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P.O. BOX 2370 RESTON, VIRGINIA TELEPHONE 703-620-4646

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NCAB URGES REPROGRAMMING IF NEEDED TO ASSURE $150 MILLION FOR CONSTRUCTION THROUGH FY 1985

The National Cancer Advisory Board has recommended that NCI ask Congress for $150 million in construction funds over the next six years to support upgrading of cancer research facilities to meet safety codes and expanding research activities. In a reversal of NCI policy in recent

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In Brief

SHINGLETON PROBABLE REPLACEMENT FOR MARKS ON PANEL; CONNIE HENKE HEADS ONCOLOGY NURSES

WILLIAM SHINGLETON, director of the Duke Univ. Comprehensive Cancer Center, probably will be the second new appointee to the President's Cancer Panel. Shingleton will replace Paul Marks, whose term expired this year. Joshua Lederberg will be named to Benno Schmidt's position as chairman of the Panel (***The Cancer Letter***, June 1). Neither appointment had been made official by the White House by press time. The Panel's next meeting is July 25. . . . **NIH IS SOLICITING** nominations for membership on the various institute advisory councils and boards, including the National Cancer Advisory Board. The terms of six NCAB members will expire next year—those of William Baker, Denman Hammond, Mary Lasker, Joseph Ogura, William Powers, and William Shingleton. Lasker is the only public member of that group. Anyone may nominate one or more candidates, and self nominations will be considered. Send them to Joan Bailey, DRA—Nominations, Office of the Director, NIH, Rm 1B58 Bldg 31, Bethesda, Md., 20205. . . . **ALAN RABSON**, Director of NCI's Div. of Cancer Biology & Diagnosis: "By 1981, tumor biology will be one of the most exciting fields we'll have. A lot of things now called viral oncology will be classed as tumor biology. I predict grants will be very competitive in this area, but they may be competing for a bigger pool of money." . . . **CONNIE HENKE**, nurse coordinator for the Univ. of Alabama Comprehensive Cancer Center, was elected president of the Oncology Nursing Society at the group's fourth annual meeting last month in New Orleans. She takes over from Lisa Marino, who headed the organization since it was founded. Laura Hilderly, Rhode Island Hospital, was elected secretary. Joan Piemme, George Mason Univ., and Pearl Moore, Montefiore Hospital, remain as vice president and treasurer, respectively. . . . **MORE THAN** a quarter of a million persons have called the toll free phone numbers of the Cancer Information Service with questions about cancer since the program started three years ago. The program is funded by NCI's Div. of Cancer Control & Rehabilitation and is sponsored by 19 comprehensive cancer centers. About 60% of calls are inquiries on five major cancer sites—breast, lung, colon/rectum, female reproductive system and skin. The remaining 40% ask about other cancers and a wide range of related subjects.

BOARD APPROVES WITHOUT ARGUMENT BIG INCREASE IN NCI CONSTRUCTION BUDGET

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years which resulted in drastic construction budget cuts, Director Arthur Upton indicated he would comply with the recommendation.

The NCAB, in an even more stunning policy switch, approved without objection a recommendation of its Subcommittee on Construction that if Congress fails to provide the $25 million a year the construction program needs, Upton should "reallocate funds from other areas, excluding investigator initiated grants," to bring the construction budget up to that amount.

The construction budget has been one of the first places NCI management has looked when money was needed to beef up dwindling research support funds since the budget squeeze became serious four years ago. An attempt was made to reprogram $10 million in FY 1977 construction funds to research support; since construction is a line item in the appropriations bills, congressional approval was required, and it was denied.

Nevertheless, construction grant support dwindled from the high of $47 million in FY 1972 to $11 million in the proposed FY 1980 budget.

Upton, anticipating the subcommittee's estimate of construction needs on the basis of its preliminary report (*The Cancer Letter*, Jan. 19), had increased the construction grants budget request in the proposed 1981 fiscal year budget to $20 million (plus another $5 million for construction contracts, which is primarily for work at Frederick Cancer Research Center and NCI's share of expansion of the NIH Clinical Center).

Subcommittee Chairman Denman Hammond, presenting the recommendations to the Board, asked that NCI seek an appropriation of $51 million for FY 1980, with authority to obligate that amount over a three year period as was done with the 1972 construction appropriation. The subcommittee also recommended that $20 million a year be allocated for fiscal years 1981 through 1985.

With the House HEW Appropriations Subcommittee already having completed its work on the 1980 money bill, it is probably too late to get any change in the line item for construction ($11 million for grants, $4 million for contracts). NCI could submit a request for a supplemental appropriation, but that would have practically no chance of either getting Administration support or approval by Congress.

