A STATEMENT ON THE AMENDMENTS TO THE NATIONAL CANCER ACT BY CONGRESSMAN ANDREW MAGUIRE AT THE MEETING OF THE NATIONAL CANCER ADVISORY BOARD

Dr. Upton, Board Members, Division Chiefs, and other Members of the Institute, it is a pleasure to be here today, and to have the opportunity of discussing with you some aspects of the vitally important work in which you are engaged.

Cancer is one of the most devastating diseases with which our scientists and our society must contend. The societal importance of cancer is not due only to the fact that it is our nation's second leading killer. Nor is it simply a matter of the extent to which the disease causes premature death, since, while that does occur and is important, statistical analyses show us that there would not be a major increase in average length of life even if the disease were eradicated.

It is the <u>way</u> that cancer kills people, what happens to them psychologically and socially, the effects on family and friends which are so often devastating. And it is also the unpredictability of the disease — the fact that young, apparently healthy people, for no discernible reason, may be stricken with cancer when they might have otherwise expected many more years of active and productive living.

All of us marveled a year ago at the courage with which Senator Hubert Humphrey faced the ravages of cancer. We marveled in part because few people have the emotional resources to respond so positively in the face of so much suffering. But it should also not be forgotten that cancer also frequently afflicts people far younger than the Senator.

It was because of the particularly pernicious nature of cancer — as well as the many millions of Americans who will be affected by it — that the Congress and the Administration decided in 1971 to launch an unprecedented attack on this disease. Since that time, the National Cancer Institute has consumed annually approximately one—third of the budget of the National Institutes of Health. The decision to place so much emphasis on the problem of cancer in preference to allocations of similar dimensions to other major diseases such as heart disease, was a basic decision by the government about our health priorities. And it reflected accurately, I believe, the priority of concerns within our society.

When that public policy decision was made in 1971, it was clearly hoped that with the additional expenditures on cancer research it would be possible to achieve a cure for cancer within a relatively short period of time — perhaps even within five years. There were, of course, some elements of over-optimism and naivete in that belief. The important point, however, is that because Congress had initially hoped that research would lead rapidly to a complete cure for the disease, it did not focus to any significant extent on alternative strategies for the money that was made available to the institute.

As it became obvious to the Congress, however, that there was not going to be an early cure for cancer, discussion began to center on alternatives which would have more immediate benefits, while the basic research into biological mechanisms of cancer continued. Leading members of the scientific community suggested that there was an opportunity to identify and, to a significant extent, to protect people from exposure to environmental carcinogens. Dr. James Watson, for example, said in 1975: "It makes most sense, rather than striving for early detection, to spend most of this National Cancer Institute money to see that known environmental carcinogens are kept away from the American public." Some of these carcinogens, of course, involve lifestyle questions requiring public education. Cigarette-smoking is the most obvious example. Others, such as asbestos and vinyl chloride, involve relatively involuntary exposures in the workplace and in the environment.

At the National Cancer Institute, there has, as well been on-going concern with this issue. Under the leadership of Dr. Upton, the Institute has played a major role in the recent bold initiative to create the National Toxicology Program. The cooperation of NCI, FDA, CDC, NIOSH and NIEHS in this joint venture, the majority of funds for which come from the Cancer Institute, in my judgement is precisely the kind of effort the nation requires. And the objectives proposed in the Secretary's announcement of the Program stated well the relationship between research and public policy concerns: that the intention of the Program is to strengthen work in "testing the chemicals of public health concern, as

well as in the development and validation of new and better integrated test methods." In addition, the program is to "Provide needed information to regulatory and research agencies, . . . to strengthen the science base, . . . (and to) develop and begin to validate a series of protocols more appropriate for regulatory needs."

Nonetheless, there has been concern by Congress that the National Cancer Institute's carcinogenesis programs were not receiving a high enough priority. And, as Dr. Upton recognized when he assumed the directorship, the carcinogenesis screening program was failing woefully to live up even to its own schedule. The failure of the program to live up to expectations was a significant factor in the Congressional concern which expressed itself in the revisions to the National Cancer Act last Fall. The amendments were the product of a broad bipartisan effort, passing in turn, the Health Subcommittee, the full Commerce Committee, and the entire House.

