Ave., Kearny, N.J. 07032. Applicant's representative: George A. Olsen, 69 Tonnele Ave., Jersey City, N.J. 07306. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: (1) *Electronic equipment, household appliances;* and (2) *Supplies, equipment and materials* used in the manufacture and sale of (1) above (except commodities in bulk), between the facilities of Sharp Electronics Corporation, located at Paramus and South Plainfield, N.J., on the one hand, and, on the other, Boston, Mass.; Atlanta, Ga.; Nitro, W. Va.; Memphis and Nashville, Tenn.; Providence, R.I.; Pittsburgh and Altoona, Pa.; Richmond, Va.; Indianapolis, Ind.; Chicago Country La Grange, Ill.; Toledo, Ohio; Louisville, Ky.; Little Rock, Ark.; Dallas, Houston and San Antonio, Tex.; Jacksonville, Orlando, Largo, Tampa and Miami, Fla.; Jackson, Miss.; Detroit, Mich., under a continuing contract with Sharp Electronics Corporation, Paramus, N.J., for 180 days. Supporting shipper: Sharp Electronics Corporation, 10 Keystone Place, Paramus, N.J. Send protests to: Julia M. Papp, Transportation Assistant, Interstate Commerce Commission, 9 Clinton St., Newark, N.J. 07102.

No. MC 142767 TA, filed December 27, 1976. Applicant: LEROY'S WRECKER SERVICE, Route 2, Box 45, Loveland, Colo. 80537. Applicant's representative: Leroy I. Davis (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Wrecked or disabled vehicles*, between points in Colorado, Wyoming, Nebraska, South Dakota, North Dakota, Montana, New Mexico and Kansas, for 180 days. Supporting shippers: There are approximately 12 statements of support attached to the application which may be examined at the Interstate Commerce Commisison in Washington, D.C., or copies thereof which may be examined at the field office named below. Send protests to: Roger L. Buchanan, District Supervisor, Interstate Commerce Commission, 721 19th St., 492 U.S. Customs House, Denver, Colo. 80202.

By the Commission.

ROBERT L. OSWALD,
Secretary.

[FR Doc.77-1300 Filed 1-13-77;8:45 am]

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FRIDAY, JANUARY 14, 1977

PART II

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Office of the Secretary

■

PROTECTION OF HUMAN SUBJECTS

Research Involving Prisoners

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

Report and Recommendations

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Office of the Secretary

[45 CFR Part 46]

PROTECTION OF HUMAN SUBJECTS

Research Involving Prisoners and Notice of Report and Recommendations of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

Basic regulations governing the protection of human subjects involved in research, development, and related activities supported or conducted by the Department through grants and contracts were published in the FEDERAL REGISTER on May 30, 1974 (39 FR 18914). At that time, it was indicated that notices of proposed rulemaking would be developed to provide additional protection for subjects of research who may have diminished capacity to provide informed consent, including prisoners.

On July 12, 1974, the National Research Act (Pub. L. 93-348) was signed into law, thereby creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. One of the charges to the Commission was to identify the requirements for informed consent to participation in biomedical and behavioral research by prisoners. The Commission was also required to investigate and study biomedical and behavioral research conducted or supported under programs administered by the Secretary of HEW and involving prisoners to determine the nature of the consent obtained from such persons or their legal representatives before such persons were involved in research; the adequacy of the information given them respecting the nature and purpose of the research, procedures to be used, risks and discomforts, anticipated benefits from the research, and other matters necessary for informed consent; and the competence and the freedom of the persons to make a choice for or against involvement in such research. The Commission was further required to make such recommendations to the Secretary as it determined appropriate to assure that biomedical and behavioral research conducted or supported under programs administered by him met the requirements respecting informed consent identified by the Commission. Pursuant to Section 202(a)(2) of that Act, the Commission has transmitted its Report and Recommendations to the Secretary regarding research on prisoners. Pursuant to Section 205 of the Act, the Secretary is required to publish the Report and Recommendations as received from the Commission and is taking that action in this issue of the FEDERAL REGISTER. Since the Department has not yet completed its final review of this report, the views set forth in it are not necessarily those of the Department of Health, Education, and Welfare. The Department will be evaluating the Report during the comment period.

Written comments, data, views, arguments and inquiries concerning the Recommendations of the Commission may be sent to the Office for Protection from Research Risks, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20014. To facilitate analysis of the comments, it would be appreciated if they were arranged by Recommendation number (5). Additional copies of this notice may be obtained by writing to the same address. All comments received will be available for inspection at Room 303, Westwood Building, 5333 Westbard Avenue, Bethesda, Maryland, weekdays (Federal holidays excepted) between the hours of 9 a.m. and 4:30 p.m. To assure full consideration, all comments should be submitted on or before March 15, 1977. After receipt and review of such comments, it is the intent of the Department to issue final rules, taking into consideration its earlier proposed rules (39 FR 30648, Aug. 23, 1974), this Report and Recommendations, and relevant comments submitted with respect to the earlier proposed rules and this Report and Recommendations.

Dated: November 26, 1976.

R. MOURE,
Acting Assistant Secretary for Health.

Approved: January 4, 1977.

MARJORIE LYNCH,
Acting Secretary.

NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH

OCTOBER 1, 1976.

REPORT AND RECOMMENDATIONS: RESEARCH INVOLVING PRISONERS

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PREFACE

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was established under the National Research Act (Pub. L. 93-348) to develop ethical guidelines for the conduct of research involving human subjects and to make recommendations for the application of such guidelines to research conducted or supported by the Department of Health, Education, and Welfare (DHEW). The legislative mandate also directs the Commission to make recommendations to Congress regarding the protection of human subjects in research not subject to regulation by DHEW. Particular classes of subjects that must receive the Commission's attention include children, prisoners and the institutionalized mentally infirm.

The duties of the Commission with regard to research involving prisoners are specifically set forth in section 202(a)(2) of the National Research Act, as follows:

> The Commission shall identify the requirements for informed consent to participation in biomedical and behavioral research by * * * prisoners * * *. The Commission shall investigate and study biomedical and behavioral research conducted or supported under programs administered by the Secretary [DHEW] and involving * * * prisoners * * * to determine the nature of the consent obtained from such persons or their legal representatives before such persons were involved in such research; the adequacy of the information given them respecting the nature and purpose of the research, procedures to be used, risks and discomforts, anticipated benefits from the research, and other matters necessary for informed consent; and the competence and the freedom of the persons to make a choice for or against involvement in such research. On the basis of such investigation and study the Commission shall make such recommendations to the Secretary as it determines appropriate to assure that biomedical and behavioral research conducted or supported under programs administered by him meets the requirements respecting informed consent identified by the Commission.

This responsibility is broadened by the provision (section 202(a)(3)) that the Commission make recommendations to Congress regarding the protection of subjects involved in research not subject to regulation by DHEW, such as research involving prisoners that is conducted or supported by other federal departments or agencies, as well as research conducted in federal prisons or involving inmates from such prisons.

To carry out its mandate, the Commission studied the nature and extent of research involving prisoners, the conditions under which such research is conducted, and the possible grounds for continuation, restriction or termination of such research. Commission members and staff made site visits to four prisons and two research facilities outside prisons that use prisoners, in order to obtain first-hand information on the conduct of biomedical research and the operation of behavioral programs in these settings. During the visits, interviews were conducted with many inmates who have participated in research or behavioral programs as well as with nonparticipants.

The Commission held a public hearing at which research scientists, prisoner advocates and providers of legal services to prisoners, representatives of the pharmaceutical industry, and members of the public presented their views on research involving prisoners. This hearing was duly announced, and no request to testify was denied. The National Minority Conference on Human Experimentation, which was convoked by the Commission

in order to assure that viewpoints of minorities would be expressed, made recommendations to the Commission on research in prisons. In addition to papers, surveys and other materials prepared by the Commission staff, studies on the following topics were prepared under contract: (1) alternatives to the involvement of prisoners; (2) foreign practices with respect to drug testing; (3) philosophical, sociological and legal perspectives on the involvement of prisoners in research; (4) behavioral research involving prisoners; and (5) a survey of research review procedures, investigators and prisoners at five prisons. Finally, at public meetings commencing in January 1976, the Commission conducted extensive deliberations and developed its recommendations on the involvement of prisoners in research.

Part I of this report contains the recommendations as well as the deliberations and conclusions of the Commission and a summary of background materials. The nature and extent of research involving prisoners are described in Part II. The activities of the Commission and reports that were prepared for it are summarized in Parts III and IV, respectively. An appendix to this report contains papers, surveys, reports and other materials that were prepared or collected for the Commission on various topics related to research involving prisoners. Most of such materials that were prepared or collected for the Commission on various topics related to research involving prisoners. Most of such materials are summarized in Part IV of the report.

GLOSSARY OF TERMS USED IN THIS REPORT

Phases of drug testing. FDA regulations require three phases for the testing of new drugs. Phase I is the first introduction of a new drug into humans (using normal volunteers), with the purpose of determining human toxicity, metabolism, absorption, elimination and other pharmacological action, preferred route of administration and safe dosage range. Phase 2 covers the initial trials on a limited number of patients for specific disease control or prophylaxis purposes. Phase 3 involves extended clinical trials, providing assesment of the drug's safety and effectiveness and optimum dosage schedules in the diagnosis, treatment or prophylaxis of groups of subjects involving a given disease or condition. (Source: 21 CFR 312.1)

Prison. "Any place for the confinement or rehabilitation of juvenile offenders or individuals charged with or convicted of criminal offenses" (42 U.S.C. 3781).

Prisoner. Any individual involuntarily confined in a prison.

Theraupetic research, nontherapeutic research. The Commission recognizes problems with employing the terms "therapeutic" and "nontherapeutic" research, notwithstanding their common usage, because they may convey a misleading impression. Research refers to a class of activities designed to develop generalizable new knowledge. Such activities are often engaged in to learn something about practices designed for the therapy of the individual. Such research is often called "therapeutic" research; however, the research is not solely for the therapy of the individual. In order to do research, additional interventions over and above those necessary for therapy may need to be done, *e.g.*, randomization, blood drawing, catheterization; these interventions may not be "therapeutic" for the individual. Some of these interventions may themselves present risk to the individual—risk unrelated to the therapy of the subject. The Commission has employed the term "research on practices which have the intent and reasonable probability of improving the health or well-being of the subject" or variants of this term. Since the reports prepared for the Commission by outside contractors or consultants generally employ the terms in common usage, such terms have been retained in the summaries of those reports.

PART I. DELIBERATIONS, CONCLUSIONS AND RECOMMENDATIONS

CHAPTER 1. DELIBERATIONS AND CONCLUSIONS

Introduction. Prior to 1940, prisoners in the United States seldom participated in biomedical research that had no reasonable expectation of improving the health or well-being of the research subjects. During World War II, however, large numbers of prisoners participated in voluntary research programs to develop treatment for infectious diseases that afflicted our armed forces. This involvement of prisoners was considered to be not only acceptable, but praiseworthy. Following the war, the growth of biomedical research and the imposition of requirements for testing drugs as to safety led to the increased use of prisoners. Their participation in biomedical research not related to their health or well-being has continued in this country to the present time. This participation is now primarily in phase 1 drug and cosmetic testing, which is conducted or supported by pharmaceutical manufacturers in connection with applications to the Food and Drug Administration for licensing new drugs. Other research of this sort in which prisoners participate, or have participated, includes studies of normal metabolism and physiology, conducted by the Public Health Service (PHS); studies of the prevention or treatment of infectious diseases, conducted or supported by the PHS and the Department of Defense; a study of the effects of irradiation on the male reproductive function, supported by the Atomic Energy Commission; and testing of the addictive properties of new analgesics by giving them to prisoners with a history of narcotic abuse, conducted at the Addiction Research Center in Lexington, Kentucky. (The involvement of federal prisoners in the Lexington program is scheduled to be phased out.[1])

Prisoners also participate in research on practices that have the intent and reasonable probability of improving their health or well-being. This research includes, for example, studies (supported by various components of DHEW and the Federal Bureau of Prisons) to develop methods to reduce the spread of infections, improve dental care, help the subjects stop smoking and remove tattoos. A major focus of this sort of research involving Federal prisoners has been the development of new treatments for narcotic addiction.

A third type of research in which prisoners participate includes studies of the possible causes, effects and process of incarceration, and studies of prisons as institutional structures or of prisoners as incarcerated persons. Components of DHEW have undertaken research of this sort for such purposes as learning the etiology of drug addiction and deviant or self-destructive behavior, and the factors relating to parole performance and recidivism.

Research is also conducted on the methods of treatment or "rehabilitation" of prisoners. The National Institute of Mental Health, the Federal Bureau of Prisons, and the Law Enforcement Assistance Administration have supported research on the experimental treatment of aggressive behavior with drugs and aversive conditioning techniques, as well as behavior modification based upon depriving inmates of basic amenities which they must then earn back as privileges. Rehabilitative practices have not always been based upon prior scientific design and evaluation, however, despite the fact that there are few, if any, approaches to the treatment or rehabilitation of prisoners for which effectiveness has been clearly demonstrated.

Outside the United States prisoners do not generally participate in biomedical research. This exclusion may be ascribed in part to continuing concern over experiments that were conducted on prisoners in Nazi concentration camps. Revelations of those experiments led to the enunciation of the Nuremburg Code (1946–1949), which required that human subjects of research "be so situated as to be able to exercise free power of choice" but did not expressly prohibit research involving civil prisoners. The Declaration of Helsinki, adopted by the World Medical Association in 1964 and endorsed by the American Medical Association in 1966, contained similar language that was subsequently deleted in 1975. Although little if any drug testing is conducted in foreign prisons, other kinds of research have been conducted in prisons throughout the world, such as studies dealing with the incidence and implications of chromosome abnormalities.

Since the 1960's, the ethical propriety of participation by prisoners in research has increasingly been questioned in this country. Among the events that have focused public attention on this issue was the publication of Jessica Mitford's book, Kind and Usual Punishment, in 1973. Eight States and the Federal Bureau of Prisons have formally moved to abandon research in prisons. The Health

[1] Letter dated March 1, 1976 to Honorable Robert W. Kastenmeier from Norman A. Carlson, Director, U.S. Bureau of Prisons.

Subcommittee of the Senate Committee on Labor and Public Welfare held hearings (Quality of Health Care—Human Experimentation, 1973) on research involving prisoners in late 1973. Those speaking against the use of prisoners cited exploitation, secrecy, danger and the impossibility of obtaining informed consent as reasons to impose a prohibition or moratorium on the conduct of research in prisons. The advantages of using prisoners in research (e.g., opportunity for close monitoring and controlled environment) and the procedures that are employed to protect prisoner participants were also described in the hearings. The Health Subcommittee held extensive hearings on other areas of human experimentation as well, and reported the bill establishing this Commission with a mandate that included a directive to study and make recommendations concerning the involvement of prisoners in research.

More recently, the House Subcommittee on Courts, Civil Liberties, and the Administration of Justice held hearings (Prison Inmates in Medical Research, 1975) on a bill (H.R. 3603) to prohibit "medical research" in federal prisons and prisons of states that receive certain federal support. Following these hearings, the Director of the Federal Bureau of Prisons determined that "continued use of prisoners in any medical experimentation should not be permitted," and he ordered that such participation by prisoners under federal jurisdiction be phased out.

Some of the more extreme behavioral programs have also raised questions. In her 1973 book, Jessica Mitford expressed concern about new approaches to "treatment" for offenders. Concurrently, others raised questions about the use of psychosurgery in prisons. In the early 1970's, the first challenges to behavior modification and aversive conditioning programs in prisons were argued in the courts, with mixed results. Most of the cases involved the right to refuse to participate in such programs, although prisoners have also petitioned for the right to be included in programs designed to alter sexually aggressive behavior.

Concern over behavior modification programs in prisons was expressed in a study, Individual Rights and the Federal Role in Behavior Modification (1974), prepared by the staff of the Constitutional Rights Subcommittee of the Senate Judiciary Committee. The study contained information on a number of such programs and suggested that this Commission make use of the information in attempting to resolve the issues that they raised. It should be noted that a number of the "treatment" programs mentioned in the study are reported to have been discontinued.

General concerns. In conducting its investigations and studies, the Commission has noted and cannot ignore serious deficiencies in living conditions and health care that generally prevail in prisons. Nor can the Commission ignore the potential for arbitrary exercise of authority by prison officials and for unreasonable restriction of communication to and from prisoners. The Commission, although acknowledging that it has neither the expertise nor the mandate for prison reform, nevertheless urges that unjust and inhumane conditions be eliminated from all prisons, whether or not research activities are conducted or contemplated.

Ethical considerations about using prisoners as research subjects. There are two basic ethical dilemmas concerning the use of prisoners as research subjects: (1) whether prisoners bear a fair share of the burdens and receive a fair share of the benefits of research; and (2) whether prisoners are, in the words of the Nuremberg Code, "so situated as to be able to exercise free power of choice"—that is, whether prisoners can give truly voluntary consent to participate in research.

These two dilemmas relate to two basic ethical principles: the principle of justice, which requires that persons and groups be treated fairly, and the principle of respect for persons, which requires that the autonomy of persons be promoted and protected. Disproportionate use of prisoners in certain kinds of research (e.g., phase 1 drug testing) would constitute a violation of the first principle; closed and coercive prison environments would compromise the second principle. It is within the context of a concern to implement these principles that the Commission has deliberated the question of use of prisoners as research subjects.

The Commission recognizes, however, that the application of these principles to the problem is not unambiguous. To respect a person is to allow that person to live in accord with his or her deliberate choices. Since the choices of prisoners in all matters except those explicitly withdrawn by law should be respected, as courts increasingly affirm, it seems at first glance that the principle of respect for persons requires that prisoners not be deprived of the opportunity to volunteer for research. Indeed, systematic deprivation of this freedom would also violate the principle of justice, since it would arbitrarily deprive one class of persons of benefits available to others—namely, the benefits of participation in research.

However, the application of the principles of respect and justice allows another interpretation, which the Commission favors. When persons seem regularly to engage in activities which, were they stronger or in better circumstances, they would avoid, respect dictates that they be protected against those forces that appear to compel their choices. It has become evident to the Commission that, although prisoners who participate in research affirm that they do so freely, the conditions of social and economic deprivation in which they live compromise their freedom. The Commission believes, therefore, that the appropriate expression of respect consists in protection from exploitation. Hence it calls for certain safeguards intended to reduce the elements of constraint under which prisoners give consent and suggests that certain kinds of research would not be permitted where such safeguards cannot be assured.

Further, a concern for justice raises the question whether social institutions are so arranged that particular persons or groups are burdened with marked disadvantages or deprived of certain benefits for reasons unrelated to their merit, contribution, deserts or need. While this principle can be interpreted, as above, to require that prisoners not be unjustly excluded from participation in research, it also requires attention to the possibility that prisoners as a group bear a disproportionate share of the burdens of research or bear those burdens without receiving a commensurate share of the benefits that ultimately derive from research. To the extent that participation in research may be a burden, the Commission is concerned to ensure that this burden not be unduly visited upon prisoners simply because of their captive status and administrative availability. Thus it specifies some conditions for the selection of prisoners as a subject pool for certain kinds of research. In so doing, the Commission is not primarily intending to protect prisoners from the risks of research; indeed the Commission notes that the risks of research, as compared with other kinds of occupations, may be rather small. The Commission's concern, rather, is to ensure the equitable distribution of the burdens of research no matter how large or small those burdens may be. The Commission is concerned that the status of being a prisoner makes possible the perpetration of certain systemic injustices. For example, the availability of a population living in conditions of social and economic deprivation makes it possible for researchers to bring to these populations types of research which persons better situated would ordinarily refuse. It also establishes an enterprise whose fair administration can be readily corrupted by prisoner control or arbitrarily manipulated by prison authorities. And finally, it allows an inequitable distribution of burdens and benefits, in that those social classes from which prisoners often come are seldom full beneficiaries of improvements in medical care and other benefits accuring to society from the research enterprise.

Reflection upon these principles and upon the actual conditions of imprisonment in our society has led the Commission to believe that prisoners are, as a consequence of being prisoners, more subject to coerced choice and more readily available for the imposition of burdens which others will not willingly bear. Thus, it has inclined toward protection as the most appropriate expression of respect for prisoners as persons and toward redistribution of those burdens of risk and inconvenience which are presently concentrated upon prisoners. At the same time, it admits that, should coercions be lessened and more equitable systems for the sharing of burdens and benefits be devised, respect for persons

and concern for justice would suggest that prisoners not be deprived of the opportunity to participate in research. Concern for principles of respect and justice leads the Commission to encourage those forms of inquiry that could form a basis for improvement of current prison conditions and practices, such as studies of the effects of incarceration, of prisons as institutions and of prisoners as prisoners, and also to allow research on practices clearly intended to improve the health or well-being of individual prisoners.

The Commission has noted the concern, expressed by participants at the National Minority Conference and by others, that minorities bear a disproportionate share of the risks of research conducted in prisons. This concern is fostered, in part, by evidence that prison populations are disproportionately nonwhite. Evidence presented to the Commission indicates that where research is done in prison, those prisoners who participate tend to be predominantly white, even in institutions where the population as a whole is predominantly nonwhite; further, those who participate in research tend to be better educated and more frequently employed at better jobs than the prison population as a whole. This evidence suggests that nonwhites and poor or less educated persons in prison do not carry a greater share of the burdens of research.

However, the evidence is inconclusive for two reasons: first, because it does not fully satisfy questions related to the risks of research; and second, because it raises questions of justice with respect to the equitable distribution of benefits (as well as burdens) of research.

With respect to risks, the Commission notes that different research projects carry different risks; it is possible, though the Commission has no evidence to this effect, that one race or another may participate in more research of higher risk. And of course, the ratio of nonwhites to whites participating in research and hence bearing the burdens of research may still be disproportionate when compared to the ratio of the populations as a whole.

But the Commission also notes that those who participate in research consider the benefits sufficient to outweigh the burdens. Thus, the greater participation of whites may mean that there is an inequitable distribution of benefits between racial groups. Hence the greater participation by whites does not necessarily resolve the issue of distributive justice.

Similarly, the Commission notes that less research is conducted in women's prisons. While the reasons for this may well be the same reasons that women in general are used less frequently than men as research subjects (*e.g.*, the possibility of pregnancy), questions of distributive justice, similar to those raised above, may still need to be addressed with respect to participation in research by women prisoners.

Discussion. Among the issues discussed by the Commission are two on which no specific recommendations are made, but concerning which the considerations of the Commission should be expressed: (1) remuneration, and (2) alternatives to conducting research in prisons. (1) Remuneration is a subject that should be analyzed by human subjects review committees, in consultation with prison grievance committees and prison authorities. There are at least two considerations that must be balanced in the determination of appropriate rates for participation in research not related to the subjects' health or well-being. On the one hand, the pay offered to prisoners should not be so high, compared to other opportunities for employment within the facility, as to constitute undue inducement to participate. On the other hand, those who sponsor the research should not take economic advantage of captive populations by paying significantly less than would be necessary if nonprisoner volunteers were recruited. Fair solutions to this problem are difficult to achieve. One suggestion is that those who sponsor research pay the same rate for prisoners- they pay other volunteers, but that the amount actually going to the research subjects be comparable to the rates of pay otherwise available within the facility. The difference between the two amounts could be paid into a general fund, either to subsidize the wages for all inmates within the prison, or for other purposes that benefit the prisoners or their families. Prisoners should participate in managing such a fund and in detetrmining allocation of the monies. Another suggestion is that the difference be held in escrow and paid to each participant at the time of release or, alternatively, that it be paid directly to the prisoner's family.

A requirement related to the question of appropriate remuneration for participation in research is that prisoners should be able to obtain an adequate diet, the necessities of personal hygiene, medical attention and income without recourse to participation in research.

(2) Some of the Commission members endorse the alternative of permitting prisoners to participate in research provided it is conducted in a clinic or hospital outside the prison grounds, and provided also that nonprisoners participate in the same projects for the same wages. Other members of the Commission believe that such a mechanism would serve only to increase the disparity between the conditions within the prison and those within the research unit, thereby heightening the inducement to participate in research in order to escape from the constraints of the prison setting. All of the members of the Commission endorse the suggestion that the use of alternative populations be explored and utilized more fully than is presently the case. This may be especially important to permit drugs to continue to be tested, as required by current law and regulations of the FDA, during any period in which prisons have not satisfied the conditions that are recommended for the conduct of such research. Increased utilization of alternative populations would have the added benefit of providing nonprisoner populations to participate in research projects along with prisoners, or in parallel with similar projects within prisons, in order to satisfy the general concern that prisoners not participate in experiments that nonprisoners would find unacceptable. The Commission also suggests that Congress and the FDA consider the advisability of undertaking a study and evaluation to determine whether present requirements for phase 1 drug testing in normal volunteers should be modified.

Conclusions. In the course of its investigations and review of evidence presented to it, the Commission did not find in prisons the conditions requisite for a sufficiently high degree of voluntariness and openness, notwithstanding that prisoners currently participating in research consider, in nearly all instances, that they do so voluntarily and want the research to continue. The Commission recognizes the role that research involving prisoners has played. It does not consider, however, that administrative convenience or availability of subjects is, in itself, sufficient justification for selecting prisoners as subjects.

Throughout lengthy deliberations, the strong evidence of poor conditions generally prevailing in prisons and the paucity of evidence of any necessity to conduct research in prisons have been significant considerations of the Commission. An equally important consideration has been the closed nature of prisons, with the resulting potential for abuse of authority. Some of the Commission members, who are opposed to research not related to the health or well-being of prisoner-participants, have, however, agreed to permit it to be conducted, but only under the following standards: adequate living conditions, separation of research participation from any appearance of parole consideration, effective grievance procedures and public scrutiny at the prison where research will be conducted or from which prospective subjects will be taken; importance of the research; compelling reasons to involve prisoners; and fairness of such involvement. Compliance with these requirements must be certified by the highest responsible federal official, assisted by a national ethical review body. The Commission has concluded that the burden of proof that all the requirements are satisfied should be on those who wish to conduct the research.

CHAPTER 2. RECOMMENDATIONS

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research makes the following recommendations on research involving prisoners, to:

(i) The Secretary, DHEW, with respect to research that is subject to his regulation, *i.e.*, research conducted or supported under programs administered by him and research reported to him in fulfillment of regulatory requirements; and

(ii) The Congress, except as otherwise noted, with respect to research that is not subject to regulation by the Secretary, DHEW.

Recommendation (1): Studies of the possible causes, effects and processes of

incarceration and studies of prisons as institutional structures or of prisoners as incarcerated persons may be conducted or supported, *Provided*, That (A) they present minimal or no risk and no more than mere inconvenience to the subjects, and (B) the requirements under recommendation (4) are fulfilled.

Comment. The Commission encourages the conduct of studies of prisons as institutions and prisoners as incarcerated persons. Because the inadequacies of the prisons may themselves be the object of such studies, the Commission has not set any conditions for the conduct of such research other than a limitation of this category to research that presents minimal or no risk and no more than mere inconvenience, and the requirements of Recommendation (4)

Studies of prisoners consisting of questionnaires, surveys, analyses of census and demographic data, psychological tests, personality inventories and the like rarely involve risk and are essential for proper understanding of prisons and the effects of their practices. Research designed to determine the effects on general health of institutional diets and restricted activity, and similar studies that do not manipulate bodily conditions (except innocuously, *e.g.*, obtaining blood samples) but merely monitor or analyze such conditions, also present little physical risk and are necessary to gain some knowledge of the effects of imprisonment. Such research is a necessary step toward understanding prison practices and alternatives, without which there can be no improvement.

Recommendation (2): Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the individual prisoner may be conducted or supported, provided the requirements under recommendation (4) are fulfilled.