Upton could start reprogramming some money in the 1980 budget, but substantial increases for construction—either through congressional action or reprogramming—probably will not be seen until FY 1981.

The subcommittee's estimate of construction needs was based on a survey conducted by the staff of NCI's Research Facilities Branch, whose chief is Donald Fox. The survey attempted to determine what institutions conducting cancer related research would need to bring their facilities up to requirements of local codes and federally mandated regulations for biohazard and chemohazard containment and animal facilities.

The evaluation addressed the funding needs in four categories—clinical research facilities, standard research laboratories, biohazard/chemohazard containment facilities and animal facilities. The evaluation was accomplished through four essentially independent surveys, Hammond noted. One questionnaire covering needs for both clinical and standard research facilities was sent to 106 institutions having NCI research or construction grants. Another similar questionnaire on the need for animal facilities was sent to 86 institutions. Finally, in two separate efforts, 59 member institutions of the Assn. of American Cancer Institutes and 172 NCI R01 grantees were queried concerning their biohazard facility needs. The response rates ranged from 60-100%.

NCAB members Harold Amos, Henry Pitot and Hammond worked with the staff in the survey effort.

Institutions responding to the surveys indicated that their current construction needs totaled $221 million. Of that amount, the respondees estimated that they would ask NCI for about $97 million. When asked to project ahead for five years, they estimated the need was $449 million, with $190 sought from NCI (in addition to the $97 million for current needs).

Historically, NCI has awarded about 52% of the amount requested by grantees in construction applications, which is how the estimates of $51 million for current needs and $100 million for the estimated needs from 1981 to 1985 were arrived at.

NCI until two years ago provided funds on a 3 for 1 basis, requiring the grantees to put up at least $1 for every $3 contributed by the government. However, since the awards were rarely if ever as much as requested, institutions ended up providing $2 for every $1 they received from NCI.

Amos commented that the Board should be aware "this is not for new construction but is required to bring facilities up to snuff. There are a lot of people working in facilities, involving both biohazards and chemohazards, which would not pass muster."

Current funding needs break down like this among the four categories:

Clinical research labs—required, $61 million; to be requested from NCI, $21 million; probable awards, $11 million.

Standard research labs—$74 million, $34 million, $17 million.

Animal facilities—$34 million, $17 million, $9 million.

Biohazard/chemohazard containment labs—$53 million, $27 million, $14 million.

The five year projected needs, 1981-85:

Clinical research labs—$160 million, $55 million, $29 million.

Standard research labs—$190 million, $86 million, $45 million.

Animal facilities—$51 million, $25 million, $13 million.

Biohazard/chemohazard containment labs—$48 million, $24 million, $13 million.

"The NCAB Subcommittee on Construction feels that the upgrading of facilities to meet safety codes is critical to the cancer research effort. The subcommittee is also concerning that NCI is funding hazardous research in unsafe (non-biohazard containment) facilities," Hammond's report concluded.

REGULATORY COUNCIL REFUSES SUPPORT FOR STUDY OF CARCINOGEN ASSUMPTIONS

Assumptions which have become accepted as facts form the basis for much of the federal government's regulatory activities against carcinogens, and the government should support a National Academy of Sciences study to determine the total incidence of cancer that "might reasonably be attributed to exposure to industrial chemicals."

That recommendation was made by John Elliott, a consultant to the Regulatory Council, a White House office made up of the heads of the federal regulatory agencies. The Council chose not to act on Elliott's recommendation at this time.

Elliott told ***The Cancer Letter*** that he developed his recommendation with the assistance of "several people at EPA." It is not an EPA document, however; in fact the Environmental Protection Agency owes its existence largely to the assumption that control of chemical carcinogens in the environment would significantly reduce cancer incidence and mortality.

Among the conclusions Elliott reached in making his recommendation was that "regulations are almost never based upon direct evidence that the specific chemical exposures of concern actually cause cancer. They are based rather upon an untested assumption that industrial chemicals in general are responsible for an appreciable amount of cancer."

Moreover, Elliott cited a study which shows that when the effect of the increasing age of the American population is removed, the total U.S. cancer mortality rate has been decelerating since 1920. When the effect of smoking cigarettes is removed, the cancer mortality rate has been declining. "Therefore, industrial pollution cannot be responsible for—and its elimination is unlikely to reverse—the post World War II increase in the overall U.S. cancer mortality rate."

Elliott's recommendation and arguments supporting it follow:

Introduction:

The government's policy toward regulating industrial chemicals suspected of causing cancer is an ideal topic for study by the Regulatory Council because:

1. The regulations that flow from this policy are very costly. 2. The evidence of need for these costly regulations is, at best, conjectural. 3. This cost/benefit anomaly is unlikely to be critically examined by the agencies in their normal course of business.

