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RECOMMENDATIONS

Recommendations for Remedies Pertaining to Experiments and Exposures During the Period 1944-1974*

Biomedical Experiments

Recommendation 1

The Advisory Committee recommends to the Human Radiation Interagency Working Group that the government deliver a personal, individualized apology and provide financial compensation to the subjects (or their next of kin) of human radiation experiments in which efforts were made by the government to keep information secret from these individuals or their families, or from the public, for the purpose of avoiding embarrassment or potential legal liability, or both, and where this secrecy had the effect of denying individuals the opportunity to pursue potential grievances.

The Advisory Committee has found three cases to which the above applies. These are the surviving family members of:

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*In preparing these recommendations, the Advisory Committee addressed only the question of whether the federal government owes remedies to subjects or their surviving immediate family members. The remedies identified below are not intended to preclude any remedies that subjects or their family members may otherwise be entitled to from nonfederal institutions or from individuals.

Part IV

1. The eighteen subjects of the plutonium injection experiments;
2. The subject of a zirconium injection experiment, known only as Cal-Z; and
3. Several subjects of total-body irradiation experiments conducted during World War II.[1]

Deliberate attempts by public officials in trusted and often sensitive government positions to conceal the fact of participation from subjects or their families, particularly in the absence of sufficient national security justification and for the declared purpose of avoiding potential liability and public embarrassment, are assaults upon the foundations of individual privacy and self-determination. Such actions violate an individual's right to information about him- or herself and must be taken with the utmost seriousness.

In the cases listed above, this secrecy served to prevent people who may have been wronged from seeking redress within their lifetimes. Secrecy regarding the participation of particular subjects was maintained until as late as 1974. Documents showing that the government kept information secret about particular 1940s experiments on grounds of potential liability and embarrassment remained secret until retrieved by the committee in 1994. Even though at the time justice might not have required financial compensation for the failure to disclose information in the absence of direct physical harm, the fact that the government's actions limited the opportunity of these subjects to seek justice is undeniable. Because of the offensiveness of the government's actions, justice today warrants a remedy of financial compensation.

Moreover, efforts to cover up governmental wrongdoing are assaults upon the polity itself, and not just upon the directly affected individual, because such efforts undermine the ability of a civil society to ensure that the government and its agents act within the rule of law. Such a situation warrants the extension of compensation to the next generation.

Implementation:

Congress may need to consider legislation to provide compensation for the immediate families of the subjects in the plutonium injection experiments whose identities are known. The identities of the subject known as Cal-Z, as well as the subjects in the wartime total-body irradiation experiments, are not now known. Should their identities come to light, they or their families also should be compensated. In addition, should additional cases be identified that satisfy the criteria outlined above, further legislation should be enacted or other steps taken to provide those individuals or their family members with similar compensation.

Recommendation 2

The Advisory Committee recommends to the Human Radiation Interagency Working Group that for subjects of human radiation experiments that did not involve a prospect of direct medical benefit to the subjects, or in which interventions considered to be controversial at the time were presented as conventional or standard practice, and physical injury attributable to the experiment resulted, the government should deliver a personal, individualized apology and provide financial compensation to cover relevant medical expenses and associated harms (pain, suffering, loss of income, disability) to the subjects or their surviving immediate family members.*

The Advisory Committee has identified several experiments that are candidates for remedies to former subjects under this recommendation; these are described below in the section on implementation.

When the government puts an individual at risk in order to serve some collective national interest, it must take steps to ensure that the rights and interests of the individual are adequately protected. The Advisory Committee presumes, however, based on our understanding of the historical context, that such steps were not uniformly undertaken. As a consequence, it is possible that a citizen who was harmed as a result of participation in nontherapeutic research did not adequately consent to this use of his or her person. That the government did not have a system in place to ensure that individuals were not wronged by their use as research subjects in nontherapeutic research without their adequate consent, when that use resulted in harm, warrants a personal, individualized apology and financial compensation to subjects or to their surviving immediate family members.

Analogous cases exist to support this recommendation. In awarding substantial compensation to victims (or their families) of the CIA's MKULTRA experiments who were killed or suffered other serious harm, Congress and the

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* The Advisory Committee was convened in response to concerns about human radiation experiments that offered no prospect of medical benefit to human subjects. In our historical analysis, the experiments we investigated either offered no prospect of medical benefit or they involved interventions alleged to be controversial at the time (see Overview to Part II). As a consequence, the Advisory Committee focused its consideration of remedies for subjects of human radiation experiments only on those experiments that fit these descriptions. The Committee makes no recommendations about whether, or under what conditions, remedies are appropriate for subjects of human radiation experiments that were considered at the time to offer a plausible prospect of medical benefit to subjects.

courts recognized that individuals used for government purpose without direct benefit to the experimental subject and without their consent deserved substantial awards.[2]

Nothing in this recommendation should be taken as having implications for how future policies governing compensation for research injuries should be constructed.

Implementation:

Of the experiments that the Advisory Committee studied in detail, we have identified several that are candidates for remedies under this recommendation. These are as follows: the total-body irradiation (TBI) experiments (should it be determined that TBI was considered at the time to be a controversial treatment for patients with "radioresistant" tumors, and it was not presented as such to potential subjects, and should a determination of harm attributable to the experiments be made); the testicular irradiation experiments using prisoners as subjects (should a determination of harm attributable to the experiments be made); the uranium injection experiments at Rochester and Boston (should a determination of harm attributable to the experiments be made); and some of the iodine 131 experiments involving children (should a determination of harm attributable to the experiments be made). Because of the scope of the Advisory Committee's charge and our limited tenure, we were not in a position to undertake the individualized and detailed fact-finding required to resolve the uncertainties in each of these cases, including the evaluation of medical and research records of all the patients or subjects involved.

In addition, two experiments that the Committee did not study in detail, the iodine 131 experiment in Alaska and the Vanderbilt radioiron nutrition experiments, are currently in legal proceedings in which claims of harm have been made.

If an appropriate forum such as the courts or a properly constituted review committee determines that subjects were harmed as a consequence of nontherapeutic research, or as a consequence of research in which controversial treatments were presented to patients as conventional or standard therapy, it is the Advisory Committee's view that the government should take steps to ensure that the remedies of apology and financial compensation are awarded.

The question of causation is key to any such determination. The Advisory Committee has heard from many public witnesses regarding the standards of proof and presumptions involved in the administration of existing radiation compensation statutes, which cover atomic bomb testing and uranium mining. In those cases the nature of the exposure for all applicants is relatively uniform and well defined, and the exposures have been the subject of a relatively large amount of study; by contrast, in the case of human radiation experiments, each experiment may present a different set of circumstances. In some cases, as in the

administration of iodine 131, there is considerable knowledge of the relation between exposure and subsequent injury. In many other situations, less is known.

A decision should be made about how strict a causal association ought to be required, with a more strict standard making financial compensation available to fewer individuals. Whether the standard for presuming "causation" should be strict or loose is a policy decision that depends on values, not science. The standards/values problem speaks both to what should be done about whether the illness should be treated as experiment-related for purposes of compensation if (1) it is impossible to determine the likely range of association between the exposure and the illness (because the facts about dose or method of exposure are not available); and (2) the likely range of association is broad or the probability of association between the exposure and the illness is low.

To determine reasonable medical expenses, a schedule of projected medical costs appropriate for reimbursement could be created for specific diagnoses, rather than compensating for actual costs incurred. This approach would relieve the burden on the subject or immediate family members to prove actual costs, streamline the process for determining level of compensation, and allow for compensation for costs not yet incurred.

Recommendation 3

The Advisory Committee recommends to the Human Radiation Interagency Working Group that for subjects who were used in experiments for which there was no prospect of medical benefit to them and there is evidence specific to the experiment in which the subjects were involved that (1) no consent, or inadequate consent, was obtained, or (2) their selection as subjects constituted an injustice, or both, the government should offer a personal, individualized apology to each subject.*

The Committee believes that people who were used as research subjects without their consent were wronged even if they were not harmed. Although it is surely worse, from an ethical standpoint, to have been both harmed and wronged than to have been used as an unwitting subject of experiments and suffered no harm, it is still a moral wrong to use people as a mere means without their consent. Although what we know about the practices of the time suggests it is likely that many people who were subjects in nontherapeutic research were used without their consent or with what today we would consider inadequate consent, in most of these cases we have almost no information about whether or how

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*For a discussion of the Committee's deliberations about this recommendation, see "Overview to Part IV."

consent was obtained. Moreover, in most of these cases, the identities of the subjects are not currently known; even if considerable resources were expended, it is likely that most of their identities would remain unknown.

The Committee is not persuaded that, even where the facts are clear and the identities of subjects known, financial compensation is necessarily a fitting remedy when people have been used as subjects without their knowledge or consent but suffered no material harm as a consequence; the remedy that emerged as most fitting was an apology from the government.

The Committee struggled with the issue of whether to recommend that the government extend such an apology. Our deliberations were complicated by what we all agreed was a murky historical record. In the case of some experiments, there was evidence of some disclosure or some attempt to obtain consent, and the issue emerged as to how poor these attempts must be for an apology still to be in order. In the great majority of cases, there was simply too little documentary evidence to draw any conclusions about disclosure or consent. In most cases, as noted above, the identities of subjects are unknown and are unlikely to be uncovered even with a substantial expenditure of resources.

What kind of evidence is necessary to determine that an apology is warranted? In the preceding recommendation, the remedy is linked to evidence of harm to particular individuals. While requiring evidence of harm specific to individuals, we did not require such specific evidence of lack of consent. Rather, in that recommendation, we presumed that the government did not uniformly undertake steps to ensure that the rights and interests of individual subjects were adequately protected, and thus that it is possible that people who were harmed as a result of participation in research did not adequately consent to this use of their person. In this recommendation, by contrast, a remedy is linked to a showing that people were *wronged*, not harmed. Thus the Committee believes that an apology should be offered only where there is evidence specific to an experiment or subject that no consent, or inadequate consent, was obtained, or the subject's selection constituted an injustice, or both.

The Committee believes that, among those experiments we have had the opportunity to review in depth, there is sufficient evidence that wrongs were committed against the children who participated in the experiments at the Fernald School. This case is discussed in detail in chapter 7.*

In recommending an apology to individuals who were subjects of these experiments, the Committee wishes to emphasize that there are likely many other

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* Several other experiments studied by the Committee are candidates for remedies under Recommendation 2. Where it is determined that subjects in these experiments were not harmed, they may be due an apology under this recommendation if it is determined that they were wronged.

instances in which an apology is warranted but for which experiment-specific factual support is not currently available.[3]

Recommendation 4

In the research that we reviewed for this recommendation, the Advisory Committee has found no subjects of biomedical experiments for whom there is a need to provide notification and medical follow-up for the purpose of protecting their health. In the event that other experiments of concern come to light in the future, we recommend to the Human Radiation Interagency Working Group that subsequent decisions for notification be based on evaluation of both the level of risk from radiation exposure and the potential medical benefit from medical follow-up in exposed individuals.