Comment. Research would fall under this recommendation if the practices under study are designed solely to improve the health or well-being of the research subject by prophylactic, diagnostic or treatment methods that may depart from standard practice but hold out a reasonable expectation of success. The Commission intends that prisoners not be discriminated against with respect to research protocols in which a therapeutic result might be realized for the individual subject. The committees that review all research involving prisoners should analyze carefully any claims that research projects are designed to improve the health or well-being of subjects and should be particularly cautious with regard to research in which the principal purpose of the practice under study is to enforce conformity with behavioral norms established by prison officials or even by society. Such conformity cannot be assumed to improve the condition of the individual prisoner. If the review committee does not consider such claims to be sufficiently substantiated, the research should not be conducted unless it conforms to the requirements of Recommendation (3).

Recommendation (3): Except as provided in recommendation (1) and (2), research involving prisoners should not be conducted or supported, and reports of such research should not be accepted by the Secretary, DHEW, in fulfillment of regulatory requirements, unless the requirements under recommendation (4) are fulfilled and the head of the responsible federal department or agency has certified, after consultation with a national ethical review body, that the following three requirements are satisfied:

(A) The type of research fulfills an important social and scientific need, and the reasons for involving prisoners in the type of research are compelling;

(B) The involvement of prisoners in the type of research satisfies conditions of equity; and

(C) A high degree of voluntariness on the part of the prospective participants and of openness on the part of the institution(s) to be involved would characterize the conduct of the research; Minimum requirements for such voluntariness and openness include adequate living conditions, provisions for effective redress of grievances, separation of research participation from parole considerations, and public scrutiny.

Comment. Detailed standards expressing the intent of the Commission with respect to Requirement (C) of this Recommendation are as follows:

(i) *Public scrutiny.* Prisoners should be able to communicate, without censorship, with persons outside the prison and, on a privileged, confidential basis, with attorneys, legal organizations which assist prisoners, the accrediting office which assists the certifying federal official or national ethical review body, the grievance committee referred to in paragraph (ii) below, and the human subjects review committee or institutional review board referred to in Recommendation (4). Each of such persons or organizations with whom prisoners should be able to communicate on a privileged, confidential basis should be able to conduct private interviews with any prisoner who so desires. The accrediting office, grievance committee and human subjects review committee or institutional review board should be allowed free access to the prison.

(ii) *Grievance procedures.* There should exist a grievance committee composed of elected prisoner representatives, prisoner advocates and representatives of the community. The committee should enable prisoners to obtain effective redress of their grievances and should facilitate inspections and monitoring by the accrediting office to assure continuing compliance with requirement (C).

(iii) *Standard of living.* Living conditions in the prison in which research will be conducted or from which subjects will be recruited should be adequate, as evidenced by compliance with all of the following standards:

(1) The prison population does not exceed designed capacity, and each prisoner has an adequate amount of living space;

(2) There are single occupancy cells available for those who desire them;

(3) There is segregation of offenders by age, degree of violence, prior criminal record, and physical and mental health requirements;

(4) There are operable cell doors, emergency exists and fire extinguishers, and compliance with state and local fire and safety codes is certified;

(5) There are operable toilets and wash basins in cells;

(6) There is regular access to clean and working showers;

(7) Articles of personal care and clean linen are regularly issued;

(8) There are adequate recreation facilities, and each prisoner is allowed an adequate amount of recreation;

(9) There are good quality medical facilities in the prison, adequately staffed and equipped, and approved by an outside medical accrediting organization such as the Joint Commission on Accreditation of Hospitals or a state medical society;

(10) There are adequate mental health services and professional staff;

(11) There is adequate opportunity for prisoners who so desire to work for remuneration comparable to that received for participation in research;

(12) There is adequate opportunity for prisoners who so desire to receive education and vocational training;

(13) Prisoners are afforded opportunity to communicate privately with their visitors, and are permitted frequent visits;

(14) There is a sufficiently large and well-trained staff to provide assurance of prisoners' safety;

(15) The racial composition of the staff is reasonably concordant with that of the prisoners;

(16) To the extent that it is consistent with the security needs of the prison, there should be an opportunity for inmates to lock their own cells; and

(17) Conditions in the prison satisfy basic institutional environmental health, food service and nutritional standards.

(iv) *Parole.* There should be effective procedures assuring that parole boards cannot take into account prisoners' participation in research and that prisoners are clearly informed that there is absolutely no relationship between research participation and determinations by their parole boards.

If an investigator wishes to present evidence of the importance and fairness of conducting a type of research on a prison population (requirements (A) and (B)) and proposes that the conditions of voluntariness and openness would be satisfied at a particular prison (requirement (C)), the case should be presented to the Secretary, DHEW (or the head of any other department or agency under whose authority the research would be conducted). Such official should seek the advice of an existing or newly created advisory body (such as the Ethical Advisory Board established within the Public Health Service) in determining whether to approve the type of research at the specific institution. Such official or advisory body should be assisted by an accrediting office, which makes inspections, certifies compliance with re-

quirement (C), and monitors continuing compliance of any prison involved in research. In determining such compliance, the accrediting office should be guided by the above description of the Commission's intent in recommending requirement (C).

Recommendation (4): (A) The head of the responsible Federal department or agency should determine that the competence of the investigators and the adequacy of the research facilities involved are sufficient for the conduct of any research project in which prisoners are to be involved.

(B) All research involving prisoners should be reviewed by at least one human subjects review committee or institutional review board comprised of men and women of diverse racial and cultural backgrounds that includes among its members prisoners or prisoner advocates and such other persons as community representatives, clergy, behavioral scientists and medical personnel not associated with the conduct of the research or the penal institution; in reviewing proposed research, the committee or board should consider at least the following: the risks involved, provisions for obtaining informed consent, safeguards to protect individual dignity and confidentiality, procedures for the selection of subjects, and provisions for providing compensation for research-related injury.

Comment. The risks involved in research involving prisoners should be commensurate with risks that would be accepted by nonprisoner volunteers. If it is questionable whether a particular project is offered to prisoners because of the risk involved, the review committee might require that nonprisoners be included in the same project.

In negotiations regarding consent, it should be determined that the written or verbal comprehensibility of the information presented is appropriate to the subject population.

Procedures for the selection of subjects within the prison should be fair and immune from arbitrary intervention by authorities or prisoners.

Compensation and treatment for research-related injury should be provided, and the procedures for requesting such compensation and treatment should be described fully on consent forms retained by the subjects.

Prisoners who are minors, mentally disabled or retarded should not be included as subjects unless the research is related to their particluar condition and complies with the standards for research involving those groups as well as those for prisoners. (Recommendations concerning research participation of children and the institutionalized mentally infirm will hereafter be made by the Commission.)

There should be effective procedures assuring that parole boards cannot take into account prisoners' participation in research, and that prisoners are made certain that there is absolutely no relationship between research participation and determinations by their parole boards.

Recommendation (5): In the absence of certification that the requirements under recommendation (3) are satisfied, research projects covered by that recommendation that are subject to regulation by the Secretary, DHEW, and are currently in progress should be permitted to continue not longer than one year from the date of publication of these recommendations in the FEDERAL REGISTER or until completed, whichever is earlier.

PART II. BACKGROUND

CHAPTER 3. NATURE OF RESEARCH INVOLVING PRISONERS

Research activities involving prisoners may be divided into four broad categories: biomedical research not related to the health or well-being of the subject, biomedical research on practices intended to improve the health or well-being of the subject, social research, and behavioral research on practices intended to improve the health or well-being of the subject. The first category of research using prisoners mainly involves phase 1 testing of new drugs and testing of vaccines as to efficacy. Biomedical and behavioral research related to the health or well-being of the prisoner-participants generally involves the study of conditions associated with prisoners or prisons. In addition, innovative practices in prisons, intended to rehabilitate or treat prisoners, often have many attributes of behavioral research but are seldom introduced as such. The major controversy over participation of prisoners surrounds their use as subjects of biomedical research not related to their health or well-being and their unwilling involvement in experimental treatment or rehabilitative programs.

Biomedical research unrelated to the health or well-being of prisoner-participants was conducted in the United States only in isolated instances prior to the establishment in 1934 of a program at Leavenworth Prison to assess the abuse potential of narcotic analgesics; such research is now conducted at the Addiction Research Center in Lexington, Kentucky, although it was announced recently that the program will be terminated by the end of 1976. The current involvement of prisoners in biomedical research unrelated to their health or well-being can be traced to three sources. First, during World War II, prisoners volunteered in large numbers for studies, such as those to develop effective anti-malarial drugs, which were viewed as contributing to the national interest. Reviews of these prison research activities by several state commissions resulted in their endorsement. In fact, prisoner participation in research was felt to be such a salutary experience that the American Medical Association formally opposed allowing persons convicted of particularly serious crimes to have the privilege of participating in scientific experiments. Second, the enthusiastic support of biomedical research by the government and the public following the war brought an enormous growth to research enterprises, and prisoners served as subjects in many of these new endeavors. Third, the thalidomide experience was followed by pasage in 1962 of the Kefauver-Harris amendments to the Food and Drug Act, which established additional requirements for testing the safety and efficacy of all drugs to be sold in interstate commerce and thereby encouraged the continued use of prisoners in research. The phase 1 testing requirements established under these amendments required evaluation of the safety of new drugs in normal volunteers under controlled conditions, and prisoners became the population on which much of this testing was performed.

Innovative prison practices are often difficult to distinguish from what might be termed behavioral research on practices intended to improve the health or well-being of prisoner-participants. Since the early 1900's, innovations such as flexible sentences, indeterminate sentences, behavioral therapies during imprisonment, and parole and probation based on evidence of rehabilitation have been introduced into the prison system. These innovations have not generally included provisions for design, review and evaluation as research. Frequently, though, the behavioral programs have had many characteristics of behavior modification research. Examples range from use of "therapeutic community" and reinforcement techniques in prison, to use of aversive conditioning (employing electric shock or drugs with unpleasant effects) in treating sex offenders or uncontrollably violent prisoners, to use of a structured tier system (token economy) in which a prisoner progresses from living conditions of severe deprivation to relative freedom and comfort as a reward for socially acceptable behavior. At the extreme of research or treatment designed to change behavior were castration for sexual offenders and psychosurgery for uncontrollable violence.

The peak of enthusiasm for the application of behavior modification techniques in the prison system was marked by the establishment of the Special Treatment and Rehabilitation Training (START) program in the Federal Bureau of Prisons, and the planning of a new federal prison at Butner, North Carolina, with research in applying behavioral modification throughout a prison as its primary purpose. The START program was abandoned, after 1½ years of operation, under considerable criticism and after some challenges in court. Similar activities led to a reevaluation of the programs planned for Butner, which opened in May 1976. It now offers a variety of vocational and academic courses as well as general counseling. Participation in these programs is voluntary, and changes in the program content will be introduced only with the approval of both the inmates and the staff.

Social research and psychological testing are also conducted in prisons. Projects include studies of the factors which may contribute to criminal behavior (such as cytogenetic anomalies or socioeconomic and psychological stress), comparison of effectiveness of various rehabilitative programs in reducing recidi-

vism, psychological assessment of criminals as compared with noncriminal counterparts, tracking the outcome of judgments concerning "dangerousness," and evaluating standards for determining competency to stand trial.

Examples of biomedical research on practices intended to improve the health or well-being or subjects in prisons are studies to reduce the spread of infections in crowded environments or to develop new methods of treating drug addiction. Other research, which may or may not be intended to benefit subjects, includes investigations to increase understanding of the nature and causes of narcotic or alcohol abuse and addiction.

Research conducted or supported by DHEW. Information was made available to the Commission by the Public Health Service (PHS) regarding all biomedical research projects involving prisoners that were conducted or supported since January 1, 1970. In addition, the National Institute of Mental Health (NIMH) provided information on all behavioral research with prisoners that was conducted or supported since July 1, 1971. A summary of this information follows.

Biomedical research with prisoners was conducted or supported by five of the six PHS agencies, the exception being the Health Resources Administration. The Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) reported conducting over 40 intramural research projects in its testing facility at the Addiction Research Center in Lexington, Kentucky. These studies involved a wide range of activities, such as developing methods for detecting drugs of abuse through urinalysis, studies of various properties of morphine and other narcotics, evaluations of methadone, studies of the effects of amphetamines, analysis of interactions of various drugs with narcotics, and assessment of the addictive or abuse potential and psychoactive effects of new drugs. ADAMHA also supported nine extramural studies involving prisoners, including studies of the XYY chromosome anomaly, assessment of clinical methods to predict episodic violence, study of the use of narcotic antagonists to treat addict inmates in a prison and in a work release program, and study of behavioral and biological correlates of alcoholism.

The Center for Disease Control reported three studies with prisoners; these involved vaccines and skin test studies for a parasitic disease. FDA conducted five studies with prisoners, all of which involved oral administration of a standard dose of a commercially available antibiotic (Penicillin or Tetracycline). FDA also supported three studies with prisoners (two evaluating skin sensitization by irritants and one studying cyclamates). In the Health Services Administration, research involving prisoners was conducted by physicians at one PHS hospital (13 studies of metabolic responses to prolonged bed rest) and by physicians and behavioral scientists at the Research Division, Bureau of Prisons (33 studies involving a wide range of activities, such as dental care, weight reduction and tattoo removal; many were behavioral and rehabilitative rather than biomedical in focus). Seven institutes of the National Institutes of Health reported support of a total of 19 research programs involving prisoners. This research included studies of vaccines (rubella, rubeola, cholera toxoid, influenza and other respiratory viruses, streptococcus), testicular cell function, treatment of sun-induced skin conditions, responses to infectious diseases (colds, cholera), pathogenesis of acne, and the effect of diet on blood pressure and lipids.

Behavioral research with prisoners conducted or supported by NIMH included psychological and social research studies of crime and delinquency, individual violence, institutionalization, and law-mental health interactions. Participation of prisoners as subjects in these studies was essential due to the nature of the inquiries. A small number of intramural studies conducted at St. Elizabeths Hospital were related to analysis of procedures used to determine competency to stand trial or assess dangerousness of criminally insane patients. Support was provided for 19 extramural studies, some of which had biomedical as well as behavioral components. This research included studies (1) to identify sources and patterns of criminal and delinquent behavior (the XYY syndrome, attitudes toward criminal behavior); (2) to develop, test or evaluate models for the prevention, treatment or remediation of criminal behaviors (prediction of violence, lithium treatment for aggressive behavior, impact of imprisonment on the families of black prisoners, perceptions of the minority prison community, effects of prison environment stress on physical and mental health of inmates and staff); and (3) to define and analyze critical issues in law and mental health interactions (due process in determination of criminal insanity, assessment of adequacy of treatment for offenders committed to mental institutions, release of dangerous mental patients, the impact of a "dangerousness" standard as the sole criterion for involuntary commitment). In addition, NIMH has been directed by Congress to study the factors contributing to homosexual rape in prisons.

CHAPTER 4. EXTENT OF RESEARCH INVOLVING PRISONERS

The Commission obtained information from all fifty states and the Federal Bureau of Prisons on the policies of each toward research involving prisoners and whether or not research, if permitted, is being conducted. Also, the Pharmaceutical Manufacturers Association surveyed its members to assess the extent of pharmaceutical research involving prisoners. These surveys do not document what is generally considered to be a significant amount of social and behavioral research conducted by scholars and by the prison system itself.

Research in state and federal prisons. To ascertain the status of state laws, regulations and policies governing research involving prisoners, and to determine where such research is being conducted, state correctional agencies and the Federal Bureau of Prisons were surveyed during the summer of 1975. The following information is based on the reports received at the time from the state-wide agencies and the Bureau of Prisons. It should be noted that the policies and research activities of county and municipal jails were not surveyed.

1. Of the 21 states that permit biomedical research and the 23 states that permit behavioral research in prisons, studies are being conducted in the state prisons of only seven and five states, respectively.

2. Of the seven states in which biomedical research is conducted, all of the programs are unrelated to the health or well-being of the subjects and primarily involve drug and cosmetic testing.

3. Of the five states in which behavioral research is conducted, all of the programs are characterized as therapeutic in four states, and both therapeutic and nontherapeutic research (so characterized) in one state. No state reported conducting research programs involving behavior modification.

4. Eight states prohibit biomedical research: one by legislation, six by departmental policy, and one by moratorium; twenty-two have no specific policy.

5. Five states prohibit behavioral research: one by legislation, three by departmental policy, and one by moratorium; twenty-three have no specific policy.

6. Research is being conducted only in states that have specific legislation or departmental policies permitting and regulating it.

7. Information provided by the Federal Bureau of Prisons indicated that both biomedical and behavioral research are permitted by departmental policy. Biomedical research (limited to addiction research at Lexington) and behavioral research projects are being conducted.[3]

Participation of prisoners in pharmaceutical testing. The Pharmaceutical Manufacturers Association conducted a survey of its members to ascertain the extent to which they used prisoner volunteers as subjects for drug testing in 1975, with the focus primarily on phase 1 studies. Fifty-one companies, representing three-fourths of the members' annual expenditures for research and development, responded to the survey. Sixteen of the 51 used prisoners as subjects.

Of these 16 companies, 14 conducted phase 1 drug research with prisoners, employing a total of nearly 3600 prisoners in 100 protocols studying 71 substances. For nine companies, phase 1 testing represented their only use of prisoners as subjects. The percentage of phase 1 testing subjects who were prisoners ranged from 100% (one company) to 2%, with a median of 50% (an

[3] In March 1976, the Director of the Federal Bureau of Prisons announced that all biomedical research in federal prisons would be discontinued.

average could not be calculated from the data given). The companies listed a total of eight state and six county or municipal prisons as research sites. Ten companies used only minimum security prisons. No companies used detainees in their research. Other categories of volunteer subjects which the companies reported using in phase 1 studies included college students, medical students, company employees, residents of foreign countries, military personnel, members of fraternal organizations, medical personnel, and the general population.

Thirty-three of the 51 companies indicated that they had insurance policies or other mechanisms for compensating subjects who might be injured in research. (There was no determination of the extent to which such policies or other mechanisms would provide compensation in the absence of legal liability.)

PART III. ACTIVITIES OF THE COMMISSION

CHAPTER 5. SITE VISITS TO PRISONS

The Commission made a site visit to the State Prison of Southern Michigan at Jackson on November 14, 1975. In addition, groups of Commission members visited Washington State Penitentiary in Walla Walla, the Michigan Intensive Program Center at Marquette, and the California Medical Facility at Vacaville. Prior to the visits, Commission members were briefed by a former prison administrator, a former prisoner, and a director of research from a pharmaceutical manufacturing firm, regarding conditions to look for and questions that might be asked.

The *State Prison of Southern Michigan at Jackson* is the largest penitentiary in the United States, housing over 5000 residents. It is also the site of one of the largest nontherapeutic biomedical research operations, with special buildings on the grounds constructed by two pharmaceutical manufacturers (Parke-Davis and Upjohn) specifically to conduct phase 1 drug studies.

Commission members toured the prison facilities, including regular and honor cellblocks, prison industries, the prison infirmary, and the research buildings. They discussed prison procedures with the deputy warden, and research procedures with the vice-chairman of the committee that reviews each research protocol and with members of the research teams. Most of their visit was devoted to discussion of prison conditions and the research program with prisoners.

According to materials made available to the Commission, the research conducted at Jackson is primarily phase 1 drug testing, although some phase 2 studies and device testing are also performed. Research protocols must be reviewed and approved by the Protocol Review and Protection Committee (composed of five physicians in the community and at Michigan medical schools, two lawyers and a third lay member) and by the Director of the Department of Corrections. Annual reports of research performed are made to the Review and Protection Committee and the Department; any adverse reactions that occur are reported to the Committee immediately.

Information about the research program is included in the packet of information an inmate receives upon entering the prison; there is no additional recruitment or contact with the prisoners by the research personnel unless he requests information about participation. Then the program is described to him in a group meeting, and if he wishes to be considered for research he undergoes a physical examination and laboratory screening tests. Eligibility is contingent upon approval of the prison authorities and passing the screening tests; in addition, subjects must have an IQ of at least 70.

Those who qualify enter a common subject pool maintained for the two companies on a card file. When a new protocol is initiated, prisoners' cards are pulled from the front of the file, and the specific protocol is described to them. If they decline to enter the study, they reenter the pool. The studies are about equally divided between inpatient and outpatient trials. Pay is based on the procedures involved, according to a schedule devised by the Protection Committee and approved by the Department of Corrections, and is comparable to pay received in prison industries. Of the 5200 prisoners at Jackson, approximately 800 are in the research subject pool. The Commission was advised that medical supervision is close, that a physician is present or on call in the immediate vicinity at all times, that a prisoner can at any time,[*] and that no notation of his participation in research is made in his official prison record, so that the parole board is not advised of it.

Commission members talked with a representative sample of 80 prisoners both individually and in groups. The sample was selected by Commission staff from the master list of all prison residents, and included both research participants and nonparticipants who responded to an invitation to meet with the Commission. In addition, prisoners suggested by other inmates were interviewed in a group setting. Overall impressions from this experience were that prisoner-participants valued the research opportunity. In general, they felt that they were free to volunteer for or withdraw from the program at will and were given adequate information about research protocols. Nonparticipants expressed various reasons why research was not for them, but did not object to its being available for others.

Participants gave many reason for volunteering for research, including better living conditions, need for a good medical evaluation, and desire to perform a worthwhile service to others, but it was clear that the overriding motivation was the money they received for participating. In fact, their strongest objection was that they pay for participation in research was held down to levels comparable to prison industries. Other complaints focused on limitations to participation rather than on research excesses: if a prisoner stayed on an inpatient study for more than a week, he would lose his prison job seniority; prison officials were said to exclude certain prisoners arbitrarily; some prisoners did not seem to get called to participate in research as often as others. They generally rejected the notion that they were coerced into participating in research, and stated they know their participation would not be revealed to the parole board.

The major complaints of the participants were directed toward the prison system, not the research program. When asked if research in prisons should be stopped, the prisoners interviewed unanimously said no. They urged correction of what they viewed as inequities (*e.g.*, that pay be increased, that authorities be forbidden arbitrarily to withhold permission to participate), but asked that biomedical research programs in prisons be allowed to continue.

As a follow-up to the visit to Jackson, the Commission staff compared the characteristics of the 792 men in the drug-testing pool on November 27, 1975 with a randomly selected control sample of similar size. Data came from a computer print-out of the prison's daily roster. Subjects were disproportionately white; although blacks comprise almost 68% of the nonsubject prison population, they are only about 31% of the subject pool. (Data furnished to the Commission by Dr. William Woodward of the University of Maryland showed a similar inverted racial pattern in the biomedical research program at the Maryland House of Corrections at Jessup.) At Jackson, subjects tended to be older than nonsubjects, to have been in prison much longer (an average of almost two years, compared to one year for nonsubjects), and to have been sentenced to Jackson more times (2.1 times compared to 1.8 times for nonsubjects). There was also a striking over-representation among the subjects of men housed in the prison's two honor blocks.

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In order to observe behavioral programs operating in a prison setting, groups of Commission members visited a unit of the Washington State Penitentiary at Walla Walla and the Michigan Intensive Program Center at Marquette. Neither program is conducted as research, and the Commission is not aware of a behavior modification program in a state or federal prison that is so conducted at present.

The program at Walla Walla utilized a therapeutic community approach, and dealt with the state's most difficult-to-manage prisoners, who were sent to the unit generally because of unacceptable conduct in the regular system. The unit is operated almost entirely by the prisoners themselves, who serve as the therapeutic community, establishing and en-

[*] A consent form provided as a sample for review contained a contrary implication. The drug company representatives readily acknowledged that this was a mistake, however, and they gave assurances that the form would be corrected.

forcing rules of conduct. On entering the program, a prisoner is placed in an isolation cell. His only contacts are visits by the director and other prisoners on the unit, who explain the rules to him and urge him to conduct himself in such a way as to be able to join them. When he is willing to conform, he is released from his cell to the open ward. There, the main emphasis becomes retraining in appropriate patterns of social interaction, using such mechanisms as group discussions of current events, recreational programs, and group therapy. Swearing, use of jargon, and fighting are among the numerous forbidden behaviors; violations are punished by a return to the isolation cell, with the group serving as enforcer of the rules and determining when the violator can return to the ward.

The primary purpose of the Walla Walla program is to encourage learning of socially acceptable behavior rather than specifically to prepare the prisoners for return to the outside world or the regular prison system. Most men remain on the unit for long terms. Those who have been released outside the prison are said to have done remarkably well, with recidivism a rare event (follow-up records are apparently not maintained). Return to the regular prison system would be dangerous, since those in the program gain reputations as informers. Interviews with prisoners in the program yielded only the highest praise for it. Prisoners admitted initial resentment of the isolation treatment, but claimed that it was the only way they had ever been made to think seriously about themselves and their behavior, and that it provided the necessary impetus for their behavior change.

The *Michigan Intensive Program Center (MIPC) at Marquette* is a maximum security facility housing difficult-to-manage prisoners who have been transferred from other facilities in the state. The behavioral program there is based on a six-level token economy. Privileges and comforts increase as a resident earns enough tokens to progress from the lower to the higher levels. Tokens are earned for correct behavior (making the bed, cleaning the cell, attending educational activities, not fighting, etc.) and are awarded at frequent intervals throughout the day. The purpose of the program is to improve the prisoners' behavior sufficiently to enable him to return to the regular prison system and be manageable there.

Interviews with prisoners at the MIPC indicated no enthusiasm for the program The prisoners seemed to tolerate it grudgingly and submit to the process in order to get back into regular prison life, but with the determination that nothing done to them in the program was really going to change their behavior. They generally viewed the program as "just another lock-up," no better or worse than the segregation blocks to which they might have been assigned alternatively. Their major objection was the arbitrariness by which the prison system could decide to send them to the MIPC. No figures were available on recidivism, nor was there any other means to document the effectiveness of the program.

Commission members also visited the California Medical Facility at Vacaville, which houses approximately 1,400 inmates. Most of the prisoners are referred to Vacaville for medical or psychiatric reasons, and one-fourth of the population is excluded from particiaption in research for security reasons. Those who wish to volunteer sign a roster at the research office, and selection of subjects is made in numerical order from this list.

Research conducted at Vacaville includes a large program of skin-testing for hypersensitivity, as well as internal administration of experimental drugs. New volunteers begin with a skin-test study before advancing to higher paying pharmaceutical studies.

Other paying prison jobs are available, and at the time of the visit there were unfilled slots for reasons that were unclear but possibly had to do with disparity in pay or difficulty of the work as compared with participation in research. Legal counseling is available from law students who visit the prison weekly. Educational programs range from elementary school through a baccalaureate degree. There is spot censorship of mail. Telephones are available, but the inmates must pay to use them.

The inmates' council reviews all research projects and can veto any protocol. Most of the active protocols have also been reviewed by Institutional Review Boards of outside institutions. Informed consent is obtained in writing, and the prisoner receives a copy of the signed form. Examination of a card file indicated a significant dropout rate from studies; apparently prisoners feel free to withdraw, even though they know that if they do so frequently, their chances of being invited to participate in future studies will be reduced.

CHAPTER 6. NATIONAL MINORITY CONFERENCE ON HUMAN EXPERIMENTATION

In order to assure that minority viewpoints would be heard, the Commission contracted with the National Urban Coalition to organize a conference on human experimentation. The conference was held on January 6–8, 1976, at the Sheraton Conference Center, Reston, Virginia. Attended by over 200 representatives, it provided a format for presentations of papers and workshop discussions from which a set of recommendations emerged. The papers and the recommendations relevant to prison research are summarized below.

Joyce Mitchell Cook, Ph.D. Dr. Cook suggests that ethically acceptable research may be assured by a principle of equality (i.e., that researchers not propose experiments which they or members of their family would not participate in). She argues that the term "informed consent" is ambiguous, since it wrongly places the emphasis upon process and information rather than on voluntariness. Dr. Cook adopts the position that volunteering is genuine only if the end to be pursued is one to which the volunteer is devoted. Because of the extraneous motives of prisoners, she concludes that they are volunteers in name only. She recommends that behavioral research be permitted only if it directly benefits the participants and can be conducted on hospital wards rather than in prisons. Dr. Cook concludes that experimentation on prisoners ought to be abolished and that the risks of experimentation should be distributed more equally among members of the free-living world.