Discussion:

Recently enacted federal environmental regulatory authorities are based in large part upon the assumption that industrial chemicals (other than tobacco and those intentionally put in food or drink) are causing a dramatic increase in the incidence of cancer.

This assumption has been fostered by extensive publicity given to expert opinion that:

1. Cancer has become the second leading cause of death in the United States.
2. Eighty to 90% of all cancer is caused by environmental factors.
3. Cancer mortality rates have increased sharply, in recent decades, in the face of declining mortality rates for most other diseases.
4. During the same period such factors as the petrochemical industry, use of pesticides, and the combustion of fossil fuels have increased exponentially.

The accumulated weight of the publicity given to these and similar assertions persuaded Congress that industrial chemicals are, indeed, probably causing a significant and increasing amount of cancer. This cause/effect relationship was not really demonstrated but was, rather, simply adopted as a "working assumption" to be examined by the relevant agencies.

As the agencies implemented the new authorities, however, this assumption became, for regulatory decision-making purposes, a "fact". Congress had expressed its concern by enacting remedial laws and the regulatory agencies, predictably, considered it their business to implement those laws—not to question the soundness of the underlying premise. In effect, the agencies adopted not only the original assumption, but also the corollary assumption that regulations are needed. Thus, regulatory efforts are not, as one might suppose, focused upon determining whether industrial chemicals are actually causing human cancer. Because there is usually no reasonable alternative, experimental animal data are almost invariably used to assess the human carcinogenic potential. Such data—typically generated by exposing a very small number of rodents, throughout their lifetimes, to massive doses of the chemical—are extrapolated to draw inferences about the probable consequences of exposing very large populations of humans, for some generally small but unspecified fraction of their lifetimes, to doses several orders of magnitude lower than those administered. The yawning uncertainties that surround such inferences are further compounded by near-total ignorance of how many people are actually exposed to the chemical, for how long, or at what concentrations.

In considering the utility of this approach to assessing the human carcinogenic potential of a chemical, it is helpful to bear in mind that in spite of all of the animal testing that has been undertaken to date to detect carcinogenicity, there are presently only 26 known human carcinogens, and, of these, only six were discovered by testing animals—the remaining 20 were initially identified by direct evidence in humans.

The enormity of uncertainty is such that, as a practical rule-making matter, any chemical found to cause cancer in test animals is assumed to cause cancer in man, and the postulated degree of risk is based almost entirely upon the estimated human exposure. It is within this context that agencies are disposed to promulgate costly regulations designed to protect human health, while rejecting out of hand any suggestion to "quantify" (read "indicate") the anticipated health benefits.

This regulatory method does not "fit" our state of knowledge. If we were reasonably confident that the population of industrial chemicals, in general, do significantly contribute to the indicence of cancer, there would be at least some justifica-

tion for selecting specific chemicals for regulation, from that population, on the basis of surrogate data that do not actually demonstrate risk. Without assurance that industrial chemicals cause cancer, however, the adopted approach is tantamount to attempting to identify, without direct evidence, the source of a problem that may not exist.

Ideally, of course, regulations to control industrial chemicals would be based upon, and tailored to, direct evidence that the selected chemical(s) actually caused cancer in humans. This approach would not only ensure that the benefits conferred by such regulations exceeded the costs incurred, but would also obviate the need to postulate a general cancer-causing role for industrial chemicals. Unfortunately, it is apparently impossible to acquire the requisite direct evidence.

The adopted alternative of relying upon animal bioassay and other surrogate evidence to infer the potential risk of cancer to man, however, must necessarily rest upon a reasonable assurance that industrial chemicals in fact cause human cancer.

That assurance is eroding. As shown below, the factors cited at the outset of this paper, which initially seemed to suggest that industrial chemicals do significantly contribute to the incidence of cancer, do not, upon scrutiny, support that contention.

1. Cancer has become the second leading cause of death in the United States.

This is due far less to an increase in the cancer mortality rate, itself, than to our remarkable success in reducing mortality rates for other causes of death—most notably infective and parasitic diseases.

2. Eighty to 90% of all cancer is caused by environmental factors.

"Environmental factors," in this statement first publicized by John Higginson, director of the International Agency for Research on Cancer, has been popularly misapprehended to mean "industrial chemicals." It does not. It means, rather, all chemicals in the environment, man-made or not, and including such things as aflatoxin, alcohol, and tobacco. Put another way, the statement simply says that only 10 to 20% of cancer is inherited. . . . Higginson stated that "occupational hazards are far less important than such factors as individual lifestyle in explaining the causes of cancer," and that "point-source occupational hazards are responsible for only about 6% of cancer incidence in Britain."

