epidemiological data into health hazard assessments, and put this group at the full disposal of every Federal regulatory agency involved in control of chemicals, on some priority basis. Such a group, acting as an Interagency Hazard Assessment Council, could provide

the evaluative function for chemical hazards under all mandated authorities given to regulatory agencies in the Executive Branch of the Federal Government. The decision on July 22, 1977, by the Chairman of the Consumer Product Safety Commission, the Administrator of the Environmental Protection Agency, the Commissioner of the Food and Drug Administration, and the Assistant Secretary of Labor, Occupational Safety and Health Administration, to act collectively in assessing and regulating chemicals which impact upon people and the environment is a major step forward in the decisionmaking process. They have agreed to examine collectively risk and safety assessment, information sharing, compliance and enforcement. These agencies may wish to examine the proposal to establish an Interagency Hazard Assessment Council.

The Health Sciences Directorate Should Devote its Research Efforts to the Development of Methods in Chemical Analysis and Toxicology as they Relate to Compliance.

The present CPSC laboratory facilities consist of a central group of laboratories in the Food and Drug Administration building, with some additional space and facilities in a warehouse in Rockville, Maryland. In addition, there are three area laboratories located in New York City, Chicago, and San Francisco. Basically, the Washington and Rockville laboratory facilities are devoted to research, while the three area laboratories are concerned only with compliance activities. Although the Washington laboratories are engaged in research designed to assist the area laboratories, there appears to be relatively little exercise of authority from Washington over the regional activities. After extensive discussions with health science personnel, including the laboratory director, and a visit to the Washington laboratories, the committee believes that some changes in the present and projected activities of the laboratories should be made for more efficient use of personnel.

A vital ingredient in any successful laboratory is a competent and committed staff. The CPSC is fortunate in having a small but dedicated group of highly motivated and generally competent scientific personnel. The same cannot be said of the laboratory facilities, and it is rather surprising to note the high degree of enthusiasm for the mission of the CPSC which the research scientists appear to evidence, even though working in substandard laboratories. With respect to analytical instrumentation and equipment, the laboratories are reasonably well equipped to pursue various avenues of research. In fact, considering the size of the staff, the laboratories are probably overequipped. In both the Rockville and Washington facilities, several highly sophisticated pieces of equipment have been purchased but await installation and sufficient personnel to put them to use. The principal shortcoming of the Washington laboratories is the inadequacy of the laboratories themselves, which in general are small, cluttered, and in the committee's judgment, substandard in terms of safety and health. There is far too little bench space for the volume of work being under-

taken, and supplies are frequently stored in some degree of disarray in areas and on surfaces that should be reserved for ongoing studies.

It was evident from our review that several kinds of research are in progress. There appears to be some attempt at fundamental research regarding the biochemical or toxicological properties of a given substance, some of which deals with the substance regardless of its matrix and some of which attempts to address unique problems of substances found in consumer products. The overall effort of the laboratory can only be described as a mixture of highly basic and theoretical research, applied research, research devoted to a substance or occasionally a product, and methods development.

The animal facilities are small and totally inadequate to meet today's needs for conducting toxicological investigations. The laboratories are staffed with competent and interested scientists but so cramped as to preclude anything other than token studies of an elementary nature. The committee recommends that these conditions be vastly improved if the CPSC is to continue to attract and hold highly professional scientists in the Division of Toxicology and Medicine. Although the Commission has available, under contract, extensive laboratory facilities with the capability of doing more elaborate long-term studies, immediate attention should be given to improving its own in-house capability.

The present restrictions on manpower, budget, and space dictate the need for selectivity in the commitment of these resources. Efforts must be made to avoid needless duplication of activities on currently "popular" materials. There is a need to be certain that every agency with health interests does not initiate toxicity studies on the same compound because it happens to be popularized by the media.

The committee believes that the scientific mission of the Health Sciences Directorate within the CPSC is best served by concentrating on those things it can do well and for which it has specific operational requirements. Chief among these are the development and validation of methodology for acute toxicity studies. The emphasis on methodology should be interpreted to include not only the usual consideration of accuracy, reproducibility, and reliability, but also species variability, sites of action, development of models, and extrapolation of the animal data to man. Product studies should be devoted to developing ways of studying classes of materials and ranking the effects associated with members of a class of compounds. Some product testing is obviously required for reasons of compliance, but in general each component of a consumer product should be considered individually.