Larry I. Palmer, J. D. Mr. Palmer begins with the premise that the ethical problems posed by prison experimentation derive from racial, religious and nationalist conflicts and that the issues of prisoners and race are merged. He recommends guidelines to encourage scrutiny of: (1) The appropriateness of using prisoners in a particular protocol, (2) the societal priorities associated with the research, and (3) the potential risks and procedures to minimize such risks. He suggests that research involving prisoners might be regulated by state officials, with additional monitoring and scientific evaluation by professionals and some supervision of the consent process. All decisions and consequences regarding experimentation in prisons should be open to public scrutiny. Mr. Palmer sees little justification for a ban on all research in prisons; rather, he advocates a "scrutiny of values," through a statement of the nature, purposes and risks of each protocol in relation to the interests of the prison population.

L. Alex Swan, Ph.D., LL.B. Dr. Swan argues that behavioral research is aimed at quelling dissident prisoners who view their incarceration in political and economic terms. He suggests that such research ought instead to promote "human liberation" by exposing oppressive conditions in prison. He advocates self-determination for prisoners, particularly with regard to the goals of social and behavioral research, and challenges social and behavioral scientists to accept responsibility for the possible misuse of their research findings. Dr. Swan asserts that scientific manipulation of prisoners to conform to the will of the state is unethical, just as it is unethical to use scientific techniques for disciplinary or punitive purposes. He further states that experimentation on the brain to alter behavior violates the inmate's independence and right to free speech, that the prison system is so inherently coercive that informed and voluntary consent is impossible, that labeling of prisoners as aggressive or violent for research purposes is dishonest and repressive, and that civil liberties are endangered by behavior modification techniques in prisons because of the closed nature of such institutions.

Recommendations of minority conference workshops on research involving prisoners. Two workshops were devoted to the topic of research involving prisoners. The first of these recommended a moratorium on all nontherapeutic biomedical research in prisons until a comprehensive evaluation of human experi-

mentation has been made. This evaluation should include consideration of the purpose of research involving prisoners, criteria for selection of subjects, assessment of risks, government responsibility for regulating research in prisons, responsibility of professional organizations regarding such research, the role of prisoners in the supervision of the research, the fixing of financial responsibility including compensation for harm resulting from research, and access of prisoners to official bodies outside the prison. The workshop also recommended that behavioral research be redirected from a focus on the individual prisoner to the goal of understanding the nature of prisons and their effects on individual prisoners. Recommendations were not proposed regarding informed consent because of doubts that it is possible to obtain informed consent in our prisons.

The second workshop recommended the establishment of a permanent commission to regulate human experimentation, a ban on biomedical research and psychosurgery in prisons, establishment of a human subjects review committee with prisoner representation, and the provision of technical and legal resources to prisoners who are potential subjects of human experimentation.

CHAPTER 7. PUBLIC HEARING

On January 9, 1976, the Commission conducted a public hearing on the issue of research involving prisoners. Summaries of the presentations that were made to the Commission follow.

Gabe Kaimowitz (Senior Staff Attorney, Michigan Legal Services) suggested that researchers assume that there is informed consent, and that they often fail to use adequate control subjects, particularly in behavioral research. Further, investigators may limit public access to information about prison research projects. He stated that they often use captive populations without considering the availability of community volunteers, and too often apply medical or psychological models inappropriate to economic and social problems. Prisoners are in an inherently coercive environment, and their consent to research is always suspect. Mr. Kaimowitz is not opposed to therapeutic biomedical or behavioral research when the prisoners themselves request its implementation. In such situations a review committee should examine the conditions that caused the prisoners to make such a request.

Matthew L. Myers (National Prison Project of the American Civil Liberties Union Foundation) stated that informed consent is not feasible in the prison environment. Regardless of prison policy concerning participation in research and parole, prisoners may believe that involvement contributes to early release. They may also participate to escape from the routine of prison life or to earn money for necessities. Mr. Myers said that most medical experimentation is conducted in medium or maximum security facilities in which conditions are oppressive, alternatives are few, and there is a potential for abuse due to the closed, isolated and coercive nature of the prisons.

William R. Martin, M.D. (Director, Addiction Research Center, National Institute on Drug Abuse, DHEW) stated that addiction research is important and necessary both for society and for the prisoners. Limiting such research will retard development of therapy for addicts and will prohibit the evaluation of the addictive properties of new analgesics. Research participation is beneficial to most prisoners, he said, in that it is generally a safe and constructive experience, often improves health, and is a source of pride. Dr. Martin has been unable to identify any other population in which such studies can be done as validly and safely as in prisoners. He feels that prisoner participation may be altruistic, and therefore society should compensate participants for their involvement and for any injuries that may occur. There is empirical evidence that prisoners can and do make informed judgments, and are equally knowledgeable about research programs as other subjects. Practical measures can be taken to minimize the seductiveness of the research setting compared to the prison environment.

Theodore Francis (Occupational Drug Use Program, New York State Office of Drug Abuse Services) urged that biomedical and behavioral research in prisons continue, but that more attention be paid to compensation, the level of health care provided to subjects, and review of behavioral research. Participation of prisoners should be judged an acceptable means of earning money, and inmates should be reimbursed according to discomforts and risks incurred. Money earned should be held in escrow for prisoners until release or paid to their families. A national board should review all behavior modification research for efficacy, validity, and risks to individuals and to the community. This board would issue public notices in lay language, describing dates and place of the research, as well as the reimbursement provisions.

Michael S. Lottman (Commission on the Mentally Disabled, American Bar Association, and the National Association for Retarded Citizens) urged that special care be given to protecting the rights of mentally disabled prisoners. Thereafter, testifying as an individual, he opposed nontherapeutic biomedical research on prisoners which exposes them to risk of discomfort, pain or incapacity. He stated that the coercive and oppressive nature of penal institutions precludes obtaining voluntary informed consent. Prisoners are not physiologically unique and therefore provide no information which cannot be gained from a free population. Research on prisoners benefits drug companies and researchers, he said. If research is to continue in prisons, particular care should be given to protecting the rights of mentally retarded prisoners, and an independent body should certify that each subject can and has given informed consent. Mr. Lottman is not opposed to therapeutic biomedical research in a prison setting, provided there are proper controls and consent procedures.

Joseph Stetler (President, Pharmaceutical Manufacturers Association) stated that to the best of his knowledge no prisoner has died or been permanently injured from research sponsored by drug companies. He advocated continuation of drug research in prisons provided that: (1) researchers are qualified, (2) facilities are adequate, (3) participation is voluntary and informed, (4) research is monitored, and (5) prisoners are compensated fairly. He stated that prisons are practical and safe for drug testing, and that discontinuance of such research might delay development of new drugs. He estimated that 85% of all phase 1 drug testing is done on prisoners, and that the rate of compensation could increase substantially and still be insignificant relative to the total cost of new drug development. Prisoner testing of cosmetics or over-the-counter drugs is minimal relative to research involving prescription medications. A 1975 policy statement of PMA on the conduct of clinical research was summarized.

Allan H. Lawson (Executive Director, Prisoners' Rights Council of Pennsylvania) held that prisoners should be permitted to participate in experimentation only if the decision is absolutely voluntary. This is impossible in today's prisons, he said, because of economic pressures, forced idleness and inhuman conditions. In his view, research programs provide an excuse to prison administrators to neglect responsibilities such as housing, medical care and job programs. Because of the reality of economic pressures, the Prisoners' Rights Council would permit some research in prisons provided safeguards are instituted, until other means of earning money are available. However, the Council would ban research which involves exposure to incurable diseases or is otherwise dangerous or unnecessary. Mr. Lawson urged that medical care and compensation be provided for inmates injured during research.

The Reverend Americus Roy (Prisoners Aid Association of Maryland, Inc.) testified against medical experimentation in prisons based on personal experience at the Maryland House of Corrections. Prisoners participate in research, he said, because of economic deprivation and as a temporary escape from inhuman conditions. Use of prisoners is exploitative of the economically depressed. Risks of research should be widely distributed, especially among those who are likely to benefit.

PART IV. REPORTS TO THE COMMISSION

CHAPTER 8. PHILOSOPHICAL PERSPECTIVES

Papers on the ethical issues involved in research with prisoners were prepared for the Commission by Roy Branson, Ph. D., Cornel Ronald West, M.A., and Marx W. Wartofsky, Ph. D.

Dr. Branson first analyzes the ethical principles underlying the standard arguments for and against research involving prisoners, and, secondly, examines several policy alternatives. He concludes by recommending a moratorium, appealing

to the principles of free and informed consent and justice.

In reviewing arguments for experimentation, Dr. Branson cites three justifications generally advanced in support of research involving prisoners: (1) That it contributes to the good of society; of which prisoners are members and therefore recipients of benefits; (2) that it is an appropriate way for prisoners to make reparation; and (3) that prisoners can, in fact, give free and informed consent. A varient of the third argument is that criminal conviction presupposes competence and responsibility; therefore, prisoners must be presumed to have the capacity to volunteer. In fact, advocates of this position point out that prisoners are permitted to choose work in hazardous industries and so should be permitted to choose work as research subjects as well.

Opponents of prison research assume that experimentation is different from other occupations. A person's relationship to his body is not his relationship to his goods. A person's body, in a special and real sense, is the person. In experimentation risk to bodily integrity is primary to the activity, whereas in other occupations, the risk is secondary.

The two fundamental principles to which opponents of experimentation appeal are free and informed consent and justice. Those citing consent can say that prisoners cannot in principle give free consent because of the inherent nature of prisons as coercive, total institutions. Other opponents appealing to free consent do not go so far. They claim that sufficiently free consent to experimentation cannot in fact be given in American prisons. They cite not only the coercive structure of prisons, but such administrative features as limited alternative to earn money in prisons (none for equivalent rates of pay), and indeterminate release dates with nonobjective or unknown conditions for leaving the prison. Dr. Branson identifies himself with the second position, saying that empirical analyses leave a serious and reasonable doubt that inmates of American prisons can in fact give a sufficiently free consent to experimentation.

Justice is the other principle to which opponents of prisoner experimentation appeal. Injustice can take the form of injury, when a person is wrongfully harmed through exploitation or negligence by others. Injustice can also result from failure to follow the basic requirement of distributive or comparative justice: that like cases are to be treated alike and different cases be treated differently. Since prisoners are in relevant respects equal to free persons, the burdens of risk and harm should be proportional to those of free-living citizens, which would entail a significant reduction in at least phase 1 drug trials. On the other hand, prisoners are unequal to free persons in important respects in that they have been placed in total institutions. Dr. Branson, citing comparative justice, says the similarities of prisoners to free persons requires that the proportion of experimentation utilizing prisoners should be reduced. The differences between experimentation conducted on prisoners and those conducted on free persons require that prisoner experimentation be stopped, at least until conditions change.

In applying principles to policy alternatives, Dr. Branson sees remuneration as a major and finally insurmountable practical obstacle to prisoner experimentation. The principle of informed consent dictates that in order for prisoners to give consent that is not coerced, they should not be paid more for experimentation than for other prison jobs. But the principle of justice requires that rates of remuneration to prisoners should be equivalent to the rates paid to free volunteers. Schemes relying on committees of prisoners (or prisoners and prison officials) controlling funds created by the difference between the standard amount paid by drug companies and what an individual prisoner received run into practical problems, for the committee itself could manipulate and coerce prisoners.

Dr. Branson's recommendation, therefore, is that the Commission declare a moratorium on prison research and suggest that if and when conditions in American prisons have improved, then research might be resumed in those facilities which can meet the requirements of informed consent and justice. He would not preclude the possibility of offering innovative therapy to an individual inmate in need of treatment, but this, he says, should be distinguished from programs of "therapeutic research" which blur the distinction between individual therapy and experimentation. He suggests, in addition, that the moratorium extend to behavioral research, since new vehavioral therapies may be evaluated first on nonprisoners, but that observational research (noninterventional behavioral research), as well as educational programs, be permitted to continue.

Mr. West advocates a contractual approach to human experimentation which requires full disclosure, written consent and choices that are rational. These requirements reflect the human rights to know, to choose and to be treated fairly. He distinguishes between coercion (which involves threats) and bribery (which involves manipulation of incentives). Mr. West considers requests for prisoners to participate in research to be bribery, not coercion; hence, choice is at play. The paucity of alternatives and the conditions of domination within prisons, however, undermine the rational basis for such choice. Mr. West concedes that a certain degree of control over prisoners might be warranted, but only to the extent that basic human rights are not violated. The necessity for such control, he believes, suggests that prisoners are less appropriate subjects for research than are nonprisoners. Therefore, he urges that normal volunteers be recruited, instead; but he cautions against shifting the burden of research to Third World populations.

Mr. West views behavioral research in prisons to be nontherapeutic, inasmuch as the rehabilitative efficacy of behavior modification programs has not been demonstrated. Thus, he would restrict such research according to the same principles he applied for nontherapeutic biomedical research.

Mr. West recommends termination of both nontherapeutic biomedical and "therapeutic" behavioral research involving prisoners until such time as prison reform creates the conditions necessary for their legitimate participation in such research.

Dr. Wartofsky begins his essay on selling the services of one's body for research by discussing the extent to which being a subject is similar to other forms of wage-labor. He examines the nature of that which is being sold (and bought) and the extent to which a person has the right to offer his or her body in exchange for money. His position is that whereas one may not sell one's body, as such, nevertheless one may sell the disposition over the use of one's body for specified purposes, for a specified time and under specified conditions. In other words, while one's life and liberty are inalienable rights (which cannot be separated from one's person and sold), one's services or capacities are commodities which, in our free-market social and economic system, are regularly exchanged for wages.

Dr. Wartofsky then considers the problem of risk-taking. In general, he says, no ethical question arises concerning the risks inherent in dangerous occupations, since the workers are seen as having free choice in undertaking or refusing such jobs, and the risks involved are secondary to the needs of society which the occupations (e.g., coal mining, construction work, chemical manufacturing) are designed to meet. By contrast, the nature of risk in research is such that one is placing one's health or well-being at risk not as a by-product of some other purpose, but as the primary commodity; and it is the intimacy of the relation between one's person and one's well-being which makes the exchange disturbing.

With respect to motivation, Dr. Wartofsky observes, it is generally assumed that placing oneself at risk for monetary gain is for one's own benefit, whereas doing it without tangible reward is more altruistic. However, he points out that one may place oneself at risk for monetary gain and, at the same time, be self-sacrificing (if, for example, the purpose is to support one's family or otherwise satisfy the needs of others). Whether working for the abstract "good of society" is a higher motive than working for one's family is a question which cannot be settled. Thus, he concludes, motivation should be considered (if at all) only to the extent that the seriousness of the motivation should be commensurate with the degree of risk to be undertaken.

Next, he considers the extent to which prostitution is like wage-labor, involv-

ing, as it were, the sale of a disposition over one's body for a certain purpose, at a certain rate and for a certain time. The relevance of the inquiry lies in the fact that what is being bought and sold in prostitution is (just as in participation in research) something which is "so intimate to one's person that there is something disturbing in the notion that it is alienable, as a commodity." In his view, the ethical objections to prostitution, and to being a paid research subject, derive from the translation of relations which are supposed to express fundamental aspects of humanity into an economic exchange. In the paid research context, both the investigator and the subject are reducing an essential human capacity (putting oneself at risk for others) to a commodity; so doing, they may dehumanize each other.

Here, he observes, society is faced with a dilemma: on the one hand, research with human subjects is important for the preservation and well-being of the species; on the other hand, the only means of conducting such research is ethically questionable. He sees three obvious solutions: (1) To stop paying the subjects; (2) to conduct only that research which can be carried out with unpaid volunteers; and (3) to restructure society in order to eliminate the economic need which induces (or coerces) the disadvantaged into making up the largest portion of paid research subjects. All of these "solutions," however, are impractical. The pragmatic solution which he recommends, therefore, is to minimize the exploitive elements which "commodify" the situation. An alternative would be to follow the model proposed by Hans Jonas in which the most valuable members of society (rather than the most expendable) undertake the risks, but Dr. Wartofsky considers this also to be impractical. Finally, he proposes that both paid and unpaid research subjects be organized, educated as to their rights, and represented at all levels of review (Institutional Review Boards as well as state and federal commissions). This, he believes, would socialize the interaction, reduce the alienation, and ameliorate the dehumanizing effects of the commodity relationship for both the paid subjects and the researchers.

CHAPTER 9. SOCIOLOGICAL AND BEHAVIORAL PERSPECTIVES

In order to obtain an understanding of the nature of the social structure of a prison and its implications for the prisoner's freedom and competence to make a choice for or against involvement in research, the Commission requested papers by two sociologists: Jackwell Susman, Ph. D., and John Irwin, Ph. D. In addition, Martin Groder, M.D., prepared a paper on behavioral research aimed at rehabilitation of prisoners. These essays are summarized below.

Dr. Susman suggests that a determination regarding prisoners' participation in biomedical or behavioral research depends on understanding their value system and how it deviates from conventional norms. He describes two sets of norms in prison society: (1) The norms which the staff and officials endorse and which support their authority, and (2) the norms of the inmates, which encourage diversity of behavior and subversion of the official system.

It is generally agreed that custody involves profound attacks on the prisoner's self-image through deprivation and control. Inmates cope with the "pains of imprisonment" through various social structures, norms and values. From the sociological literature on prisons and prison life, Dr. Susman identifies two descriptive models of prison society: the "prisoner solidarity" image and the "prisoner diversity" image.

As directed by Dr. Susman, the prisoner solidarity image classifies prisoners according to their conformity to or deviation from the inmate code which encourages cohesion and mutual support among prisoners vis-a-vis their captors. Adherence to the inmate code helps protect the average inmate and strengthens his dignity. A negative aspect of this social structure is the dependence of most prisoners on the few leaders for privileges and protection. The convict leaders are granted special privileges by the administration in return for maintaining order, and thus seem to have little incentive to participate in biomedical and behavioral research. The rest of the inmates may adapt differently to prison life. Some may conform with varying degrees of intensity to the demands of the inmate code, and might reject biomedical and behavioral research since the code rejects conventional values and cooperation. Others may deviate from the norms of the prisoners' world and participate in research to obtain the goods and services their outcast status denies them. Still others may combine conformity and deviance to maximize their chances of leaving prison emotionally and physically unscathed; their participation in research would depend on a careful analysis of the costs and benefits, in terms of their life in prison and their chances of getting out. Finally, some may conform completely to the official norms and may volunteer for research for both altruistic and pragmatic reasons.

The second model of prison society, the prisoner diversity image, focuses on the inmates' identification with persons or groups outside the prison. In this view, the inmates bring subcultural norms and values with them into prison, and, thus, prison society is diverse. This model describes inmates according to three categories. First is the career criminal or professional thief, who assumes a commitment not to prison life but to criminal lifestyles. His objective is to do his time and get out, not to manipulate the prison environment. He may volunteer for research believing that it will be considered favorably by the parole board, or merely to maximize his comfort until he is released. Second is the "convict," who is oriented primarily to prison life and seeks status by manipulating the environment, winning special privileges and asserting influence over others. His participation in research is improbable because it might imply cooperation with the staff. The third group of inmates identify with "legitimate" subculture outside the prison. They have no commitment to the values of thieves or convicts and seek status through the means provided by the prison administration. They are usually rejected by the convict and thief subcultures, and might be expected to volunteer for research projects.

Dr. Susman examines the implications of these models of prison society for the requirements of informed consent: competency, knowledge and voluntariness. Rejecting the Kaimowitz court's view of the effects of institutionalization, Dr. Susman believes that prisoners are able to maintain an identity. He suggests that prisoners' autonomy may expand or contract depending on their circumstances, and that at least some prisoners have sufficient autonomy to give informed consent to participate in research. Providing prisoners with knowledge of the risks associated with research may be difficult, but Dr. Susman believes in principle that it can be done satisfactorily. With respect to voluntariness, both images of prison society indicate that prisoners have a great deal of power and influence over how the prison is run. This implies that mechanisms could be developed to insulate research activities from staff and peer pressure. Dr Susman concludes that prisoners can have the freedom and competence to give informed consent.

Dr. Irwin agrees with Dr. Susman that biomedical research involving prisoners should not be categorically denied, but rather permitted under conditions that protect against the disparity of bargaining power between prisoners and authorities. Instead of a contract model (which assumes relatively equal bargaining power) Dr. Irwin suggests a "rights model," in which minimal rights are established and guaranteed against abuse of power. He observes that conditions of degradation and coercion vary with the degree of autonomy and isolation under which prisons operate, and he believes that most of the constraints (including arbitrary use of discretionary powers) are, in fact, unnecessary and could be abandoned without interfering with effective operation of the penal system. This, he says, woud make the prison environment compatible with conditions necessary for the ethical conduct of research.

Dr. Irwin recommends, therefore, an accreditation process and an ongoing rereview mechanism, in which prisoners, their families and civil rights groups all participate, with a concomitant reduction of discretionary powers now held by prison authorities. He would also require that drug firms pay at the same rate that they pay nonprisoner participants, but that the difference between those wages and the prevailing prison wages be placed in a fund to increase the wages for the general prison population. He would also eliminate any leakage of in-

formation to parole boards about research participation. Finally, he recommends that there be established a review and grievance mechanism independent of the prison system in which prisoners, their families and civil rights organizations would participate. This mechanism would review all decision-making relative to prisoners' rights and perhaps consider, as well, such factors as the adequacy of the health care available to the prisoners.

Dr. Groder, formerly warden-designate of the Federal Correctional Institution at Butner, North Carolina, observes that of all research involving prisoners, only therapeutic psychosocial research directly addresses "the promise of rehabilitation." Unless society is willing deliberately and intentionally to abandon its commitment to rehabilitation, he argues, research of high quality is essential if services are to be provided to offenders in a safe, effective and humane manner. He believes that offenders, as wards of the state, have a "right to treatment" that will be abridged if correctional research is abolished or stifled through overregulation.

Dr. Groder accepts the likelihood that the Commission will wish to recommend additional regulatory procedures, and suggests the following goals: (1) "wards of the state" should be provided an opportunity to rejoin the social mainstream; (2) the quality of consent should be audited to protect basic rights of volunteers; (3) provision should be made for care, compensation, and possible reversal if a bad effect occurs; and (4) the outcome of all research should be published. Dr. Groder recommends that Congress appoint regional boards with the responsibility of achieving the four goals and ensuring prisoner rights. The boards would approve or disapprove projects, and appeals could be made to the federal court of appeals. The boards should sponsor studies of the correctional process and the impact of research, and make the recommendations to Congress regarding pertinent legislation.

Dr. Groder believes, on the basis of his experience, that therapies can be devised to enable prisoners to reenter and remain in the mainstream of society, and he cautions that a ban or limitation on such research will ensure that no correctional innovations will be developed. Therapeutic techniques that become available in nonprison society may also be denied to prisoners, and that would pervert the desire to rehabilitate prisoners as well as infringe upon their right to treatment.

CHAPTER 10. LEGAL PERSPECTIVES

The Center for Law and Health Sciences, Boston University School of Law, prepared for the Commission an analysis of the law relevant to determining the validity of consent by prisoners to their participation in research. This analysis proceeded on the assumption (consistent with the findings of the Commission) that quality of information and ability to comprehend do not generally constitute problem areas in prison research. The key issues reviewed by the Center are whether consent can be given voluntarily in the prison environment, and whether voluntary consent to treatment (and, by extension, to behavioral programs that might not constitute "treatment") is required. The first of these issues is discussed primarily in the context of nontherapeutic biomedical research, and the second is raised in connection with behavior modification programs.

Motivations of prisoners to participate in nontherapeutic research include financial reward, hope for reduction of sentence, seeking of medical or psychiatric help, relief from tedium, desire for better or more secure living conditions, attraction of risk-taking, altruism, etc. The conditions that give rise to these motivations may constitute duress such as would render a contract voidable and, by analogy, render it difficult if not impossible to uphold a prisoner's "informed consent" to participation in research. It has been argued, but not determined as a matter of law, that incarceration inherently constitutes such coercion (or duress) that nontherapeutic research should not be conducted in prisons. In the absence of such a determination, courts will examine particular prison situations for evidence of duress in obtaining consent to participation in research.

Thus, as to financial reward, the questions to be asked are whether there are alternative sources of equal income and, more importantly, whether participation in research is the only way prisoners can earn enough money to maintain a minimum standard of living. As to living conditions, the questions would concern the extent of deprivation in the prison, and the contrast between the prison environment and conditions in the research center. These are matters of fact that would be examined in a particular situation to determine whether a consent was voluntary.

Promise of reduction of sentence is now generally thought to be inherently coercive, but, at least with respect to rehabilitative treatment that may be of experimental nature, sentence reductions have been tied to prisoners' consent. Cases involving waiver of rights indicate that even in a coercive situation, rights may be waived if adequate safeguards, e.g., counsel, are provided.

Medical treatment generally constitutes a battery if the patient has not consented to it. Although one jurisdiction has not applied this rule in cases involving prisoners, other jurisdictions have held to the effect that imprisonment does not deprive a person of the capacity to decide whether or not to consent to health care. The latter rule has been applied in cases dealing with physically invasive behavior modification techniques, but there is no holding on the right to withhold consent to noninvasive behavior modification techniques. Whether or not the techniques were experimental does not appear to have been material in any of the holdings. Rather, the courts appear to have taken into account the degree of invasiveness.

State regulations and statutes dealing with experimentation on prisoners cover the entire spectrum, from permission to total bans of such research. Where any sort of research involving prisoners is permitted, a requirement that informed consent be obtained is explicitly set forth. Where financial or other rewards are explicitly covered, they are generally limited or prohibited. The recently published DHEW proposals related to research on prisoners follow the states that permit such research by accepting the view that prisoners can consent to be subjects so long as adequate safeguards are provided. The proposals published for public comment by DHEW (November 16, 1973) include such safeguards as a required certification by a review committee that there are no undue inducements to participation by prisoners, taking into account the comparability of the earnings otherwise offered; a requirement that no reduction in sentence or parole in return for participation in research be offered unless it is comparable to what is offered in return for other activities; and a provision for accreditation by DHEW of prisons in which research is to be supported or conducted. A subsequent DHEW Notice of Proposed Rulemaking (August 23, 1974) adds a requirement that the reveiw committee also take into account whether living conditions, medical care, etc. would be better for participants than those generally available to prisoners, but deletes the provision for accreditation by DHEW.

The report by the Center for Law and Health Sciences concludes with the following recommendations: that provision for accreditation by DHEW should be made, to ensure that research will not be conducted under such circumstances that participation is the only way for a prisoner to obtain minimally decent living conditions; that the rewards for participation should not be such that they provide the only way for a prisoner to maintain his health and personal hygiene, or induce a person to incur great personal risks; that parole or a reduction in sentence should never be offered in return for participation in research; that there should be some provision for the protective role of an independent counselor; that full information about the research should be given the prospective participant, and that he should not be asked to waive his rights against anyone for injuries that he might sustain. If these safeguards are adopted, the law generally will recognize the informed consent of a prisoner to participation in research.

CHAPTER 11. ALTERNATIVES AND FOREIGN PRACTICES

Alternatives employed in the United States and foreign countries to the conduct of biomedical research in prisons were examined by the Commission. A

paper on alternative populations for conducting phase 1 drug studies was prepared by Dr. John Arnold. Information on two programs using normal volunteers as alternatives to prisoners, one for vaccine testing and one for general physiologic testing, was provided by staff reports. An additional staff report was prepared on the use of prisoners in a research program located in a hospital outside of the prison. Practices in foreign countries related to development and testing of new pharmacologic agents were surveyed and reported to the Commission by Mr. C. Stewart Snoddy and Dr. Marvin E. Jaffe, Clinical Research International, Merck Sharp & Dohme.