3. Cancer mortality rates have increased sharply, in recent decades, in the face of declining mortality rates for most other diseases.

Most if not all of the increase in U.S. cancer mortality rates since 1930 can be attributed to (1) the increasing age of the U.S. population, and (2) smoking. An analysis of U.S. age-adjusted and age-specific mortality trend data, prepared by Ed Brooks and Anne Barton in 1976 (appears following Elliott's recommendation).

4. During the same period such factors as the petrochemical industry, use of pesticides, and the combustion of fossil fuels have increased exponentially.

It is true that these factors appeared and matured during the same time period that (a) medical discoveries virtually eliminated infectious diseases, thereby enabling an increasingly greater proportion of the population to live long enough to die of degenerative diseases, (b) the American people began smoking cigarettes in large numbers and great quantities, and (c) cancer mortality rates increased. While the functional relationships among these coincident trends are not fully understood, it would appear that the role of industrial factors in the causation of cancer has been vastly overestimated.

Conclusions:

1. A considerable amount of public money and effort is allocated to developing, promulgating, and enforcing regulations to protect man from the threat of cancer posed by industrial chemicals.
2. An even greater amount of private resources are expended to comply with these regulations.
3. The regulations are almost never based upon direct evidence that the specific chemical exposures of concern actually cause cancer.
4. They are, rather, based upon (a) an untested assumption that industrial chemicals in general are responsible for an appreciable amount of cancer, and (b) indirect or surrogate evidence that certain specific chemical(s) may, within the context of this assumption, pose the greatest risks.
5. Confidence in the validity of the untested assumption is crucial to the integrity of the logic of this regulatory approach.

Recommendation:

Although we cannot know precisely how much human cancer is caused by exposure to industrial chemicals, we should, since the regulatory rationale depends upon it, obtain the most informed opinion possible. An ideal activity for the Regulatory Council, then, would be to sponsor a study of this question by the National Academy of Sciences.

Specifically, the Regulatory Council could ask the Academy to provide an opinion regarding the proportion of the total incidence of U.S. cancer that might reasonably be attributed to exposure to industrial chemicals. In addition, the Academy might be asked to address such specific questions as:

1. How much of the cancer attributable to industrial chemicals can we reasonably expect to eliminate with federal regulations?
2. How much of the cancer attributable to industrial chemicals is due to occupational exposures regulable under OSHA?
3. How much of the cancer attributable to industrial chemicals is due to relatively low levels of ubiquitous pollutants broadly affecting the general population, as opposed to relatively high concentrations affecting small pockets of localized populations?
4. How confident can we be of the answers to these questions, and what are the probable margins of error?
5. Are there chronic health effects other than cancer that might be attributable to industrial chemicals about which, from a regulatory point of view, we should be equally or more concerned?

If such a study concludes that industrial chemicals probably do contribute significantly to U.S. cancer rates, we can proceed with renewed confidence that our regulatory sights are set, if not on the bullseye, at least on the right target.

If, on the other hand, it appears that industrial chemicals contribute only negligibly to the incidence of cancer, we would certainly reassess and radically modify the present federal legislative and regulatory approach. Regardless of what directions this might take, it is hard to imagine a more fertile opportunity to improve regulatory cost-effectiveness.

Following is a summary of the Brooks-Barton study:

This study was undertaken to identify causes of death which might be increasing due to regulable environmental pollutants. All causes of death were grouped into 14 categories selected to differentiate diseases (maintly degenerative) with increasing mortality rates from those with declining or stable rates. Age-specific rates were then computed for each category at each of six age levels. The age levels were also selected to emphasize degenerative diseases.

Cancer was first considered separately from all other causes of death. The crude total cancer mortality rate, which takes population size but not age into account, has been increasing

at a fairly constant rate since 1900. The age-adjusted rate has been decelerating.

Any increases in the total age-specific cancer mortality rates since 1930, among all age groups under age 85, are more than accounted for by smoking. Tobacco consumption causes 85 to 90% of all lung cancer, and respiratory cancer is the major component of the total cancer mortality rate increase since 1950. With respiratory cancer removed, the total cancer mortality rate has declined, since 1930, in every age group under 75. The duration and rate of the decline has been longer and steeper among the younger age groups. Most if not all of the publicized increase in the national cancer mortality rate is due to:

a. Increases in the size of the U.S. population.
b. Increases in the proportion of elderly in the population.
c. Decreases in deaths from other causes.
d. Tobacco consumption.