The net effect of the laboratory review is a strong feeling that the personnel are totally overwhelmed with the enormity of their mission and are devoted almost entirely to "targets of opportunity." Unless a budget many times greater than the present and projected budget is made available to the Health Sciences Directorate, consideration should be

given to several changes in the mission of the laboratory divisions of the Health Sciences Directorate:

- The toxicology laboratory should limit its investigations to general toxicological research dealing with chemicals of concern in consumer products. To attempt basic research with the existing facilities and staff, would, by and large, be a wasted effort;

- The animal facilities in the Washington area should be greatly expanded and adequately staffed if they are to contribute to the identification and control of potentially hazardous chemicals in consumer products;

- The laboratory should continue to use the facilities available through contracts for which its own laboratory does not have the proper skills;

- Specialized toxicological research related to the unique problems associated with a substance in a product, and not addressed by any other groups, should be identified by the laboratory division and necessary studies performed. For example, there should be no need for the CPSC to engage in basic research on the toxicology of asbestos but it would be appropriate to determine whether the asbestos content of a product would or could be hazardous to the consumer;

- The laboratories should expand and strengthen their activities with respect to the development of reliable methods for use by the laboratories responsible for compliance. To determine the composition of a product is a real challenge to the analyst and all the instrumentation in the laboratory should be brought to bear on this problem. The Washington laboratories could become even more involved in compliance analyses by having area laboratories refer difficult product analyses to the central laboratory for examination by more sophisticated instrumentation than is likely to be found in the area laboratories.

<u>The Health Sciences Directorate Should Develop a Long-Range Planning Program, with Particular Reference to Setting of Priorities</u>

Discussions with the scientific and management staff of the Consumer Product Safety Commission structural sectors under the direction of the Deputy Associate Executive Director for Health Sciences have led the committee to some understanding of the complex processes by which chemical substances of concern to the CPSC come to the attention of the Deputy Associate Executive Director for study or other action leading to regulation. One process leading to very high-priority action in this

Health Sciences Directorate is an expression of urgent concern or interest by a Congressional Committee, usually in relation to a chemical component of a consumer product. It is recognized that an expression of concern from such a source will always be a galvanizing force to members of a Federal regulatory agency. Rapid study and response to such an expression is both correct and desirable to protect public interest.

Yet, the total professional program of any sector of the CPSC should not be driven solely by the priority pressures emanating on an unpredictable schedule from oversight committees or individual members of the Congress. Rather, effective management of the resources, personnel, and facilities of CPSC Directorates would seem to call for an established and long-term planning document in which priorities are set for study and information gathering on the toxic properties of important chemicals found as constituents of consumer products. Long-range planning for action on key chemicals in some priority sequence, if established and made known within the Federal and Congressional eschelons interested in CPSC activities, might actually diminish the incidence of sudden alarms on specific consumer chemicals from Congressional or other Federal sources.

Given the logical requirement for long-range planning on consumer chemicals for which a data/information base must be established in the CPSC, it is important to develop a set of criteria by which priorities are established for studies. To make effective use of in-house and contract test facilities to supplement the existing data base on specific consumer chemicals, it would be important to establish two priority schemes: one for short-term testing leading to data bearing on acute hazards to humans, and the second for the more expensive and laborious procedures germane to evaluating chronic chemical hazards encountered by consumers. In planning for either scale of testing, some philosophy for aligning chemicals for study in a priority sequence, extending perhaps over a 5-year projection of the total work pattern, should be developed.

It is proposed that the basis for such a 5-year projection of study priorities be based on the CPSC's master list of chemicals entering consumer products, with emphasis on extraction of information in five categories:

1. chemicals which enter products in significant amounts and/or get widespread distribution in the population;

2. chemicals whose properties are such that significant penetration into human tissues might be expected in the course of normal usage of their vehicle products;

3. chemicals that might be expected to migrate widely into the environment after packages containing their vehicle products are opened;

4. substances for which at least preliminary evidence for significant intrinsic toxicity, either acute or chronic, can be found or inferred;

5. substances for which evidence of high toxicity with irreversible effects in animal models or humans is at hand.

From such available information over the full gamut of CPSC chemicals, one study priority system relating to acute exposures and another to chronic hazard studies might be constructed on the following proposed basis:

- Substances rating high in all five categories might well be considered worthy of the highest hazard assessment by the toxicological, medical, and epidemiological personnel at the CPSC.