The Quincy Research Center, Dr. John Arnold, Director, is an innovative phase 1 drug testing program using cloistered, normal volunteers. It was recently established in Kansas City, Missouri. Dr. Arnold, an investigator with 29 years of experience in drug testing in prisons, highlights some of the practical and ethical problems associated with the use of such a research population, and explains the reasons he now believes that the use of prison inmates as research subjects should be phased out. He identifies limitations imposed by the prison system on the optimal conduct of such studies, and his reasons for believing that the use of nonprisoner volunteers for them is preferable. Cloistering, he says, is necessary to enable the researcher to strictly control the medications received, to intensively monitor subjects for signs of adverse effects, and to identify drug properties with greater confidence. In contrast with research facilities designed exclusively for the cloistering of free-world volunteers for phase 1 studies, however, prisons are neither built nor operated around the needs of medical research. The prison environment may be poorly controlled, particularly with regard to the presence of contraband drugs that may seriuosly influence the result of a clinical trial. Further, the dropout rate for his free-world studies has been about 1.5 percent, a lower rate than he experienced in a prison setting.

Dr. Arnold suggests that the behavioral problems associated with cloistering volunteers are the greatest barrier to the development of alternative populations, and require sensitivity with regard to volunteer selection, adequate preparation for the experience of complete control of life-style, and physical facilities that are attractive and interesting. The second largest problem is the cost. While lodging and food contribute to this expense, the single largest increment stems from the greater degree of supervision and closer medical control required for volunteers in a nonprison setting.

Despite the problems, Dr. Arnold believes the advantages make the use of nonprisoners preferable. One advantage he cites relates to compensation for injury, which the consent form should address. While an indemnification plan similar to those governing other occupational hazards can be arranged for nonprisoner volunteers, it cannot necessarily be done for prisoners. Rates for the Quincy workman's compensation insurance are based on data that show the risks for participants in phase 1 drug research to be only slightly greater than the occupational risks for office secretaries, one-seventh of those for window washers, and one-ninth of the risks for miners. The problem of rendering long-term follow-up and extended care, because prisoners are not likely to return to prison for follow-up examinations or medical attention, is also reduced by using a free-living population.

Dr. Arnold believes that three advantages of the free-world volunteer system will eventually lead to its exclusive use: (1) paid stipends can be comparable to wages paid for other services, (2) indemnification can be offered under plans similar to workman's compensation, and (3) volunteers may chose medical research against other forms of limited employment without any special coercive force.

Dr. Arnold described characteristics of the population attracted to his nonprisoner volunteer program, based on the last 150 subjects at the Quincy Research Center. The men were 80% white, 15% black, and 5% other racial background. Agegroup was 50% age 20–30, 40% age 30–40, and 10% age 40–55. Ninety percent were recently or seasonally unemployed, 8% steadily unemployed, and 2% were college students. Most had completed 8th grade, 60% had completed 12th grade, 2% were college students, and 0.5% were college graduates. Approximately 60% of the subjects were former prisoners; 5 to 10% had been subjects in Dr. Arnold's earlier studies in prisons.

The Clinical Research Center for Vaccine Development (CRCVD) was developed to provide an alternative to the use of prisoners in infectious disease research. It was established in 1974 under a contract with the National Institute of Allergy and Infectious Diseases (NIAID), the primary inpetus being NIAID's desire to develop a dependable source of healthy, adult volunteers that would circumvent many of the problems plaguing its prison-based research and allow infectious disease research to continue. A contract was awarded to the University of Maryland School of Medicine to demonstrate the feasibility of recruiting adult volunteers from the community for research in which live attenuated vaccines for respiratory viruses and mycoplasma are administered to subjects to test infectious capability, symptoms produced, ability to induce immunity, and contagiosity.

The CRCVD is under the direct supervision of two physician-researchers who conduct the protocols developed by NIAID. They are assisted by two part-time recruiters, a consulting psychologists, and support staff. The facility is part of the University of Maryland School of Medicine complex in Baltimore; its major unit is a self-contained, limited access, air-sealed isolation ward, where volunteers reside for the duration of the study.

Recruiting procedures have focused on attracting young, intelligent and healthy adults, to minimize problems with informed consent and adjustment to the dormitory-like setting of the isolation ward. College students were selected as the free-world population most likely to meet these requirements. Recruiters present information on the program at college campuses; interested students subsequently meet with the recruiters so that a blood sample may be drawn. Those volunteers who pass this initial screening procedure are contacted by the recruiters and offered the opportunity to participate as subjects.

Most of the studies conducted by the CRCVD last between 15 and 30 days. During a two-day acclimation period on the unit, there are intensive educational presentations concerning vaccine development and the upcoming study, preliminary medical and psychological screening procedures are conducted, and the volunteers become acquainted with the isolation ward environment and staff. The researchers reserve the right to dismiss volunteers prior to inoculation, but thereafter only the subject may choose to withdraw from a study. To supplement the consent form, an examination is administered prior to inoculation, to assess and document the participant's comprehension of the research protocol. Each volunteer must pass this exam before being permitted to participate in a study.

The volunteers earn $20 per day on the isolation ward, based on what the average college student might earn in a summer job. Volunteers who withdraw from the study are paid up to the point they drop out, whether or not a public health quarantine has been imposed, requiring every subject to remain on the ward until completion of the study. The consent forms note that any medical problems that may arise will be treated at the CRCVD's expense.

As of June 1975, 70 volunteers had participated in nine studies, and the subject pool consisted of 547 people. The age range is between 18 and 50. Of the 70 people who have completed studies, there were 4 with less than four years of high school, 30 high school graduates, 19 college undergraduates, 12 college graduates, and 5 with advanced degrees; 84 percent were white, 7 percent were former prisoners.

The Normal Volunteer Patient Program of the Clinical Center, National Institutes of Health, was established in 1954 and represents one of the earliest efforts to involve members of the community in experimental studies. Volunteers participate in research designed primarily to measure the parameters of normal body functions. Most of the subjects are members of certain religious sects which view participation in this program as part of their public service commitment (e.g., Church of the Brethren, Mennonites, Mormons) and college students. While the volunteers in both categories receive little in terms of financial compensation (usually restricted to transportation and living expenses),

the student volunteers, who reside at the Clinical Center for up to three months on "career development internships," are offered an opportunity to study with NIH scientists in many of the research laboratories. Hence, the program appeals primarily to students interested in careers in the health sciences and related fields.

Recruitment of many of the volunteers for the program is done by colleges under contract with the NIH. The contractor college or university is responsible for handling all the local recruitment details, transporting the volunteers to and from the Clinical Center, and providing any transportation required for follow-up procedures. In return, the contractor receives a fixed fee for each volunteer (to cover the cost of round trip air fare and ground transportation to and from the airport) plus a certain amount for each day of the volunteers' time and inconvenience.

Prospective participants in the program are advised of its purposes and the restrictions in life-style they may experience during their sojourn at the Clinical Center. Studies in which they are asked to participate include, for example, studies of normal physiology (awake, asleep and during exercise), psychological studies (reaction time, attention), dietary manipulation, studies involving drugs, hormones or tracer doses or radioisotope administered either orally or by injection, and exposure to viruses or biochemical products derived from viruses or bacteria.

The Eli Lilly Company Research Unit located at Wishard Memorial Hospital, Indianapolis, Indiana, employs prisoner and nonprisoner normal volunteers in phase 1 drug studies. The prisoners come to the hospital unit from Pendleton State Reformatory 30 miles away; most of them have previously participated in pharmaceutical studies in the Lilly unit at the prison. All studies involving the initial administration of an agent to humans, use of radioisotopes, or tests requiring complex monitoring equipment are done at the hospital unit rather than at the prison unit.

Prisoner volunteers, in order to qualify for participation in the Lilly hospital research program, generally must meet the basic work-release requirements: a date set for parole or for a parole hearing, and one year of good behavior. In addition, specific permission from the warden is required. These restrictions are imposed to make escape less likely. Other work-release choices, when available, generally offer better pay and more freedom of movement. A prisoner participates at the hospital only once and returns to the prison afterward. The stay at the hospital may be as long as three months. While at the hospital, prisoners are required to remain on the research ward. They have limited recreation facilities but may have visitors daily. No special security precautions are taken, but escapes from the unit have been rare.

Two hospital wings adjoining the prisoner research unit are used for phase 2 studies in patients and phase 1 studies in nonprisoner normal volunteers. The latter are generally men off the streets, chronically unemployed, who know of the program and request on their own, often repeatedly, to participate in drug studies. Prisoners and nonprisoners usually are not involved in the same protocol, although the types of studies are the same. Nonprisoners are paid $7 a day; the prisoners receive $3 a day (the rate established as the maximum by the prison).

Advantages of the hospital as the setting for research of this type are the availability of excellent emergency care (although no serious adverse reactions requiring it have occurred in 10 years of operation), the ease of access of the investigator to the subjects, and surroundings that are pleasant in comparison with the prison. Disadvantages are the limited number of prisoners who can qualify for the program and the boredom of the research. The main reason men drop out of a study is that they become bored and ask to return to their friends and activities at the prison.

Human studies in pharmaceutical research and development in other countries. The survey[4] conducted on practices of foreign countries regarding use of prisoners and other groups in the development and testing of new pharmaceutical agents included seven European nations, five English speaking countries, four Latin American nations and Japan. In all the countries surveyed, clinical pharmacology studies (pharmacokinetic and dose-ranging studies) can be conducted in normal subjects. Almost uniformly, these countries do not permit such studies to be conducted in prisoners. In theory, prisoner studies could be done in the United Kingdom, but in practice no such research is conducted in prisoners outside the United States. In most countries, volunteers, when used, are students, civil servants (imilitary, police and firemen), and medical and paramedical personnel.

In general, clinical pharmacology studies conducted abroad involve patients with the disease which the drug is intended to treat, rather than normals. The use of patients with other diseases is not uniformly approved, but may be permitted if data relevant to the primary indication can be obtained. The requirement for specific governmental approval (IND or clinical trials certificate) to conduct clinical pharmacology studies in normal subjects or patients also varies among countries. In all the countries surveyed, human pharmacokinetic and pharmacodynamic data are "helpful" to support new drug registration. In about half the countries, such data are mandatory. Only France and Japan require that such data be generated in the indigenous population; other countries accept foreign data.

With the exception of Italy, no country requires long-term (1–3 months) controlled safety studies in volunteers before initiating studies in patients. For registration purposes, however, Belgium, Italy, Canada, and in some cases the United Kingdom require such data. Since prisoners are not used in those countries for such studies, it is assumed that such data often are generated elsewhere. In most countries, longer term studies to determine the safety of a new drug entity are done in the patient population which the drug is intended to treat. This provides a measure of how the drug may be expected to behave in clinical practice under the more usual conditions of use and when combined with the usual concomitant therapies. The subjects of such studies receive the presumed benefits of therapy with the new agent to balance its unknown risks.

Although prisoners have not been subjects in phase 1 drug testing in other countries, they have been subjects of nontherapeutic research. For example, prisoners in a number of countries, including Australia, Canada, Denmark, England, Germany, Greece, Ireland, Mexico, Poland and Japan, have been surveyed to determine the incidence of the XYY chromosome anomaly.

CHAPTER 12. SURVEY OF REVIEW PROCEDURES, INVESTIGATORS AND PRISONERS

Data on research in prisons were presented by the Survey Research Center, University of Michigan, in a preliminary report to the Commission on a study of institutional review procedures, research on human subjects, and informed consent. Data were presented from interviews done in early 1976 with investigators in 41 studies and representatives of review committees in five prisons, with 181 prisoner-subjects in four of these prisons, and with 45 prisoner-non-subjects in two of these prisons. The subjects had all participated in research since July 1, 1974. No individuals or institutions were identified in the report.

The research. As described by principal investigators in the five prisons, their research was predominantly pharmaceutical research, mostly phase 1 testing. In most of the studies, drugs were administered orally and blood and urine samples were analyzed. Very few of the experiments, according to investigators, were intended to benefit subjects, although researchers felt that a medical or psychological benefit might occur in some cases. The research also entailed some medical and psychological risk according to investigators, although they estimated the probability of serious risk to be very low or nonexistent. All investigators reported the existence of procedures for treating subjects who might suffer harmful effects of the research.

Review procedures. The Survey Research Center found that the structure of the review process differed among the five prisons. In some places it included Institutional Review Boards (IRB's) established in compliance with DHEW regulations on protection of human subjects; in others it included review committees appointed by the State department of corrections, by prison authorities, or by university officials. The review process at some prisons included com-

[4] Provided to the Commission by Marvin E. Jaffe, M.D. and C. Stewart Snoddy, Merck Sharp & Dohme Research Laboratories.

mittees created by drug companies. Biomedical and legal consultants and prisoner representatives played a role in some review procedures. At all prisons, the review was conducted in stages involving different combinations of the above mechanisms. Membership on review committees was reported as being very stable.

While few proposals are rejected in the review process, it was reported that few are approved as submitted. Most frequent changes are in consent procedures, though modifications were also reported in research design. The process was said to work smoothly, at least in part because of long-standing relations between review committees and investigators, and awareness of mutual expectations. Little monitoring of the actual conduct of research was reported, although most members of review committees were said to have visited the prison or research facilities at some time.

The prisoner subjects. The interviews with prisoner subjects revealed them to be generally supportive of biomedical research in prisons. The near consensus of favorable attitude among subjects occurred in all four institutions where prisoners were interviewed. Practically all of these subjects said that the information they received in advance of the experiment was understandable and correct, that the researchers were willing to answer subjects' questions, and that participation was voluntary. About one-third of the subjects indicated that they expected the research would involve some risk. A few subjects nonetheless felt that they had experienced specific difficulties as a result of the experiments that they did not fully expect. Subjects offered a number of reasons for participating in research, the most prevalent being financial. About 90% of them said that they would be willing to participate in future experiments.

Consent forms. The Survey Research Center's analysis of consent forms provided by investigators indicated that almost all described the purpose of the experiment, and all described the procedures. About 85% mentioned and listed risks. An analysis of the reading ease of consent forms indicated that a large proportion were at a difficult reading level. The difficulty did not appear to be solely attributable to the use of medical and technical terminology; some of the difficulty was related to the complexity of sentence structure and the nature of many of the nontechnical terms that were employed. Reading difficulty appeared to be greater for consent forms associated with projects that investigators estimated to entail relatively higher risks. The explanations provided in the consent forms, however, were supplemented in all cases by oral explanations.

Nonsubject prisoners. Prisoners who have never participated in research projects, or whose participation was not recent, were less favorable, on the average, toward research in prisons than were the current subjects. Differences of opinion about research were more apparent within the group of nonsubjects than within the group of subjects. Some nonsubjects were strongly opposed to research in prisons. Prisoners offered a number of explanations for not participating, including assertions that they had not been asked, that they feared the possibility of serious harmful effects, that they mistrusted research or researchers, or that they were opposed to the idea of research in general. Some said that they would participate if they were asked and/or if the benefits to themselves were more substantial. Nonsubjects who were interviewed had a slightly lower level of formal education than did the subjects, and the former were less likely to have prison jobs. Furthermore, for those inmates who held jobs, the number of hours worked per week was lightly lower for nonsubjects than for subjects.

Suggestions from respondents. Relatively few prisoners offered suggestions about how studies on human beings might be improved. Increased payment, better facilities (e.g., rooms to be used exclusively for research purposes), more complete explanation of possible harmful effects (e.g., pamphlets or written materials explaining projects), and better treatment (e.g., taking more time with subjects and exercising more care) were among the suggestions of prisoners. Some nonsubject prisoners suggested abolishing the research program.

Principal investigators also offered few suggestions. Some proposed that rules and review procedures be simplified and made less rigid. Others suggested that larger review committees be established, that committee members should have experience in dealing with prisoner volunteers, and that the committee procedure be made less susceptible to the biases of individual members.

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PART III

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

■

PUBLIC INFORMATION

Final Regulations

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

[Docket No. 76N-0067]

PUBLIC INFORMATION

Final Regulations

The Food and Drug Administration (FDA) is issuing a second final regulation concerning public information in response to comments on the initial promulgation of such regulations. This final order does not change most of the agency's current regulations, either because no comments were received or because the comments submitted did not persuade the Commissioner of Food and Drugs that changes were in order. Certain provisions are being revised, however, to make it clear that the agency will not ordinarily provide more than one copy of a record to the same person, to clarify the agency's policy respecting waiver of fees, and to effect other changes. This order shall be effective February 14, 1977.

In the FEDERAL REGISTER of December 24, 1974 (39 FR 44602), the Commissioner of Food and Drugs issued final regulations governing the disclosure of information to the public in conformity with the public information section of the Administrative Procedure Act, known commonly as the Freedom of Information Act (FOIA) (5 U.S.C. 552). Interested persons were invited to file, within 60 days of publication of the final order in the FEDERAL REGISTER, written comments regarding matters not raised in the notice of proposed rule making published in the FEDERAL REGISTER of May 5, 1972 (37 FR 9123), and considered in the preamble to the final regulation. The final regulation provided that any changes justified by the comments would be the subject of a further regulation amending the specific regulations involved.

The Commissioner received 28 comments; the majority repeated substantive comments previously made on one or more sections of the original proposal, although some dealt with matters not previously raised and considered. The majority of the responses, mainly from trade associations and representatives of companies subject to regulation under the laws administered by FDA, objected to specific provisions of the final regulation and suggested changes that would make less information in government files available for public disclosure. The few comments received from individuals and consumer groups generally supported the provisions of the final regulation, and suggested changes to further liberalize agency disclosure policies.

Those letters making new substantive comments or suggestions and the Commissioner's conclusions concerning them are discussed in this preamble. The respondents that raised matters that were previously considered in the preamble to the December 24, 1974 final regulation, and references to the specific paragraphs of that preamble wherein they were considered, are also briefly set out below. For the convenience of the reader, wherever this preamble are grouped under the appropriate headings of the preamble to the December 24, 1974 final regulation.

FDA EXPERIENCE UNDER THE FREEDOM OF INFORMATION ACT

1. In the preamble to the December 24, 1974 final regulation, the Commissioner noted that the May 1972 proposal represented a major change from prior agency policy. Before the regulations were proposed, the agency retained approximately 90 percent of its records as confidential; since the May 1972 proposal, approximately 90 percent of FDA records have been available for public disclosure. The Commissioner concluded in the preamble to the December 24, 1974 final regulation that the impact of this policy change on FDA was beneficial rather than detrimental. The policy of open disclosure, the Commissioner concluded, impeded neither communication with persons outside the Federal government nor internal agency deliberations, but had the salutary effect of encouraging closer public scrutiny of FDA actions and "fostered greater public accountability of the agency." The beneficial effects of the FDA openness policy, reflected only in part in its public information regulations, caused the Commissioner to enlarge the categories of documents available to the public by his conclusion in the preamble to commit the agency to liberal use of its discretion under FOIA to disclose records that could be withheld from the public under strict terms of the act's nine exemptions.

Since publication of the final regulations in December 1974, FDA experience confirms the Commissioner's conclusion that a policy of open disclosure is in the best interests of the public and the government. Remaining fully committed to this policy, FDA will continue to strive to meet both the spirit and letter of the FOIA.

Although the FOIA and these regulations have generally resulted in substantial public benefits, they have also produced some unexpected and, for the agency, disappointing consequences. The volume of freedom-of-information (FOI) requests received by FDA has been much larger than anticipated. During fiscal year 1975, FDA received approximately 5,300 requests; in fiscal year 1976, the total number of requests ballooned to nearly 20,000. This trend continues today and the Commissioner expects that FDA will receive over 24,000 requests in fiscal year 1977. A large proportion of the requests received by FDA are lengthy, voluminous and complex, which makes responding to them involved, time consuming, and costly.

Last year, FDA's uncompensated cost of responding to FOI requests exceeded $1 million. Fees charged, which are supposed to reflect actual cost to the government, totaled only $78,340. This disparity between the cost to FDA and the revenue from fees is disturbing because 86 percent of the FOI requests received by FDA are from industry and private attorneys, while only 14 percent come from the general public, consumers, press, health professionals, and scientists. It is, in the Commissioner's view, inappropriate that the general public must subsidize the "industrial espionage" in which many commercial firms engage.

The Commissioner does not intend to modify the FDA disclosure policy because of this "imbalance" in requests. However, the Commissioner does intend to take steps to secure a revision in the fee schedule to more closely reflect the actual cost incurred by FDA in searching for requested documents. The Commissioner's views concerning the fee schedule are fully set forth elsewhere in this preamble; namely, an increase in the fee schedule coupled with a more liberal application of agency policy on waiver of fees will result in a more equitable distribution of the costs of responding to FOI requests without affecting the amount or type of records available to the public.

PROCEDURAL ISSUES RELATED TO PROMULGATION OF FINAL ORDER

2. Many comments contended that the promulgation of the final regulation in December 1974 represented a novel concept in agency rule making not in accordance with the notice and comment requirements of section 4 of the Administrative Procedure Act. It was asserted that the regulations are more than a mere particularization of the FOIA, and reflect FDA interpretation of the provisions of the act and their applicability to specific categories of documents in FDA files. It was argued that, because the final regulation differs in numerous and substantial respects from the May 1972 proposal, these regulations should be treated as entirely new and published as a proposal with a full comment period before their issuance in final form. It was further asserted that the justification in the preamble for the procedure used by FDA, i.e., that the FOIA is self-executing, even if assumed to be a correct statement, is not dispositive of the procedural objections. Comments noted that the preamble and regulations endeavor to interpret and reconcile seemingly conflicting statutes and to make substantive determinations as to what constitutes trade secrets and confidential commercial or financial information. These interpretations, reconciliations, and determinations were said to be of such significance and were such a substantial departure from past practice that they cannot be viewed as merely the implementation of a self-executing statute.

The Commissioner does not agree with these comments. The FOI regulations were promulgated in accordance with 5 U.S.C. 552(a)(1), to apprise the public of how FDA intended to respond to the congressional mandate. The issuance of these detailed regulations also enables persons, in advance of disclosure, to determine whether documents that they have previously submitted to FDA and

believe to be confidential fall into a disclosable category and to seek immediate judicial review if they disagree with the classifications of the agency. Many agencies, in implementing the FOIA, have issued regulations without affording any time for public comment. Others have issued regulations that merely parallel the language of the statute, providing no more guidance as to the disclosability of certain records that the FOIA itself. In contrast, FDA published in the FEDERAL REGISTER a notice of proposed rule making with a 60-day comment period. That proposal and the subsequent final regulation contained a detailed statement of how categories of records in the files of the agency were to be treated. The Commissioner concludes that the procedures followed more than met the requirements of any provision of the Administrative Procedure Act and were not legally defective in any respect.

Moreover, a 60-day comment period was provided after the promulgation of the final regulation to enable persons to comment further on issues not previously raised. The comments received during that 60-day period are the subject of this preamble and final regulation. Any asserted error in failing to issue the December 1974 publication as a proposal was therefore corrected by providing this additional time for comment. Thus, the Commissioner is confident that the procedures followed in promulgating these regulations have fully satisfied all applicable procedural requirements.

3. Comments also asserted that the request in the preamble to the December 24, 1974 final regulation that "comments submitted within this additional period should address new issues and should not reopen matters raised by the initial proposal and fully discussed in this preamble" makes it impossible to delineate those portions of the final regulation deemed proper for comment and that a rule making procedure that restricts comments to unspecified portions of the regulations and preamble is procedurally defective.

The Commissioner concludes that there is nothing improper about requesting comments on new matters and discouraging those raised by the initial proposal and fully discussed in the preamble to the December 24, 1974 final regulation. To determine whether a matter had been previously raised and discussed, persons merely had to refer to that preamble. If the matter they desired to comment upon was not the subject of earlier comment and was not discussed in the preamble, it was appropriate to submit a comment upon it.

Moreover, many comments ignored the Commissioner's request quoted above and commented upon matters raised and fully discussed previously, sometimes in language identical to that used in earlier comments. Nonetheless, these comments have been reviewed by the Commissioner and, in most instances, they are briefly discussed in this preamble. The Commissioner therefore concludes that no person was constrained from making any comment on any portion of the final regulation.

4. Comments contended that, to the extent that the lengthly preamble is deemed by FDA to have the effect of a legal advisory opinion or to modify, limit, or expand the meaning of the regulations, the preamble constitutes rule making subject to the notice and comment requirements of the Administrative Procedure Act (5 U.S.C. 553).

The Commissioner does not agree with these comments. The preamble is intended to explain the regulations and has the status of an advisory opinion. It does not modify, limit, or expand the meaning of the regulations. The preamble is a discussion of specific situations expected to arise involving the application and interpretation of the regulations. The preamble, accordingly, merely sets forth the Commissioner's interpretation of the regulations as applied in specific situations, and thus does not constitute rule making subject to the notice and comment requirements of the Administrative Procedure Act.

5. A few comments contended that the determination of disclosability is not amendable to quasi-legislative treatment by regulation according to category or type of record. It was argued that each determination involves the exercise of the adjudicative function of the agency and must be evaluated on its own merits in a proceeding affording not only notice, but opportunity for hearing and the presentation of comment by persons who might be affected by disclosure.

The Commissioner advises that the requirements imposed by this comment before agency disclosure of any record within its files are inconsistent with the mandate of the FOIA and would frustrate the implementation of that act by the agency. This point has been recognized by the United States District Court for the District of Columbia in *Pharmaceutical Manufacturers Association* v. *Weinberger*, 401 F. Supp. 444, (D.D.C. 1975), subsequent opinion, 411 F. Supp. 576, 579 (D.D.C. 1976), where the court noted,

> Broad, categorical regulations are therefore imperative. Ad hoc inquiries or item by item consultations would not only be impractical but also undercut the open disclosure policy of the FOIA and the FDA regulations.

The Commissioner therefore rejects this comment.

6. Comments contended that the final regulation of December 24, 1974, does not comply with Executive Order 11821, issued November 27, 1974, requiring a statement certifying that the inflationary impact of all major legislative proposals, regulations, and rules emanating from the executive branch of the Federal Government has been considered.

The Commissioner notes that FDA is required by law to implement the FOIA, a fact not altered by the Executive Order. These regulations are intended to implement the act and to provide guidance on the manner in which various types of documents will be handled by the agency. Records available under a specific section of the regulations would, in most instances, also be available whether or not FDA determined to issue detailed regulations. Accordingly, the Commissioner concludes that Executive Order 11821 is not applicable to these public information regulations. Moreover, the Commissioner is unable to discern, nor did any comments identify, any inflationary impact that these regulations could have.

SECTION 305 HEARING RECORDS

7. Several comments objected to the availability for public disclosure of information contained in the file relating to a section 305 hearing (an informal hearing held prior to institution of criminal proceedings, provided for by (section 305 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355)) after the file is closed or the statute of limitations has run, whichever occurs first. The comments objected sharply to the availability for public disclosure of records pertaining to an individual considered for prosecution, but not prosecuted, and to the release of company and product names. It was argued that no useful regulatory purpose would be served by such disclosures, and that disclosure of company and product names may deprive persons of their right to a fair trial in matters not involving FDA. The assertion was also repeated that disclosure of company and product names would subject the company to an "onslaught of adverse publicity." Comments also asserted that the release of section 305 hearing records constitutes an unwarranted invasion of privacy.

The Commissioner has, in paragraph 16 of the preamble to the December 24, 1974 final regulation, previously concluded that Congress has determined that the right of the public to this type of information in government files outweighs any potential harm caused by the release of such information. It is only through the release of section 305 hearing records after the matter is closed that the exercise of prosecutorial discretion by FDA and the Department of Justice may be subject to scrutiny and public accountability. This is particularly true when prosecution is not recommended or is recommended but not instituted. Furthermore, the names and other information that would identify individuals are deleted before disclosure except when the Commissioner concludes that there is a compelling public interest in the disclosure of the names. The privacy rights of individuals will, accordingly, be protected.