I believe the passage of the amendments by the House and Senate and their signing into law by the President reflected a feeling in Congress that the National Cancer Institute has tended to neglect the original concern of Congress with achieving, as rapidly as possible, some beneficial impact on public health. All of us understand the vital long-range importance of basic research into cell processes and we would not presume to judge how the dollars allocated to this research should be spent. But the decision as to whether some proportion of the considerable budget given to NCI shall be allocated for preventive programs with a combination of more immediate applicability and very promising long-term impact is a matter of public policy. It is that issue which Congress has addressed in these amendments.

There is one point here which needs to be stressed. These amendments were proposed and passed in Congress by those of us who are essentially supportive of the work of the Institute. In a period of increasingly austere budgets, there are many in Congress who now look at NCI's share of the NIH budget as disproportionately large, particulary in light of the discrepancy between the original expectations in 1971 and actual accomplishments. While I, and the many who worked with me on this legislation, believe that we and you need to look together at priorities within the Institute, we do not believe that severe overall cutbacks in Institute programs would be wise, and we would vigorously oppose them. I believe that whatever our particular differences, we must work as cooperatively as possible with each other if the public interest is to be served.

I think it would be useful at this point to look at some of the major points in the new amendments to the law governing the National Cancer Institute.

First, the bill provided for an expansion of the National Cancer Advisory Board to include, as ex-officio members, the heads of regulatory agencies most concerned with the kind of research undertaken and information provided by the Cancer Institute. In addition, it stipulated that of the 18 appointed Board members, at least five must be individuals "knowledgeable in environmental carcinogenesis." Our objective in specifying these changes in membership was to ensure that the Board would have within its membership adequate expertise to make sound judgements about research priorities in environmental carcinogenesis, and to ensure that the Board would be sensitive to the concerns of those responsible for regulating carcinogenic substances.

Second, the new law specifically calls for "an expanded and intensified research program for the prevention of cancer caused by occupational or environmental exposure to carcinogens." In addition, the law requires that the demonstration centers program include "basic and clinical research into" and "training in" the area of prevention. The Congress has thus determined that research focused on prevention is to be a mandatory, rather than an optional part of the National Cancer Institute's programs. The addition of this requirement to the National Cancer Act reflects the feeling in Congress that the Institute has not given adequate priority to such programs in the past. The committee report on the Bill recognized and commended the fact that the Institute, under Dr. Upton, was "taking administrative steps to reverse its previously inadequate attention to the prevention of cancer caused by environmental, occupational and other sources." Nonetheless, the report concluded that Congress felt that progress in this area was still not satisfactory, and that "statutory emphasis on research into environmental carcinogenesis . . . is essential to underscore its concerns."

Third, the act revised the authority for the cancer control programs to

place more emphasis on education and dissemination of information to regional and local networks of physicians and to the general public. The purpose was to make certain that new information on detection, diagnosis, treatment and prevention of cancer was made widely available. As the committee explained in its report, "it is expected that this type of organization would help to identify deficiencies in local diagnostic and treatment capabilities and facilitate the continuing education of physicians." This clearly will assist in providing patients who have cancer with the most effective therapy, and facilitate the identification of at-risk populations where preventive measures could be undertaken. And, of course, stress has been placed on the importance of educating the public because it is clear that individuals often can take actions to reduce their risk of cancer — either by changing aspects of their personal lifestyles, or by acting in concert with others to reduce their exposure to occuaptional or environmental hazards.

If a strategy which places more emphasis on prevention of cancer is to achieve maximum effectiveness, it is not only necessary that there be an effective mechanism for the dissemination of information. It is also critical that there be some means for centralizing and assessing the best available scientific information on carcinogens. This, of course, is the point of the annual report on carcinogens required in the act.

The report is to include substances which are known to be, or may reasonably be anticipated to be, carcinogenic. It is to indicate, to the extent known, the nature and extent of human exposure to such substances. And, with respect to each of these substances, the report is to include a summary of effluent, ambient or exposure standards, along with the best possible judgement as to the extent to which such standards reduce human risk. The final requirement of the report is for a summary of intra-and inter-departmental requests for assistance for research and testing on carcinogenicity.