Mortalities from lung cancer, breast cancer, and a residual category which includes leukemia and cancer of the urinary organs, brain, eye, and thyroid gland, have been increasing among relatively young segments of the population. Other cancer mortality rates broken out in this analysis have either been declining for all age groups, or increasing only among the very old.

All causes of death (including but not limited to cancer) were then divided into five categories, again grouping those with increasing mortality rates separately from those with declining rates. Although mortality rates for three of the five categories (cardiovascular diseases; diabetes, bronchitis, emphysema, and asthma; and cancer) have been increasing, most of these increases occurred in the population over age 74. Infective and parasitic diseases, and a residual category including all other causes of death, declined very sharply at all age levels.

The mortality rates for cancer are an order of magnitude lower than those for cardiovascular diseases. During the past 30 years, diabetes mellitus has increased only among those over age 74. In contrast, the mortality rates for the emphysema, bronchitis, and asthma category increased at younger ages as well. These latter trends bear a marked similarity to those for lung cancer—suggesting that here again smoking may play a major role.

Total mortality rates have been sharply lower every decennial census year since 1930 for all age groups. Mortality rates for cardiovascular diseases are higher, and account for an increasingly larger proportion of all mortalities, at each older age level. Cancers comprise an increasing share up to age 64, then decline in relative importance at each successively older age group.

Major Implications:

Four implications of this study warrant mention:

1. Analyses and public statements regarding causes of death that might result from regulable environmental pollution should be based upon age-specific mortality rates, rather than upon raw numbers of deaths, crude death rates, age-adjusted rates, proportional mortality or other statistics which inadequately control for changes in population size, age distribution, decreases in death from other causes, and other extraneous factors which, when not taken into account, confound and exaggerate the impact of environmental pollution in the U.S. since 1930.

2. The national cancer mortality rate does not provide a useful index of the health effects of industrial pollution since World War II—because no discernible increase attributable to these factors has occurred.

The attention presently focused on the national cancer mortality rate should be shifted to (1) other diseases and (2) abnormally high mortality rates among specific local populations, which are more likely to be caused by environmental pollution.

3. Significant reductions in national mortality rates from any of the diseases examined here appear unlikely to result from environmental regulation—simply because those few which are increasing among persons under age 75 are, like lung cancer, probably strongly influenced by smoking. Again, focusing on local populations to find pockets of abnormally high mortality rates which may be caused by environmental pollution is far more promising.

4. Each disease category examined here consists of many specific diseases combined, for the purposes of this analysis, on the basis of similar trends in their crude mortality rates. Particular diseases within these categories undoubtedly differ in their age-specific trends and, hence, in their significance for EPA regulatory policy. A more detailed analysis of the age-specific trends for these particular diseases is therefore recommended.

Specific Findings:

A list of conclusions follows:

1. When the effect of the increasing age of the American population is removed, the total U.S. cancer mortality rate has been decelerating since 1920.

2. When the effect of smoking cigarettes is removed, the cancer mortality rate has been declining—probably since 1930 and certainly since 1950.

3. Therefore industrial pollution cannot be responsible for —and its elimination is unlikely to reverse—the post-World War II increase in the overall U.S. cancer mortality rate.

4. Respiratory (trachea, bronchus and lung) cancer mortality rates have increased phenomenally and inexorably since 1930 among all groups over age 44. Eighty-five to 90% of this is caused by smoking. No other cancer sites have experienced percentage increases even remotely as high. This is particularly true among the population under age 75.

5. Other cancer site rates have also increased over the 40 year period, albeit more slowly. Some of these increases may be due to factors regulable by EPA. Among the cancers that have shown such increases are:

a. Cancer of the breast.

b. Leukemia and other neoplasms of lymphatic and hematopoietic tissue and cancer of the urinary organs, brain, eye, and thyroid gland.

c. Cancer of the intestines, duodenum, rectum, and pancreas.

6. The most likely candidates for EPA regulatory policy implications are probably in group 5b, above. Considered collectively this group had, next to respiratory cancer, the highest relevant 1970 age-specific mortality rates and, from 1950 to 1970, the highest relevant age-specific mortality rate increases. Breast cancer is another possible candidate.

7. The 1970 "cardiovascular" mortality rate was more than two and a half times the cancer rate.

8. From 1930 to 1970 the mortality rate increased 110% for "cardiovascular" diseases; 100% for diabetes, bronchitis, emphysema, and asthma; and 63% for cancer.

9. All other major causes of death declined during this period. The fact that cancer accounts for an ever increasing proportion of all mortalities is due in large part to the decline in these other causes, rather than to any increase in cancer. More than 40% of the proportional share increase attributable to cancer from 1930 to 1970 was due to this eroding base.

