

disabilities, unless they can demonstrate that taking such steps would fundamentally alter the nature of their program, services or activities, or would result in an undue burden. See 42 U.S.C. 12182(b)(2)(A)(iii). The ADA requires public accommodations, including health and social service providers, to furnish appropriate auxiliary aids to ensure effective communication with individuals with disabilities without the imposition of a surcharge to cover the cost of such measures.

OCR believes that exercising its authority under 45 CFR 84.52(d)(2) is consistent with Congress' intent to ensure consistency between Section 504 and the ADA. 42 U.S.C. 2117(b) of the Americans with Disabilities Act addresses coordination between agencies with enforcement authority under the ADA and Section 504 of the Rehabilitation Act of 1973. Consistent with that provision, agencies must ensure that administrative complaints filed under both the ADA and Section 504 are dealt with in a manner that prevents the imposition of inconsistent or conflicting standards for the same requirements. See, e.g., 42 U.S.C. ss. 12117(b), 12134(b) and 12201(a). Other evidence of Congress' desire for consistent enforcement standards can be found in several amendments to Title V of the Rehabilitation Act of 1973. For example, Section 102(f) of the Rehabilitation Act Amendments of 1992, Pub. L. 102-569, incorporated the exclusions from the term "individual with disability" that are set forth in the ADA. Also, Section 504 of the Rehabilitation Act Amendments of 1992 amended the Rehabilitation Act of 1973 by adding a new subsection to clarify that the standards used for determining whether Section 504 has been violated in a complaint alleging employment discrimination are the same standards applied under the ADA.

As noted above, Title III of the ADA does not require a public accommodation to provide auxiliary aids and services if it can demonstrate that taking such steps would fundamentally alter the nature of the services being offered or result in an undue burden. The undue burden defense established under the ADA evidences that Congress favored a case-by-case approach for determining a public accommodation's obligation to provide auxiliary aids rather than a broad exemption for small providers. OCR believes that requiring recipients with fewer than 15 employees to provide auxiliary aids under the Section 504 regulation at 45 CFR 84.52(d)(2), where the provision of such aids would

not significantly impair the ability of the recipient to provide its benefits or services, is consistent with the legislative scheme intended by Congress under the ADA.

Most of the entities that receive federal financial assistance from HHS are also subject to the effective communication requirements established under the ADA. OCR is confident that the enforcement of Section 504's auxiliary aids requirement can be applied in a manner that will not unduly burden small providers.

OCR will enforce Section 504 as it applies to recipients' responsibilities under the notice through procedures provided for in the Section 504 regulations. These procedures include complaint investigations, compliance reviews, efforts to secure voluntary compliance and technical assistance. OCR will always provide recipients with a complete opportunity to come into voluntary compliance with Section 504 prior to initiating formal enforcement proceedings, and will provide technical assistance to help entities resolve complaints in a collaborative fashion with OCR.

Dated: December 6, 2000.

Thomas E. Perez,

Director, Office for Civil Rights.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Bioethics Advisory Committee Request; International Research Ethical and Policy Issues; Comment Request

ACTION: Notice for comment on the draft report of the National Bioethics Advisory Commission (NBAC), *Ethical and Policy Issues in the Oversight of Human Research*.

SUMMARY: Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is given for comment on a draft report written by the National Bioethics Advisory Commission (NBAC). The Commission will consider all comments it receives as part of its ongoing deliberations in finalizing this report.

Purpose of the Report

In October 1995, President Clinton established NBAC to advise on bioethics and public policy issues related to conducting human research. NBAC makes recommendations to the White House and other departments and

agencies. This report, therefore, falls within NBAC's mandate.

Prior to NBAC's creation, in 1994, the Advisory Committee on Human Radiation Experiments (ACHRE) was created to investigate reports of federally sponsored human research involving radioactive materials and to assess the current state of protections for research participants. With regard to the latter charge they found, "evidence of serious deficiencies in some parts of the current system." Specifically, ACHRE was concerned with variability in the quality of IRBs, persistent confusion among human participants as to whether they were involved in research or therapy, and insufficient attention to the implications of diminished decision-making capacity in the consent process. ACHRE also recommended the creation of a national advisory group to examine these issues. When NBAC was established, one of its first priorities was to examine the system for protecting human research participants.

In May of 1997, NBAC unanimously resolved that "No person in the United States should be enrolled in research without the twin protections of informed consent by an authorized person and independent review of the risks and benefits of the research." The following year, NBAC wrote to the President indicating areas of concern and preliminary findings regarding the oversight of human research in the United States. The key concerns identified were:

- Federal protections for persons serving as subjects in research do not yet extend to all Americans.
- Despite widespread implementation of federal regulations by those departments and agencies sponsoring substantial amounts of biomedical research, a number of departments and agencies who sponsor primarily non-biomedical research or little research overall have failed to implement fully these federal protections.
- Federal protections do not always include specific provisions for especially vulnerable populations of research subjects.
- Many federal agencies find the interpretation and implementation of the Common Rule confusing and/or unnecessarily burdensome.
- Federal protections are difficult to enforce and improve effectively throughout the Federal Government, in part because no single authority or office oversees research protections across all government agencies and departments.
- New techniques are needed to ensure implementation at the local level.