- A lower level of potency in terms of possible irreversible tissue effects of the chemical (category 5 above) would automatically drop the priority rating of that chemical to a lower level.

- Still lower in the priority system would be chemicals with a high rating in categories 1 and 2, and moderate-to-high ratings in categories 3 and 4.

- Further down in the priority plan would be the chemicals in consumer products for which categories 1 and 2 are at least moderate magnitude, and category 4 is significantly different from zero.

- Finally, as categories 1, 2 and 3, which relate to potential exposure, and category 4, which defines toxicity, drop toward the weak-to-zero scale of intensity, priority for study would also drop to zero.

Once the compounds have been scaled for potential health hazards to consumers from the point of view of both acute and chronic exposure, the list might be scanned one final time using a socioeconomic judgment parameter. A compound rating high on this parameter might be elevated slightly on the priority list for study, and the reason for the judgment documented accordingly.

The Health Sciences Directorate Should be Concerned with Both Acute and Chronic Toxicity.

Section 2(a)(3) of the Consumer Product Safety Act says "the public should be protected against unreasonable risks of injury associated with consumer products." The Act also allows the Commission to

promulgate safety standards and says "any requirement of such a standard shall be reasonably necessary to prevent or reduce an unreasonable risk of injury associated with such product," (Section 7(a)). It is the opinion of the committee that the CPSC should concern itself with chronic as well as acute injury. Although the Bureau of Biomedical Sciences, now called Health Sciences, focused its attention almost entirely on acute injury, the section of the Act referred to above indicates to the committee that the CPSC should be equally responsive to problems associated with injury from chronic exposure to potentially hazardous substances. Real or potential injury can occur which differs only in terms of subtlety and time. A product which produces immediate anoxia or one that produces pulmonary fibrosis five years hence, falls within the spirit and intent of the Act. Both are subject to prevention or regulation. The time required for a substance to exert its impact should have no influence on decisionmaking in the CPSC except to highlight the Commission's role in defining incubation periods and preventing the ultimate injury. In a recent decision by the U.S. Court of Appeals in the District of Columbia regarding the interpretation of "imminent hazard" the Court said that a hazard can be imminent even though its effects do not occur until many years hence. (Env. Defense Fund vs. Ruckelshaus 439F.2d.584)

Consumer products for which the Commission has responsibility vary widely in chemical components, any of which might produce injury or illness. Chronic exposure to many of these substances could produce insidious effects that make it difficult to evaluate their potential hazard. The Health Sciences Directorate should develop a program for collecting or generating the kind of data needed for evaluating the potential hazard of substances that have not been clearly identified and thoroughly studied.

The Health Sciences Directorate Should Develop a Balance of Professional Skills.

The committee has reviewed the scientific and professional skills of the CPSC health professionals in light of the tasks mandated or implied by the statutes under which the Commission operates. The committee's assessment was complicated by the very recent organizational changes affecting the Health Sciences group. Under the old structure, the Bureau of Biomedical Sciences consisted of 12 doctorate-level scientists: the Director (a toxicologist), a veterinarian, a statistician, three chemists, two toxicologists, and four others whose skills were not evident from their work assignments. Two other members of the staff, though not at the doctorate level, are listed as pharmacologists. The committee is aware that the June 1977 reorganization has added at least two physicians to the staff of what is now described as the Deputy Associate Executive Director for Health Sciences.

Independent of organizational considerations, the scope of product safety information and research permitted by Section 5(a) and (b) of the

Consumer Product Safety Act would appear to require the following disciplines in the health sciences -- clinical medicine, epidemiology, toxicology, pharmacology and human and veterinary pathology. If the traditional exclusive concern with acute hazards is set aside and chronic hazards are included, additional skills will be needed in such areas as experimental oncology, teratology, mutagenesis, biochemistry, and pharmacokinetics. Of these skills, Section 4(g) stipulates only a requirement for a Director of Epidemiology.

In the earlier organizational structure, the physicians and epidemiologists were both in other Bureaus with no easy access to the Bureau of Biomedical Sciences. In the June 1977 reorganization, the Medical Director was moved to the Office of Strategic Planning and retitled Senior Medical Advisor. As far as can be determined, the remaining physicians were moved to a Division of Toxicology and Medicine in the Health Sciences Directorate, but the epidemiology function is inexplicably in an entirely separate Associate Executive Directorate.