10. Most of the mortality rate increases in "cardiovascular" diseases, cancer, and most particularly diabetes, from 1930 to 1970, occurred among the population over age 74. The mortality rate increases for bronchitis, emphysema and asthma, in contrast, were quite steeep among all groups over age 44.

11. Aside from "cardiovascular" diseases the most significant mortality rate increases since 1950 occurred with respiratory cancer; the "increasing" residual cancer group; and bronchitis, emphysema, and asthma. Respiratory cancer is almost entirely due to smoking and, based upon similarities in the mortality rate trends, the same cause may be suspected for the bronchitis, emphysema, and asthma group.

12. The total U.S. mortality rates fell at every age level from 1930 to 1970. The magnitude of the decline ranged from 67% among those under age 45 to about 30% among those over 54.

13. The mortality rate for "cardiovascular" diseases declined for the population under age 45, increased by about 12% among those 45 to 74, by 22% for those 75 to 84, and by 44% for those over 84.

14. Although the respiratory cancer mortality rate increased sharply at every age level, the mortality rates for all other cancers, considered collectively, declined over the 40 year period in every group under age 75. The rate increased by seven percent in the 75 to 84 age group, and by 17% among those over age 84.

15. Cancer and "cardiovascular" diseases played a relatively minor part in mortalities under age 45.

16. "Cardiovascular" diseases were responsible for an increasingly larger proportion of all mortalities at each successively older age level. Among those age 45 to 54 they comprised more than one-third of all 1970 mortalities; by age 85 and over they accounted for two-thirds.

17. In contrast, total cancer comprised an increasing share of all deaths only up to age 64, at which point it declined in relative importance at each successively older age group. This is also true of both sub-components examined—i.e., respiratory and "all other" cancer.

The Regulatory Council was established by President Carter last year to coordinate policy development among the regulatory agencies. One of the jobs it is tackling is development of a common policy for the regulation of carcinogens; "we're in the very early stages of that," a Council spokesman told ***The Cancer Letter.***

He said the Council did not go along with Elliott's recommendation to support an NAS study because "we're not a supplementary research body. Our job is to pull together and coordinate the efforts of the agencies, not to impose our will on them."

He agreed the questions Elliott said should be addressed by NAS were important, "but we don't think we need the answers to coordinate the work of other agencies."

If the regulatory agencies, research agencies (NCI, NIEHS), or any other agency or group feel the answers to those questions should be determined, then they are the proper ones to request the study, the spokesman said.

NCI'S JUSTIFICATION FOR FISCAL YEAR 1981 BUDGET REQUEST OF $1.135 BILLION

In its request to the White House for a budget of $1.135 billion for the fiscal year that starts Oct. 1, 1980 (FY 1981), NCI briefly described the various projects it hoped to support if it did receive that amount. The first portion of that justification appeared last week in ***The Cancer Letter;*** the rest follows:

Clinical Treatment Research (continued)—Biological research will be initiated studying hyperthermia including mechanism studies in in vitro and in vivo systems, therapeutic studies with in vivo models, studies on the effects of hyperthermia on physiological parameters in man and animals, and clinical studies when appropriate. A linear accelerator will be installed in the NIH Clinical Center operating rooms to permit high dose, single dose intraoperative radiotherapy directly to the tumor bed with retraction of critical organs out of the field. Improved methods of treatment planning including integration of computer and CAT scanning with radiation therapy will be further developed.

In the clinical cooperative groups, additional support will be provided in areas of radiotherapy, surgery, pathology and statistics reflecting expansion of multimodal therapy. New sophisticated clinical trials planned in all solid tumors and hematologic malignancies will result in increased support to all modalities, pathology review, and expanded statistical input. Intergroup studies will be launched in the following areas: sophisticated cell biology techniques of prognostic significance (CML-blast crises); pathology review and surgical staging (mesothelioma); and histochemistry and marker studies (mycosis fungoides and pediatric brain tumors).

Projects will be initiated involving exploration of the value of retinoids in high risk populations for treatment of primary or secondary neoplasms such as carcinoma of the cervix and cervical dysplasia, stage I lung cancer, and carcinoma of the bladder. Esophageal cancer currently has a prognosis worse than either cancer of the pancreas or acute myelogenous leukemia with no current effective systemic treatment regimens. Coordinated research involving surgery, radiotherapy and chemotherapy into an effective local and systemic approach will be initiated.