Additionally, the Advisory Committee has found no evidence to indicate that the subjects of human radiation experiments we reviewed would have had greater likelihood of incurring heritable (genetic) effects than the general population and thus does not recommend notification or medical follow-up for descendants of subjects of human radiation experiments.

In formulating this recommendation, the Advisory Committee considered those subjects for whom there is a significant risk of developing a radiation-related disease that has not yet occurred, or has occurred but may still be undetected or untreated, and in whom there might be an opportunity to prevent or minimize potential health risks through detection and treatment. In considering notification, we focused only on biomedical experiments, as stated in our charter.

The Advisory Committee based its present recommendation on the specific guidelines stated below and recommends that future decisions for medical notification and follow-up of subjects of government-sponsored human radiation experiments not examined by the Committee, or that have not yet come to light, be based on these same guidelines, as follows:

1. The subject was placed at increased lifetime risk for development of a fatal radiation-induced malignancy. The level of increased risk was set by the Advisory Committee at 1/1,000 remaining lifetime risk and an excess relative risk of greater than 10 percent (organ specific). This level of risk was arbitrarily chosen by the Advisory Committee. When compared with the normal risk of dying of cancer (220 out of 1,000), this level of risk is small. The Advisory Committee chose this small remaining lifetime risk as a reasonable initial criterion to decide if an analysis of the utility of screening and intervention (criterion 2 below) was needed.

2. There is a recognized medical benefit from early detection and treatment of the cancer, which outweighs whatever medical risks are associated with detection and treatment interventions. In addition, the government should consider the public health and financial costs as well as the potential benefits before making a decision to offer such a notification and screening program.

Eligible subjects for whom medical follow-up to protect health is recommended should be notified of their participation in a human radiation experiment, and voluntary screening programs offered to them. Such a program should include adequate disclosure of both the nature of the potential benefits as well as the potential risks of medical follow-up, which might include some of the following aspects:

- medical harm, discomfort, inconvenience, or anxiety from the screening test itself or subsequent follow-up exams;
- the possibility of incorrect test results, either false positive or false negative;
- the possibility of stigmatization by friends, family, employers, or life/health insurance carriers;
- the costs to themselves of the screening program (if any) and subsequent medical tests and treatments.

Thus the Advisory Committee's recommendations for notification and medical follow-up of individuals who were subjects of a human radiation experiment depend equally on risk estimates and the medical utility of early detection and treatment for changing the course of disease or the quality or length of life in such an exposed individual, as shown in the accompanying table.

The Advisory Committee database includes articles and other documents describing approximately 4,000 government-sponsored human radiation experiments. Because of the limited data available on most of these, and the Advisory Committee's limited resources, it has not been feasible for the Advisory Committee to systematically apply the two criteria described above to the majority of experiments identified within its database. The Advisory Committee therefore selected for review types of experiments that seemed most likely to include subjects who might still be alive and meet the risk criteria chosen by the Committee and who might medically benefit from notification and medical follow-up.

DETERMINATION OF THE NEED FOR NOTIFICATION AND MEDICAL FOLLOW-UP

		Risk Analysis (For Development of Fatal Cancer)	
		Remaining Lifetime Risk ≥ 1/1,000 AND RR ≥ 10%	Remaining Lifetime Risk < 1/1,000 OR RR< 10%
Medical Benefit from Early Detection and Treatment	Yes	**RECOMMEND NOTIFICATION AND MEDICAL FOLLOW-UP**	**NO NOTIFICATION**
	No	**NO NOTIFICATION**	**NO NOTIFICATION**

Specifically, the Advisory Committee has reviewed twenty one studies involving three types of experiments:

1. Children who received iodine 131;
2. Prisoners subjected to testicular irradiation; and
3. Children and military personnel exposed to nasopharyngeal radium treatments.

Following this detailed analysis, the Advisory Committee concluded that none of the experiments examined satisfied both of the guidelines identified in this recommendation. If in the future new methods of screening are developed or new information about increased risk is discovered, then these experiments should be reevaluated to assess whether they meet the criteria. (For a full discussion, see the addendum on medical notification and follow-up at the end of this chapter.)

Though it was beyond the scope of the Advisory Committee to evaluate individually all the experiments in our database, the results of our review of these carefully selected studies suggest that the remaining experiments would be unlikely to meet the proposed criteria for notification and medical follow-up. However, another important group of studies not considered in detail by the Advisory Committee were tracer studies in pregnant and nursing women.

It is possible that experiments that would satisfy the Committee's criteria for notification and medical follow-up will be identified. Implementation of a notification and medical follow-up program would have to be done carefully if a follow-up program is to provide former research subjects with greater health benefit than harm. Considerable effort would be needed to educate both subjects and physicians about the realistic benefits and the possible harms of medical

follow-up, as well as the specific screening modalities and follow-up care that would be indicated. It is particularly important to distinguish follow-up that is intended to benefit medical science from follow-up that is intended to medically benefit patients. An additional concern is that, for most experiments, no list of subjects exists. Performing screening tests in people who are incorrectly identified as having an increased risk is unlikely to result in any benefit and may result in harm.

The Advisory Committee also recognizes that individuals who have received therapeutic radiation treatments, either in a purely clinical setting or research setting, may have been exposed to substantially higher doses of radiation and should seek medical follow-up pursuant to the advice of their treating physician.

With regard to the need to notify descendants of subjects of human radiation experiments of potential genetic effects, it is likely that the risk of radiation-induced mutations is small in relation to natural rates. Thus it would be impossible to distinguish whether the condition was caused by the parent's radiation exposure or by other factors. Based on these considerations, the Advisory Committee does not recommend notification and medical follow-up for descendants of subjects of radiation experiments.

In the event that specific genetic effects attributable to radiation exposure could be identified in a particular population of descendants at some future time, the guidelines would be the same as those previously outlined for subject populations--there would need to be evidence to indicate that early intervention would change the course of a particular disease before notification and follow-up would be recommended.

Population Exposures

In recent years Congress has enacted a body of laws to provide relief to service personnel exposed to radiation in connection with atmospheric nuclear tests, citizens who lived downwind from the tests, and workers who mined uranium to be used by the government in nuclear weapons production. These include the Veterans Dioxin and Radiation Exposure Compensation Standards Act of 1984, the Radiation-Exposed Veterans Compensation Act of 1988, and the Radiation Exposure Compensation Act of 1990.

In the Committee's view, these existing laws provide the framework on which to base continued provision for relief. In the interim since these laws were passed, experience with the laws and more current scientific knowledge strongly suggest the need for revisiting the laws and their administration and for extending their coverage to similarly situated groups--such as those exposed to intentional releases--who are not now covered.

The following recommendations address the circumstances of groups exposed to intentional releases, service personnel who were exposed in connection with nuclear weapons tests, and workers who mined uranium for use in government programs. We also address the circumstance of the citizens of the Republic of the Marshall Islands, for whom a different framework of remedies has been fashioned.

Recommendation 5

The Advisory Committee recommends to the Human Radiation Interagency Working Group that it, together with Congress, give serious consideration to amending the provisions of the Radiation Exposure Compensation Act of 1990 to encompass other populations environmentally exposed to radiation from government operations in support of the nuclear weapons program, should information become available that shows that areas not covered by the legislation were sufficiently exposed that a cancer burden comparable to that found in populations currently covered by the law may have resulted.

The Advisory Committee did not have the time or resources to undertake our own epidemiologic studies of the cancer burden surrounding the Hanford facility in Washington state, where the Green Run took place. The preliminary radioiodine dose estimates now available raise the issue of whether the releases from Hanford may have caused cancers. The Advisory Committee found that the Green Run itself contributed only a very small portion of that cancer burden, so small that it would be impossible to attribute any cancers to the Green Run as opposed to other sources (including routine Hanford releases). The Advisory Committee believes that in addressing the Green Run intentional release, the appropriate response is to redress injury without regard to whether exposures were in the course of routine or research activities. There would be no practical way to make this distinction, if it were desired. We also note that the Radiation Exposure Compensation Act provides relief for downwinders and uranium miners without regard for whether they were subjects of research (and in many cases they were not).

Recommendation 6

The Advisory Committee recommends to the Human Radiation Interagency Working Group that it, together with Congress, give serious consideration to reviewing and updating epidemiological tables that are relied upon to determine whether relief is appropriate for veterans who participated in atomic testing so that all cancers or other diseases for which

there is a reasonable probability of causation by radiation exposure during active military service are clearly and unequivocally covered by the statutes.

Congress has provided for compensation for veterans who participated in atmospheric atomic tests or the American occupation of Hiroshima or Nagasaki, Japan. The provision of compensation depends on evidence that the veteran has sustained disability from a disease that may be related to radiation exposure.

The Veterans Dioxin and Radiation Exposure Compensation Standards Act of 1984 required the Veterans Administration to write a rule governing entitlement to compensation for radiation-related disabilities. The resulting regulation contains criteria for adjudicating radiation claims, including consideration of a radiation-dose estimate and a determination as to whether it is at least as likely as not that the claimed disease resulted from radiation exposure. The Radiation-Exposed Veterans Compensation Act of 1988 provides that a veteran who was present at a designated event and subsequently develops a designated radiogenic disease may be entitled to benefits without having to prove causation.[4]

The Committee recommends that the radioepidemiological tables prepared by the National Institutes of Health in 1985, which identify diseases that may be causally connected to radiation exposures, be updated. The Committee understands that the Department of Veterans Affairs agrees with this recommendation.

The Advisory Committee further recommends to the Human Radiation Interagency Working Group that it review whether existing laws governing the compensation of atomic veterans are now administered in ways that best balance allocation of resources between financial compensation to eligible atomic veterans and administrative costs, including the costs and scientific credibility of dose reconstruction.

While the Committee's inquiry focused on participants at atmospheric testing who were subjects of experimentation, the Committee found that the risks to which experimental subjects were exposed were typically similar to those to which many other test participants were subjected. Those service members who were participants in the experiments reviewed by the Advisory Committee would, as veterans of atmospheric atomic tests, be eligible for relief under the laws enacted in 1984 and 1988, as amended, concerning radiation-exposed veterans.

The Committee found that the government did not create or maintain adequate records regarding the exposures of all participants, the identity and test locale of all participants, and the follow-up, to the extent it took place, of test participants. Witnesses before the Advisory Committee, and others who communicated with us by mail, telephone, and personal visit, expressed strong

concerns about the adequacy and operation of the current laws, including, specifically, record-keeping practices. Although the Committee did not have the time or resources to pursue these concerns to the degree they merit, we believe that the concerns expressed by veterans and their family members deserve attention, and we urge the Human Radiation Interagency Working Group in conjunction with Congress to address these concerns promptly. The concerns reported to us include the following:

1. The listing of diseases for which relief is automatically provided--the "presumptive" diseases provided for in the 1988 law--is incomplete and inadequate.
2. The standard of proof for those without a presumptive disease is impossible to meet and, given the questionable condition of the exposure records retained by the government, inappropriate.
3. The statutes are limited and inequitable in their coverage; for example, the inclusion of those exposed at atmospheric tests does not protect those who were exposed to equal amounts of radiation in activities such as cleanup at Enewetak atoll.
4. The time and expense needed to prosecute a claim is too great. For example, veterans whose claims are initially denied at the VA regional offices and are seeking appeal of the initial decision receive a form letter stating that it will take at least twenty-four months to process their appeal.
5. Time and money spent on contractors and consultants in administering the program would be better spent on directly aiding veterans and their survivors.