The committee believes that the staff resources and skill mix are not adequate to meet the agency's traditional exclusive concern for acute hazards. They are unquestionably inadequate to address chronic hazards. The limited laboratory program can be continued by the existing staff, although outside review of proposed research would measureably improve the value and relevance of the program.

QUALITY CONTROL OF BRIEFING PACKAGES

The multifaceted briefing packages that are forwarded to the Commissioners must provide an adequate and well-rounded data base for rational decisionmaking by the Commissioners. They must also be structured so that they provide a legally defensible basis for any regulatory action that may follow. The high quality of these briefing packages is of the utmost importance to the implementation of the beneficial intent of the Consumer Product Safety Act. It follows that considerable thought should be given to the most appropriate means to assure quality control of this information in the area of health sciences.

The committee believes that these documents should be a critical review of available data, not simply a compilation thereof. Only expert critical evaluation of biomedical data, when combined with risk/benefit assessment, can provide the rational basis for regulatory action. Unless the appropriate biomedical expertise is available to the CPSC, this need will not be met.

As a first step in the quality control of a briefing package, adequacy of the source material must be assured. A literature search depending entirely upon such established data bases as MEDLINE and TOXLINE misses the older literature. For chemicals that have been in use for several decades or longer, such an omission could be of importance in the total evaluation. A manual search of Chemical Abstracts and

other indexes should be a part of any literature survey. The period covered by the literature review should be clearly indicated for those who subsequently receive and review the document.

The briefing package should also clearly indicate the strengths and weaknesses of available data as well as identify gaps in available knowledge. The total package might be similar to the EPA's Air Quality Criteria Documents which delineate the state of knowledge regarding a given pollutant in order to aid the Administrator in setting an Air Quality Standard.

The biomedical conclusions and opinions presented in the briefing package must be well documented, and should contain scientific value judgments as well as the means by which these judgments were reached. This would aid in a higher level scientific review and serve as a basis for legal defense of any resultant regulatory action. The final package should also contain a series of well-documented options with associated risks and benefits, for consideration by the Commission in its decision-making process.

The committee finds it distressing that the present structure of the CPSC does not provide top-level scientific review of a briefing package beyond that of the Deputy Associate Executive Director for Health Sciences as it moves upward to the Commissioners. It appears from the organizational structure that subsequent review, if any, could only be made by persons not specifically trained in the interpretation and evaluation of biomedical data. Highly qualified toxicological and medical input to the final package is not only desirable but necessary. Such expertise should be available on a permanent basis above the level of the Directorate. In addition to the needed in-house expertise, ad hoc panels at the level of the Executive Director's Office could be convened as specific situations warrant. Unless there is scientific input and review at the level of the essentially completed package, a proper assessment of the risk/benefit would be very difficult and could lead to an unsupportable decision on the part of the Consumer Product Safety Commission.

RECOMMENDATIONS

1. The Division of Toxicology and Medicine of the Health Sciences Directorate of the CPSC should supplement its national data bases with specialized data collection dealing with specific mission requirements.

2. The CPSC should provide the Health Sciences Directorate with medically trained epidemiologists and biostatisticians to design and maintain an ongoing program for the evaluation of consumer products and determinants of injury and disease.

3. The CPSC should recruit additional talent in the biomedical and toxicological area for hazard evaluation or consider the establishment of an Interagency Hazard Assessment Council to provide the evaluative function for chemical hazards for all regulatory agencies responsible for human health and safety.

4. The Health Sciences Directorate should develop a balance of skills by adding professionally trained people in oncology, teratology, mutagenesis, biochemistry, and pharmacology.

5. The Executive Director of the Consumer Product Safety Commission should extend the development of scientific leadership to echelons below the level of the Deputy Associate Executive Director for Health Sciences.

6. The chemical hazard assessment function, which currently resides in the Division of Hazard Analysis, should be assigned to the Division of Toxicology and Medicine and appropriately staffed with skilled personnel.

7. The facilities for carrying out analytical and toxicological research should be vastly improved for more efficient operation and protection of the personnel.

8. The Division of Toxicology and Medicine should devote its toxicological research to unique problems associated with a substance in a product that is not of particular concern to any other regulatory group. It should continue to use facilities available through contracts for which its own laboratory does not have proper skills.