In October 1999, Dr. Neal Lane, Assistant to the President for Science and Technology, reinforced the request that NBAC examine the federal system of oversight. This report addresses the basic purpose, structure, and implementation of research oversight. We recommend broad, strategic changes to the oversight system. This report is not intended to be a rewrite of federal regulations but instead to provide the guidance, direction, and justification for change. Providing Comments to the Draft Report.

You may provide written comments electronically or through mail or fax. Electronic submissions (by email or by website) are preferred as they will be processed more efficiently. The following are addresses for submitting comments: e-mail: nbac@od.nih.gov, NBAC website: www.bioethics.gov, mail: 6705 Rockledge Drive, Suite 700, Bethesda, Maryland 20892-7979, fax: (301) 480-6900.

If your comments are not postmarked by February 17, 2001, we can not guarantee they will be given full consideration.

TO RECEIVE A COPY OF THIS DRAFT REPORT

CONTACT: National Bioethics Advisory Commission, 6705 Rockledge Drive, Suite 700, Bethesda, Maryland 20892-7979, telephone (301) 402-4242, fax number (301) 480-6900, or visit the website at www.bioethics.gov.

SUPPLEMENTARY INFORMATION: The President established the National Bioethics Advisory Commission (NBAC) on October 3, 1995 by Executive Order 12975 as amended. The mission of the NBAC is to advise and make recommendations to the National Science and Technology Council, its Chair, the President, and other entities on bioethical issues arising from the research on human biology and behavior, and from the applications of that research.

Dated: December 13, 2000.

Eric M. Meslin,

Executive Director, National Bioethics Advisory Commission.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-01-08]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506 (c)(2)(A) of the Paperwork reduction Act of 1995, the Center for Disease Control and Prevention is providing opportunity for public comment on proposed data collection projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 639-7090.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques for other forms of information technology. Send comments to Anne O'Connor, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Project

Linking Epidemiologic Research to Disease Prevention: A Pilot Program to Test Approaches for Communicating Increased Risk of Cervical Cancer to Female Workers in the Dry-Cleaning Industry —NEW—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

The National Institute for Occupational Safety and Health (NIOSH) has conducted worker notification formally since 1988. This program informs workers in NIOSH-conducted epidemiological studies about the study results and hence, of their risks. The intervention research to be conducted under this application will extend the risk communication beyond the mortality study cohort (an aging and mostly retired cohort) to similarly exposed women, younger and still employed.

Several studies, including one conducted at NIOSH, have documented elevated mortality from cancer among dry cleaning workers. Some of the cancers involved—most notably cervical cancer—can be successfully treated if detected early. Thus, along with better hazard control, better secondary disease prevention is urgently needed to help women workers already exposed. Exiting NIOSH procedures for notifying workers about the agency's research findings seem unlikely to reach the larger at-risk population of women dry cleaners who were not actually study subjects.

The ultimate purpose of this research is to increase understanding of how to encourage medical screening among workers at risk. The project has two main objectives: (1) To assess descriptively the feasibility and potential public health benefits of a broader than usual approach to NIOSH worker notification about occupational health risks, based on results of NIOSH epidemiologic research; and (2) to determine whether a follow-up reminder about the importance of medical screening makes a significant difference in the notified workers' long-term health behavior.

The primary study population will consist of a minimum 300 current female dry cleaning workers in New York City (ages 18-65), selected from the membership list (a respondent universe of 375) from the dry cleaners' local labor union. A separate population of 100 former dry cleaning workers randomly selected from a cohort list of approximately 226 surviving women dry cleaners in a NIOSH cohort mortality study will provide descriptive data only and will not be included in the data analysis of the primary group of currently employed dry cleaners. All study participants will be mailed a packet of risk information from NIOSH, along with a letter of endorsement of the study from the local union in New York, encouraging participation in the study. The risk information packet will include the NIOSH mortality study results as well as other information about cancer and cancer screening, with a special emphasis on cervical cancer screening.

Brief (15-minute) telephone interviews will follow the mailed notifications to workers and will be used to evaluate (1) the effects of an intervention (mailed written notification materials) on post-intervention cervical cancer screening behaviors; and (2) the effects of a reminder message mailed six months after the initial notification.

The effect of the first intervention will be measured by comparing the pre- and post-intervention screening behaviors