The Commissioner concludes that the possibility that the release of section 305 hearing records will interfere with any person's right to a fair trial or impartial adjudication in matters not involving FDA is too remote and speculative to justify nondisclosure of those records. Finally, the possibility of adverse publicity stemming from the release of records such as section 305 hearing records without the deletion of company or product names was considered by Congress and, absent any provision in the FOIA for the deletion of such names, must be deemed to be outweighed, in the judgment of Congress, by the public's right to the infor-

mation. The Commissioner has previously concluded that the protection of privacy afforded by the Constitution and the sixth exemption of the FOIA (5 U.S.C. 552(b)(6)) extends only to individuals. The recently enacted Privacy Act (5 U.S.C. 552a) also protects only the privacy rights of individuals.

8. A seeming anomaly was also noted, in that paragraph 18 of the preamble to the December 24, 1974 final regulation provides that if records relating to a closed section 305 hearing for a specific individual are requested by name, they will be released only after deletion of the names and any information that would identify the individual.

The Commissioner advises that the names and identifying details are deleted from section 305 hearing records requested by name to protect against indiscriminate subsequent disclosures. The requesting party obviously knows the name of the person, but deletion minimizes the possibility of additional widespread publicity. Accordingly, section 305 hearing records will be released only after the names and identifying information are deleted.

9. Several comments objected to the provision in § 1.6(c)(4) (21 CFR 1.6(c)(4)) for the release of section 305 hearing records respecting possible criminal prosecution of individuals without deleting the names and identifying information when the Commissioner determines that there is a "compelling public interest" to do so. The contention was made that such discretionary disclosure exceeds the authority of the Commissioner under the FOIA and, without guidelines for such discretionary disclosure, the release of section 305 hearing records relating to possible criminal action without first deleting the names and identifying information would be unreasonable and arbitrary. One comment suggested that the written consent of the individual who was the subject of the investigation be obtained before the release of any names or identifying information.

The Commissioner advises that disclosure of section 305 hearing records respecting possible criminal prosecution with the names and identifying details intact may, depending on the particular circumstances, be completely consistent with the FOIA and the Privacy Act. If the public's interest in disclosure is indeed "compelling," the benefits in disclosure outweigh any infringement of personal privacy. In applying 5 U.S.C. 552(b)(6), the courts have required that the benefits from disclosure be weighed against any possible infringement of personal privacy. The determination that a "compelling public interest" exists that warrants release of the names and identifying information pertaining to individuals considered for prosecution will be made in accordance with traditional criteria for such determinations, and after due consideration of those factors listed in § 4.82 (21 CFR 4.82) of the final regulation.

The Commissioner rejects the suggestion that the written consent of the individual who was the subject of the investigation be obtained before the release of names or identifying information. The ultimate responsibility for compliance with the FOIA by FDA rests with the Commissioner. There is no requirement in the FOIA that the consent of individuals be obtained before the release of disclosable information. When the Commissioner concludes that there is a compelling public interest warranting release of names or identifying information, the records will be released without deletions whether or not consent is given by the individual who was the subject of the investigation.

OFFICIAL RECORDS AND INFORMATION

10. Questions have arisen as to whether the phrase, "testimony before any tribunal," as used in § 4.1(a) (21 CFR 4.1(a)) of the final regulations includes committees of Congress.

The Commissioner advises that § 4.1 was first published in the FEDERAL REGISTER of December 20, 1955 (20 FR 9554). It was designed to prevent the subpoena of agency officials in private litigation and similar matters. The phrase "testimony before any tribunal" has not been, is not intended to be, and will not be interpreted to include committees or subcommittees of Congress.

11. One comment contended that FDA employees should be free to give testimony without first securing the permission of the Commissioner because the public is entitled to information from FDA employees which is not filtered through the Commissioner.

The Commissioner regards this suggestion as impractical and contrary to the public interest. The Food and Drug Administration now receives a very large number of requests for agency employees to testify in private litigation and other matters in which FDA is not a party. Were agency employees free, or required, to testify in private litigation whenever requested, the regulatory activities of the agency could be severely disrupted. The agency could not adequately function if its 6,500 employees were constantly preparing for and giving testimony in private litigation. Section 4.1 is therefore necessary for the agency to fulfill its primary regulatory responsibilities.

UNIFORM ACCESS TO RECORDS

12. One comment requested that disclosure of drug experience reports submitted by physicians and hospitals be restricted to health care professionals and institutions on the grounds that the general public does not possess sufficient expertise to interpret the significance of such reports and that release, upon request, to any member of the public would result in undue public alarm and unjustified concern by individuals under medication.

The Commissioner has previously advised, in paragraph 31 of the preamble to the December 1974 final regulation, that, if any information is available to one member of the public, it must be available to all. Under the FOIA, the disclosure of information does not depend ordinarily on the requestor's interest in or ability to understand the information sought.

PARTIAL DISCLOSURE OF RECORDS

13. A comment suggested that, whenever FDA determines that a document contains both disclosable and nondisclosable material, the agency should consult with the submitter of the document before any release to determine the extent to which the disclosable material may be segregated from the nondisclosable. It was argued that consultation is especially necessary when the requested document is technical because the expertise necessary to identify nondisclosable material is likely to be possessed only by the submitter.

The Commissioner concludes, and has previously stated, that the submitting person, and possibly other affected persons, will be consulted only if there exists a close question of the confidentiality of the requested records. If a close question exists, because of the intermingling of disclosable and non disclosable information, be it technical or otherwise, consultation will occur. The mere fact that disclosable and nondisclosable information is contained in a single document, as is often the case, does not warrant automatic consultation. If the information contained in the document is of such a nature that the disclosable information cannot be reasonably separated from the nondisclosable information by FDA without the benefit of additional information, this would constitute a close question.

14. Several comments asserted that the application of these regulations to material in FDA files submitted in confidence before the effective date of the final regulations is a retroactive application of the regulations that constitutes a denial of administrative due process to the submitters of such material unless notice is given to the submitter in advance of public disclosure of a particular item.

The Commissioner advises that Congress intended in enacting the FOIA to reverse the disclosure policies of Federal agencies to make disclosure the rule and nondisclosure the exception. Congress did not distinguish between information submitted before the FOIA was passed and that submitted after passage. Furthermore, information that is not otherwise exempt under one of the nine exemptions of FOIA cannot be made exempt on the basis of a "pledge of confidentiality." *Petkas* v. *Staats*, 501 F. 2d 887, 889 (D.C. Cir. 1974); *Charles River Park A Inc.* v. *HUD*, 519 F. 2d 935, (D.C. Cir. 1975). The application of the final regulations to all records in FDA files, regardless of when submitted, has been squarely upheld in *Pharmaceutical Manufacturers Association* v. *Weinberger*, 401 F. Supp. 441 (D.D.C. 1975), subsequent opinion, 411 F. Supp. 576, 580 (D.D.C. 1976). The question of notice to the submitter before disclosure was also an issue in that case and is discussed in paragraph 37 below.

PROHIBITION ON WITHDRAWAL OF RECORDS FROM FOOD AND DRUG ADMINISTRATION FILES

15. A few comments contended that information previously submitted to FDA on a voluntary basis should be permitted to be withdrawn from agency files. It was argued that § 4.29 (21 CFR 4.29) is based on an erroneous assumption that some form of property right passes to the government whenever a private party submits trade secret or confidential commercial or financial information to it. The comments concluded that, because no property right does in fact pass to the government, submitters of material should be permitted to withdraw the records under certain circumstances, e.g., when a product is finally abandoned.

The Commissioner advises that under no circumstances will documents submitted to FDA and thereafter made part of agency files be returned to the submitting person. The Food and Drug Administration does not maintain that the government acquires any property right in data and information submitted to it. That does not mean, however, that persons are entitled to withdraw material received by FDA in furtherance of its regulatory responsibilities from agency files. Once such material becomes a part of agency files it may be used at any time and in any reasonable way to support appropriate regulatory action by the Commissioner.

PERMANENT FILE OF REQUESTS FOR FDA RECORDS

16. One comment requested that § 4.31 (21 CFR 4.31) be revised to reflect the fact that the permanent file of FOIA requests and responses (the "public log") did not exist until January 1, 1975.

The Commissioner notes that the 1974 amendments to the FOIA require all agencies to file an annual report with Congress on the administration of the act. The public log enables FDA to compile the data necessary to comply with that requirement. Thus, although the May 5, 1972 proposal did not contain a requirement that a public log be maintained, § 4.1 was added to the final regulations to assist FDA to comply with the 1974 FOIA amendments. The public log of all requests and responses has been maintained, and all requests numbered sequentially since January 23, 1975. The Commissioner sees no need to revise § 4.31 to state when the log began.

17. One comment suggested that, in addition to the permanent file of FOIA requests and responses, FDA maintain a topical index of those requests and responses.

The Commissioner concludes that it is not possible for FDA to index all FOIA requests and responses in light of the enormous number of requests received by the agency. The administrative burden that would be borne if the agency undertook to develop and maintain such an index would greatly overtax the personnel available to handle FOIA matters.

18. Section 4.40(c) (21 CFR 4.40(c)) has been revised to reflect the fact that the public log maintained by the Public Records and Documents Center of FDA does not contain the time a request is received, the address of the person making the request, the number of staff hours and grade levels of persons who spent time responding to the request, or the payment requested and received. The Commissioner advises that these items have not been maintained on the public log because experience has demonstrated that the time required to collect and record the information is not justified by any possible benefit from having the information available for each logged request. Furthermore, the address of the person making the request and the payment requested and received are readily ascertainable from other sources, such as the actual file containing the request and any correspondence from FDA concerning the request.

PROCEDURES AND FEES

19. One comment contended that provision should be made for the reduction of the fee whenever the fee is "excessive" due to inefficiencies within FDA, such as in recordkeeping procedures.

The Commissioner advises that a blanket rule providing for the reduction of excessive fees due to inefficiencies within FDA would be inappropriate. However, such inefficiencies will be taken into consideration as one factor in determining whether a request for a reduction in the fee should be granted. The Commissioner notes, in passing, that some of the FOI requests received by the agency are from companies that have previously submitted the documents to the agency and are not able to locate a copy in their own files.

20. Experience in recent months has shown that a number of persons and organizations make requests on a frequent and regular basis for certain agency records, such as, the public log containing all FOI requests and FDA responses. The fee for providing those records does not generally exceed $5.00 and, accordingly, they have often been provided free of charge.

The Commissioner advises that, in accordance with § 4.43(a)(1) (21 CFR 4.43(a)(1)), FDA will aggregate the costs for such regular requests made by the same person or organization or related persons or organizations on a monthly basis in order that such persons or organizations may appropriately bear the cost of copying, which is now often borne by FDA.

Additionally, experience in recent months has shown that a number of persons and organizations, primarily the numerous organizations that file requests for records with FDA on behalf of their clients, make numerous requests for the identical records, presumably to enable them to provide them to different clients. This practice of making several requests for the identical records has generated a substantial number of so-called "third-party" requests, i.e., requests seeking the records disclosed in response to a previous request. In fiscal year 1976 nearly one-quarter of all requests received by FDA were for records previously disclosed in response to an earlier request. A substantial portion of those requests was for records previously disclosed to the same requestor. Quite obviously, these third-party requests have added significantly to the FOI workload of FDA.

The Commissioner concludes that the FOIA does not require that FDA provide two, three, and sometimes more sets of identical records to the same persons and organizations. This practice has significantly taxed available agency resources for responding to FOI requests, sometimes causing delays in responding, and resulting in FDA and the taxpayers subsidizing the profitmaking activities of the organizations making the third-party requests. Accordingly, the Commissioner advises that, except in unusual circumstances, FDA will not provide more than one copy of requested records to the same requesting person or organization.

21. One comment suggested that those employees of FDA responsible for disclosing records in response to an FOI request be identified on the determination letter in the same manner that those who are responsible for denying records are identified. To do otherwise, it was argued, is to subtly coerce employees into granting requests rather than be identified as responsible for a denial.

The Commissioner advises that 5 U.S.C. 552(a)(6)(C), a provision of the 1974 amendments to the FOIA, requires that any letter of determination denying a request for records identify by name and title or position those persons responsible for the denial. The Commissioner rejects the suggestion that FDA employees will be coerced into granting requests rather than be identified as responsible for a denial.

The Commissioner concludes that it would be unnecessarily burdensome for letters of determination granting requests to contain the names and titles or positions of employees responsible for granting the request, and that no useful public interest would be served.

DISCLOSURE OF DOCUMENTS IN THE OFFICE OF THE HEARING CLERK

22. Questions have arisen as to whether requests made in person to review, and in many instances copy, documents on file in the office of the FDA Hearing Clerk must be handled in accordance with all the provisions of the regulations, or whether an expedited procedure is feasible.

The Commissioner concludes that because virtually all documents on file with the Hearing Clerk are clearly disclosable to any member of the public, and because large numbers of persons make requests to review and copy such documents, it is appropriate to facilitate such review and copying by providing an expedited procedure applicable solely to material on file in that office. According-

ly, requests made in person to view or copy documents on file with the Hearing Clerk will continue to be responded to by the staff of the Hearing Clerk as rapidly as possible. The requestor will need merely to fill out a one-page form available in the office of the Hearing Clerk in order that FDA may maintain accurate records of all FOI requests. The fee schedule applicable to records obtained from the Public Records and Documents Center will apply to records obtained from the FDA Hearing Clerk.

Requests for material in the office of the Hearing Clerk not made in person shall continue to be treated in the same manner as all other FOI requests and must be sent to the Public Records and Documents Center (HFC–18) pursuant to § 4.30 (21 CFR 4.30).

FILING A REQUEST FOR RECORDS

23. Suggestions have been made that the regulations include a provision to encourage requestors to identify FOI requests by marking both the envelope containing the request and the request itself with the phrase "FOI Request."

The Commissioner concludes that the suggestion is worthwhile and should be adopted. It is emphasized, however, that requestors are only encouraged, not required, to identify their requests with the phrase "FOI Request." Those so identified will simply be more readily identified as FOI requests. A new sentence is added to § 4.40(a) (21 CFR 4.40 (a)) to state this policy.

24. One comment asserted that the provision in § 4.41 (21 CFR 4.41) that records will be provided "as soon as possible" leads to misunderstandings between FDA and the public. This occurs, according to the comment, because the phrase is undefined and does not have the urgency of either the FOIA or paragraph 45 of the preamble to the December 1974 final regulation, both of which state that records shall be made "promptly available." The comment recommended amending the regulations to require that determination letters include an estimate of the date on which the records will be available.

The Commissioner advises that the phrase "as soon as possible" is intended to convey the same urgency as "promptly available." Insofar as possible, records are sent to requestors immediately upon receipt of payment. The sheer volume of requests received by FDA does, on occasion, result in unavoidable delay in providing records. The Commissioner is confident that additional personnel and streamlined internal procedures will reduce those delays to an absolute minimum. The Commissioner also concludes that while every effort is made to make records available immediately, it is not feasible and would be unnecessarily time-consuming to include an estimate of the date on which records will be provided in each determination letter.

TIME LIMITATIONS

25. Comments expressed concern that, in an effort to make a determination on all FOI requests within 10 working days, FDA regulatory responsibilities will suffer. It was suggested that determinations on requests be made "within a reasonable time period" and that a special staff be created within FDA to handle all FOI requests so that other employees are not diverted from normal regulatory responsibilities.

The Commissioner advises that the recent amendments to the FOIA require that determinations on requests be made within 10 working days of receipt of the request. The Food and Drug Administration intends to comply with that congressional mandate. Documents for which requests have been granted will be sent to the requestor as soon as possible thereafter.

The Commissioner advises that each major organizational component within FDA has specially trained FOI officers who handle most requests. Additionally, a staff manual guide has been prepared that explains the responsibilities of each agency employee under the FOIA. Consequently, although all agency employees may be called upon to assist in carrying out the mandate of the FOIA, most day-to-day responsibilities have been assigned to the specially trained FOI officers.

FEES

26. The fees set out in the December 24, 1974 final regulation were based primarily on the fees established by the Department of Justice in 28 CFR 16.9, because the Department of Justice has the lead responsibility for implementation of the FOIA. In the FEDERAL REGISTER of January 13, 1975 (40 FR 2443), the Department of Justice revised its fee schedule to reflect actual costs of $4.00 per hour for clerical search time and $8.00 per hour for search time by nonclerical personnel. In the FEDERAL REGISTER of May 1, 1975 (40 FR 18997), the Department of Health, Education, and Welfare (HEW) revised its fee schedule to include a flat charge of $3.00 per hour for search time by both nonclerical and clerical personnel, which represents a charge substantially below actual cost to the government.

The Commissioner concluded that to achieve uniformity of fees within HEW, the fee schedule adopted by HEW should be incorporated in § 4.42 (21 CFR 4.42), which is revised accordingly. The fee schedule has been followed by FDA for well over a year.

The Commissioner notes, however, that the HEW fee schedule results in charges substantially below cost to the government and thus results in some taxpayers subsidizing the public information requests of other taxpayers. This subsidy is especially inequitable when one considers that 86 percent of the FOI requests received by FDA are from corporations, FOI service companies, and private attorneys—groups best able to bear the cost of obtaining records from FDA. The taxpayers are thus subsidizing the "industrial espionage" engaged in by many commercial organizations who use the FOIA to obtain information about their competitors. The HEW fee schedule also means that agency personnel who would otherwise be engaged in regulatory activities are instead spending their time responding to FOI requests without the government being reimbursed for the actual cost of the time spent locating requested records.

The Commissioner has been closely monitoring the results of the HEW fee schedule and concludes that the circumstances warrant an increase in the fee schedule to reflect actual costs to the government. The Commissioner has initiated discussions with the appropriate officials in HEW regarding the fee schedule and anticipates that the FDA fee schedule will soon be revised to reflect the actual costs incurred by the agency in searching for requested records. A new fee schedule reflecting actual costs to the government, coupled with the liberalization of the FDA policy on waiver or reduction of fees discussed elsewhere in this preamble, will be more equitable and fully in agreement with the policy in the FOIA providing for charging fees and for waiver or reduction of those fees when that is in the public interest.

WAIVER OF FEES

27. Experience in recent months suggests that there may be some confusion among both the public and agency employees about the FDA policy on waiver or reduction of fees under § 4.43 (21 CFR 4.43). The Commissioner is restating the agency's policy to avoid further confusion.

Section 4.43 establishes two distinct bases for obtaining waiver or reduction of fees: paragraph (b) of the section provides that the fees may be waived if the person making the request is: (1) indigent and (2) the disclosure has a "strong public interest justification." Paragraph (c) of the section, on the other hand, provides that the fees may be waived or reduced when the waiver or reduction is in the public interest "because furnishing the information can be considered primarily as benefiting the general public." No showing of indigency is required for a waiver or reduction of fees under § 4.43(c). To obtain consideration of a request for waiver or reduction under paragraph (c), however, the request must be accompanied by a statement of the intended purpose to which the requested information will be put. This statement enables FDA to determine whether the intended use will benefit the public generally.

The Commissioner emphasizes that narrow and specific requests for records are much more likely to meet the standard in paragraph (c) than requests that are vague and open-ended. Similarly, requests for documents intended to be used in connection with administrative proceedings before FDA, e.g., formal evidentiary hearings, are more likely to satisfy the standard than requests for documents that do not relate to a pending or potential formal or informal administrative proceeding. For example, two public interest organizations that desired to participate in the hearing on the withdrawal of the new animal drug approvals (NADA's) for diethylstilbestrol (DES) sought and obtained waiver

of fees in connection with their requests for copies of the requests for hearing filed by various holders of approved NADA's for DES. On the other hand, FDA frequently receives and denies requests for waiver of fees in connection with general requests for agency records from public interest groups where the sole basis for the waiver is that the request for waiver of fees in connection limited resources of the agency do not permit FDA to routinely provide records free of charge to all public interest groups.

The Commissioner advises that FDA is fully committed to the policies embodied in the waiver of fees provision of the FOIA and intends to interpret liberally those provisions and § 4.43. The Food and Drug Administration will give careful and sympathetic consideration to requests for waiver or reduction of fees that are submitted in accordance with § 4.43. The Commissioner encourages persons to seek waiver or reduction of the fees under § 4.43(c) when disclosure of the records sought will broadly promote the public interest. To facilitate consideration of requests for waiver of fees, the directors of the various bureaus within FDA will evaluate the requests and recommend to the Assistant Commissioner for Public Affairs those requests that are meritorious.

PRESUBMISSION REVIEW OF REQUEST FOR CONFIDENTIALITY OF VOLUNTARILY SUBMITTED DATA OR INFORMATION

28. One comment requested that FDA pledge not to revoke assurances of confidentiality given respecting data and information submitted under § 4.44 (21 CFR 4.44) for a presubmission determination of confidentiality.

The Commissioner advises that material received by FDA for presubmission review under § 4.44 and accepted in confidence pursuant to a letter signed by the Assistant Commissioner for Public Affairs pledging confidentiality will remain confidential unless a court order directs that it be disclosed or the status of the material is affeced by external factors, e.g., the company that submitted the material discloses it to a member of the public subsequent to its submission to the agency.

29. One comment requested that persons who submit information for presubmission review under § 4.44 be advised within 10 working days after receipt of the records by FDA whether the material qualifies for such review.

The Commissioner concludes that prescribing a fixed number of days for notifying persons who have submitted information for presubmission review is not feasible. The time required to review the material will vary according to the number and complexity of the documents submitted, among other variables. After receipt of the information by FDA, persons will be notified as soon as possible as to whether the material qualifies for presubmission review.

30. One comment requested that § 4.44 be revised to state that a person who voluntarily submits material to FDA but does not seek presubmission review does not waive any right subsequently to assert confidentiality or bar a subsequent determination by the agency to that effect.

The Commissioner concurs with this comment and concludes that no change in the regulation is needed to implement it. Presubmission review is not a mandatory procedure. A decision not to seek such review does not bar either a subsequent assertion of confidentiality by the submitting person or a finding of confidentiality by the agency. Neither a subsequent assertion of confidentiality by the person who submitted the information nor a finding of confidentiality by FDA would, however, invoke the presubmission review procedures provided in § 4.44 or require FDA to consult or give notice.

31. One comment requested that § 4.29 (21 CFR 4.29) be revised to permit persons who have previously voluntarily submitted data and information to FDA to resubmit such information for review under § 4.44.

The Commissioner concludes that, for all practical purposes, this comment requests that FDA permit material to be withdrawn from its files. No purpose would be served by allowing presubmission review under § 4.44 of material previously submitted voluntarily unless the submitting person was also permitted to withdraw and retain information for which no pledge of confidentiality was given. The Commissioner accordingly sees no difference between this comment and those comments requesting that persons be permitted to withdraw information from government files without any reference to resubmitting the information. The Commissioner rejects this suggestion for the reasons previously stated.

32. Questions have arisen about the status of records submitted for presubmission review when those records are ineligible for presubmission review either because their status under these regulations is clearly specified or because the submission is not voluntary, i.e., the submitter is under a legal obligation to provide the records to FDA upon request.

The Commissioner advises that records submitted for presubmission review that are ineligible for such review because the submission is not voluntary within the meaning of the regulations will be retained as part of the FDA permanent files and the submitter will be so notified. Records that are voluntarily submitted but are nonetheless ineligible for presubmission review because their status under the regulations is clear will be returned to the submitter, without complete review. The Commissioner admonishes persons to use the presubmission review procedure sparingly and only when appropriate. Abuse of the procedure may cause the agency to reconsider the procedure's utility.

SITUATIONS IN WHICH CONFIDENTIALITY IS UNCERTAIN

33. A number of comments requested clarification of the standard for consultation under § 4.45 (21 CFR 4.45). It was noted that paragraphs 62 and 63 of the preamble to the December 24, 1974 final regulation and § 4.45, respectively, describe the situation in which FDA will notify the person whose records are requested when there is "some question" or a "close question" as to the status of the material or when the status is "uncertain." The comments asserted that the "some question" standard is the appropriate one.

The Commissioner advises that the phrases "some question," "close question," and "uncertain status" will be construed as identical in meaning. The Commissioner rejects any implication that the use of the phrase "some question" in the preamble suggests a standard for consultation that is less rigorous than either the "close question" description in the preamble or the "uncertain status" language of § 4.45.

The Commissioner emphasizes that FDA will not consult with the submitting person in every instance in which any argument, however tenuous, can be made in support of the confidentiality of the requested material and will not consult if the argument would simply be that these regulations are wrong. The question about the confidentiality of the requested record must be such that a reasonable basis for confidentiality exists before consultation will be pursued.

34. Several comments pointed out that § 4.45 provides no time period for consultation and that in cases of uncertain confidentiality it was unlikely that FDA would be able to review, consult, and make a determination on a request for public disclosure within 10 working days. To provide for adequate time for consultation, it was suggested that the requestor be asked to agree to a specific extension of time; in the event that no extension is agreed upon and the 10-working-day limit cannot be met, the request should be denied. The alternatives, it was suggested, would be to grant the request on the basis of insufficient information, to ignore the 10-working-day requirement and thereby lose the 20 days to review an appeal of a denial, or to deny the request. Denial, it was asserted, would permit FDA to use the additional 20 days for consultation and review and ultimately either affirm the denial or reverse it and grant the request.

The Commissioner concludes that the suggestion is too complicated to administer and is unnecessary, and therefore it is rejected. If ongoing consultation makes a determination within 10 working days impossible, an interim response may appropriately be sent to the requestor to inform him that FDA is working on the request and that a final and complete determination will be made as soon as possible.

35. Questions have arisen about whether consultation under § 4.45 will be with only the person who submitted the records or with both that person and persons who might be affected by disclosure.

The Commissioner advises that consultation under § 4.45 will be with those persons who, in the agency's judgment, are likely to be able to assist FDA in

determining the confidentiality of the requested records. In most instances consultation with the person who submitted the records will be sufficient to make the determination. The decision about whom to consult will, of necessity, have to be handled on a case-by-case basis.

36. Several comments on §§ 4.45 and 4.46 (21 CFR 4.45 and 4.46) dealt with matters raised, fully discussed, and disposed of in the preamble to the December 24, 1974 final regulation. One comment, for example, expressed the fear that decisions on the necessity for consultation will be made by low level clerical staff. Paragraph 62 of the preamble to the final regulation makes it clear that decisions on whether the status of requested records is uncertain will be made by those persons administratively responsible for making disclosure decisions.

PREDISCLOSURE NOTICE

37. By far the greatest number of comments related to § 4.45 and the circumstances in which FDA will provide predisclosure notice of the agency's intention to disclose certain records to the person who submitted them. Most comments contended that FDA should consult with the person who submitted the records, or whose data and information are contained in them, in every case in which the agency intends to disclose the records in response to a request under the FOIA. The general theme throughout these comments is that FDA cannot, consistent with due process, release material, including that submitted to the agency ostensibly pursuant to a pledge of confidentiality, without first providing notice to the person who submitted the data and information.

On May 6, 1975, the Pharmaceutical Manufacturers Association (PMA) filed suit in the United States District Court for the District of Columbia (*Pharmaceutical Manufacturers Association* v. *Weinberger*, No. 75-0725, D.D.C.) seeking an order declaring invalid and enjoining the enforcement of certain provisions of the December 24, 1974 final regulation. The primary issue in the lawsuit was whether member companies of PMA are entitled to administrative notice of, and an opportunity to consult with FDA on, every contemplated disclosure by the agency of information submitted by, obtained from, or pertaining to them or their products. On August 1, 1975, PMA's Motion for a Preliminary Injunction on the notice and consultation issue was denied by the District Court for the District of Columbia (401 F. Supp. 444 (D.D.C. (Sirica, J.) 1975)). Thereafter, in granting the FDA Motion for Summary Judgment as to all the issues in the lawsuit, the court reaffirmed that notice and an opportunity for consultation with FDA in advance of every contemplated disclosure is not required (411 F. Supp. 576 (D.D.C. (Smith, J.) 1976)). The Pharmaceutical Manufacturers Association has announced that it does not intend to appeal this decision.