Recommendation 7

The Advisory Committee recommends to the Human Radiation Interagency Working Group that it, together with Congress, give serious consideration to amending the provisions of the Radiation Exposure Compensation Act of 1990 relating to uranium miners in order to provide compensation to *all* miners who develop lung cancer after some minimal duration of employment underground (such as one year), without requiring a specific level of exposure. The act should also be reviewed to determine whether the documentation standards for compensation should be liberalized.

The uranium miners were exposed to extremely high levels of radon daughters, which were recognized at the time to be hazardous yet were not controlled by the government, despite the availability of feasible means to

ventilate the mines. Furthermore, the government studied the miners without disclosing the purposes of the examinations or warning them of the hazards to which they were exposed. As a result of their continued exposure, hundreds of miners developed lung cancer or nonmalignant respiratory diseases that could have been prevented, and many of them have died.

In recognition of this tragedy, Congress included provisions for compensating certain uranium miners in the Radiation Exposure Compensation Act of 1990 (RECA). However, the criteria for compensation set in this act were far more stringent than for the two other groups (atomic veterans and downwinders of the Nevada Test Site) for which compensation was provided, despite the fact that the risks were far higher for the uranium miners.

Since 1990, additional scientific information has become available to support the view that radon exposure is responsible for a much higher proportion of the lung cancer cases among the miners than had been previously thought. In particular, the act's current requirement of a minimum of 200 WLM (working level months) exposure for nonsmokers or 300 to 500 WLM (depending on age) for smokers translates to quite large probabilities of causation, according to a recent report by the National Cancer Institute.[5] That analysis finds little evidence to support a distinction between smokers and nonsmokers and suggests that a majority of lung cancer deaths among Colorado white miners and New Mexico Navajo miners are attributable to radon exposure. Furthermore, it finds that the lung cancer risk is strongly modified by a number of factors and uncertainties that are not accounted for in the total dose; thus, for many miners, the level of exposure that would merit compensation on the basis of the principle of "balance of probabilities" might be far lower than the present criteria. In particular, no exposure measurements are available for 90 percent of the years in most mines, so that any requirement to reconstruct exposure histories is likely to require some degree of extrapolation or estimation and be quite uncertain. Furthermore, many mines have since gone out of business, so that records needed to establish an exposure history are simply unavailable.

Also since 1990, there has been considerable experience with the administration of the act, and apparently much of it has been negative. The Advisory Committee took extensive testimony regarding the difficulties faced by miners in meeting the documentation requirements, particularly those related to the requirement to provide a reconstruction of their radon dose. For these practical reasons, and in light of the additional information, we suggest that the requirement that a miner demonstrate that he had been exposed to a certain minimum cumulative dose be replaced by a simple requirement that he worked underground for a certain minimum length of time. Since more than half the lung cancer deaths in the cohort who worked at least one month underground appear to be attributable to radon, we suggest that minimum length of service be set quite low, preferably not more than a year. At most this should then lead to

compensation being awarded to twice as many miners as would be entitled to it under the balance of probabilities principle, while not denying it to any who are entitled to it.

The grave injustice that the government did to the uranium miners, by failing to take action to control the hazard and by failing to warn the miners of the hazard, should not be compounded by unreasonable barriers to receiving the compensation the miners deserve for the wrongs and harms inflicted upon them as they served their country.

Recommendation 8

The Advisory Committee supports the Department of Energy's program of medical monitoring and treatment for the exposed inhabitants of the Marshall Islands atolls of Rongelap and Utirik and recommends that this program be continued as long as any member of the exposed population remains alive. Furthermore, the Advisory Committee recommends that the program be reviewed to determine if it is appropriate to add to the program the populations of other atolls to the south and east of the blast whose inhabitants may have received exposures sufficient to cause excess thyroid abnormalities. The Advisory Committee also recommends that consideration be given to the involvement of the Marshall Islanders in the design of any further medical research to be conducted upon them and the Advisory Committee recommends that the Human Radiation Interagency Working Group consider establishing an independent panel to review the status and adequacy of the current program of medical monitoring and medical care provided by the United States to the exposed population of the Marshall Islands.

The 1954 Bravo hydrogen bomb test caused the populations of several Marshall Islands atolls to be exposed to hazardous levels of radiation. The United States has provided a medical follow-up program that combines research on radiation effects with treatment for radiation-related illnesses. It is noteworthy that as a result of the ongoing program to study radiation effects, many cases of thyroid disease were detected and treated, but not all exposed Marshallese received the benefits of the program. The people of Ailuk, for example, who according to early reports received about the same exposure as the people of Utirik, were never evacuated from their atoll and were not followed up medically, even though they received a radiation dose of more than six roentgens. Moreover, an epidemiological study reported in the *Journal of the American Medical Association* in 1987 demonstrated that inhabitants of several atolls to the east and south of Bikini had elevated levels of thyroid disease and that there was a "strong inverse linear relationship" between incidence of thyroid nodules and

distance from the blast. It should also be noted that the exposed populations received additional doses of radiation over the years from later bomb tests and residual radiation on the atolls. The medical program is ongoing, but Congress has the authority to reduce or eliminate funding.

Available evidence indicates that many Marshallese--it is impossible to identify specific individuals--were not adequately informed about the purposes of the medical tests to which they were subjected. There is also evidence in the documentary record that the Marshallese often did not understand the relationship between the research and medical care components of the medical follow-up program. For example, Dr. Robert A. Conard headed the program, and according to his report on twenty years of medical treatment and monitoring, "the people did not always understand the need for the examinations, or their results." Although this situation has improved in recent years, it would nevertheless be appropriate to consult with the Marshallese in the design and implementation of further medical research so as to minimize any possibility of misunderstanding and to ensure that the priorities of the Marshallese are a consideration in the planning of such research.

The Advisory Committee supports the continuation of the Department of Energy's program of medical monitoring and medical care for the exposed inhabitants of the Marshall Islands. Questions have been raised during the course of our deliberations as to whether this program is running as well as it should, both with respect to the research and monitoring activities conducted by Brookhaven National Laboratory (BNL) and with respect to the medical care provided. In particular, the issue has emerged whether the medical care ought to be expanded to include treatment for conditions that are not radiogenic as a further remedy to Marshallese people who were exposed, however inadvertently, as a result of weapons tests. The Advisory Committee did not have the resources to pursue these issues, but we believe that they deserve serious consideration. One mechanism through which this could be accomplished is the establishment of an independent panel to review the program with input from the Marshallese as to the panel's composition.

Recommendations for the Protection of the Rights and Interests of Human Subjects in the Future

While we were constituted to consider issues related to human radiation experiments, in critical (but not all) respects, the government regulations that apply to human radiation research do not differ from those that govern other kinds of research. In comparison with the practices and policies of the 1940s and 1950s, there have been significant advances in the protection of the rights and interests of human subjects. These advances, initiated primarily in the 1970s and 1980s, culminated in the adoption of the Common Rule throughout the federal

government in 1991. Although the Common Rule now affords all human subjects of research funded or conducted by the federal government the same basic regulatory protections, the work of the Advisory Committee suggests that there are serious deficiencies in some parts of the current system. These deficiencies are of a magnitude warranting immediate attention.

The Committee was not able to address the extent to which these deficiencies are a function of inadequacies in the Common Rule, inadequacies in the implementation and oversight of the Common Rule, or inadequacies in the awareness of and commitment to the ethics of human subject research on the part of physician-investigators and other scientists. We urge that in formulating responses to the recommendations that follow, the Human Radiation Interagency Working Group consider each of these factors and subject them to careful review.

Recommendation 9

The Advisory Committee recommends to the Human Radiation Interagency Working Group that efforts be undertaken on a national scale to ensure the centrality of ethics in the conduct of scientists whose research involves human subjects.

A national understanding of the ethical principles underlying research and agreement about their importance is essential to the research enterprise and the advancement of the health of the nation. The historical record makes clear that the rights and interests of research subjects cannot be protected if researchers fail to appreciate sufficiently the moral aspects of human subject research and the value of institutional oversight.

It is not clear to the Advisory Committee that scientists whose research involves human subjects are any more familiar with the *Belmont Report*[6] today than their colleagues were with the Nuremberg Code forty years ago. The historical record and the results of our contemporary projects indicate that the distinction between the ethics of research and the ethics of clinical medicine was, and is, unclear. It is possible that many of the problems of the past and some of the issues identified in the present stem from this failure to distinguish between the two.

The necessary changes are unlikely to occur solely through the strengthening of federal rules and regulations or the development of harsher penalties. The experience of the Advisory Committee illustrates that rules and regulations are no guarantee of ethical conduct. The Advisory Committee has also learned, in responses to our query of institutional review board (IRB) chairs, that many of them perceive researchers and administrators as having an insufficient appreciation for the ethical dimensions of research involving human subjects and the importance of the work of IRBs. The federal government must

work in concert with the biomedical research community to exert leadership that alters the way in which research with human subjects is conceived and conducted so that no one in the scientific community should be able to say "I didn't know" or "nobody told me" about the substance or importance of research ethics.

The Advisory Committee recommends that the Human Radiation Interagency Working Group institute, in conjunction with the biomedical community, a commitment to the centrality of ethics in the conduct of research involving human subjects. We urge that careful consideration be given to the development of effective strategies for achieving this change in the culture of human subjects research, including, specifically, how best to balance policies that mandate the teaching of research ethics with policies that encourage and support private sector initiatives. It may be useful to commission a study or convene an advisory panel charged with developing and perhaps implementing recommendations on how best to approach this challenge for the research community.[7]

The Committee suggests that such an examination include consideration of the following:

- Extending to all federal grant recipient institutions and all students and trainees involved or likely to be involved in human subject research the current federal requirement that institutions receiving NIH National Research Service Award training grants offer programs in the responsible conduct of research.
- The role of accrediting bodies such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).
- Establishing competency in research ethics as a condition of receipt of federal research grants, both for institutions and individual investigators.
- Incorporating of research ethics, and the *differences* between the ethics of research involving human subjects and the ethics of clinical medical care, into curricula for medical students, house staff, and fellows.
- Encouraging the nation's leaders in biomedical research to spearhead efforts to elevate the importance of research ethics in science.

Recommendation 10

The Advisory Committee recommends to the Human Radiation Interagency Working Group that the IRB component of the federal system for the protection of human subjects be changed in at least the five critical areas described below.