9. Both the analytical and chemical laboratories should devote their resources and personnel to the development and validation of methodology.

10. The CPSC should concern itself with chronic as well as acute toxicity.

11. The CPSC Directorates should prepare a long-term planning document establishing priorities for study and information gathering of important chemicals found as constituents of consumer products.

12. The CPSC should take steps to ensure that the briefing package forwarded to the Commission is thorough, well documented and has received expert scientific review as it moves through the organizational structure.

There is no doubt among the members of the committee that the Health Sciences Directorate is and should continue to be an integral part of the Consumer Product Safety Commission's organizational structure. But if the Commission is to discharge its duties of protecting the consumer from potentially hazardous chemicals in consumer products, the Health Sciences Directorate must be strengthened, supported, and adequately funded in order to function efficiently and effectively in its overall mission.

The full implementation of the recommendations in this report will, in our opinion, meet these needs.

FIGURE 1

ORGANIZATION OF THE U. S. CONSUMER PRODUCT SAFETY COMMISSION

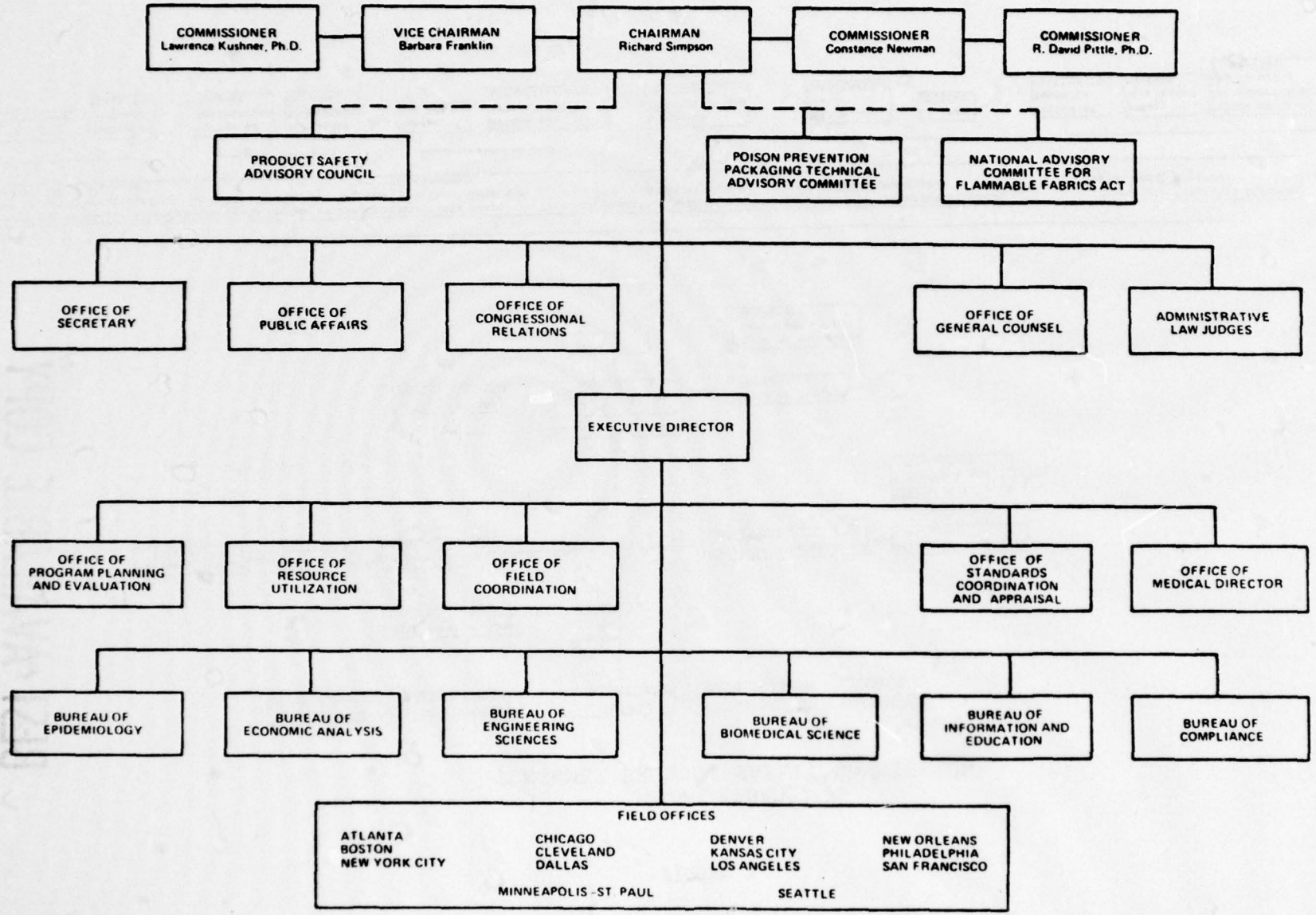

FIGURE 2

ORGANIZATION CHART
CONSUMER PRODUCT SAFETY COMMISSION

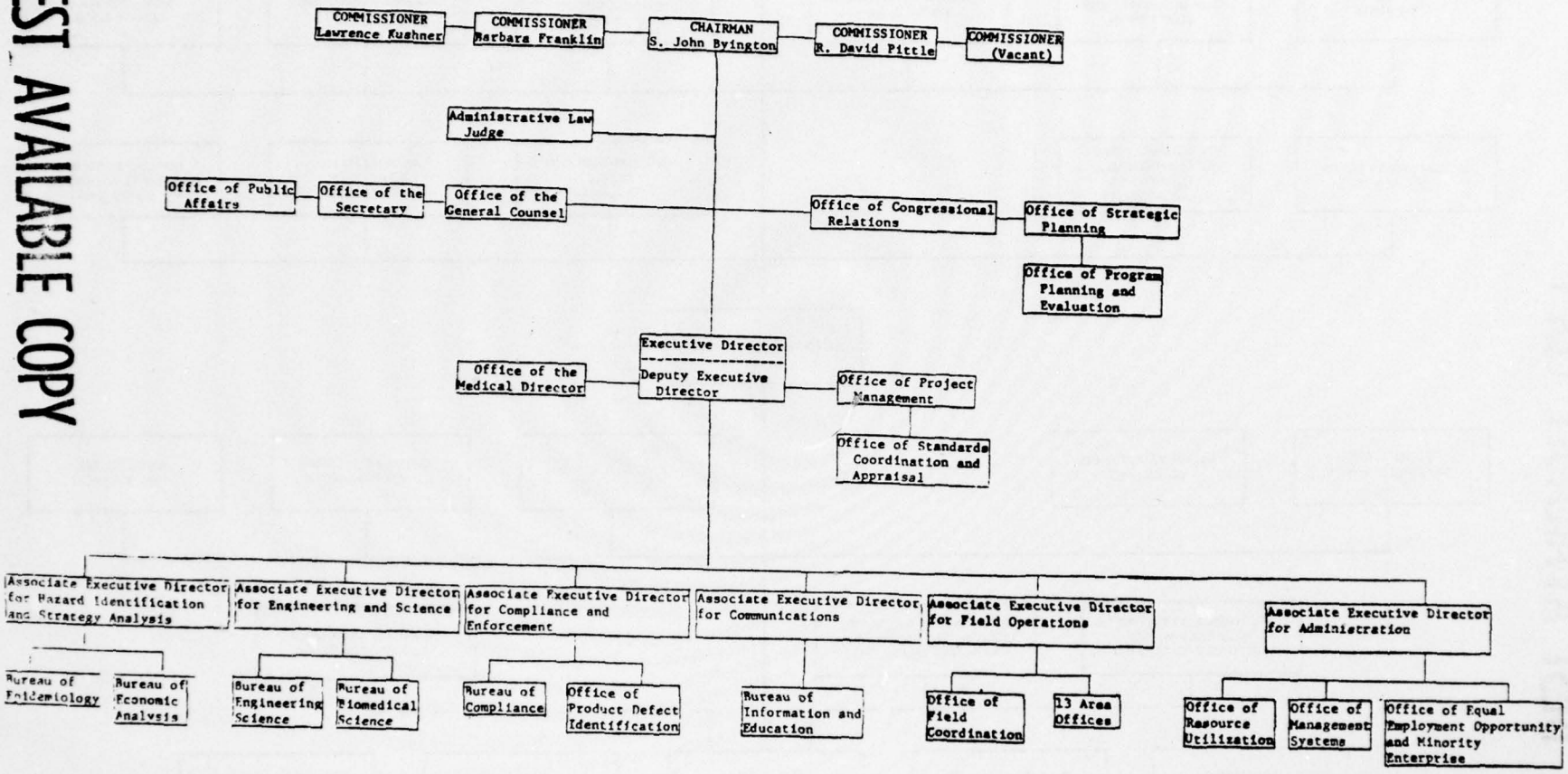

FIGURE 3

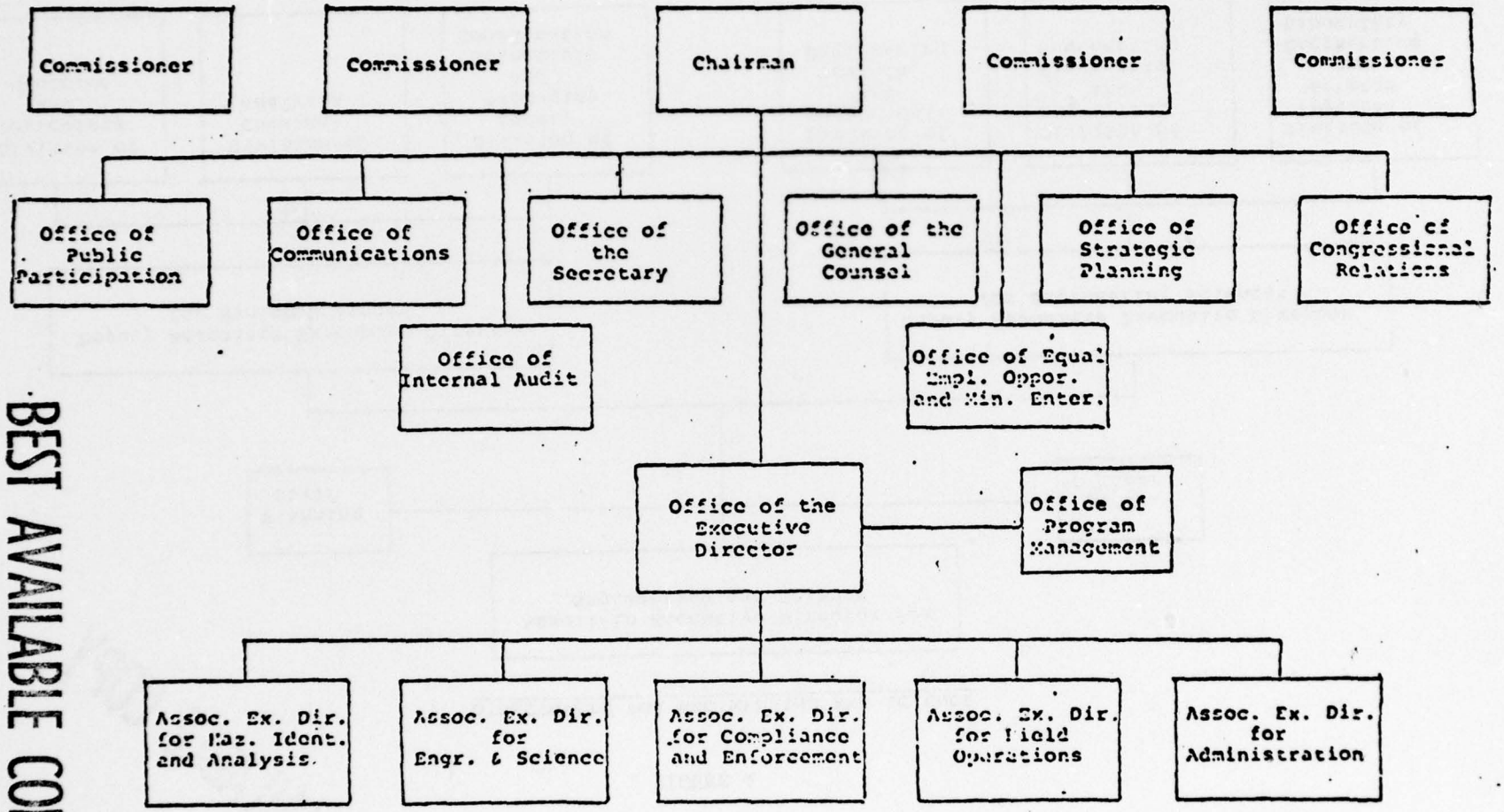

FIGURE 4

DIRECTORATE FOR ENGINEERING AND SCIENCE