The Commissioner advises that when the status of requested records is uncertain, notice and consultation with the submitting person under § 4.45 will be undertaken. In those situations, FDA may request additional information from the submitting person in order to determine whether the requested records are disclosable. In all other situations, that is, when the status of the requested records can be determined by FDA and is not "close" or "uncertain," the agency will proceed to make a determination in accordance with the FOIA and the regulations. The Commissioner is confident that the notice and consultation provisions in § 4.45 adequately protect the rights of persons who have submitted data and information to FDA.

Persons who become aware of the impending release of records containing data or information submitted by them pursuant to § 4.45, as a subscriber to the commercial services that provide this type of information, or in any other fashion, and who believe that the records should not be disclosed, may institute suit against FDA to enjoin the release of the requested records. If instituted in timely fashion, the agency will not release the records, pending judicial resolution of the suit, unless directed by court order to do so. FDA will not deprive any person of the opportunity to pursue a timely instituted court action to enjoin the release of records by disclosing the records and thereby mooting the judicial proceedings.

The Commissioner emphasizes, as he did in the preamble to the final regulation of December 24, 1974, that the proper remedy for any person who in the past has submitted to FDA data or information that he believes to be confidential, but which, under the final regulations, is included within a category that is subject to public disclosure, is to bring a declaratory judgment action contesting the validity of that portion of the regulations. All persons have been put on notice that records in the FDA files will be handled in accordance with these regulations. Notice to all affected persons of each request for records submitted by them or which identifies them or their products is, as stated in the preamble to the December 24, 1974 final regulation, "unnecessary as well as impracticable."

38. A number of comments contended that administrative due process would not be satisfied even if FDA, upon receipt of a request for records in the agency files, notified the submitter and all affected persons of an intended disclosure. These comments asserted that, in all instances of planned release, not only must notice be given, but the agency must provide the submitter an opportunity to consult with it and to present objections to the release, as well as an intra-agency appeal mechanism.

The Commissioner concludes, for the reasons stated in paragraph 37 of this preamble, that notice, an opportunity to consult with FDA and present objections, and an intra-agency appeal mechanism, as suggested in the comment, are unnecessary, impracticable, and not legally required.

39. Comments contended that it is anomalous that a person requesting access to agency records, if refused, has a clearly defined appeal procedure whereas the submitter and persons who might be affected by disclosure do not have assurance even of notice and an opportunity to be heard before release. It was argued that this places the submitter, with a potential property right in the requested data and information, in a procedurally inferior position to the party requesting the records, who clearly has no property interest in them.

The Commissioner advises that this is the procedure established by Congress in the FOIA. Congress has concluded that all documents submitted to the government become public property i.e., available to the public, subject to narrow exceptions, and has accordingly provided for a statutory right of appeal only by the requesting party.

40. Numerous comments contended that the assertion by the agency that the administrative burden or inconvenience of giving notice is too great was rejected in the case of *American Sumatra Tobacco Corp.* v. *SEC*, 93 F. 2d 236 (D.C. Cir. 1937). It was suggested that the agency assess submitters and affected persons the costs of sending notice.

The Commissioner has stated previously, in paragraph 96 of the preamble to the December 24, 1974 final regulation, that the general principles laid down in the *Sumatra* case have been fully satisfied. The *Sumatra* case does not require notice and an opportunity to consult in advance of every disclosure of privately generated information. This position was sustained in *PMA* v. *Weinberger*, 401 F. Supp. at 447–448. The Commissioner has also concluded in the preamble to the December 24, 1974 final regulation and elsewhere in this preamble that the FOIA does not require that notice be given to submitting persons or persons who might be affected by disclosure, and that such notice in all instances would be impracticable. The money that is generated by any fee under these regulations must be paid to the United States Treasury, and cannot be used by the agency to finance its public information services.

41. One comment contended that Congress, in enacting section 6(b)(1) of the Consumer Product Safety Act (15 U.S.C. 2055(b)(1)), reflected its intent that, at least with respect to the Consumer Product Safety Commission, "not less than 30 days prior to its public disclosure of any information obtained under this Act, or to be disclosed * * * in connection therewith * * * the Commission shall, to the extent practicable, notify, and provide a summary of the information to, each manufacturer or private labeler of any consumer product to which such information pertains * * *." The comment argued that this section represents a recent congressional statement on the advisability of advance notice to submitters and persons who might be affected by disclosure and that this procedure should be followed by FDA.

The Commissioner does not agree with this comment. Neither the FOIA nor the Federal Food, Drug, and Cosmetic Act contains provisions similar to section 6(b)(1) of the Consumer Product Safety Act. To the extent that section 6(b)(1) can be said to require notice to submitting persons and persons who might be affected by disclosure, its provisions are not applicable to FDA.

42. One comment pointed to the notice provisions of the public information regulations of the Environmental Protection Agency (40 CFR 2.105(b) and 2.107(a)) as a model for FDA to follow.

The Commissioner concludes that the notice provisions of the public information regulations of the Environmental Protection Agency are not required by the FOIA, and, given the number of requests received by FDA, adoption of a similar notice provision would be an unmanageable administrative burden that would impair the ability of the agency to adhere to the 10-day requirement for ruling on requests as mandated by the 1974 amendments to the FOIA and to carry out its important regulatory functions.

43. One comment requested that whenever FDA discloses records to special government employees under 21 CFR 4.84, other Federal departments or agencies under 21 CFR 4.85, State and local government officials under 21 CFR 4.88, and officials of foreign governments under 21 CFR 4.89, the person who submitted the information to FDA be given notice consisting of the date, actual content, and person to whom the disclosure was made.

The Commissioner advises that all the classes of persons referred to in the comment have a special status entitling them to the information, and they are prohibited from releasing data and information that is exempt from disclosure, such as trade secrets, in the same fashion and to the same extent as all employees of FDA. No purpose would be served by providing notice of the sort requested when disclosures are made in accordance with the regulations to persons in those categories.

44. Another comment asserted that under no circumstances should notice to affected persons be given because such notice permits the submitter to attempt to persuade FDA that the request should be denied, and the requestor has no similar opportunity to persuade the agency that the request should be granted.

The Commissioner does not agree with the position expressed in this comment. On the limited occasions when the confidentiality of a requested record is uncertain, consultation with the submitting person and other persons to obtain additional information related to the status of the record is essential if a proper determination is to be made by FDA. Consultation under § 4.45 (21 CFR 4.45) is not an opportunity for affected persons to persuade the agency, by argument alone, not to release the requested material. It is, rather, an opportunity for the agency to examine and consider additional data and information not otherwise available to it, which will be of assistance in making a correct determination respecting the confidentiality of the requested record.

JUDICIAL REVIEW OF PROPOSED DISCLOSURE

45. A number of comments stated that the 5 days provided in § 4.46 (21 CFR 4.46) within which to institute suit to enjoin the release of records is an inadequate period of time for affected persons to make the decision to seek an injunction and to prepare and file the appropriate pleadings. It was variously suggested that 10, 15, or 20 days, or 10 working days, be provided within which to institute suit. One comment suggested that 5 days be provided to notify FDA of the intent to sue and an additional 90 days within which to institute suit. If no court suit was initiated after 90 days, the comment suggested, FDA could then release the material.

The Commissioner concludes that the 5-day period is adequate time for the appropriate pleadings to be filed. The Commissioner notes that the complaint for injunction and supporting documents necessary to institute suit are simple and can easily be prepared in advance as standard legal pleadings and held ready should the occasion for their use arise. Legal counsel for several companies regulated by FDA have in fact publicly made the suggestion that the appropriate pleadings be prepared in advance. The Commissioner also notes that in the 4 years since the proposed rule making was published and documents released in accordance with its provisions, only one suit to enjoin disclosure of specific records has been instituted.

46. One comment objected to any time period for the institution of suit to enjoin the release of records and argued that once FDA determines to disclose records, those records should be made available immediately to the requesting party.

The Commissioner regards the provision of a limited time period for the institution of suit to enjoin the release of records when confidentiality is uncertain and FDA has determined to release the records as reasonable and consistent with the provisions of the FOIA and its mandate.

DENIAL OF REQUEST FOR RECORDS

47. Questions have arisen about the circumstances in which FDA will, under § 4.47(d) (21 CFR 4.47(d)), delete certain information from requested records without treating the deletions as a denial of the request. Concern has been expressed that persons making a request for records who subsequently receive records with certain information deleted may not always realize that deletions have been made or that they may appeal those deletions to the Assistant Secretary for Health, Department of Health, Education, and Welfare.

The Commisioner advises that it has been the consistent policy of FDA to treat substantial deletions of material from a record that is nevertheless disclosed as a denial and FDA has accordingly informed the person who made the request of his appeal rights. In order that there be no question about this policy, § 4.47(d) is revised to apply explicitly only to minor deletions of nondisclosable data and information from otherwise disclosable records.

The Commissioner further advises that the agency's policy with respect to minor deletions of nondisclosable data and information from disclosable records is to identify clearly such deletions on the record that is disclosed, but not to view such minor deletions as a withholding of the requested record. This policy is premised on three considerations. The majority of records in the files of FDA are disclosable to the public under the regulations. However, a large number of these clearly disposable records do contain small items of data and information that under the FOIA exemptions and the regulations, are exempt from disclosure. Deletions are, therefore, common.

For example, FDA receives many requests for adverse drug reaction reports that are submitted to the agency by physicians, hospitals, and drug manufacturers. In many cases, these reports contain the name and address of the patient who incurred the adverse reaction as well as the name and address of the physician or institution submitting the report. In order to protect the personal privacy of such persons, it is standard practice to delete the name and address as well as any other identifying details from adverse reaction reports. This policy is clearly stated in §§ 4.63 and 4.111 (21 CFR 4.63 and 4.111) and is unquestionably consistent with the sixth exemption of the FOIA (5 U.S.C. 552(b)(6)).

Deletions of this sort, minor in nature, ubiquitous, and clearly authorized by the FOIA, the regulations of HEW that implement the act (45 CFR 5.71(a)) and these regulations (§§ 4.63 and 4.111), have not been treated by the agency as denials. Furthermore, in the Commissioner's view, persons making requests to FDA for records ordinarily fully expect that minor deletions will, of necessity, be made and that their requests do not encompass the types of data and information that are regularly deleted before disclosure. This is particularly so because a large number of the FOI requests received by the agency are from persons who frequently make such requests and who are, no doubt, familiar with the agency's public information regulations and practices. Finally, under the 1974 amendments to the FOIA, agencies are required to disclose "[a]ny reasonably segregable portion of a record" after deleting exempt portions (5 U.S.C. 552(b)). It would be anomalous if Congress intended this amendment to result in denials of requests. It was obviously the intent of Congress that more disclosures would result, not more denials.

In view of these considerations, the Commissioner believes that the agency's policy regarding minor deletions is consistent with the FOIA. Nevertheless, to assure that all persons who request records from FDA fully understand the policy of the agency regarding minor deletions, the Commissioner has recently instituted a policy of including in every

letter of determination issued by the agency granting a request for records that, when disclosed, will contain minor deletions, a paragraph that (a) calls attention to the deletions; (b) states that the agency assumes that the deleted material was not intended to be covered by the request; (c) indicates that if the agency's assumption is erroneous, the person making the request should advise the agency that he or she does indeed desire to receive the deleted material; and (d) states that if the agency should then deny the requested additional information, a letter would issue that fully explains the appeal rights and procedure available to the person making the request. The Commissioner is confident that this policy will preclude any misunderstanding by persons requesting records from the agency when the records that are disclosed contain minor deletions.

USE OF PRIVATE CONTRACTOR FOR COPYING

48. A few comments requested that § 4.51 (21 CFR 4.51) be revised to provide that a private contractor will not be used for copying when a record contains disclosable and nondisclosable material unless the contractor agrees in writing not to disclose the material to anyone and adequate precautions are taken by FDA to guard against the loss of or failure to return records loaned for copying purposes.

The Commissioner concludes that the recommendation is unnecessary. Ordinarily records containing nondisclosable material will not be provided to a private contractor for copying. In the rare circumstance that this might occur, the safeguards suggested in the comment would be established as a matter of course.

INDEXING TRADE SECRET AND CONFIDENTIAL COMMERCIAL OR FINANCIAL DATA AND INFORMATION

49. A number of comments contended that, when suit is instituted challenging the denial of records or portions thereof on the basis of the exemption for trade secrets and confidential commercial or financial information, FDA may neither waive its obligation to itemize and index the disputed material nor require the intervention of the affected person. It was argued that requiring the intervention of the affected person would unfairly put smaller manufacturers at a disadvantage in that they might not be financially or physically able to itemize, index, and defend every suit involving the trade secret status of their material. It was suggested that the smaller manufacturer would have no choice but to defend only those suits involving large amounts of assertedly valuable trade secret material.

The Commissioner concludes, for the reasons stated in paragraph 73 of the preamble to the December 24, 1974 final regulation, that the requirement that the person who submitted the disputed documents index and itemize those documents and intervene to defend their trade secret status is an appropriate requirement. The Commissioner again emphasizes that, regardless of size, the affected person is in the best position to present a trade secret defense to the court.

Section 4.53 (21 CFR 4.53) is revised to state more clearly that the failure of the affected person to intervene to defend the exempt status of the records or, if the court requires, to itemize and index such disputed documents, will constitute a waiver of any trade secret defense, and FDA will promptly make the quested records available for public disclosure.

50. One comment contended that § 4.53 of the final regulations reflects a misconception on the part of FDA about the interests Congress was protecting in exempting trade secret and confidential commercial or financial information from disclosure. It was argued that the exemption is based on the recognition by Congress that there are both private and public interests to be served by protecting the confidentiality of trade secret and confidential commercial or financial information. It was asserted that, by proposing to waive its obligation to defend the trade secret status of disputed material, FDA does not appear to be aware of the public interest in protecting trade secret material from disclosure.

The Commissioner advises that FDA is cognizant of the congressional recognition that both public and private interests are served by protecting the confidentiality of trade secret and confidential commercial or financial information. The Commissioner, notes, however, that the private interests and benefits are greater than the public interest involved, and the burden of defending the status is appropriately borne by private interests who are in the best position to explain why data are valuable commercial secrets.

51. One comment suggested that the requirement in § 4.53 that the affected person itemize and index disputed trade secret material be retained but that a requirement that the affected person assist FDA in defending the trade secret status of the disputed material be substituted for the requirement of intervention by the affected person. It was also noted that, if a court declined to permit an affected person to intervene for some unknown reason, § 4.53 would allow the release of the disputed material.

The Commissioner concludes that there is no significant difference between requiring the person affected by disclosure to intervene in a suit to defend the trade secret status of the disputed information and requiring that an affected person assist FDA in defending such a suit. In either formulation of the requirement, FDA will insist upon formal intervention by the affected person and that, upon intervention, that person bear the burden of defense. The Commissioner advises that, in the extremely unlikely event that a court declines to permit intervention of an affected person, FDA will consider a request for an exception to the requirements of § 4.53 to the extent that the affected person could not, under the circumstances, formally intervene. All other obligations imposed upon the affected person by § 4.53 would remain in effect.

CLEARLY UNWARRANTED INVASIONS OF PERSONAL PRIVACY

52. Comments have asked whether the names of clinical investigators will generally be disclosed. A seeming inconsistency was noted between § 4.63(d) and §§ 314.14(e)(2)(i)(a) and 314.14(e)(4) (21 CFR 314.14(e)(2)(i)(a) and (e)(4)) in that § 4.63(d) appears to provide that the names of investigators will be disclosed, absent extraordinary circumstances, while §§ 314.14(e)(2)(i)(a) and 314.14(e)(4) appear to state that the names of investigators will not be disclosed. Paragraphs 117 and 241 of the preamble to the December 24, 1974 regulation, it was stated, also reflect this inconsistency.

The Commissioner advises that § 4.63(d) states that, as a general rule and in the absence of extraordinary circumstances, the names of individuals, including clinical investigators, will not be deleted from records before disclosure. Section 314.14(e)(2)(i)(a) applies to safety and effectiveness summaries for new drug applications (NDA's) approved prior to July 1, 1975. Those summaries consist of internal agency records that describe safety and efficacy data and information. The names of investigators and any information that identifies them will be deleted because, when those internal memoranda were prepared, there was no thought that they might ever be made public and comments were often included that would otherwise have been omitted if intended for public dissemination.

The names of, and any other information that would identify, third parties such as physicians, hospitals, investigators involved with adverse reaction reports, product experience reports, consumer complaints, and similar data and information voluntarily submitted to FDA will not be disclosed under § 314.14(e)(4). The names of investigators and any information that would identify them that is contained in an NDA file after an approval letter is sent will be disclosed as a part of safety and effectiveness summaries for new drugs approved after July 1, 1975, in accordance with § 4.63(d). Neither the names of investigators nor identifying information contained in an investigational new drug notice (IND) or NDA file will be disclosed before an approval letter is sent.

53. One comment noted a seeming inconsistency in that, although § 4.63(a) provides for the deletion of the names and information that would identify patients in medical and similar files and makes no mention of disclosure upon a showing of extraordinary circumstances, paragraph 103 of the preamble to the December 24, 1974 final regulation states that disclosure of the names and information is unwarranted except in extraordinary circumstances.

The Commissioner advises that the right of privacy of individuals is paramount and that FDA will not release the names and other information that would identify patients in medical and similar files, where such release would constitute a clearly unwarranted invasion of per-

sonal privacy. Section 4.82 (21 CFR 4.82) so provides. Upon further consideration, the Commissioner concludes that paragraph 103 of the preamble was in error, and should be revoked, to the extent that it stated that there would lie an "extraordinary circumstances" exception to this rule. The Commissioner anticipates no such exceptions.

54. Questions have arisen about the status of records relating to FDA investigations of clinical investigators. In particular, requests have been received for records concerning the disqualification of individual investigators, lists of all investigators who have ever been disqualified by FDA, and records relating to investigators who have been investigated by FDA but who were not disqualified.

The Commissioner advises that upon the completion of an investigation of a clinical investigator and any regulatory action that may ensue, e.g., a hearing under Subpart F of Part 2, published in the FEDERAL REGISTER of November 2, 1976 (41 FR 48258), records relating to the investigation, including most intra-agency memoranda, will be available to the public. Disclosure of records before the completion of the investigation would ordinarily interfere with the investigation; the records are therefore exempt under the seventh exemption of the FOIA (5 U.S.C. 552(b)(7)) and § 4.64 (21 CFR 4.64). The public, however, has a substantial interest in FDA investigations of clinical investigators; upon completion of an investigation, disclosure of the records is not a clearly unwarranted invasion of personal privacy. Records of the investigation that contain patient names and identifying details will be disclosed only after such information is deleted.

55. Questions have arisen about whether medical records or reports of adverse drug reactions are available to the subject of the records.

The Commissioner advises that medical records and adverse drug reaction reports are available to the individual who is the subject of the reports. Such records would not, under § 4.111(c)(3)(vi), be available to a third person without the written consent of the subject. However, an individual's privacy is obviously not invaded when he obtains his own medical records or adverse drug reaction report. The Commissioner notes, however, that FDA seldom obtains medical records, and has received only a few requests from persons for their own medical records. Section 4.111(c)(3)(vi) is revised to clarify this policy.

DATA AND INFORMATION PREVIOUSLY DISCLOSED TO THE PUBLIC

56. Comments asserted that the disclosure of trade secret information on a limited basis to physicians, veterinarians, or other health professionals for their use in caring for patients should not result in the loss of the confidentiality of the information. The comments argued that such limited disclosures would not prevent the company that disclosed the information from maintaining a suit against a competitor who had unlawfully obtained the same information and should therefore not be deemed by FDA to be disclosure to any member of the public.

The Commissioner advises that the substance of this comment was raised and fully discussed in several paragraphs of the preamble to the December 24, 1974 regulation. The Freedom of Information Act does not contemplate selective availability of records to the public. Trade secrets must either be protected as such by the owner or they will be disclosed by the agency. This position was upheld in the opinion of Judge Smith in *PMA* v. *Weinberger*, supra.

57. Comments suggested that data and information otherwise exempt from disclosure should not lose their confidential status by virtue of disclosure to "any" member of the public. As an alternative test, one comment suggested that the confidentiality of previously disclosed information be recognized by FDA unless the information had been disseminated to members of the public on a general basis so that the information is available generally to competitors. Another comment suggested that the appropriate test is whether good faith efforts to prevent widespread disclosure had been taken.

The Commissioner advises that use of either of the tests suggested in the comment would make decisions under the FOIA highly inconsistent and would require FDA to make an extensive ad hoc inquiry into the extent to which the information has been disseminated to the public, the extent of its availability to competitors, and the nature of the efforts taken to prevent widespread disclosure as well as a determination that those efforts were made in good faith. Such an approach is neither practicable nor contemplated by the law. The test provided for in § 4.81 (21 CFR 4.81) for determining whether the information has been disclosed to any member of the public is more practicable, can be applied consistently by the agency, and is fully consistent with the congressional mandate that records be disclosed unless they fall within the narrow exemptions specified.

58. One comment suggested that if previous disclosure to the public is asserted as the basis for disclosure of otherwise exempt material, the submitting person be given an opportunity to demonstrate that the disclosure, if in fact it occurred, was made with appropriate safeguards, was inadvertent or extremely limited in scope, or that in spite of the disclosure the information is not generally known outside of his business and is of appreciable value.

The Commissioner rejects this suggestion. If previous disclosure to the public is asserted as the basis for disclosure of otherwise exempt material, the only issue to be decided before a determination is made on the request is whether the initial disclosure was lawful. If it was, the records will be released. If the initial disclosure was unlawful and the material is exempt from disclosure, the request will be denied. In short, the circumstances surrounding the initial disclosure are relevent only insofar as they relate to the determination of whether the initial disclosure was lawful.

59. Questions have arisen about whether the disclosure of trade secret material to a foreign government as a condition for obtaining marketing approval constitutes disclosure to any member of the public within the meaning of § 4.81.

The Commissioner advises that disclosure to any Federal, foreign, State or local government or government official, on an official basis, does not constitute disclosure to any member of the public within the meaning of § 4.81.

60. A question has arisen about whether the disclosure of trade secret information regarding an investigational new animal drug notice or new animal drug application to inspectors of the Animal Plant Health Inspection Service, U.S. Department of Agriculture, or to a slaughter house in order to secure permission to slaughter animals for clinical research purposes, would result in the loss of the confidentiality of the information disclosed.

The Commissioner advises that the Animal and Plant Health Inspection Service is a governmental entity and that the disclosure of confidential information to it would not constitute disclosure to the public. Disclosure to a slaughter house in the situation described would be a necessary disclosure in the course of a routine business relationship within the meaning of § 4.81(a) and, if done with appropriate safeguards to minimize the extent of the disclosure, also would not constitute disclosure to the public.

61. In the FEDERAL REGISTER of March 4, 1976 (41 FR 9317), the Commissioner amended § 4.81 by adding a new paragraph (a)(3). The amendment, which was made effective immediately, codified existing FDA practice and clarified § 4.81 to state explicitly that disclosures to clinical investigators and institutional review committees do not result in a loss of confidentiality for the information disclosed.

DISCRETIONARY DISCLOSURE BY THE COMMISSIONER

62. A few comments asserted that there is no statutory basis for the discretionary disclosure of information by the Commissioner as provided for in § 4.82. (21 CFR 4.82). It was suggested that, if this provision is retained, provision be made for judicial review of the FDA decision to disclose the information before any disclosure is made.

The Commissioner concludes that there is no support in the FOIA for accepting this comment. With the exceptions of trade secret material protected from disclosure by section 301(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)) and 18 U.S.C. 1905 and records the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, the statutory exemptions are permissive. Agencies and departments subject to the FOIA may decide not to disclose exempt material; they are not required to withhold it. The statute expressly commits to the discretion of

the Commissioner, as the head of the agency, the decision whether exempted material should be disclosed.

63. One comment noted the apparent absence of any standards or guidelines for the exercise of discretionary disclosure by the Commisisoner and asserted that, without such standards or guidelines, any discretionary disclosures by the Commissioner would constitute unreasonable and arbitrary administrative action.

The Commissioner advises that the FOIA clearly embodies the concept of discretionary disclosure and contains no standards for the exercise of that discretion. This is a matter that is committed by law to the discretion of the Commissioner. It would be consistent with the FOIA for the Commissioner to decide that all material covered by one of the exemptions in that act should be disclosed under all circumstances, except when the material is prohibited from disclosure by section 301(j) and 18 U.S.C. 1905. Having decided not to adopt that alternative, it is clearly within the Commissioner's prerogative to make discretionary disclosures of material otherwise exempt from mandatory disclosure when he determines that disclosure would be in the public interest and release is not otherwise prohibited by law.

64. Questions have arisen about whether there are any circumstances in which a consultant, i.e., a special government employee, may submit written comments to FDA with respect to a pending matter published in the FEDERAL REGISTER, e.g., a proposal or petition, without having those comments placed on display in the office of the Hearing Clerk with all other written comments.

The Commissioner advises that, as a general rule, the written comments of special government employees on any pending matter published in the FEDERAL REGISTER will be placed on display in the office of the Hearing Clerk along with all other comments. This policy was stated in paragraph 128 of the preamble to the December 24, 1974 regulations.

In one particular circumstance, however, the Commissioner has decided that the written comments of a special government employee will not be placed on public display in the office of the Hearing Clerk. Whenever a matter that has appeared in the FEDERAL REGISTER is specifically referred to a consultant for consideration as part of his official duties as a consultant, the consultant may submit his comments to the agency without the necessity that they be placed on public display in the office of the Hearing Clerk. This is true whether the consultant is a member of an advisory committee or is an ad hoc consultant. Nondisclosure of such comments is justified by the exemption for inter- and intra-agency memoranda under 5 U.S.C. 552 (b)(5).

Comments received from consultants who have not been specifically and officially requested to comment will remain subject to the provisions in paragraph 128, i.e., the comments will be placed on display with all other comments.

DISCLOSURE IN ADMINISTRATIVE OR COURT PROCEEDINGS

65. Minor clarifying amendments are made in § 4.86 (21 CFR 4.86).

COMMUNICATIONS WITH STATE AND LOCAL GOVERNMENT OFFICIALS

66. One comment contended that all communications between FDA and State or local government officials not under Commission or contract to FDA that pertain to the development of uniform Federal-State enforcement policies should be exempt from disclosure for the duration of the deliberations on uniform policies, or longer, if so requested by a participating State or local government official. Other comments supported the provisions in § 4.88 (21 CFR 4.88) for the exchange of certain information between Federal, State, and local officials on a confidential basis.

The Commissioner concludes that § 4.88 ordinarily provides adequate protection to maintain the confidentiality of communications between Federal, State and local officials and need not now be changed. The Commissioner is confident that § 4.88 will permit, as some comments have noted, government officials on all levels to communicate in confidence on law enforcement matters as necessary to fulfill their respective responsibilities to the public.

ADMINISTRATIVE ENFORCEMENT RECORDS

67. One comment objected to the availability for disclosure to any member of the public of records relating to administrative enforcement action at the time disclosure is first made. Fundamental fairness, it was said, dictates that the person who is the subject of the administrative enforcement action be given an opportunity to receive the records before they are made available to the public generally. It was suggested that the records be sent by registered mail, return receipt requested, to the person who is the subject of the action and that no subsequent disclosures be made until FDA receives the return receipt.

The Commissioner concludes that the recommendation is too cumbersome to administer and would significantly add to the already complex recordkeeping duties necessary for ensuring compliance by the agency with the FOIA. Moreover, it is not permissible under the FOIA to distinguish between persons in determining whether records are available for disclosure.

68. One comment objected to the availability for public disclosure of Forms FD-483 and FD-2275 (lists of observations made during food and drug plant inspections) before the availability of the establishment inspection report (EIR). The comment stated that the factual information generally contained in Forms FD-483 or FD-2275 is the same as that in the EIR and that availability of such information may deprive persons of a fair trial or impartial adjudication.