1. Mechanisms for ensuring that IRBs appropriately allocate their time so they can adequately review studies that pose more than minimal risk

to human subjects. This may include the creation of alternative mechanisms for review and approval of minimal-risk studies.

The majority of the Advisory Committee's concerns in its Research Proposal Review Project centered on research that exposed subjects to greater than minimal risk of harm. If human subjects are to be adequately protected, such research must be carefully scrutinized. However, higher risk research is often complex, and careful review is time-consuming and difficult. The Advisory Committee heard from several chairs of IRBs who underscored the difficulties their committees experience in finding the time to adequately review such research. Members of IRBs have only so many hours they can devote to review of proposals. This problem of inadequate time appears to have worsened in recent years. Institutional review boards are required to review research proposals prior to their review for funding by the National Institutes of Health. As the probability that a proposal will be approved for funding has decreased over time, due to increasing competition for limited research monies, the number of proposals being submitted to NIH from many institutions has significantly increased. This has resulted in a substantial increase in the workload of some IRBs, whose members are spending considerable time reviewing proposals that are never implemented. Without guidance from the federal government, and perhaps regulatory relief, IRBs may not have the flexibility necessary to concentrate their efforts where subjects are in greatest need of protection--on the proposals that pose the greatest risks to subjects and that are actually implemented.

2. Mechanisms for ensuring that the information provided to potential subjects (1) clearly distinguishes research from treatment, (2) realistically portrays the likelihood that subjects may benefit medically from their participation and the nature of the potential benefit, and (3) clearly explains the potential for discomfort and pain that may accompany participation in the research.

The Advisory Committee's empirical studies and public testimony suggests that there may be considerable confusion in the minds of many members of the public concerning what is "research" or "experimentation," and what is simply an application of a new technology or even standard medical care. There is reason to worry that participants in research may have unrealistic expectations both about the possibility that they will personally benefit from participation and about the discomfort, pain, and suffering that sometimes accompany some research. This seemed particularly to be the case in Phase I and Phase II drug trials. It is important that in the informed consent process it is clearly communicated to the potential subject, particularly the potential patient-subject,

that the primary intent of "research" is to advance medical knowledge and not to advance the welfare of particular subjects. Inadequate and potentially misleading information about potential benefits and harms, and about the trade-offs between enrollment in research and standard or conventional treatment, was one of the major problems identified by the Advisory Committee in our Research Proposal Review Project.

3. Mechanisms for ensuring that the information provided to potential subjects clearly identifies the federal agency or agencies sponsoring or supporting the research project in whole or in part and all purposes for which the research is being conducted or supported.

A morally complicating factor in several of the human radiation experiments the Advisory Committee has studied is the tendency to disclose to subjects only the medical purpose of the research (if that) and not those purposes of the research that advance interests other than medical science or the sponsorship of agencies other than DHEW/DHHS. For example, in the case of the total-body irradiation experiments, the data gathered from the research had a military purpose quite distinct from questions of cancer therapy. The purpose and funding source may be relevant to a person's decision to participate in human subject research and should be disclosed.

4. Mechanisms for ensuring that the information provided to potential subjects clearly identifies the financial implications of deciding to consent to or refuse participation in research.

Many of the consent forms that the Committee reviewed as part of the Research Proposal Review Project were silent on the subject of financial costs. However, knowing whether being in research costs or saves them money may be necessary for potential subjects to make an informed decision about whether to participate. Potential subjects need to know whether the interventions that are part of the research are free or must be paid for and--if there are any financial costs--what they are, the likelihood that third-party payers will pay for these research-related medical services, and the extent to which the research institution will assist patient-subjects in securing third-party payment or reimbursement.

5. Recognition that if IRBs are to adequately protect the interests of human subjects, they must have the responsibility to determine that the science is of a quality to warrant the imposition of risk or inconvenience on human subjects and, in the case of research that purports to offer a prospect of medical benefit to subjects, to determine that participating in the research affords patient-subjects at least as good an opportunity of securing this

medical benefit as would be available to them without participating in research.

In research involving human subjects, good ethics begins with good science. In our Research Proposal Review Project, the Advisory Committee was unable to evaluate the scientific merit of a significant number of proposals based on the documents provided by institutions. We suspect that this occurred in part because there is ambiguity about the role that IRBs should play with respect to evaluation of scientific merit and, thus, that documents submitted to IRBs may be inadequate in this area. The Advisory Committee also heard dissatisfaction with this ambiguity in our interviews and oral histories of researchers and from chairs of IRBs. If the science is poor, it is unethical to impose even minimal risk or inconvenience on human subjects. Although the fine points of the relative merit of research proposals are best left to study sections and other review mechanisms specially constituted to make such judgments, IRBs must be situated to assure themselves that the science they approve to go forward with human subjects satisfies some minimal threshold of scientific merit. In some cases, the IRB may be the only opportunity for this kind of scientific review.

In our Subject Interview Study interviews with patient-subjects, we confirmed that patient-subjects often base their decisions to participate in research on the belief that physicians, and research institutions generally, would not ask them to enter research projects if becoming a research subject was not in their medical best interests. For these patients, even the most candid, clearly written consent form affords little protection, for both the consent form and the consent process are of little interest to them. For patient-subjects whose decisions to participate in research are based on trust, and not on an assessment of disclosed information, the IRB review is of special importance. It is the only source of protection in the *federal* system for regulating human research positioned to ensure that their participation in research does not compromise their medical interests. Such a determination, however, often requires more specialized clinical expertise than any one IRB can possess. Federal policy must make it clear that IRBs have the responsibility to make this determination, but it must also allow mechanisms to be devised at the local level that permit this responsibility to be satisfied in an efficient and effective manner.

Recommendation 11

The Advisory Committee recommends to the Human Radiation Interagency Working Group that a mechanism be established to provide for the continuing interpretation and application of ethics rules and principles for the conduct of human subject research in an open and public forum. This mechanism is not provided for in the Common Rule.

Part IV

Issues in research ethics are no more static than issues in science. Advances in biomedical research bring new twists to old questions in ethics and sometimes raise new questions altogether. No structure is currently in place for interpreting and elaborating the rules of research ethics, a process that is essential if research involving human subjects is to have an ethical framework responsive to changing times. Also, for this framework to be effective, any changes or refinements to it must be debated and adopted in public; otherwise, the framework will fail to have the respect and support of the scientific community and the American people, so necessary to its success.

Three examples of outstanding policy issues in need of public resolution that the Advisory Committee confronted in our work are presented below:

1. Clarification of the meaning of minimal risk in research with healthy children, including, but not limited to, exposure to radiation.

2. Regulations to cover the conduct of research with institutionalized children.

3. Guidelines for research with adults of questionable competence. Of particular concern is more-than-minimal-risk research that offers adults of questionable competence no prospect of offsetting medical benefit.

Current regulations permit the involvement of children as subjects in research that offers no prospect of medical benefit to participants when the research poses no more than minimal risk. An important question that has come to the Advisory Committee's attention, both in the literature and in our Research Proposal Review Project, is whether research proposing to expose healthy children to tracer doses of radiation constitutes minimal risk. The uncertainty surrounding this issue calls into question the adequacy of the federal regulations, as currently formulated, in providing guidance for this category of research. This is a policy question that ought to be discussed and resolved in a public forum at the national level, not left to the deliberations of individual IRBs.

Current regulations do not provide any special protections for children who are institutionalized unless they are also wards of the state. Thus, researchers and IRBs have no more guidance from the federal government on the ethics of conducting such research than was available at the time of the Fernald and Wrentham experiments, decades ago.

The Advisory Committee also confronted in its Research Proposal Review Project another issue of research policy deserving public debate and resolution in a public forum. This is the issue of whether and under what conditions adults of questionable capacity can be used as subjects in research that puts them at more than minimal risk of harm and from which they cannot realize direct medical benefit. It is important that the nation decide together whether or under what conditions it is ever permissible to use a person toward a valued social end in an activity that puts him or her at risk but from which the person cannot possibly benefit medically.

Recommendation 12

The Advisory Committee recommends to the Human Radiation Interagency Working Group that at least the following four steps be taken to improve existing protections of the rights and interests of military personnel with respect to human subject research.

1. Review of policies and procedures: Policies and procedures governing research involving human subjects should be reviewed to ensure that they (1) clearly state that participation as research subjects by members of the armed services is voluntary and without repercussions for those who choose not to participate; and (2) clearly distinguish those activities that are research and therefore discretionary on the part of members of the armed services from other activities that are obligatory, such as training maneuvers and medical interventions intended to protect the troops.

2. Appreciation of regulations: Education in applicable human subjects regulations should be a component of the training of all officers and investigators who may be involved in decisions regarding research on human subjects. Mechanisms are needed to ensure that officers expected to have command responsibilities and all officers engaged in research, development, testing, and evaluation have an adequate appreciation of the regulations (including DOD regulations and directives, and service regulations) that bear on the conduct of research involving human subjects, including an appreciation of the conditions under which such regulations apply, the role of officers in interpreting such regulations, and how such regulations are to be implemented.

3. Maximizing voluntariness: The service secretaries should consider the situations under which it would be appropriate to make obligatory two practices for maximizing voluntariness that have been employed on an ad hoc basis in some military research: first, that unit officers and senior noncommissioned officers (NCOs) who are not essential as volunteers in the research be excluded from recruitment sessions in which members of units are informed of the opportunity and asked to participate in research by investigators; and second, that an ombudsman not connected in any way with the proposed research be present at all such recruitment sessions to monitor that the voluntariness of participation is adequately stressed and that the information provided about the research is adequate and accurate.

The Advisory Committee recommends consideration of steps 1 through 3 above in light of our examination of history that makes plain how difficult it often is in a military context to distinguish an order from a request for voluntary participation and to distinguish research from training. (These tensions are similar in many respects to tensions in the clinical context between research and

treatment.) Although the military has a long tradition of commitment to the use of volunteers in research and has introduced significant advances in the military's system of protection for human subjects since the 1940s and 1950s, without constant attention to these inherent tensions, the potential for confusion and inappropriate practice continues.

The military setting, with its strict hierarchical authority structure and pervasive presence in the lives of its members, poses special problems for ensuring the voluntariness of participation in research activities. Thus, although the DOD has adopted and implemented the consent requirements of the Common Rule, additional procedural safeguards and educational activities for officers may be warranted to counteract the generalized deference to authority inherent in military culture. Also, because the opportunity to serve the nation as subjects in defense-oriented research projects is closely akin to the demands placed on members of the military in their routine duties, it is desirable to emphasize the distinction between research and course-of-duty risks both in consent procedures and in officer training programs.

The Advisory Committee recognizes that additional procedural requirements in soliciting research volunteers and augmenting already demanding training curricula would have administrative costs and, to a limited extent, would shift organizational priorities. It is the Advisory Committee's understanding that the DOD is preparing to revise its directive implementing the Common Rule and that the Advisory Committee's recommendations with respect to steps 1 through 3 above are a timely contribution to the department's deliberations.