J. Rehabilitation Research—Increase of $169,000 over 1980 estimate of $6,044,000. Increases will be used primarily to support nutrition research as it relates to rehabilitation of the cancer patient. New initiatives will be developed to evaluate dietary practices related to rehabilitation and continuing care. Support of research in pain control, terminal care, and the psycho-social aspects of cancer will continue. Demonstrations will be supported on use of multidisciplinary teams to deal with cancer related pain, epidemiologic studies of pain incidence and studies to evaluate the pattern of pain management throughout the U.S. Field testing will be carried on to evaluate the Hospice concept in the U.S. Patient-family units will receive "full service" support from the at home service and in-facility components of the hospice. A full range of supportive services for the patient-family unit will be provided through support of appropriate activities, companionship, social services support, training for at-home care medical support for crisis intervention, and bereavement spiritual counseling. This grant supported research program continues to solicit research efforts dealing with the morbidity of young adult long-term survivors; new approaches to rehabilitation programs of head and neck cancer patients in relation to speech and swallowing; and the

development and evaluation of new biomaterials for better prosthesis construction.

II. Resource Development

A. Cancer Centers Support—Increase of one position and $10,013,000 over the 1980 estimate of 24 positions and $67,931,000. The Cancer Center Support (core) activity provides and administers grant funds to assist in the development and maintenance of multidisciplinary cancer facilities for laboratory and clinical research, as well as training and demonstration of the latest diagnostic and treatment techniques. Exploratory grants provide funds to institutions for planning new cancer programs or centers; strengthening ongoing programs by coordinating and consolidating existing cancer activities; and developing or expanding specific programs such as cell biology, carcinogenesis, or radiation. The Centralized Cancer Patient Data System in comprehensive centers has been designed to encourage use of uniform cancer diagnostic terminology and staging in clinical research to facilitate the exchange among centers of compatible data relating to cancer as a disease. These funds will permit maintenance of most centers at existing levels of effort and make possible establishment of four new centers. There will be an expansion of the regional activities directed toward cancer prevention and cancer treatment research. To evaluate effectiveness of prevention and treatment, funds will be provided for the CCPDS. Expansion of cancer prevention activities will also expand efforts in the tumor registries, epidemiological-statistic units and bio-statistical units.

B. Research Manpower Development—Increase of $4,820,000 over the 1980 estimate of 17 positions and $37,033,000. Additional scientists are needed in the several medical disciplines important to clinical cancer research and in the many basic disciplines that have integral and important roles in investigating the fundamental nature of cancer. New cancer scientists are needed not only to fill places vacated by individuals leaving cancer research, but also to provide innovation in cancer research. There is a continuing need to improve and integrate multidisciplinary cancer teaching to undergraduate and graduate students in the curricula of medical and dental schools and similar teaching institutions.

1. Clinical Cancer Education—Increase of $1,613,000 over the 1980 estimate of five positions and $11,344,000. Clinical cancer education grants assist medical and dental schools and other selected institutions. Currently 89 of more than 300 eligible institutions have these grants, directed toward undergraduate and graduate, medical and dental students, and practicing physicians and dentists, enabling institutions to define their teaching objectives relative to cancer, to plan core cancer curricula, to offer additional cancer electives, to develop new teaching materials, and to provide a broad, coordinated multidisciplinary approach to undergraduate cancer education. High priority projects include: Development of a reference center for cancer education materials and teaching aids that will assist educators in selecting up-to-date, effective teaching materials relative to cancer. A program of grants for graduates and the clinical oncology specialties, essential to providing adequately trained physicians for optimum diagnosis and management of cancer patients. Additional workshops conducted to meet educational needs relative to cancer in various clinical disciplines such as neurology, orthopedics, and urology. Grants for teaching of cancer in medical and dental schools to strengthen the exposure of students to the best and most promising aspects of cancer care. Support of 400 undergraduate and graduate students specializing in cancer education by means of cancer education grants.

2. National Research Service Awards—Increase of $2,590,000 over the 1980 estimate of 11 positions and $21,233,000. Increased funding would provide for the projected 5% rise in the cost of stipends. An additional 40 postdoctoral research trainees and fellows would be supported. Of that number, 34 would be integral to five new institutional grants. These would support additional clinical and fundamental cancer research training sites of excellent quality. The other six fellowship awards would complement the slight increase in institutional fellowships by providing support directly to individuals who present research training plans best executed outside of institutional grant framework.

3. Research Career Awards/Research Career Development Awards—Increase of $617,000 over the 1980 estimate of one position and $4,456,000. Research career development awards provide especially promising young investigators with financial support essential to their maturation into fully independent and highly competent researchers. The additional $617,000 in this program will increase the number of awards by 16 from 119 in 1980 to 135 in 1981. Research career awards program will remain at the current level of funding.