The Commissioner concludes that any possible effect on a person's right to a fair trial or impartial adjudication caused by the release of Forms FD-483 or FD-2275 before the availability of the EIR is too remote and speculative to warrant a revision of the regulations. Those forms are given to the company that has been inspected and accordingly must be made available to the public contemporaneously with the initial disclosure.

FOOD AND DRUG ADMINISTRATION MANUALS

69. Paragraph 193 of the preamble to the December 24, 1974 final regulation contained a partial list of FDA manuals available to the public and a statement that "copies of these manuals may also be purchased at cost." Paragraph 193 also contained a statement that FDA does not maintain a mailing list for amendments to these manuals because of the prohibitive expense involved.

A substantial portion of the FOI requests received by FDA during fiscal years 1975 and 1976 were for FDA manuals. Additionally, because many of those manuals are frequently amended, many requests for the amendments have been received and, in a few instances, mailing lists maintained. The Commissioner is reconsidering the present agency policy of not generally maintaining mailing lists for amendments to FDA manuals and will soon explore various alternative mechanisms for maintaining mailing lists.

Additionally, the Commissioner believes that it would be useful, efficient, and in the public interest to develop a more expeditious system for making manuals available and maintaining mailing lists for them. The Commissioner has therefore initiated discussions with the National Technical Information Service (NTIS) in Springfield, Virginia, to determine whether NTIS could provide FDA manuals to the public promptly and at a reasonable cost and also maintain mailing lists for those manuals. The preliminary discussions between NTIS and FDA have been encouraging, and the Commissioner is confident that a satisfactory arrangement will be worked out in the very near future. The details of such an arrangement will be announced in the FEDERAL REGISTER. In the meantime, FDA manuals will continue to be available to the public from the FDA Public Records and Documents Center.

DATA AND INFORMATION OBTAINED BY CONTRACT

70. Questions have arisen as to whether cost and technical proposals submitted to the agency in response to a request for proposals will be disclosed.

The Commissioner concludes that all cost proposals and technical proposals that are not accepted by FDA are exempt from disclosure as confidential commercial or financial information. When a contract is awarded, however, there is generally no competitive advantage associated with any portion of the technical proposal of the successful contractor, and it will be available for public disclosure except to the extent that specific portions of the technical proposal are exempt from disclosure as trade

secrets or confidential commercial information under § 4.61. Section 4.109 (21 CFR 4.109) has been revised by the addition of a new paragraph to state this policy.

71. Paragraph 196 of the preamble to the December 24, 1974 final regulation stated that "all information obtained by the Food and Drug Administration through a contract is available for public disclosure * * *." Questions have arisen about the validity of contractual agreements entered into between FDA and outside organizations before the effective date of these regulations (January 23, 1975) that provide that no data and information obtained pursuant to the contract be disclosed to persons outside the agency.

The Commissioner advises that all such contractual agreements containing nondisclosure clauses will be honored by FDA except to the extent that a court orders otherwise.

72. Questions have arisen about whether there are any circumstances in which information may be purchased by FDA from an outside organization under a contract that precludes further dissemination. Reference was made to § 4.109 (21 CFR 4.109), which provides, without distinction, that "all data and information obtained by the Food and Drug Administration by contract * * * are available for public disclosure * * *" unless independently exempt, and to paragraph 196 of the preamble to the December 24, 1974 final regulations, which provides that "the Commissioner concludes that the Freedom of Information Act does not permit the Food and Drug Administration to purchase information under a contract that prohibits its further public distribution, unless the information is otherwise exempt from disclosure."

The Commissioner has reexamined this policy and concludes that a distinction should be made between the situation in which the agency is the sole purchaser of information and the one in which the agency is but one of a number of purchasers or subscribers, each of whom must agree not to distribute the information further as a condition for buying it. Reports obtained by contract from private organizations that are in the business of preparing and selling the reports with clauses restricting further dissemination to protect the value of the product can properly be considered the "stock-in-trade" of such firms. The fourth exemption under the Freedom of Information Act (5 U.S.C. 522(b)(4)) may be invoked to protect the reports from disclosure to the public. Disclosure would obviously destroy the value of the reports to the outside organization and a policy requiring disclosure seriously impairs the agency's ability to obtain the information, because outside organizations have refused and will continue to refuse to accept FDA as a purchaser. Both *Benson* v. *GSA*, 289 F. Supp. 590 (W.D. Wash.), aff'd, 415 F.2d 878 (9th Cir. 1968) and *National Parks and Conservation Assn.* v. *Morton*, 498 F.2d 765 (D.C. Cir. 1974) support this distinction.

73. Questions have arisen about whether the disclosability of results of testing and research conducted with agency funds by an outside organization pursuant to a contract is governed by § 4.105 (21 CFR 4.105) or § 4.109 (21 CFR 4.109).

The Commissioner advises that to the extent that a contract calls for data and information covered by § 4.105 as well as by § 4.109, disclosability of the data and information will be determined in accordance with § 4.105(c).

74. One comment requested that acceptance of a report for purposes of § 4.109 be defined as the point at which FDA begins to use the report for policy, enforcement, or other purposes.

The Commissioner advises that in some instances a report may be officially accepted before FDA begins to use it for policy, enforcement, or other purposes. Because of that possibility, no change is warranted in § 4.109.

SAFETY, EFFECTIVENESS, AND FUNCTIONALITY DATA AND INFORMATION CONTAINED IN COLOR ADDITIVE, FOOD ADDITIVE AND ANTIBIOTIC DRUG PETITIONS AND FORMS

75. Comments contended that the availability to the public of safety and functionality data contained in color and food additive petitions when the notice of filing of the petition is published in the FEDERAL REGISTER will deprive the petitioner of the competitive advantage from "lead" time that he might have over other manufacturers. It was argued that this lead time could be very significant because the final order approving a color or food additive petition is generally not issued until several years after the petition is filed.

The Commissioner concludes that the notice of filing of the color or food additive petition itself destroys any competitive advantage from lead time that the petitioner might have over other manufacturers. The Commissioner rejects the suggestion in this comment for the additional reasons stated in paragraph 235 of the preamble to the December 24, 1974 final regulation.

76. Comments contended that safety and functionality data and information contained in color and food additive petitions that are not promptly filed due to deficiencies should not be made available for public disclosure after the review of the submission by FDA is complete and the petitioner informed of the deficiencies as provided in §§ 8.9(a) and 121.51(h)(1) (21 CFR 8.9(a) and 121.51(h)(1)). It was argued that the public interest is not served by disclosure at that time. The result, it was asserted, is solely disclosure to competitors of the interest of the petitioner in the color or food additive at a time when the status of the substance is not formally before FDA for consideration. It was suggested that safety and functionality data and information in a deficient petition that is not filed should not be made available for public disclosure if the petitioner indicates that he intends, within a reasonable period of time, to endeavor to correct the deficiencies.

The Commissioner concludes, as stated in paragraph 235 of the preamble to the December 24, 1974 regulation, that such records are properly disclosed after initial agency review. Such records provide no competitive advantage at that time and thus are not exempt from disclosure.

77. A few comments asserted that it was improper to make safety and functionality data contained in color and food additive petitions available to the public at the time the notice of the filing of a petition appears in the FEDERAL REGISTER. The preamble to the December 24, 1974 final regulation had noted that such data and information are frequently published in scientific journals and are not customarily regarded as privileged. The proper test, the comment argued, is whether the data and information in a particular petition have in fact been published in scientific journals and whether the petitioner regards and treats the data and information as privileged.

The Commissioner advises that a similar comment was fully discussed in paragraph 89 of the preamble to the December 24, 1974 final regulation. The Commissioner noted there that, if the test proposed in this comment were adopted, "decisions under the Freedom of Information Act would be highly inconsistent and would require the Food and Drug Administration to conduct an ad hoc inquiry into the way that each manufacturer handles documents submitted to the agency. Such an approach is neither practicable nor contemplated by the law."

78. Comments objected to the availability to the public of safety and effectiveness data contained in an antibiotic drug file when an approval letter is sent to the sponsoring manufacturer by FDA. The comments contended that such full disclosure permits the "latecomer" to benefit from the skills and diligence of an innovator who may have expended considerable research and development funds in obtaining the data and information. Disclosure of the safety and effectiveness data, it was said, would discourage research by denying to the innovator the full benefits to his skills and diligence and would enable competitors to obtain marketing approval in foreign markets in direct competition with the innovator at an earlier point than would be possible were the data and information not revealed until a monograph was published.

The Commissioner does not agree with these comments. In the past, monographs have sometimes not been published in the FEDERAL REGISTER for 2 or 3 years after an approval letter was sent. The holder of the approval letter has been permitted to market the antibiotic during that period on a "release" status, pending publication of the monograph, at which time other manufacturers would have access to the data necessary to manufacture the antibiotic. The Commissioner notes that permitting marketing during this release period has had the effect of providing a competitive advantage through an exclusive license to the holder of the approval letter when no such licensure is contemplated by the statutory scheme.

The creation of this advantage, by permitting marketing during release status, is attributable solely to delays in promulgating monographs and the desire of FDA to make the antibiotics involved available to the public as soon as possible. Steps will be taken by FDA to develop procedures that will resolve this problem by assuring the publication of the monograph on a date substantially contemporaneous with the sending of the approval letter. Accordingly, the Commissioner concludes that the FOIA requires that the safety and effectiveness data and information be available upon the sending of an approval letter.

SAFETY AND EFFECTIVENESS DATA FOR NEW DRUGS OR NEW ANIMAL DRUGS

79. One comment asserted that FDA has not previously treated safety and effectiveness data for new drugs derived from studies performed on animal and human subjects under an investigational new drug notice (IND) or NDA as trade secret material and should not now, for FOIA purposes, begin to do so.

The Commissioner advises that this comment is not an accurate statement of the policies followed in the past by FDA. On the contrary, FDA has since 1938 interpreted section 301(j) of the act (21 U.S.C. 331(j)) as encompassing those data. This longstanding agency policy was fully discussed in paragraph 255 of the preamble to the December 24, 1974 final regulation.

80. Questions have arisen regarding the status of confidential data or information submitted to FDA before the filing of an IND by the potential sponsor in connection with an informal conference between representatives of the sponsor and FDA. It was suggested that such pre-IND submissions be incorporated into the IND, if later filed, and treated accordingly or, alternatively, that they be treated as voluntary submissions covered by § 4.111 and subject to presubmission review in accordance with § 4.44.

The Commissioner advises that data and information submitted to FDA before the filing of an IND by the sponsor are considered a part of the IND file if the IND is subsequently submitted, and they will be treated in the same manner as other data contained in the IND file.

81. Questions have arisen about whether data and information on investigational indications or dosage forms for an approved new drug are available for disclosure if such indications and dosage forms are being actively investigated under an IND.

The Commissioner advises that data and information about dosage forms and indications investigated under an IND or NDA will not be disclosed unless the ongoing testing is already publicly known, notwithstanding the fact that an approved NDA exists for different dosage forms and/or indications involving the same drug product.

82. Questions have arisen about whether data and information in an NDA file relating to an abandoned product or ingredient respecting manufacturing methods or processes, production, sales, distribution and similar data or information, and quantitative or semiquantitative formulas are exempt from disclosure under § 314.14(g) (21 CFR 314.14(g)) unless it is determined that such data and information no longer represent trade secret or confidential commercial or financial information, or whether such data and information are available to the public upon the abandonment of the product or ingredient. It was suggested that such data and information not be made available to the public unless a determination is made that they no longer represent trade secret or confidential commercial information as defined in § 4.61 (21 CFR 4.61).

The Commissioner advises that the data and information are available if the product or ingredient is finally abandoned unless the abandoned product or ingredient directly affects another product or ingredient. Data and information of the sort referred to by the comment are not by definition trade secret or confidential commercial or financial information if contained in an abandoned NDA file, except when the information directly affects another product or ingredient.

83. One comment supported the release, as a part of the summary of safety and effectiveness data and information, of the medical officer's reports and requested that the regulations state that such reports will continue to be released after July 1, 1975. The comment also requested that the summaries now prepared by Bureau of Drugs personnel for internal review be included in the summaries of safety and effectiveness data and information made available to the public.

The Commissioner advises that the medical officer's report and any summaries prepared by Bureau of Drugs personnel are available as part of the summaries of safety and effectiveness data and information only for drugs approved before July 1, 1975. For drugs approved after that date summaries of safety and effectiveness data and information are specially prepared in accordance with § 314.14. Thereafter, disclosure of the medical officer's report or other internal agency records will be denied based upon the FOIA exemption for intra-agency memoranda.

84. One comment contended that withdrawal of an NDA or abandonment of a product ingredient as a result of adverse findings by an over-the-counter (OTC) drug review panel should constitute per se an "extraordinary circumstance" that warrants exemption from disclosure of material concerning the NDA or ingredient.

The Commissioner advises that the regulations do not include a definition of "extraordinary circumstance," and that the term embraces those rare and essentially unforeseeable situations that justify the nondisclosure of material that would otherwise be available to the public. The determination of an extraordinary circumstance must, of necessity, be made on a case-by-case basis.

The Commissioner is not aware of any justification for treating data and information in an NDA file or data and information related to a product ingredient that has been withdrawn or abandoned because of adverse findings by an OTC drug review panel differently from data and information in withdrawn NDA files or data and information related to product ingredients withdrawn or abandoned for other reasons.

85. Questions have arisen concerning the status of the contents of a master file which, pursuant to permission given by the basic manufacturer, is referenced by an investigator working under an independent IND, when the investigator subsequently abandons the IND.

The Commissioner advises that the referenced master file would not be disclosable to the public upon the termination of the independent IND. The data and information in the abandoned or terminated IND file, however, would be available for public disclosure in accordance with § 314.14(f), unless that IND directly affects another IND or NDA.

86. One comment asked which portions of § 314.14 of the final regulations apply to IND files and which portions apply to NDA files.

The Commissioner advises that the provisions of § 314.14 apply in their entirety to IND files, subject to the following limitations: (1) If the existence of an IND has not been publicly disclosed or acknowledged, no data or information in the file will be disclosed by FDA. (2) If an IND file's existence has been publicly disclosed or acknowledged, FDA will, upon request, confirm the existence of the IND. The Commissioner, in this circumstance, may, in his discretion, release a summary of selected portions of the safety and effectiveness data contained in the IND file, e.g., for discussion by an advisory committee. (3) Upon the filing or approval of an NDA, although the IND is technically terminated or discontinued, the material in the IND has the same status as the material in the NDA and is subject to disclosure in accordance with the provisions of § 314.14. (4) If an IND is finally terminated or abandoned, however, as a result, for example, of adverse animal findings, all safety and effectiveness data and information are available for public disclosure in accordance with § 314.14(f). (5) If the termination is temporary and the sponsor of the IND is working to reactivate the file, the safety and effectiveness data retain their confidential status.

87. A number of comments asked what information regarding an IND or pending NDA will be released by FDA when the existence of the IND or pending NDA has been publicly disclosed or acknowledged, whether by disclosure to a member of the public, discussion with outsiders, marketing of the drug abroad, or appearance of published literature on the drug.

The Commissioner reemphasizes that FDA will, upon request, disclose information concerning the IND or pending NDA only to the extent that such infor-

mation has been previously disclosed. In other words, once the existence of an IND or pending NDA has been disclosed or acknowledged, FDA will no longer pretend that the IND or NDA does not exist. In confirming the existence of the IND or NDA the agency will not release any data or information in the files if the data or information itself has not been previously disclosed or acknowledged, unless the Commissioner, in his discretion, decides to release a summary of such selected portions of the safety and effectiveness data as are appropriate for public consideration of a specific pending issue, e.g., at an open session of an advisory committee or pursuant to an exchange of important regulatory information with a foreign government. Prior disclosure of otherwise exempt data and information triggers the release by FDA of only that information already released.

88. A question was raised about whether the existence of a supplemental NDA is considered confidential if the existence of the file has not been publicly disclosed or acknowledged.

The Commissioner advises that a supplemental NDA for a new use will be treated in the same manner as an IND or NDA, that is, its existence will not be disclosed by FDA unless the existence of the application has previously been publicly disclosed or acknowledged. A supplemental NDA that is technical, e.g., one filed to reflect a reformulation to remove an ingredient such as FD&C Red No. 2, is not confidential.

89. One comment noted that the list of available computer printouts in § 4.117 (21 CFR 4.117) does not include printouts of investigational new animal drug (INAD) and new animal drug application (NADA) data and information. It was suggested that the availability of such information be specifically noted in § 4.117.

The Commissioner advises that the data and information respecting NADA's have been and will continue to be published in the FEDERAL REGISTER. Thus, there is no reason to make computer printouts available. There is no computer program currently in existence that would permit the retrieval of the INAD data and information.

90. Comments contended that studies and tests on drugs for identity, stability, purity, potency and bioavailability are an integral part of quality control procedures and are not a part of safety and effectiveness data. It was suggested that § 314.14(i) be revised to exempt such studies and tests from public disclosure.

The Commissioner concludes that although the studies and tests referred to may be considered by a pharmaceutical company conducting them as part of its quality control procedures, the results of those tests have a direct bearing on the safety and effectiveness of the drug product involved, e.g., a subpotent, impure, or unstable drug may be unsafe or less effective than anticipated relative to an identical drug product that is potent, pure, and stable. Such tests are accordingly properly classified, for purposes of these public information regulations, as safety and effectiveness data and information. Summaries are therefore available to the public.

91. A large number of comments duplicated previous objections to the disclosure of safety and effectiveness data and information contained in IND or NDA files. These comments were fully discussed and disposed of in the premable to the December 24, 1974 final regulations. These include comments about the situation in which the termination of one IND or NDA and disclosure of data and information relating to it may affect another IND or NDA that has not been terminated—discussed in paragraph 260 of that premable; the adverse effect of the release of safety and effectiveness data on competition in foreign markets—discussed in paragraphs 245 and 269 of that preamble; the Commissioner's conclusion that safety and effectiveness data in abandoned, unapprovable, or withdrawn NDA's, or those for which a determination has been made that the drug product is not a new drug or that the drug may be marketed without submission of safety and/or effectiveness data and information, will be available for public disclosure—discussed in paragraphs 267 through 272 of that preamble; the determination that the existence of an IND notice will not be regarded as confidential if the drug is marketed abroad or if published literature exists on the drug—discussed in paragraph 240 of that preamble; and the contention that the manufacturer should have the final say on the contents of all summaries of safety and effectiveness data—discussed in paragraph 260 of that preamble.

92. In the FEDERAL REGISTER of March 4, 1976 (41 FR 9317), the Commissioner amended § 314.14(f) to correct an inadvertent omission. Before the amendment, paragraph 269 of the preamble to the December 24, 1974 final regulation contemplated, but § 314.14(f) did not expressly provide for, nondisclosure of safety and effectiveness data and information in abandoned, terminated, or withdrawn IND's or NDA's if extraordinary circumstances were shown. The "extraordinary circumstances" language was also inadvertently omitted from § 514.11(f) (21 CFR 514.11(f)), the new animal drug counterpart to § 314.14(f), and was not added by the March 4, 1976 amendment. Accordingly, § 514.11(f) is amended to correct the inadvertent omission.

A PROTOCOL FOR A TEST OR STUDY

93. Several comments asserted that protocols for tests or studies reflect years of experience in a particular field, offer a competitive advantage, are customarily held in confidence by members of the industry, and should therefore be treated as trade secrets.

The Commissioner concludes that, as a general rule, protocols for tests or studies are not properly regarded as trade secrets. However, protocols for tests or studies may be regarded as trade secrets if the facts in a specific case warrant such a conclusion. Without attempting to list all the relevant factors, the Commissioner notes that those factors include the cost involved in developing the protocol, the extent to which the protocol is unique, as well as other criteria contained in the "Restatement Comment" definition of trade secret and discussed in paragraph 81 of the preamble to the December 24, 1974 final regulation.

ADVERSE REACTION REPORTS

94. One comment agreed that reports of adverse reactions in an IND file should be provided on request to individuals participating in a study involving an IND, as provided in § 312.5(c) (21 CFR 312.5(c)). It was contended, however, that adverse reaction reports on IND's should also be available to clinical investigators, physicians, and other health professionals. It was argued that these individuals need such reports to evaluate properly research projects involving particular drug products and in caring for patients. It was also asserted that release of adverse reaction reports on IND's would encourage manufacturers to be honest in informing investigators when investigations are terminated because of adverse results instead of the alleged current practice of attributing such termination to "commercial" reasons.

The Commissioner notes that, pursuant to § 312.1(a)(6) (21 CFR 312.1(a)(6)), the regulations governing investigational new drugs, the sponsor of the drug is required to report promptly to all investigators "any findings associated with use of the drug that may suggest significant hazards, contraindications, side-effects and precautions pertinent to the safety of the drug." Accordingly, the Commissioner concludes that it is not necessary, and would be superfluous to make such reports available to investigators under the FOIA. Any information that the agency receives is required also to be in the possession of all investigators.

PRODUCT INGREDIENTS

95. Questions have arisen about the status under these regulations of certain product formulation information for packaging materials for use with various products, including drugs. Two specific questions have been raised: (1) Will quantitative or semiquantitative formulas for drug-packaging materials submitted to FDA as part of a master file for use with one or more NDA's be available to the public; and (2) will qualitative formulas, i.e., the names of the chemical components of drug-packaging materials, submitted to FDA as part of a master file for use with one or more NDA's be available to the public.

The Commissioner concludes that quantitative and semiquantitative formulas for drug-packaging materials qualify as trade secrets under § 4.61 and thus are exempt from disclosure. Likewise, qualitative formulas for drug-packaging materials are exempt from disclosure under § 4.61.

ASSAY METHOD OR OTHER ANALYTICAL METHOD

96. One comment stated that the regulations are not clear about when an assay or analytical method serves no regulatory or compliance purpose. It was suggested that § 314.14(e)(6) be revised to provide that assay or analytical methods would be available after an approval letter is sent unless the method constitutes a trade secret as defined in § 4.61.

The Commissioner advises that assay or analytical methods, by their nature, are ordinarily devised and disseminated specifically for regulatory or compliance purposes. As was stated in paragraph 288 of the preamble to the December 24, 1974 final regulation, assay and analytical methods are available to and used by a large number of persons, including regulatory officials on the Federal, State, and local level to ensure compliance with the law. They do not provide a competitive advantage for one manufacturer over another. Accordingly, they will be disclosed as a matter of course, with the narrow and rare exception that an assay or analytical method that is not used for any regulatory function whatsoever, that is, one that is not used by anyone to ensure compliance with the law, will be exempt from disclosure unless the method has been previously made available to any member of the public within the meaning of § 4.81.

MANUFACTURING METHODS OR PROCESSES INCLUDING QUALITY CONTROL PROCEDURES

97. Clarification has been requested of the Commissioner's statement in paragraph 290 of the preamble to the December 24, 1974, final regulation that "a company's manufacturing methods and processes, quality control procedures, and quantitative formulas are per se exempt from disclosure unless previously disclosed or later abandoned * * *."

The Commissioner advises that the phrase "per se exempt" was used to indicate that manufacturers need not, as had been proposed, routinely submit a statement to FDA concerning prior disclosure or abandonment of manufacturing methods and processes, quality control procedures, and quantitative formulas. However, information is not automatically exempt from disclosure merely because it is denominated by the manufacturer as, for example, a quality control procedure. Furthermore, manufacturing methods and processes and quality control procedures in particular are available to the public where, for example, the method, process or procedure is described in the literature. It is not unusual to find a detailed description of a manufacturing method in a standard reference book. In such a situation, a claim of confidentiality for the information is unsupported.

BIOLOGICAL DRUGS

98. A few comments contended that safety and effectiveness data and information for biologics should be accorded the same status as similar data and information for new drugs under § 314.14.

The Commissioner concludes that this comment has been fully discussed and disposed of in paragraph 302 of the preamble to the December 24, 1974 final regulation. The comments presented no new information and raised no new issues warranting further discussion.

RADIATION CONTROL FOR SAFETY AND HEALTH ACT OF 1968

99. The Food and Drug Administration, through its Bureau of Radiological Health, enforces the Radiation Control for Safety and Health Act of 1968. Under that act, and implementing regulations, manufacturers are required to submit several different types of reports to FDA, e.g., initial and annual reports under §§ 1002.10 and 1002.11 (21 CFR 1002.10 and 1002.11).

The Commissioner advises that the reports and records maintained by the Bureau of Radiological Health are under review to determine their status generally under the FOIA. Upon completion of that review, a notice of proposed rule making will be published in the FEDERAL REGISTER setting forth proposed amendments to these regulations to state, as has already been done for most other agency records, the status of the records under the FOIA.

MEDICAL DEVICES AND DIAGNOSTIC PRODUCTS

100. The Medical Device Amendments of 1976 (Pub. L. 94-295) amending the Federal Food, Drug, and Cosmetic Act provide substantial new authority to FDA to regulate medical devices and diagnostic products. The Food and Drug Administration will be receiving many new types of reports and information about those products as a result of the amendments. These reports and records will be reviewed to determine their status under the FOIA. Upon completion of that review, a notice of proposed rule making will be published in the FEDERAL REGISTER setting forth proposed amendments to these regulations to state the status of the records under the FOIA.

This final order was proposed prior to Executive Order 11821, requiring agencies in the executive branch to review regulatory and legislative proposals they initiate for inflation impact, and so does not require inflation impact review.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 201 et seq., 52 Stat. 1040 et seq. as amended; (21 U.S.C. 321 et seq.)), the Public Health Service Act, (sec. 1 et seq., 58 Stat. 682 et seq., as amended (42 U.S.C. 201 et seq.)), and the Freedom of Information Act (Pub. L. 90-23, 81 Stat. 54-56 as amended by 88 Stat. 1561-1565 (5 U.S.C. 552)) and under authority delegated to the Commissioner (21 CFR 5.1) (recodification published in the FEDERAL REGISTER of June 15, 1976 (41 FR 24262)), Chapter I of Title 21 of the Code of Federal Regulations is amended as follows:

PART 4—PUBLIC INFORMATION

1. In § 4.40 by revising paragraphs (a) and (c) to read as follows:

§ 4.40 **Filing a request for records.**

(a) All requests for Food and Drug Administration records shall be filed in writing by mailing the request or delivering it to the Public Records and Documents Center (HFC-18), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, Maryland 20857. Requests should state in a prominent place on the envelope containing the request, if any, and on the request itself, "FOI request."

* * * * *

(c) Upon receipt of a request for records, the Public Records and Documents Center shall enter it in a public log. The log shall state the date received, the name of the person making the request, the nature of the records requested, the action taken on the request, the date of the determination letter sent pursuant to § 4.41(b) and the date(s) any records are subsequently furnished.

* * * * *

2. In § 4.42 by revising paragraphs (a)(4) and (5) to read as follows:

§ 4.42 **Fees.**

(a) * * *

(4) *Clerical searches.* $3.00 for each hour spent by clerical personnel searching for and producing a requested record, including time spent copying any record.

(5) *Nonclerical searches.* $3.00 for each hour spent by professional or managerial personnel searching for and producing a requested record, including time spent copying any record.

* * * * *

3. In § 4.47 by revising paragraph (d) to read as follows:

§ 4.47 **Denial of request for records.**

* * * * *

(d) Minor deletions of nondisclosable data and information from disclosable records shall not be deemed to be a denial of a request for records.

4. By revising § 4.53 to read as follows:

§ 4.53 **Indexing trade secrets and confidential commercial or financial information.**

Whenever the Food and Drug Administration denies a request for a record or portion thereof on the grounds that the record or portion thereof is exempt from public disclosure as trade secret or confidential commercial or financial data and information under § 4.61, and the person requesting the record subsequently contests the denial in the courts, the Food and Drug Administration will so inform the person affected, i.e., the person who submitted the record, and will require that such person intervene to defend the exempt status of the record. If a court requires the Food and Drug Administration to itemize and index such records, the Food and Drug Administration will so inform the person affected and will require that such person under-

take the itemization and indexing of the records. The failure of the affected person to intervene to defend the exempt status of the records and to itemize and index the disputed records will constitute a waiver by such person of such exemption, and the Food and Drug Administration will promptly make them available for public disclosure.