Military personnel are exposed to both short- and long-term risks in the course of training and regular duty activities as well as when they participate in biomedical or behavioral experiments. The demarcation of those activities that are research in contrast with those that constitute routine duty assignments and medical care in the military context is not always easy to discern from the standpoint of the potential subject-member of the military. Indeed, except in medical settings where research studies are regularly performed and military testing sites that conduct weapons, matériel, and performance trials routinely, officers as well as their troops may be uncertain as to whether the status of particular exercises is research or training. Greater clarity in communications to potential subjects about the genuinely voluntary nature of participation in research projects and procedural safeguards in recruiting volunteers could improve their understanding of what they are being asked (rather than required) to do. Likewise, educating officers throughout the military services who may be in a position to solicit volunteers for research studies as to the distinctive rights of research subjects and the particular duties to protect subjects of research from both harm and violations of rights would make the Common Rule protections of subjects more effective.

4. Maintenance of a registry: The secretaries of the Navy and the Air Force should be directed to adopt the policy of the Army, as detailed in Army Regulation 70-25, to maintain a registry of all volunteers in human studies and experiments conducted under research and development programs. Such registries make it easier to confirm participation in research by subjects and facilitates their long-term follow-up.

In analyzing the record of atomic bomb testing, the Advisory Committee has found that military personnel were exposed to radiation and nonradiation risks as participants in experiments that were conducted in conjunction with the tests, and as participants in other activities connected to the testing. While these activities were not intended to measure biological effects of ionizing radiation, the exposure to radiation risk was incurred without adequate provision for the maintenance of records to document exposures or in order to allow for monitoring and follow-up of those who were exposed. Army regulations now provide for a registry of participants in experiments conducted under the authority of the Army's research and development program. This tool for long-term monitoring and follow-up in the case of exposures to risks unknown at the time of participation should be employed by the other services as well.

Recommendation 13

The Advisory Committee recommends that the Human Radiation Interagency Working Group take steps to improve three elements of the current federal system for the protection of the rights and interests of human subjects--oversight, sanctions, and scope.

1. Oversight mechanisms to examine outcomes and performance. In most federal agencies, current mechanisms of oversight of research involving human subjects are limited to audits for cause and a review of paperwork requirements. These strategies do not provide a sufficient basis for ensuring that the current system is working properly. The adequate protection of human subjects requires that the system be subjected to regular, periodic evaluations that are based on an examination of outcomes and performance and that include the perspective and experiences of subjects of research as well as the research community. The Committee recommends that the Human Radiation Interagency Working Group consider new methods of oversight that focus on outcomes and performance of the system of protection of human subjects. The Committee's Subject Interview Study and Research Proposal Review Project, for example, yielded important and heretofore unavailable information about the current status of human subjects protections that could never be obtained from either an oversight policy that audits only "for cause" or a review that determines only

whether paperwork requirements have been satisfied.

We realize that resources available for oversight are limited and that there may be real constraints on what, practically, can be achieved. At the very least, we urge that in the setting of priorities for limited oversight dollars, a premium be placed on methods that permit an examination of what the system is actually producing with respect to the outcome of human subjects protections, in contrast to methods that focus on process.

2. Appropriateness of sanctions for violations of human subjects protections. The Committee recommends that the Human Radiation Interagency Working Group review and evaluate the options available to the government when it is determined that there has been a violation of the Common Rule in the conduct of federally sponsored research involving human subjects. The object of this review is to determine whether the current structure of sanctions that can be imposed on investigators and grantee institutions is appropriate to the seriousness with which the nation takes violations of the rights and interests of human subjects. This structure includes mechanisms for detecting violations (including issues of oversight discussed above), severity of sanctions, and dissemination of policies on sanctions to investigators and institutions. We are particularly concerned that, even in the absence of research-related injury, there be clear and severe penalties for investigators who use human subjects without their consent. Although at least one state authorizes civil and criminal penalties for failure to obtain a subject's consent,[8] in most jurisdictions civil litigation is unlikely to result in penalties to investigators for failing to obtain consent from subjects if the subjects have not been physically injured. The Committee is aware that the Common Rule provides for sanctions of violations of its provisions, including the withdrawal of multiple project assurances and, with that action, research funding. It is not clear, however, that this system of sanctions functions well; nor is it clear that it adequately addresses the public's concerns that those who abuse the trust of research subjects be dealt with accordingly.

3. Extension of human subjects protections to nonfederally funded research. While some nonfederally funded research is performed voluntarily in accordance with the Common Rule, there is a need to assess the level of research performed outside its requirements and to consider action to ensure that all subjects are afforded the protections it offers. The Committee was charged with reviewing only federally funded research, and we limited our inquiries accordingly. However, we are aware that important areas of research are conducted largely independently of federal funding--for example, some research on reproductive technologies. We recommend that the Human Radiation Interagency Working Group take steps to ensure that all human subjects are adequately protected.

Recommendation 14

The Advisory Committee recommends that the Human Radiation Interagency Working Group review the area of compensation for research injuries of future subjects of federally funded research, particularly reimbursement for medical costs incurred as a result of injuries attributable to a subject's participation in such research, and create a mechanism for the satisfactory resolution of this long-standing social issue.

A system of compensation for research injuries has been contemplated since at least the late 1940s, when the Army debated, but ultimately rejected, suggestions to establish a "uniform" program for compensating prisoner volunteers who were injured during experiments involving malaria and hepatitis. Beginning in the 1970s, a number of government-sponsored ethics panels endorsed the provision of compensation for research injuries, culminating with the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (President's Commission) in 1982. Since then, experts and commentators have continued to support this position.[9]

In our deliberations concerning retrospective remedies for injured research subjects, the Advisory Committee was unable to reference a federal policy or guide for a fair system of compensation of research subjects, as no policy exists even today. So that years from now others do not have to revisit and struggle with this issue, the federal government must take steps now to address the issue of compensation for injured research subjects. These steps should include consideration of the approach recommended by the President's Commission in its report, *Compensating for Research Injuries: The Ethical and Legal Implications of Programs to Redress Injured Subjects*.[10]

The President's Commission summarized the basic argument for compensation as follows:

> Medical and scientific experimentation, even if carefully and cautiously conducted, carries certain inherent dangers. Experimentation has its victims, people who would not have suffered injury and disability were it not for society's desire for the fruits of research. Society does not have the privilege of asking whether this price should be paid; it is being paid. In the absence of a program of compensation of subjects, those who are injured bear both the physical burdens and the associated financial costs. The question of justice is why it should be these persons, rather than others, who are

> to be expected to absorb the financial, as well as the unavoidable human costs of the societal research enterprise which benefits everyone.[11]

The Advisory Committee urges not only consideration of a compensation policy for physical injuries attributable to research but also that consideration be given to appropriate remedies for subjects who have suffered dignitary harms, even in the absence of physical injury. Subjects so wronged have little recourse in the current system; litigation in the absence of physical injury is unlikely to provide relief to people who have been used as subjects without their adequate consent. If it is determined that financial compensation is not generally an appropriate remedy in the absence of physical injury, consideration should be given to other remedies that would be fitting.

Recommendations for Balancing National Security Interests and the Rights of the Public

Recommendation 15

15a: The Advisory Committee recommends to the Human Radiation Interagency Working Group the adoption of a federal policy requiring the informed consent of all human subjects of classified research and that this requirement not be subject to exemption or waiver. In all cases, potential subjects should be informed of the identity of the sponsoring federal agency and that the project involves classified information.

15b: The Advisory Committee recommends to the Human Radiation Interagency Working Group the adoption of a federal policy requiring that classified research involving human subjects be permitted only after the review and approval of an independent panel of appropriate nongovernmental experts and citizen representatives, all with the necessary security clearances. This panel should be charged with determining (1) that the proposed experiment has scientific merit; (2) that risks to subjects are acceptable and that the balance of risk and potential benefit is appropriate; (3) that the disclosure to prospective subjects is sufficiently informational and that the consent solicited from subjects is sufficiently voluntary; and (4) whether potential subjects must have security clearances in order to be sufficiently informed to make a valid consent decision, and if so, how this can be achieved without compromising the privacy and voluntariness of potential subjects. Complete documentation of the panel's deliberations and of the informed consent documents and process should be maintained permanently. These records should be made public as soon as the national security concern justifying secrecy no longer applies.

Although the Advisory Committee believes that the interests of both science and potential subjects are best served when research involving human subjects is conducted in the open, a public policy prohibiting the conduct of human subject research in secret is unwise. Important national security goals may suffer if human subjects research projects making unique and irreplaceable contributions were foreclosed. More citizens may suffer harms for lack of such information than would be harmed if adequately safeguarded human subjects research was conducted in secret.

It also is possible that a prohibition on classified human subjects research would be circumvented through redefinition of activities or disregarded outright. If this were to occur, the participants in such activities could end up less well protected than if they were bona fide research subjects.

The Advisory Committee believes, however, that the classification of human subject research ought properly to be a rare event and that the subjects of such research, as well as the interests of the public in openness in science and in government, deserve special protections. The Advisory Committee does not believe that continuing with the current federal policy governing the protection of human subjects, which does not provide any special safeguards or procedures for classified research, is adequate.

In the current political context, classified human subjects research occurs relatively rarely. Existing policy may prove an inadequate safeguard of individual rights and welfare, however, if in the future national security crises occur that generate a perceived need for classified research. The history of human experimentation conducted in the interests of strengthening and protecting national security that the Advisory Committee has examined demonstrates how the rights and interests of citizens can be violated in secret research. The convergence of elements of secrecy, urgent national purposes, and the essential vulnerability of research subjects, owing to differentials in information and power between those conducting research and those serving as subjects, could again lead to abuses of individual rights and, upon subsequent revelation, the erosion of public distrust in government.

The Advisory Committee is particularly concerned about two aspects of current policy--exceptions to informed consent requirements and the absence of any special review and approval process for human research that is to be classified. The current requirement for the informed consent of research participants is not absolute, leaving open the possibility that subjects may serve as mere tools of the state in the interests of national security if consent is waived. A strengthened requirement for the informed consent of research subjects in classified research should safeguard against the merely instrumental use of individual people to serve national purposes.

Institutional review boards of government agencies are not sufficiently independent of the interests of the organizations of which they are a part to set

aside considerations of organizational mission when considering research construed as having the greatest national priority. Thus, determination by an agency IRB that a waiver of informed consent is warranted, or that sufficient information about a study remains in a censored protocol description for a potential subject's review, inadequately protects subjects' interests and rights and does not adequately safeguard the public's trust. By contrast, an independent panel should be less subject to unintended bias than that of an IRB of a federal agency whose mission is to protect and promote national security.

Although the Advisory Committee acknowledges that both the formation of an independent review panel and an absolute informed consent requirement create opportunities for information leaks or security breaches and delays in the progress of urgent research, these disadvantages are surmountable and are more than balanced by the increased vigilance afforded the rights and interests of citizens and the safeguarding of the public's trust in government.