The legislative mandate in this report, in combination with the other requirements of the amendments, is in keeping with, and mandates fulfillment of recommendations dating back as far as 1973, when the Ad Hoc Committee on Testing for Environmental Chemical Carcinogens, of which Dr. Upton was a member, unanimously recommended that: "In accordance with its responsibilities under the National Cancer Act of 1971, the National Cancer Institute should develop a comprehensive national program for the identification of carcinogenic chemical hazards in the environment with a view to their elimination or control. This will require close cooperation with other government agencies, nongovernmental institutions and also industry, and development of a mechanism for continual and prompt interchange of relevant information."

I want to comment on the objectives I believe the report will help us realize, and then on some of the practical concerns that many of you may have as to how the report is to be developed and what it is to include.

For a preventive approach to environmental cancer to have any significant success, it is first necessary that there be some mechanism for coordinating the multi-faceted, disparate programs within the Federal Covernment which deal with various pieces of the problem. The coordination must occur at two levels: coordination of research, and coordination of regulation. The National Cancer Institute is not a regulatory body. That does not mean, however, that the Institute can be insulated from public health concerns which are the direct responsibility of the regulators. As the report of the National Conference on Health Research Principles, held last October, put it: "protecting the public health from diverse environmental exposures requires control options ranging from information and education to regulation at the Federal level. For each of these stages, a sound knowledge base is essential if the controls are to be appropriate and effective."

While research is the central business of the National Cancer Institute, I'm sure that we can agree that research cannot entirely be research for its own sake. The relatively large funding provided to the National Cancer program since the early 1970's was a public policy decision — a decision which was intended to have public health outcomes. Nothing in the mandate of this legislation requires that the National Cancer Institute become a regulatory body. It does require, however, that the institute order a proportion of its research priorities in the light of information it receives from the regulatory agencies as well as from the scientific community, and that it participate actively in trying to provide a mechanism for coordinating the research knowledge and articulating the best possible medical and scientific judgements with respect to carcinogens. Such an endeavor is essential for prioritizing our efforts for prevention, and for increasing the coordination between the various agencies involved.

What about the report itself? Many will object that the report requires

going beyond matters of agreed scientific fact. Further, some have feared that as a result, judgements made within the report will be subject to criticism. That, of course, is absolutely right. But we cannot wait to take actions which have a reasonable prospect of protecting public health until the last shred of scientific evidence is in. Nor can we postpone the task of controlling cancer until we have developed a fundamental understanding of cell processes and the precise mechanisms through which specific carcinogens and co-carcinogens operate. It would have been possible, for example, to prevent many of the cases of asbestos-related cancer had we reduced worker exposure many years ago, even without a basic understanding of why those exposed to asbestos so often develop cancer.

If agreement or certainty is what is required, what level of agreement is necessary? There are still some scientists who argue that we lack adequate certainty about the relationship between cancer and smoking. But, I wonder how many people in this room would argue that there is inadequate knowledge to make some public policy or public health judgements about smoking. It is always going to be a matter of degree. Obviously it will be necessary for you to establish criteria for inclusion of particular substances in the report, and for making evaluations of the regulatory standards. Criticism and controversy is an unavoidable part of dealing with issues which have public policy consequences.

I understand that many who regard their role as exclusively one of research may feel uncomfortable in a context which inherently involves elements of uncertainty. But the report, nevertheless, is an essential part of any coherent effort to create a program of prevention in environmental cancer.

In the forward plan for the National Institutes of Health, Dr. Frederickson pointed to the importance of a number of factors in the work of the Institutes. In addition to the basic research, divided between "undifferentiated research isolated from specific disease orientation" and more targeted research, the plan notes the importance of "further development and assessment of knowledge for immediate practical purposes," and of dissemination and training. I fully agree that NIH, and NCI, do have these additional responsibilities. The purpose of the amendments passed by Congress last year was to focus on improving these activities, and on improving the relationship between these activities and some of the targeted research carried out by the Cancer Institute.

The Congress, and the country, have made an immense investment in the Institute and its programs. I am glad we have made that committment. And I intend to work to ensure that we continue that support. It is urgent that we continue to fully support the basic research being done at the Institute even if the fruits of that research are still years, or decades, away. But, it is equally important that we take whatever actions we can, now, which can reasonably be expected to contribute more immediately to a long-term strategy of prevention. I believe that we can work together productively towards each of these goals.