5. By revising § 4.86 to read as follows:

§ 4.86 Disclosure in administrative or court proceedings.

Data and information otherwise exempt from public disclosure may be revealed in Food and Drug Administration administrative proceedings pursuant to Part 2 of this chapter or court proceedings, where the data or information are relevant. The Food and Drug Administration will take appropriate measures, or request that appropriate measures be taken, to reduce disclosure to the minimum necessary under the circumstances.

6. In § 4.100 by revising paragraph (c) (6), to correct the cross-reference to read as follows:

§ 4.100 Applicability; cross-reference to other regulations.

* * * * *

(c) * * *

(6) Information on thermal processing of low-acid foods packaged in hermetically sealed containers, in § 90.20(1) of this chapter.

7. In § 4.109 by redesignating the existing text as § 4.109(a) and adding a new paragraph (b); as revised, § 4.109 reads as follows:

§ 4.109 Data and information obtained by contract.

(a) All data and information obtained by the Food and Drug Administration by contract, including all progress reports pursuant to a contract, are available for public disclosure when accepted by the responsible agency official except to the extent that they remain subject to an exemption established in Subpart D of this part, e.g., they relate to law enforcement matters as provided in § 4.88(b).

(b) Upon the awarding of a contract by the Food and Drug Administration, the technical proposal submitted by the successful offeror will be available for public disclosure. All cost proposals and the technical proposals of unsuccessful offerors submitted in response to a request for proposals are exempt from disclosure as confidential commercial or financial information pursuant to § 4.61.

8. In § 4.111 by revising paragraph (c) (3) (vi) to read as follows:

§ 4.111 Data and information submitted voluntarily to the Food and Drug Administration.

* * * * *

(c) * * *

(3) * * *

(vi) If a person requests a copy of any such record relating to a specific individual or a specific incident, such request will be denied unless accompanied by the written consent to such disclosure of the person who submitted the report to the Food and Drug Administration and the individual who is the subject of the report. The record will be disclosed to the individual who is the subject of the report upon request.

* * * * *

PART 314—NEW DRUG APPLICATIONS

9. In § 314.14 by revising paragraph (a), to correct the reference, to read as follows:

§ 314.14 Confidentiality of data and information in a new drug application (NDA) file.

(a) For purposes of this section the "NDA file" includes all data and information submitted with or incorporated by reference in the NDA, IND's incorporated into the NDA, supplemental NDA's; reports under §§ 310.300 and 310.301 of this chapter, master files, and other related submissions. The availability for public disclosure of any record in the NDA file shall be handled in accordance with the provisions of this section.

* * * * *

PART 514—NEW ANIMAL DRUG APPLICATIONS

10. In § 514.11 by revising the introductory text of paragraph (f) to read as follows:

§ 514.11 Confidentiality of data and information in a new animal drug application file.

* * * * *

(f) All safety and effectiveness data and information not previously disclosed to the public are available for public disclosure at the time any one of the following events occurs unless extraordinary circumstances are known:

* * * * *

Effective date: This regulation shall be effective February 14, 1977.

(Sec. 201 et seq., Pub. L. 717, 52 Stat. 1040 et seq., as amended (21 U.S.C. 321 et seq.); sec. 1 et seq., Pub. L. 410, 58 Stat. 682 et seq., as amended (42 U.S.C. 201 et seq.); Pub L 90-23, 81 State. 54-56, as amended by 88 Stat. 1561-1565 (5 U.S.C. 552).)

Dated: January 7, 1977.

SHERWIN GARDNER,
Acting Commissioner of Food and Drugs.

[FR Doc.77-1180 Filed 1-13-77;8:45 am]

federal register

FRIDAY, JANUARY 14, 1977

PART IV

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of Assistant Secretary for Housing—Federal Housing Commissioner

■

LOANS FOR COLLEGE HOUSING

Program for Fiscal Year 1977

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Assistant Secretary for Housing—Federal Housing Commissioner

[24 CFR Part 279]

[Docket No. R-77-423]

LOANS FOR COLLEGE HOUSING

Program For Fiscal Year 1977

The Department is considering amending Title 24, Part 279—College Housing by adding a new Subpart B. This amendment is proposed in connection with the reactivation of the College Housing Program for Fiscal Year 1977.

The amendment would set forth the substantive provisions and procedural requirements for direct Federal loans for the rehabilitation, alteration, construction or acquisition of dormitories by eligible applicants under Title IV of the Housing Act of 1950, as amended, 12 U.S.C. 1749 et seq., and would apply only to application submitted during Fiscal Year 1977.

In previous years, loans and debt service grants were made for the acquisition, improvement and construction of central dining facilities, student centers and infirmaries. The proposed amendment would exclude such facilities from the definition of eligible projects with respect to applications submitted during Fiscal Year 1977. In addition, no new applications for debt service grants will be accepted, since all unused grant contract authority was rescinded by Public Law 93-529, enacted December 21, 1974.

The current regulations contained in Part 279 Sections 279.1 through 279.8 will be redesignated at Part 279, Subpart A and will continue to apply to all applications submitted prior to October 1, 1976.

Interested persons may participate in this proposed rulemaking by submitting such written data, suggestions, or arguments as they may desire. All such materials should be filed with the Rules Docket Clerk, Office of the Secretary, Room 10141, Department of Housing and Urban Development, 451 7th Street, S.W., Washington, D.C. 20410. All comments received on or before February 14, 1977, will be considered before adoption of a final rule in this matter. Copies of all comments received will be available for public inspection at the above address during regular business hours both before and after the close of the comment period.

The Department has determined that this proposed rule will not have a significant impact upon the quality of the environment. A Finding of Inapplicability respecting the National Environmental Policy Act of 1969 has been made in accordance with HUD procedures. A copy of the Finding of Inapplicability is available for public inspection, during regular business hours, in the Office of the Rules Docket Clerk, Office of the Secretary, Room 10141, Department of Housing and Urban Development, 451 7th Street, SW., Washington, D.C.

It is hereby certified that the economic and inflationary impacts of this proposed rule have been carefully evaluated in accordance with OMB Circular A-107.

Accordingly, it is proposed to amend Title 24, Part 279—College Housing by inserting a centered heading "Subpart A—College Housing Program—Pre-October 1976" immediately after the centered heading Part 279—College Housing and by adding a new Subpart B reading:

Subpart B—College Housing Program for Fiscal Year 1977

Sec.

AUTHORITY: Sec. 402, Housing Act of 1950, 12 U.S.C. 1749a; Sec. 7(d) Department of HUD Act (42 U.S.C. 3535(d)).

Subpart B—College Housing Program for Fiscal Year 1977

§ 279.10 General policy.

The purpose of this program is to assist educational institutions in providing housing for students and faculty members at the lowest possible charge by means of direct loans for the rehabilitation, alteration, erection or purchase of dormitories. Loans under the College Housing Program may be made in accordance with these regulations only to the extent that applicants are unable to obtain the necessary financing elsewhere on equally favorable terms and conditions.

§ 279.11 Definitions.

As used in this Part:

(a) "Act" means Title IV of the Housing Act of 1950, as amended (12 U.S.C. 1749 et seq.).

(b) "Construction" means erection of new dormitories or the rehabilitation or alteration of existing dormitories.

(c) "Current severe housing shortage" means an existing shortage in the supply of decent, safe and sanitary housing available for currently enrolled students at reasonable rents within the commuting area of the educational institution, which shortage must at least equal accommodations for the greater of 50 students or 2 percent of the institution's full-time enrollment.

(d) "Development cost" means the cost of land and site improvements, architectural and engineering services, construction, legal and administrative services, interest during construction, and the cost of acquiring existing dormitory facilities, all as determined by the Secretary. The cost of all furnishings such as beds, dressers, chests, desks, tables and chairs is not included in the definition of development cost, regardless of whether such furnishings are built in or movable.

(e) "Dormitory" means a structure or a portion of a structure which consists of living accommodations for students and faculty members but does not contain either central kitchen or dining facilities.

(f) "Educational institution" means: (1) Any public or nonprofit private college, university, or other institution which offers, or will offer within a reasonable time after completion of the dormitory project, at least a 2-year program acceptable for full credit toward a bachelor's degree; (2) any public or nonprofit private hospital operating a school of nursing beyond the level of high school approved by State authority, or operating an internship program approved by recognized authority; (3) any public educational institution which is administered by an accredited college or university and offers technical or vocational instruction; and (4) any nonprofit corporation, or public body, eligible under Section 404(b) of the Act, and established for the purpose of providing or financing dormitories for students and faculty members at educational institutions defined in (f) (1), (2) and (3) of this section; provided that in the case of a nonprofit corporation other than the educational institution, either the corporation must have been established by the educational institution, or the payment of principal and interest on any loan to such a separate nonprofit corporation must be guaranteed by the educational institution which the project is intended to serve.

(g) "Field Office" means any HUD Area or Regional Office which is delegated authority to process and approve applications under the College Housing Program.

(h) "Secretary" means the Secretary of Housing and Urban Development or other official authorized to perform the functions of the Secretary.

(i) "State" means the several States, the District of Columbia, and the Territories and possessions of the United States, including the Commonwealth of Puerto Rico.

§ 279.12 Eligible projects.

Loans may be provided for the rehabilitation or alteration of existing dormitories which will result in greater economy in the use of fuel or will otherwise result in a reduction in operating costs, and for the construction or acquisition of dormitories by educational institutions which have a current severe housing shortage, under the following conditions:

(a) Construction must not be of elaborate or extravagant design or materials and must be undertaken in an economical manner.

(b) Construction must not have been completed at the time the application for assistance is made.

(c) A loan cannot be made solely for the purpose of refunding a long-term loan obtained prior to the filing of an application.

(d) Site acquisition is limited to the amount of land reasonably necessary for the proposed dormitory.

(e) Parking facilities are not eligible.

(f) Projects to provide facilities for religious purposes or for theological seminaries or other schools providing training primarily for religious vocations are not eligible for assistance.

§ 279.13 Applications for reservations of funds.

(a) Information and application forms may be obtained from and applications submitted to the Field Office of the Department of Housing and Urban Development which serves the area in which the educational institution is located. Applications will be accepted until August 15, 1977.

(b) Applications for assistance will consist of two parts:

(1) Part one must be submitted to receive consideration for a fund reservation and must include the following information:

(i) Name, type and accreditation of educational institution;

(ii) Description and estimated cost of proposed project;

(iii) With respect to applications proposing the rehabilitation or alteration of existing facilities, an estimate of the annual savings in operating costs which will result from the proposed rehabilitation or alterations;

(iv) Evidence of need for proposed project;

(v) Engineering data and/or appraisals on which estimated project costs and operating cost savings, if any, are based;

(vi) Preliminary plans and specifications; and

(vii) Proposed method of financing.

(2) Part two must be submitted to receive consideration for loan approval and must include the information specified in § 279.17.

(c) Each Field Office will review the applications submitted to it and will request HUD Headquarters to reserve funds for those applications which it selects in accordance with the criteria specified in these regulations.

(d) Applications for reservations of funds shall be submitted to and reviewed by HUD Field Offices. Applications will not be reviewed by HUD Headquarters.

(e) Due to the limited amount of funds available and the uncertainty as to which areas will generate the greatest demand for funds, no predetermined allocations of funds to the Field Offices will be made. Funds will only be reserved for specific projects by HUD Headquarters on the basis of Field Office recommendations, subject to the availability of funds.

(f) Subject to the availability of funds, fund reservations will be made promptly for eligible applications which meet the priority criteria specified in § 279.15(a)(1), when HUD Headquarters receives the Field Office recommendations.

(g) The priority criteria specified in § 279.15(a) (2) and (3), will be used for establishing priorities by all Field Offices. Therefore, the ranking numbers assigned to individual applications in accordance with § 279.15(a) (2) and (3) will permit a comparison by HUD Headquarters between applications in those categories which are recommended for funding by different Field Offices.

(h) In the event that HUD Headquarters receives more recommendations for fund reservations than can be funded, HUD Headquarters will prepare a nationwide priority list for each of the categories specified in § 279.15(a) (2) and (3) by using the priority numbers assigned by the Field Offices on the basis of the ranking criteria specified in said section. Fund reservations will then be made by HUD Headquarters on the basis of the nationwide lists.

(i) Field Office recommendations and rankings for the priority category specified in § 279.15(a) (2) will be due in HUD Headquarters on June 1 and September 1, 1977. HUD Headquarters will reserve funds, subject to availability, no later than June 30 and September 30, 1977.

(j) Recommendations and rankings for the priority category specified in § 279.15(a) (3) will be due in HUD Headquarters on September 1, 1977. HUD Headquarters will reserve funds, subject to availability, no later than September 30, 1977.

(k) HUD Headquarters will promptly advise all Field Offices when funds are no longer available. Field Offices will then notify all educational institutions which submitted applications but did not receive reservations of funds.

§ 2279.14 Limitations on loan amount.

(a) The maximum loan which any educational institution may request is the lesser of $7,500,000, or $2,500 per full-time student, or $12,200 per student and/or faculty member to be housed in the proposed dormitory. The number of full-time students stated in the application must be the same as reported to the U.S. Office of Education for the Fall Semester 1976.

(b) The minimum loan which may be requested is $25,000.

(c) In order to exclude projects which are uneconomical or exceed reasonable design standards, applications proposing a Development Cost (exclusive of land or extraordinary project costs as determined by the Secretary) in excess of $14,000 per student and/or faculty member to be housed in the proposed dormitory are not eligible.

(d) The limitations specified in (a), (b) and (c) of this section will be adjusted to reflect local construction costs on the basis of a nationwide cost index of local construction costs to be furnished by HUD Headquarters.

§ 279.15 Priority criteria.

(a) In recommending and making reservations of funds, the following order of priorities will be observed by HUD Field Offices and HUD Headquarters.

(1) Dormitory projects for which the construction contract was executed on or before August 9, 1976 (the date of enactment of Pub. L. 94-378), and which have not been permanently financed in whole or in part. Fund reservations may be made by HUD Headquarters for applications in this priority category as soon as the Field Office has completed its review and made its recommendation, subject to the availability of funds.

(2) Rehabilitation or alteration of existing dormitories to improve fuel economy or otherwise reduce operating costs. Applications proposing major structural alterations are not eligible in this category. Applications in this priority category will be retained in the Field Office and recommended for reservations of funds on June 1 and September 1, 1977, subject to the availability of funds. In the event that the amount of assistance requested in this category exceeds the amount available, applications will be recommended for funding in the following order:

(i) Applications proposing the rehabilitation or alteration of dormitories originally financed with assistance under the College Housing Program, which will result in greater economy in the use of fuel or will otherwise result in a reduction in operating costs. Within this subcategory, applications which demonstrate the greatest savings in fuel consumption or other operating costs in relation to the cost of the proposed rehabilitation or alteration will be given priority. This will be determined on the basis of a ranking number equal to the estimated number of months before the savings will equal the cost of the rehabilitation or alterations.

(ii) Applications proposing the rehabilitation or alteration of dormitories not originally financed with assistance under the College Housing Program, which will result in greater economy in the use of fuel or will otherwise result in a reduction in operating costs. Within this subcategory, applications which demonstrate the greatest savings in fuel consumption or other operating costs in relation to the cost of the proposed rehabilitation or alteration will be given priority. This will be determined on the basis of a ranking number equal to the estimated number of months before the savings will equal the cost of the rehabilitation or alterations.

(3) New construction or acquisition of dormitories for institutions which have a current severe housing shortage. No funds will be reserved for applications in this category until funds have been reserved for all eligible applications in the priority categories specified in § 279.15(a) (1) and (2). In the event that the amount of assistance requested exceeds the amount available, priority will be given to applications from institutions having the most severe current shortage of housing for students. The relative severity of the shortage will be determined on the basis of a ranking number equal to the number of accommodations needed to eliminate the shortage multiplied by the percentage of the institution's full-time enrollment not adequately housed.

(b) Applications that do not receive fund reservations by the close of business on September 30, 1977, will be returned to the applicant.

(c) A reservation of funds will not constitute or imply approval of an application.

§ 279.16 Approval of applications for fund reservations.

(a) To be eligible for selection, a request must be received by HUD within the period specified herein and must be complete and responsive to the requirements specified herein. Requests for fund reservations will be approved by the Secretary based on an evaluation procedure that takes into account the information provided pursuant to § 279.13.

(b) Educational institutions whose requests for fund reservations are approved shall be notified by letter, which letter shall:

(1) Specify the amount of the fund reservation;

(2) Inform the educational institution that use of the fund reservation is conditioned on approval by the Field Office of a loan application;

(3) Instruct the educational institution to submit an application for loan approval to the Field Office; and

(4) State that the amount of loan funds reserved or any portion thereof unused by the educational institution may not be transferred by the educational institution.

(c) Educational institutions whose requests for fund reservations are not approved shall be so notified in writing by the Field Office.

(d) Educational institutions whose requests for fund reservations are approved shall, as soon as possible after receiving such approval, communicate with the Field Office in order to provide the Field Office with sufficient information to enable the Field Office to process an application for loan approval.

(e) The Secretary shall cancel any reservations of loan funds for projects for which the construction or rehabilitation is not commenced or the acquisition completed within the eighteen-month period following issuance of the written notification to the educational institution that funds have been reserved, unless an extension of time, not to exceed six additional months, is requested of and granted by the Secretary.

§ 279.17 Applications for loan approval.

(a) Following approval of a reservation of funds, the educational institution shall submit to the Field Office a request for loan approval on forms prescribed by HUD.

(b) Requests for loan approval shall be accompanied by or include evidence satisfactory to the Field Office Director that:

(1) The educational institution:

(i) Has the necessary legal authority to finance, acquire, construct or rehabilitate the project, to maintain the project, and to apply for and receive the proposed loan;

(ii) Meets any requirements as to corporate organization and has authority to enter into such contract obligation and execute such security instruments as may be required by HUD;

(iii) Has met the HUD requirements (set forth in HUD 1390.1) implementing the National Environmental Policy Act of 1969 (83 Stat. 852);

(iv) Has the ability to comply with the terms and conditions governing receipt of assistance and operation of the project;

(v) Has or will have such interest in or title to the project site, including access thereto, as will assure undisturbed use, possession and operation of the facilities during the period of assistance; and

(vi) Will retain title to and all of its right, title, and interest in and to the project during the period of assistance, except as otherwise expressly approved by the Secretary.

(2) The financial condition of the applicant and the proposed security for the loan are adequate to provide a reasonable assurance of repayment of the loan.

(c) The HUD Field Office shall review the loan application and shall notify the educational institution of its approval or disapproval, indicating any deficiencies. The educational institution will be given a reasonable time, as determined by the Field Office, to correct any deficiences. The approval shall set forth fully the terms and conditions upon which the loan will be disbursed.

§ 279.18 Loan terms.

(a) The loan amount shall not exceed the total eligible Development Cost of a project, as determined by the Secretary.

(b) Loans shall be for such periods not to exceed 40 years, bear interest at such rate not to exceed 3 percent per annum, be so secured, and be subject to such terms and conditions, as shall be determined by the Secretary.

(c) Loans will be evidenced by either notes or bonds issued by the educational institution.

(d) The interest rate shall be determined by the Secretary on the basis of the formula prescribed in the Act, as follows:

(1) Section 401(c)(1) of the Act provides that the loans shall bear an interest rate of not more than the lower of:

(i) Three (3) per centum per annum, or

(ii) The total of one-quarter of one (1) per centum per annum added to the rate of interest paid by the Secretary on funds obtained from the Secretary of the Treasury as provided in section 401(e) of the Act.

(2) Section 401(e) of the Act provides that notes or other obligations issued by the Secretary to obtain funds for these loans shall bear interest at a rate determined by the Secretary of the Treasury which shall not be more than the lower of:

(i) Two and three fourths (2¾) per centum per annum, or

(ii) The average annual interest rate on all interest bearing obligations of the United States then forming a part of the public debt as computed at the end of the fiscal year next preceding the issuance by the Secretary and adjusted to the nearest one-eighth of one per centum.

(e) In the case of loans to private educational institutions, the security normally will be a general obligation secured by a first mortgage on the project and a pledge of project revenues.

(f) In the case of loans to public educational institutions, the security normally will be, in order of preference:

(1) A general obligation secured by a first mortgage on the project and a pledge of project revenues, where legally available;

(2) A special obligation secured by a first mortgage on the project and a pledge of project revenues, where legally available; or

(3) A special obligation secured by a pledge of project revenues.

(g) If the Field Office Director determines that additional security is needed to reasonably assure loan repayment, a pledge of income from endowment funds, securities or other revenue sources, and/or a mortgage on other facilities, may be required as deemed necessary to reasonably assure repayment.

(h) Loans will be amortized by approximately equal periodic payments of combined principal and interest over the life of the loan. Said payments shall be made not less often than annually and not more often than semiannually; provided, however, that the payment of interest only may be required for a reasonable period of time not to exceed one (1) year following the completion of construction.

§ 279.19 Loan agreements.

Upon approval of a direct loan together with reservation of funds, the Field Office will prepare and forward a loan agreement for execution by the educational institution. The agreement will set forth the terms and conditions of the loan and will also specify conditions which must be fulfilled precedent to making of the loan. The fully executed agreement will constitute a contract between the educational institution and the Secretary during the life of the loan.

§ 279.20 Fee for Government field expense.

For each approved loan, the educational institution is required to pay a fixed fee, which in the aggregate will be sufficient to cover the cost of the Government's field expense. The fixed fee shall be an amount equal to one-eighth of one percent (.00125) of the loan amount with a minimum charge of $500 and a maximum charge of $1,500.

(a) The fixed fee shall be computed on the loan amount at the time of the original loan agreement. After execution of the loan agreement, no adjustment shall be made in the specified fixed fee, except when the loan amount is changed by 20 percent or more. In such cases, the fixed fee shall be redetermined by the formula above and specified in the related amendment to the loan agreement.

(b) The fixed fee must be paid to the Government out of the first funds deposited into the Construction Account, regardless of source.

§ 279.21 Construction financing.

The Secretary may advance loan funds to the educational institution during the construction of the project, provided that all prerequisites to loan disbursement as specified in the loan agreement, have been met.

(a) Total HUD advances to the educational institution will normally not exceed 75 percent of the approved loan, and shall be made only in amounts necessary to meet the actual current disbursement needs of the educational institution. Where circumstances warrant, the Field Office may approve additional advances so long as the total does not exceed 90 percent of the approved loan.

(b) Interest on advances will be charged by HUD at the same rate as on the bonds or notes.

(c) If the applicant is participating in the project financing, it must deposit to the Construction Account and substantially expend its own funds prior to obtaining any advances from HUD.

§ 279.22 Loan disbursement procedures.

(a) Advances of loan proceeds shall be made directly by HUD to the depository designated by the educational institution for deposit into the Construction Account.

(b) Advances shall be made on a periodic basis in an amount not to exceed the HUD-approved cost of portions of construction or rehabilitation work completed and in place, minus the appropriate holdback or retainage, as determined by the Field Office.

(c) Loan disbursements, including advances, may only be made upon the receipt by the Field Office of a duly executed note and a mortgage on the project and its site (or other real property satisfactory to the Field Office) whenever a note and mortgage is legally available as evidence of the debt of the educational institution to be created by the loan disbursement; provided, however, that in the event a note and mortgage is not legally available, loan disbursements may only be made upon the receipt by the Field Office of bond anticipation notes or such other evidence of the debt to be created by the loan disbursement as shall be satisfactory to the Field Office. Advances will not be made in the absence of a debt instrument satisfactory to the Field Office.

(d) Requisitions for loan disbursements shall be submitted by the educational institution on forms to be prescribed by the Secretary and shall be accompanied by such additional information as the Field Office may require in order to approve loan disbursements under this part, including, but not limited to, evidence of compliance with the Davis-Bacon Act, Department of Labor regulations, all applicable zoning, building and other governmental requirements, and, where applicable, such evidence of continued priority of the mortgage, if any, as the Secretary may prescribe.

§ 279.23 Determination of final approved development cost.

(a) A certificate of project development cost prepared on forms prescribed by the Secretary and executed by the educational institution may be used at the discretion of the Secretary, in lieu of an audit by the Government, for the purpose of determining the final approved Development Cost.

(b) The educational institution shall submit to the Field Office such documentation as may be prescribed by the Secretary. The documentation hereunder shall include such information and forms as the Secretary may require in order to approve the educational institution's certificate of project development cost, and to determine the final approved development cost, including, but not limited to, a certificate of actual cost, in a form prescribed by the Secretary, showing the actual cost to the educational institution for construction, architectural, legal, organizational, offsite costs and other items of expense approved by the Field Office. The Certificate shall not include as actual cost any kickbacks, rebates, trade discounts, or other similar payments to the educational institution. Any such payments shall be deducted from the costs determined to be eligible for inclusion in the total loan amount approved by the Field Office.

§ 279.24 Other requirements.

(a) Construction plans and specifications are subject to review and approval by the Field Office.

(b) Unless otherwise agreed to in writing by the Secretary, all construction work must be undertaken pursuant to contracts approved by the Secretary.

(c) All prime construction contracts must be awarded to the responsible bidder submitting the lowest bid on the basis of open competitive bidding.

(d) All laborers and mechanics employed by contractors and subcontractors in the construction of dormitories assisted under the Act shall be paid wages at rates not less than those prevailing in the locality involved for the corresponding classes of laborers and mechanics employed on construction of a similar character as determined by the Secretary of Labor in accordance with the Davis-Bacon Act, as amended (40 U.S.C. 276a–276a–5), and shall receive overtime compensation in accordance with and subject to the provisions of the Contract Work Hours Standards Act (40 U.S.C. 327–332).

(e) All contracts for construction work paid for in whole from loan funds provided under the Act shall provide that the contractor shall comply with the Copeland ("Anti-Kickback") Act (40 U.S.C. 276c) and the regulations of the Secretary of Labor thereunder (29 CFR Part 3).

(f) The requirements of Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d et seq.) that no person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, or be denied the benefits of, or be otherwise subjected to discrimination are applicable to educational institutions receiving assistance under the Act.

(g) All contracts for construction work paid for in whole or in part from loan funds provided under the Act are subject to Executive Order 11246 (30 FR 12319, Sept. 28, 1965), as amended by Executive Order 11375 (32 FR 14303, Oct. 17, 1967), providing for equal opportunity in employment, and the rules and regulations of the Department of Labor with respect thereto.

(h) The provisions of Title VIII (Fair Housing) of the Civil Rights Act of 1968 (Pub. L. 90–284, 42 U.S.C. 3601–3619), prohibiting refusal to rent to or discrimination against any person in terms or conditions of rental or provision of services on account of race, color, religion, or national origin, are applicable to projects assisted under the Act.

(i) All projects for which loans are made pursuant to this Subpart B are subject to the following requirements:

(1) Equal Opportunity requirements, which include Executive Order 11063 and section 3 of the Housing and Urban Development Act of 1968 and regulations and guidelines pursuant thereto.

(2) HUD requirements implementing the National Environmental Policy Act of 1969 (83 Stat. 852).

(3) Governmental requirements implementing the Clean Air Act (77 Stat. 392, as amended) and the Federal Water Pollution Control Act (66 Stat. 755, as amended).

(4) HUD requirements implementing the Flood Disaster Protection Act of 1973 (87 Stat 975).

(j) Projects for which loans are made to public educational institutions or eligible public bodies pursuant to this Subpart B are also subject to the following requirements:

(1) HUD relocation requirements established pursuant to the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (84 Stat. 1894).

(2) Any special requirements for the handicapped pursuant to the standards established by HUD under the Architectural Barriers Act of 1968 (82 Stat. 718).

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JOHN T. HOWLEY,
Acting Assistant Secretary for Housing—Federal Housing Commissioner.

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