Recommendation 16

The Advisory Committee recommends to the Human Radiation Interagency Working Group that improvements be made in the protections of the public's rights and interests with respect to intentional releases.

16a. The Advisory Committee recommends to the Human Radiation Interagency Working Group that an independent review panel review any planned or intended environmental releases of substances in cases where the release is proposed to take place in secret or in circumstances where any aspect of the environmental review process required by law is conducted in secret.

In conducting its review, the independent panel should ensure that (l) secrecy is limited to that required for reasons of national security; (2) records will be kept on the nature and purpose of the release, the rationale for not informing the public (including workers and service personnel, as well as affected citizens), and alternative means of gathering data that were considered; (3) actions to mitigate risk were considered and will be taken; and (4) actions will be taken to measure the actual effect of the release on the environment and human health and safety, to the extent that measurements are deemed needed and feasible. The panel should also review the conditions on which any information kept secret should be made public, with a view toward ensuring the release of information as soon as practicable, consistent with any legitimate national security restrictions. The panel should report to Congress periodically on the number and nature of releases it has reviewed.

The Advisory Committee does not conclude that intentional releases can never be conducted in secret. It does conclude that, to the extent that the government proposes to conduct an intentional release that involves elements of secrecy, there must be independent review to ensure that the action is needed, that risk is minimized, and that records will be kept to make sure a proper accounting is made to the public at the earliest date consistent with legitimate national security concerns.

The Advisory Committee found that the government has sponsored numerous intentional environmental releases of radiation for research purposes. In many cases these releases were conducted in secret, without warning to the surrounding populations. While the risks posed by these releases appear to have been relatively small, in many cases little data remain on the precise measure of these risks or on actions taken to minimize risk and to ensure that unknowing citizens did not inadvertently expose themselves to greater risks than necessary. In addition, the Committee found that the risks and concerns posed by intentional releases for research purposes--in terms of both the magnitude of radiation exposure and the consequences of secret keeping--sometimes did not differ qualitatively from those posed by "routine" operational releases of radiation. Most notably, the radiation risk posed by the Green Run, a relatively large intentional release, was a fraction of that posed by radiation released in the normal course of operation of Hanford in the mid-1940s.

This recommendation is intended to apply to all secret releases of substances into the environment, not merely to substances determined to be hazardous. The Committee believes that the operative concern is secrecy; even if the substance released is entirely harmless, the backdrop of secrecy is sufficient to create a climate of distrust. The Committee did not have the expertise, however, to determine whether so broad a sweep was feasible. At minimum, the Committee recommends that any secret release of a substance that would necessitate an environmental impact statement be required to have a review by an independent panel.

Today, federal environmental laws and rules provide for environmental impact statements, which are subject to review, in instances in which the federal government proposes actions with a substantial effect on the environment. However, the rules also provide that part--or even all--of such reviews may be conducted in secret. In fact, reviews that are secret in whole or part do take place.

The Environmental Protection Agency has the authority and responsibility to oversee all environmental impact reviews, including those conducted in secret. However, the Advisory Committee's inquiries indicate that EPA's role in the review of secret impact statements has been limited. Moreover, the decades of secret keeping regarding intentional releases have created a basis for distrust, particularly among those living in potentially affected communities. Even today, there is little practical means by which the public can know the full extent

(whether or not great) of environmental decision making and action that is being kept secret. The location of responsibility for review of these activities in a single panel that is itself accountable and that is independent of agencies that conduct releases should be a means to restoring lost trust.

16b. The Advisory Committee recommends to the Human Radiation Interagency Working Group that an appropriate government agency, currently the Environmental Protection Agency, maintain a program directed at the oversight of classified programs, with suitably cleared personnel. This program should maintain critical records, such as environmental impact statements and environmental permits, permanently. The agencies subject to regulation should ensure the timely consideration of environmental impacts and oversight and the timely provision of all necessary clearances. EPA should provide regular unclassified reports to Congress describing the extent of its activities as well as any significant problems.

The requirements of environmental law apply to activities of the federal government, regardless of whether those activities are classified. However, classification complicates the process of regulatory oversight by the EPA or any other regulatory agency and limits the ability to report to the public and for the public to express its own concerns. Furthermore, secrecy has been used to shield activities that raise public health concerns.

For these reasons, the responsibility for environmental oversight is magnified for secret programs. There is no fundamental barrier to effective oversight--at least some regulators can be given the necessary clearances. However, ensuring timely and effective oversight requires cooperation between the regulated agency and the regulatory agency to establish the necessary oversight procedures. These mechanisms are not fully in place. For example, the EPA office with the statutory responsibility to review environmental impact statements maintains no records of classified environmental impact statements and has not historically had individuals cleared to review the most highly classified defense programs. The EPA office responsible for overseeing federal compliance with environmental regulations has just begun to establish mechanisms for overseeing secret programs.

Recommendations on Openness

Recommendation 17

The Advisory Committee recommends that the Human Radiation Interagency Working Group take steps to ensure the continued application of the lessons learned from the Human Radiation Interagency Working

Group's efforts to organize and make accessible to the public, and the government itself, the nation's historical records.

The Committee's experience confirms that with presidential directive and the strong and continued support of a multiagency records search team, substantial amounts of the nation's documentary heritage can be located and retrieved. Through the research process, important lessons were learned about ways in which to improve the accessibility and usefulness of this documentary record to both the public and the government.

We are aware that government resources are stretched thin and may well be diminishing. However, the nation's records are a precious asset that the government created, and holds in trust, for its citizens. This asset, and the commitment made to the public through the enactment of the Freedom of Information Act, is of limited value if the government itself cannot access its records as citizens rightfully expect it should. The Committee's experience confirms that there is an intense public interest in using these records, a public willingness to volunteer time and intelligence needed to help organize and research them, and great opportunity to make them available in ways that will permit citizens to do so.

The Committee recommends that the Human Radiation Interagency Working Group effect the following five steps to increase both government and citizen access to information about the past. The implementation of these steps might best be accomplished by the designation of an individual or entity with responsibility and appropriate authority for their effectuation.[12]

1. The most important historical collections should be entrusted to the National Archives. The agencies and the National Archives should review the extent to which this is now being done and develop policies to hasten the transfer of agency records to the National Archives.

Federal law basically requires that permanent records be transferred to the National Archives when (1) they are more than thirty years old; or (2) earlier if the originating agency no longer needs to use the records for the purpose for which they were created or in its regular current business, or if agency needs will be satisfied by use of the records at the National Archives.

Nonetheless, many portions of older collections have been appraised as permanently valuable but are not at the National Archives. For example, the Committee found that a great number of AEC headquarters records of substantial interest to the Committee and the public are still held by DOE either at its headquarters or at the Washington National Records Center (these include the only collection of general manager files, the post-1958 Executive Secretariat files, virtually all the Division of Military Application files, and most of the files of the Division of Biology and Medicine). In the case of the Department of Defense, the

records of the Office of the Secretary of Defense largely remain at the Washington National Records Center or with the Office of the Secretary of Defense.[13]

The public's ability to access records held by agencies is limited because (1) most agencies do not know in detail what records they still hold, and even if folder listings exist, they are not publicly available for the most part; (2) there has generally been little declassification review of these records; (3) there is no requirement that agencies permit access to even completely unclassified or declassified collections; and (4) most agencies have very limited facilities to accommodate researchers. The public's ability to gain access to documents in federal records centers is also limited because (1) the task of examining the basic inventory forms (SF-135s)[14] to determine what is in a record group is time-consuming, and in many cases, the SF-135s do not adequately describe the records; (2) there has generally been very little declassification review of these records; and (3) permission must be obtained from the appropriate agencies to review even completely unclassified or declassified collections; this permission process can be time-consuming and agencies can impose restrictions, such as permitting review but not copying.

Locating records at the National Archives has the following advantages: (1) there is generally at least some type of finding aid and, in some cases, folder listings prepared by the National Archives or the agencies when the records were sent; (2) archivists are available to assist researchers; (3) there is complete access to unclassified and declassified collections (unless Privacy Act or similar restrictions apply); and (4) many classified records at the National Archives (among the exceptions are Restricted Data records and records dealing with intelligence) are properly the subject of an informal and usually very quick in-house declassification review process called Special Declassification Review. Under Special Declassification Review, records are often reviewed within months, versus the years it takes under the Freedom of Information Act or Mandatory Declassification Review.

2. Agencies should make readily available all existing inventories, indices, folder listings, and other finding aids to record collections now under agency control. Classified finding aids should undergo declassification review, and declassified versions of these finding aids should also be made available.

Finding aids or indices to federal government records holdings are an invaluable tool, without which it would be practically impossible to locate documents of interest from among the hundreds of thousands of boxes of records maintained by the government.

Many collections of records still held by agencies have finding aids or indices that have been inaccessible to the public, either because they simply have

never been made available or because they are classified. Finding aids should be made available to the public in a headquarters office, regional offices (including all field site reading rooms), and ultimately, on the Internet. (This recommendation does not call for the creation of indices where they do not currently exist.)

For example, folder listings (which provide the titles of records files) exist for many of the AEC headquarters record collections that are still at DOE or at the Washington National Records Center. These include, among others, the only known collection of general manager's files from 1947 through 1974, all of the Division of Military Applications files from 1947 through 1974, all of the Executive Secretariat files from 1959 through 1974, and most of the Division of Biology and Medicine files from 1947 through 1974. Without the folder listings it would have been difficult for the Advisory Committee to locate particular collections of interest and, even if located, to determine the documents to be reviewed. The folder listings, however, have not been generally available to the public.

Similarly, the DOE's Oak Ridge Operations Office vault contains more than 7,000 cubic feet of classified records. The Committee found that the Records Holding Task Group (RHTG) collection in this vault (about 300 cubic feet) contained many documents of interest to the Committee, which were typically readily declassifiable. This collection has an index; however, the index is classified.

In the case of the National Archives, finding aids are generally available. However, there are fifteen National Archives facilities around the country. Currently, the only means of determining exactly what records are at a particular branch is to contact that branch directly. This is a time-consuming process, and there are understandable limits on the number of pages of finding aids archivists can copy and send to any person (a single finding aid can total hundreds of pages). It would be much simpler and easier for the public to be able to review the finding aids from all fifteen branches at any one of them.

3. The Human Radiation Interagency Working Group should ensure the development of policies to improve public access to records held by agencies or deposited in federal records centers.

In the case of a vast amount of records, particularly those not yet transferred to the National Archives, the available descriptions are often too broad or incomplete to provide meaningful clues to the contents of boxes. Thus, a Freedom of Information Act request that seeks all information on a given topic may well receive a response that ignores information located in boxes or files that are not clearly labeled or indexed. Under these circumstances, searches may be more fruitfully conducted by citizens with an interest in, and understanding of, the subject of the search. However, because so many of the nation's records

collections are off-limits to the public, even citizens who are willing to help are often precluded from lending a hand.