C. Construction—Increase of $10,043,000 over the 1980 estimate of 12 positions and $15,826,000. NCI and the National Cancer Advisory Board have recently completed a detailed investigation of the safety of current cancer research facilities and have determined that funds are needed by many facilities in order to meet federal biohazard containment, animal care, and research safety standards. These facility standards are for the protection of both the public and the cancer researchers. The requested 1981 budget will partially meet identified needs for these biohazard containment laboratories, biohazard animal facilities and oncology research areas. Construction contract funds will be used to renovate, upgrade and improve facilities on the NIH campus and at the Frederick Cancer Research Center.

III. Cancer Control—Increase of three positions and $9,297,000 over the 1980 estimate of 80 positions

and $66,365,000.

A. Prevention—Increase of three positions and $4,746,000 over the 1980 estimate of 27 positions and $22,780,000. New initiatives in medical physics will be supported, including field measurement of organ doses received from diagnostic x-rays and the enhancement of the patterns of medical physics services provided. The numbers of cancers caused by man-made ionizing radiation are reduceable. Regional centers for radiological physics will be supported to monitor dosimetry and act as a resource in consultation and continuing education for all Cancer Control contractors and grantees having diagnostic radiology or radiation therapy as a part of their program. Dissemination of the technology developed for use by these centers will be supported. This technology will be packaged for widespread dissemination to interested practicing physicians and institutions. These programs will be supplemented by training programs for x-ray technicians to form a broad based effort to reduce exposure levels associated with diagnostic x-rays and radiation therapy.

Demonstration and education programs tailored to the needs of populations at high risk as a consequence of exposure to carcinogens in the environment will be supported. Exposure may occur in the community or the work place, or may occur as the result of personal habits (e.g., smoking). The problems of identifying and notifying members of high cancer risk populations regarding their exposure to and risks from, various carcinogens are of particular concern and will be addressed by studies, trials and demonstration programs. The psychological effects resulting from notification and the implications of these effects as motivation for a more cancer-safe life style will be evaluated and the results employed in the development and demonstration of more effective notification and education programs. A carcinogenic support center to develop alerts and educational materials for industrial hygienists and family physicians is planned as one component of this new initiative. An expansion of the capability to provide information about effective methods for dealing with asbestos in the environment is a specific example of this effort. Demonstrations of more comprehensive smoking cessation programs will result from current evaluations of existing programs.

B. Detection, Diagnosis and Pretreatment Evaluation—Increase of $1,190,000 over the 1980 estimate of 23 positions and $14,109,000. A number of cytology training projects for lung, bladder, cervical, and endometrial cancer will be initiated. These will augment the projects currently in progress or in planning to deal with the effective diagnosis of minimal breast cancers. There is a critical national need for trained cytotechnologists and this program will deal directly with that need. A variety of programs designed to enhance and improve the diagnosis of colorectal and other cancers will be supported. These will include programs to develop the information necessary to make scientific cost/risk/benefit assessments of various screening procedures.

C. Treatment, Rehabilitation and Continuing Care—Increase of $3,361,000 over the 1980 estimate of 30 positions and $29,476,000. Demonstration programs dealing with problem areas related to the care of terminal cancer patients and assistance to their families will be continued.

RFPs AVAILABLE

Requests for proposal described here pertain to contracts planned for award by the National Cancer Institute, unless otherwise noted. Write to the Contracting Officer or Contract Specialist for copies of the RFP, citing the RFP number. Some listings will show the phone number of the Contract Specialist, who will respond to questions. Listings identify the respective sections of the Research Contracts Branch which are issuing the RFPs. Address requests to the contract officer or specialist named, NCI Research Contracts Branch, the appropriate section, as follows:
Biology & Diagnosis Section and Viral Oncology & Field Studies Section—Landow Building, Bethesda, Md. 20014; Control & Rehabilitation Section, Carcinogenesis Section, Treatment Section, Office of the Director Section—Blair Building, Silver Spring, Md. 20910.
Deadline date shown for each listing is the final day for receipt of the completed proposal unless otherwise indicated.

RFP NCI-CB-94329-37

Title: *Maintain an animal holding facility and provide attendant research services*

Deadline: *July 23*

NCI is soliciting proposals from organizations with experience and demonstrated capabilities in the care and maintenance of laboratory animals. The contractor shall furnish all necessary personnel labor, facilities and equipment, materials and supplies except as may otherwise be provided by the government. Offeror must have working experience in the specific type of tasks involved. Offeror must be within a 50 mile radius of NIH, Bethesda, Md.

This proposed procurement is under a 100% small business set aside, the size standard for which is a concern, including its affiliates, having average annual sales or receipts for its preceding three fiscal years not in excess of $2 million.

Contract Specialist: Robert Stallings
Biology & Diagnosis
301-496-5565

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