Many collections of interest to citizens contain no classified documents and can be made directly accessible to them. However, the Committee reviewed collections, particularly those containing decades-old records, where the entire collection was classified because it housed a small number of classified documents. For example, Record Group 326 at the College Park National Archives has approximately 160 feet of Metallurgical Laboratory/Argonne National Laboratory documentation that should be of significant historical interest. The collection itself is classified and currently inaccessible to citizens. The Committee's examination of large portions of the collection found very few classified documents, and when found, these documents were immediately declassified.

Executive Order 12958, issued by President Clinton on April 17, 1995 ("Classified National Security Information"), provides broadly for the automatic declassification (with specific exceptions) of all records that are more than twenty-five years old. In implementing the order, agencies should target collections that can be relatively quickly reviewed and made available to the public in their entirety.

4. Agencies should maintain complete records, available to the public, of document destruction.

Government records management rules provide for the destruction at varying dates in the future of all records that are appraised as temporary (that is, nonpermanent). They also provide that records be kept where certain collections, including classified records, are destroyed. But the Committee found that records of destruction are themselves routinely destroyed.

For example, upon Committee inquiry, DOE investigation revealed that the files of the AEC's Intelligence Division had been substantially destroyed during the 1970s and as late as 1989. (These files may have contained data on intentional releases, experimentation performed by the AEC for other agencies, and on the rules and practices of secret keeping regarding human data gathering). The DOE's inquiry found individuals who stated that they destroyed substantial records and that records of destruction were made. However, in accordance with DOE rules, the "certificates of destruction" were themselves later destroyed.[15] As another example, documents provided by the Department of Veterans Affairs and the Department of Defense indicate that, in 1947, the government contemplated the keeping of secret records in anticipation of potential liability claims from service personnel exposed to radiation and that some such records were kept. However, despite substantial search efforts by the DOD and the VA, the specific identity of the records referred to has not yet been determined.[16]

The Committee presumes that the vast majority of these records were destroyed in the routine course of business. Nonetheless, where records recording the destruction of important collections of records are themselves destroyed, the public cannot know whether important records have been destroyed (or merely are lost) and cannot be easily assured that destruction was in the routine course of business.

5. The Human Radiation Interagency Working Group should review and develop policies concerning public access to records generated or held by private contractors and institutions receiving federal funding.

Since World War II, the government has relied on contractors and grantees to perform an increasing number of governmental activities, including government-sponsored biomedical research. When the Advisory Committee undertook to locate information on particular government-sponsored radiation experiments, it was often told by federal agencies that, if such information was created, it would have been maintained only by nonfederal entities or investigators and not the government itself.

Where an activity is conducted by government employees (for example, researchers working in the facilities of the National Institutes of Health's Clinical Center), citizens have a right to seek access to information relating to that activity under the Freedom of Information Act. A similar right of access often does not apply, however, where a similar or even identical activity is conducted, also on federal funds, at nonfederal facilities.[17]

From the citizen's vantage point, the right to know about a government-funded activity should not depend on whether that activity is conducted directly by the government or by a government-funded private institution. At the same time, nonfederal institutions are not governmental agencies, and there may be good reasons they should not be burdened with identical obligations to retain records and to provide information to the public.

Rules are needed that accommodate both the citizen's right to know about the conduct of the government and the relevant differences between nonfederal and federal institutions with respect to duties to create and maintain publicly accessible records.[18] To ensure consistent and informed governmentwide treatment of the question, the Human Radiation Interagency Working Group may wish to call on the Office of Management and Budget (OMB) and the Office of Federal Procurement Policy (OFPP) to review the current right of members of the public to gain access to the records of government grantees and contractors.

Recommendation 18

18a: The Advisory Committee recommends to the Human Radiation Interagency Working Group that the CIA's record-keeping system be

reviewed to ensure that records maintained by that agency are accessible upon legitimate request from the public or governmental sources. This review could be performed by the CIA inspector general or an oversight panel.

18b: The Advisory Committee recommends that all records of the CIA bearing on programs of secret human research, such as MKULTRA and the related CIA human behavior projects from the late 1940s through the early 1970s, including Bluebird, Artichoke, MKSEARCH, MKDELTA, Naomi, Chance, Often, and Chickwit, become a top priority for declassification review with the expectation that most, if not all, of these documents can be declassified and made available to the public.

These recommendations are intended to ensure that the public and the government have practical access to historical records of the CIA (where access is otherwise appropriate) and to address long-standing public interest and concerns regarding secret human experiments conducted or sponsored by the CIA.

The framework of the records collections of all the Human Radiation Interagency Working Group agencies, save the CIA, is visible to the public. This is the case even in agencies, such as the Defense Nuclear Agency, where historical research records are largely classified.

While documents showing CIA participation in midcentury DOD-sponsored discussions of human experimentation were obtained from DOD, DOE, and the public National Archives, the CIA was not able to locate such documents in its own files and states that the CIA's role in these discussions was sufficiently minor that such records would not have been kept. The Advisory Committee also notes the recent report to the attorney general of the BNL Task Force, which was investigating a bank-related scandal: "While we benefited from extensive cooperation and assistance from the CIA's Office of General Counsel, the CIA's ability to retrieve information is limited. Records are 'compartmentalized' to prevent unauthorized disclosure; only some of those records are retrievable through computer databases; no database encompasses all records; and not all information is recorded. In the course of our work, we learned of 'sensitive' components of information not normally retrievable and of specialized offices that previously were unknown to the CIA personnel assisting us."[19]

In addition, while the Advisory Committee has found no evidence to show that the CIA conducted or sponsored human radiation experiments, numerous documents, some of which remain partially classified, make reference to possible CIA interest in this area. Although Advisory Committee staff has reviewed all of the available classified information concerning human radiation experiments and requested that it be declassified, the public does not as yet have the benefit of such access.

Twenty years after they were first revealed to the public, there continues to be a strong public interest in the CIA's "mind control" programs. The Advisory

Committee received numerous queries about MKULTRA and the other related programs from scholars, journalists, and citizens who have been unable to review the complete record. Although these CIA projects were the subject of significant governmental inquiry in the mid to late 1970s--by the Senate and House committees and by the presidentially appointed Rockefeller Commission--and a substantial portion of the records have been declassified and released to the public, a number of documents remain classified, and many of the documents that have been released contain numerous redactions. This has made it extremely difficult to understand the full context of the activities or to clarify discrepancies or uncertainties in the record.

A number of the declassified documents make reference to radiation experiments. However, because of the redactions, it is impossible for the public to determine from these documents whether there is additional, secret information about radiation activities. (Advisory Committee staff have reviewed the full text of these documents.) For example, the 1963 CIA inspector general report on the inspection of MKULTRA, which was declassified in redacted form in 1975, stated that "radiation" was one of the avenues explored under MKULTRA. But because so much of that document was redacted, the public reader might reasonably suspect that there is more information about radiation in the report. At the request of the Advisory Committee, the CIA re-released this document, and a handful of others, with minimal redactions.

However, few other such documents have been re-reviewed for declassification in almost twenty years. Since most of the classified CIA documents concerning MKULTRA and related programs that Advisory Committee staff reviewed were declassified upon request, the Advisory Committee believes that if the rest of these records were reviewed for historical declassification, most, if not all, of the records could be declassified without harming the national security.

So long as documents about secret human experiments are withheld from the public, it will be impossible to put to rest distrust with the conduct of government. The rapid, public release of the remaining documents about MKULTRA and other secret programs would be a fitting close to an unhappy chapter in the nation's history.

Part IV

ADDENDUM TO RECOMMENDATION 4: MEDICAL NOTIFICATION AND FOLLOW-UP

The Advisory Committee's charter requires that we consider the issue of notice to experimental subjects of potential health risk and the need for medical follow-up:

> If required to protect the health of individuals who were subjects of a human radiation experiment, or their descendants, the Advisory Committee may recommend to the Human Radiation Interagency Working Group that an agency notify particular subjects of an experiment, or their descendants, of any potential health risk or the need for medical follow-up [Sec. 4.c.].

The basic intent of this provision is not directed at subjects who have already died, or at subjects who have already become ill and been treated. It is primarily aimed at asymptomatic subjects who remain at significant risk for the development of radiation-induced cancers. Because at least two and as many as five decades have passed since the experiments took place, most of those who may eventually develop cancer as a result of the experiment will already have developed symptoms and sought treatment. However, some subjects may still be at risk and thus arguably might benefit from medical follow-up.

The initial consideration in deciding whether to implement a program of active notification and medical follow-up is the identification of populations of subjects who have been put at significant risk for the development of radiogenic cancers. The magnitude and focus of these risk estimates are driven by the specific organs placed at highest risk from the particular radiation exposure (for example, thyroid being the organ at greatest risk in the iodine 131 experiments, testes in the Oregon and Washington prisoner experiments, and the brain for the nasopharyngeal radium experiments). Risk estimates are calculated for each target organ according to a number of assumptions that may include adjustments for variables such as age at exposure, sex, or type of radiation (isotope vs. external beam) and are generally expressed in terms of excess cancer incidence/mortality for a given population over a specified period at a specified dose.

The Advisory Committee adopted an excess site-specific cancer mortality (death) greater than 1 case in 1,000 (lifetime) as a criterion for determining that a subject had been placed at increased risk. However, because of the substantial passage of time since the initial exposure, the criteria for consideration of active notification were set at 1/1,000 future or remaining lifetime risk and an excess

relative risk of greater than 10 percent (organ specific). This level of risk was arbitrarily chosen by the Advisory Committee. When compared with the normal risk of developing cancer (220 out of 1,000), this level of risk is small. The Advisory Committee chose this small remaining lifetime risk as a reasonable initial criterion to decide if a more in-depth analysis of the effectiveness of screening and intervention was needed.

Once a population has been determined to have an increased remaining lifetime risk for radiogenic cancer mortality, a second criterion must be satisfied before a government-funded medical follow-up program is recommended, namely whether the exposed individuals would likely benefit from a program of early detection or early treatment of the malignancy. Effective screening procedures for the detection of an early-stage cancer exist only for a limited number of cancer sites. Moreover, the lack of specificity of all diagnostic screening tests results in a significant number of "false positives" (a positive test result in an individual who in truth is not affected), resulting in unnecessary and potentially hazardous medical procedures that may cause health problems in and of themselves. On the other hand, most diagnostic tests are also imperfectly sensitive, meaning that some individuals who actually have the disease will be falsely reassured that they are cancer free and may thereby delay seeking attention when it becomes symptomatic. To this end the Advisory Committee has adopted the following criteria for assessing the value of screening, preventive, or therapeutic measures for exposed subjects of biomedical experiments:[20]

1. The condition must have a significant effect on the quality or length of life.

2. The condition must have an asymptomatic period during which it can be detected by available screening methods.

3. These screening methods must have high sensitivity and specificity.

4. Treatment in the asymptomatic phase must yield a therapeutic result superior to that obtained by delaying treatment until symptoms appear.

5. The medical benefits of screening and early treatment must outweigh any detrimental medical effects or risks.

These criteria were applied to each exposed population at significant risk for development of a malignancy and evaluated according to the organ(s) at risk

from radiation exposure. In each case, the conditions enumerated above must be satisfied before specific medical follow-up would be recommended.

Details of the Advisory Committee's risk calculations can be found in chapters 7 and 9. To summarize, the Advisory Committee found no experiments involving iodine 131 administration to children that met our 1/1,000 criterion for remaining lifetime risk of dying of cancer; even in the most highly exposed individuals, risks were estimated to be 1/2,000 (remaining lifetime risk). In addition, the U.S. Preventive Services (USPS) Task Force concluded that "routine screening for thyroid disorders is otherwise not warranted in asymptomatic adults or children." Although it has been suggested that people placed at risk for development of thyroid carcinoma following high-dose external irradiation to the upper body may benefit from regular physical examination of the thyroid, there are no data to support a similar risk or benefit for those who have been exposed to diagnostic or therapeutic doses of iodine 131.[21]

The Advisory Committee recognizes that in addition to the very small risk of a fatal thyroid cancer, individuals exposed as children to iodine 131 also have a larger risk of a nonfatal thyroid cancer or benign tumor, a lifetime risk that in many of the experiments we considered exceeded 1/1,000 and in a few individuals exceeded 1/100. We recognize that such conditions may require medical treatment and may be associated with considerable anxiety and discomfort. After considerable discussion, however, the Committee concluded that notification was not warranted for the purpose of detecting such conditions early, on several grounds. First, the prognosis for such conditions under standard clinical care is excellent, and there is no evidence that early detection improves the outcome. Second, even among the subgroup of about 200 children exposed to this level of risk, the number of excess cancers expected is less than one, whereas the normal prevalence in an unexposed population is about 20 to 30 percent. Third, many thyroid cancers that are detectable by screening may have no clinical significance. Finally, the most effective means of screening for thyroid cancer remains palpation, which has low sensitivity and low specificity.

For the prisoners subjected to testicular irradiation, the Advisory Committee estimates that even the most heavily exposed individual (600 rad to the testicles) would have a risk of only 0.4/1,000[22] of developing a fatal cancer, which does not attain our stated criterion. Furthermore, the USPS Task Force has concluded that "there is insufficient evidence of clinical benefit or harm to recommend for or against routine screening of asymptomatic men [other than those with a history of cryptorchidism, orchiopexy, or testicular atrophy] for testicular cancer."[23] These considerations lead the Advisory Committee to recommend against any program of active notification of these subjects. However, subjects who voluntarily request medical check-up or counseling should have such provided in a standard clinical setting.

For the children who received nasopharyngeal radium treatments, the Advisory Committee has estimated that the lifetime risk of tumors to the central

nervous system (brain), head, and neck regions is approximately 4.35/1,000 and the excess relative risk is about 62 percent, both with considerable uncertainties.[24] Although these experiments were conducted in the 1940s and much of the risk has probably already been expressed, it is still possible that the future risk is greater than or equal to our arbitrary 1/1,000 risk criterion. However, at greatest risk are the brain, and head and neck tissues, for which there is neither an accepted nor recommended screening procedure.[25] Thus, while the subjects in these experiments meet the Advisory Committee's arbitrary 1/1,000 criterion for consideration for notification and medical follow-up (criterion 1 in Recommendation 4, above), the utility of such a program has not been demonstrated, so criterion 2 of Recommendation 4 is not satisfied. Adult military personnel who participated in trials of this procedure received significantly lower radiation exposures, did not attain our arbitrary 1/1,000 criterion for risk, and would similarly fail to meet the criteria in guideline 2. Therefore, the Advisory Committee does not recommend notification and medical follow-up of children or adults in this group of experiments.

The Advisory Committee's charter also requires that we consider the need for notification of descendants of experimental subjects for purposes of health protection. The rationale for considering notification in this instance derived from the assumption that the offspring of former subjects might be at risk for disease or disability as a consequence of inherited mutations resulting from their parent's previous radiation exposure. The weight of evidence suggests that the risk of heritable genetic effects from the radiation exposures in the experiments we reviewed is very small, although it is possible that some offspring of exposed individuals might carry mutations that were caused by radiation.[26] Moreover, in most medical experiments involving external sources of radiation, efforts are made to shield the gonads (ovaries/testes) as much as possible. With the exception of the testicular irradiation experiments, where subjects agreed to undergo vasectomy to prevent transmission of any mutations that might have occurred, experiments involving external irradiation are likely to have produced relatively small gonadal doses, as would those experiments involving tracers. Even therapeutic studies involving internal radionuclides would generally involve only modest gonadal doses. Thus, in the vast majority of experiments, it is likely that the risk of radiation-induced mutations is small in relation to natural rates.

In addition to cancer and genetic effects, there are only a small number of well-established effects of radiation, including severe mental retardation among those exposed in utero (particularly between eight and fifteen weeks of gestation), sterility, cataracts, and hypothyroidism. Unlike cancer and genetic effects, however, these other endpoints appear to be "deterministic" effects that appear only after high doses that are unlikely to have been received by subjects in the experiments under consideration for notification. The Advisory Committee heard extensive public testimony about a range of other conditions that those testifying thought might be related to radiation exposures. However, the Advisory

Part IV

Committee believes that a program of active notification must be grounded on currently accepted scientific evidence concerning the conditions that are likely to be caused by radiation.

ENDNOTES

1. AEC documents reveal that in order for one researcher to publish a report on his TBI research, he had to respond to the AEC's concerns about potential public relations and legal liability consequences and did so by deleting information that might permit identification of patients. See chapter 8.

2. These awards included $750,000 in 1976 by Congress to the Olson family, $703,000 in 1987 by court order to the Blauer family, and $750,000 in 1988 by court order to nine Canadians for nonfatal brainwashing experiments. See chapter 3.

3. For example, based on facts available to the Committee, those Alaskans who were subjects of Air Force-sponsored radioisotope research (see chapter 12) and the pregnant women who were subjects of radioisotope research at Vanderbilt University (see chapter 7) may also be owed an apology. However, the Committee conducted only limited inquiry into these cases. The Advisory Committee did not attempt a full factual inquiry into the Alaskan research, which is the subject of an inquiry by a committee of the Institute of Medicine and the National Research Council, whose report is pending. The Vanderbilt research is currently the subject of litigation that may provide for fuller development of the facts.

4. Veterans who participated in weapons tests are also eligible for relief under the Radiation Exposure Compensation Act of 1990, which, however, requires claimants to elect the monetary remedy to the exclusion of other benefits to which a veteran may be eligible. We also note the Veterans Exposure Amendments of 1992.

5. National Cancer Institute, National Institutes of Health, *Radon and Lung Cancer Risk: A Joint Analysis of 11 Underground Miner Studies* (Washington, D.C.: National Institutes of Health Publication No. 94-3644, January 1994).

6. *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research* (Washington, D.C.: GPO, 1979).

7. The convening of a national panel could assist as well with the implementation of Recommendations 10 and 11.

8. *California Health and Safety Code*, vol. 40B, sec. 24176 (1995).

9. For example, in 1994, the Institute of Medicine's Committee on the Ethical and Legal Issues Relating to the Inclusion of Women in Clinical Studies recommended that the National Institutes of Health review the area of compensation for research injury. See *Women and Health Research* (Washington, D.C.: National Academy Press, 1994), 169 and appendix D to that volume titled "Compensation for Research Injuries."

10. President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Compensating for Research Injuries: The Ethical and Legal Implications of Programs to Redress Injured Subjects, Vol. 1, Report* (Washington, D.C.: GPO, June 1982).

11. Ibid., 50.

12. While lessons such as those identified above have been learned, by the same token, it seems unlikely that they will be fully taken advantage of unless some individual or entity is designated with responsibility to ensure that this takes place.

13. The post-World War II records of the Army Office of the Surgeon General are also located primarily either at the Washington National Records Center or with the Office of the Surgeon General. Similarly, very few of the post-World II records of the

Chemical Corps and its successors are located at the National Archives but are mostly found at the Washington National Records Center or the successors.

14. Standard Form 135 (SF-135) is the transmittal form agencies use when shipping records to a federal records center. A folder listing is supposed to accompany all shipments of records, with the exception of the relatively rare classified SF-135, the forms are available for examination by the public.

15. "Destruction of the U.S. Atomic Energy Commission Division of Intelligence Files," report by the Office of Human Radiation Experiments, 26 August 1994.

16. As noted in chapter 10, an investigation by the VA concluded that the "confidential Atomic Medicine Division" evidently contemplated was not activated; nonetheless, remaining documents indicate that certain records were kept in anticipation of potential liability claims. As noted further in chapter 10, the precise nature of all records at issue cannot be conclusively determined.

17. Government contractor records have been found to be beyond the reach of the Freedom of Information Act because contractors are not "agencies" who maintain "agency records," a condition required by the act. However, regulations that govern contractors may bring records that contractors maintain under the act. For example, a recent Department of Energy regulation (10 C.F.R. § 1004.3[e], 59 Fed. Reg. 63883 [12 December 1994]), provides that even if a contractor-held document fails to qualify as an "agency record" it may be subject to the act if the contract provides that the document in question is the property of DOE. For a discussion of the application of this rule, see *Cowles Publishing Company*, Decision and Order of the Department of Energy, Case No. VFA-0018, 28 February 1995.

18. In making this recommendation, the Advisory Committee emphasizes that we do not intend to alter privacy restrictions that currently limit access to records related to biomedical research (such as personal medical records).

19. 21 October 1994 Addendum to the BNL Task Force-Final Report from John Hogan, Acting Assistant U.S. Attorney, Northern District of Georgia and Counselor to the Attorney General to the Attorney General (ACHRE No. CORP-060595-A), 2-3.

20. Adapted from U.S. Preventive Services Task Force, *Guide to Clinical Preventive Services: An Assessment of the Effectiveness of 169 Interventions* (Baltimore: Williams & Wilkins, 1989), xxix-xxxii; and P. S. Frame, "A Critical Review of Adult Health Maintenance," *Journal of Family Practice* 22 (1986): 341, 417, 511.

21. National Research Council, Board on Radiation Effects Research, Committee on the Biological Effects of Ionizing Radiations, *Health Effects of Exposure to Low Levels of Ionizing Radiation: BEIR V* (Washington, D.C.: National Academy Press, 1990), 5, 287-294.

22. See footnote on testicular risk analysis in chapter 9.

23. U.S. Preventive Services Task Force, *Guide to Clinical Preventive Services,* 77.

24. See footnote on children's risk analysis in chapter 7.

25. U.S. Preventive Services Task Force, *Guide to Clinical Preventive Services.*

26. See "The Basics of Radiation Science" section of the Introduction.