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February 20, 1978

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Dr. E. A. Mirand Associate Institute Director Roswell Park Memorial Institute 666 Elm Street Buffalo, New York 14263

Dear Doctor Mirand:

Congratulations on the award you recently received from the New York Division of the American Cancer Society for your role in the development of a curriculum for teaching students about the nature of cancer and ways in which it can be prevented. Your contributions to the N.Y. Division of the ACS has aided in making their program successful.

Also, I would like to take this opportunity to express my appreciation for your many efforts in the AACI program.

Sincerely yours,

R. Lee Clark, M. D. President

RLC: jh

cc: Dr. Gerald P. Murphy Dr. Gordon Zubrod

bcc: Dr. George Blumenschein

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Timothy R. Talbot, Jr. M.D. Philadelphia, Pennsylvania

February 10, 1978

To:	Members of the Board of Directors
From:	Dr. Edwin A. Mirand, Secretary-Treasurer, AACI
Subject:	OSHA Hearing Statement

Enclosed please find comments Dr. Pitot has prepared for the OSHA hearing on April 4th. This statement must be approved by the Board of Directors.

If I do not hear from you by the 21st of February, I will assume that you approve of Dr. Pitot's statement intact and will advise him to proceed with the statement as representative of AACI.

EAM:1b Enclosure

cc: Dr. Wm. W. Singleton Dr. S. K. Carter Dr. R. Lee Clark Dr. J. R. Durant Dr. A.M. Mauer Dr. H.C. Pitot Dr. T.R. Talbot, Jr. Dr. C.G. Zubrod Dr. G.P. Murphy

MCARDLE LABORATORY FOR CANCER RESEARCH

UNIVERSITY OF WISCONSIN . MADISON, WISCONSIN 53706

January 26, 1978

COMMENTS WITH REGARD TO THE PROPOSED CLASSIFICATION OF CARCINOGENS FOR PURPOSES OF REGULATION OF EXPOSURES (29 CFR Part 1990)

We have examined the document of the Occupational Safety and Health Administration on its proposed Identification, Classification and Regulation of Toxic Substances Posing a Potential Occupational Carcinogenic Risk. We are in complete agreement with the need to reduce exposures of workpersons and of the public to chemical carcinogens and with the need for some regulations that limit exposures to these chemicals. However, we wish to make the following statements with regard to the proposed regulations.

- The proposed regulations present serious scientific and practical problems that must be remedied:
 - It is not scientifically sound to put all toxic chemicals that have carcinogenic activity (Category I) or suspected carcinogenic activity (Category II) into these comprehensive categories and to then treat all of the chemicals in each category similarly regardless of the potencies of the chemicals as carcinogens.
 - It is not scientifically sound to regulate all makers and users of a chemical in Category I or Category II in the same manner, regardless of the amount of the chemical being handled.
 - 3. Application of the regulations as drawn up will be very expensive in terms of manpower (industrial, governmental, medical) and money for the amount of protection against carcinogens provided to U. S. citizens. Expenditures of time and money for regulation of carcinogens must be used for situations where there is some real possibility of risk to individuals.
- II. We urgently propose the following modifications:
 - A system must be devised for subclassifying chemicals in each category with regard to their carcinogenic potencies (Category I) or suspected potencies (Category II). The regulations for use

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of the chemicals in these categories should be less stringent for less potent carcinogens than for more potent carcinogens. Those carcinogens that require very large doses for tumor induction in the animal should not be subject to stringent regulation (for example, the very weak carcinogens acetamide and safrole) unless there is other evidence indicating the need for such regulation.

- The regulations should be applied only to workplaces where amounts of the chemical in excess of some specified lower limit are handled in a specified period of time (pounds per month, for example).
- 3. We urge that cancer research laboratories be exempted from the proposed regulations. Cancer research laboratories have a very high ratio of professionally trained investigators to technical workers; this group of professional employees is particularly knowledgeable with regard to possible hazards and with regard to means of containing their work. Furthermore, the requirements of research will generally dictate that the laboratory have a wide variety of chemicals in it, that the specific chemicals in use vary from time to time (depending on the research problems and their states of development), and that the amounts of the individual chemicals being handled will be relatively low. These research laboratories should, of course, be subject to general requirements such as protective clothing; the availability of appropriate chemical fume hoods; facilities for storage and containment of carcinogens, flammable solvents, and other hazardous chemicals: availability of respirators for emergency use; provision of instruction for technical personnel on the use of hazardous materials, etc.

III. Background Information

It should be noted that chemical carcinogens can differ by a factor of at least 10⁶ in their potencies. For instance, aflatoxin B₁ has induced a low incidence of hepatic tumors in rats by administration of only 1 ppb in the diet for 18 months (1). A million-fold higher level of safrole in the diet for 18-20 months was required to induce a similar incidence of hepatic tumors in rats (2). Although, as emphasized in the background information for the proposed regulation, there are difficulties in extrapolating carcinogenic potencies from species to species and from high doses to low doses, quantitative differences in potencies (i.e., carcinogens with weak, moderate, and strong activities) can be recognized.

Although, as emphasized in the OSHA document, it is not possible to establish a threshold for a chemical carcinogen or even the shape of the dose-response curve at low levels of exposure, many data show that the incidence of tumors decreases markedly as the dose of a carcinogen is decreased (3,4). Furthermore, the time from first exposure to the development of a gross tumor increases as the dose of any carcinogen is decreased (3). Thus, for each carcinogen at some low dose the latent period will exceed the life-span of the individual. Although it is true that we can not specify the precise level at which the possible hazard to the individual approaches zero, it must also be recognized that living is not a "no-risk" situation. Each act has its risks (costs) and benefits, and for each situation there is a stage at which the costs (not only for industry, but for a society as a whole) of further protection outweigh the possible benefits that might be attained. We are not suggesting that workers be exposed to unsafe working conditions; we are urging that society not be burdened with Costs that far exceed the benefits that might result from those costs. Protection against real hazards is necessary and highly beneficial. Regulations that "protect" against nebulous hazards (such as would result from blanket application of the proposed regulations) mislead the public and could in the long run be detrimental to the maintenance of the United States as a strong, imaginative, industrial society that benefits workers, employers, and the public at large.

References Cited

- Wogan, G.N., Paglialunga, S., and Newberne, P.H. Carcinogenic Effects of Low Dietary Levels of Aflatoxin B₁ in Rats. Food Cosmet. Toxicol., 12: 681-685, 1974.
- Wislocki, P.G., Miller, E.C., Miller, J.A., McCoy, E.C., and Rosenkranz, H.S. Carcinogenic and Mutagenic Activities of Safrole, 1'-Hydroxysafrole, and Some Known or Possible Metabolites. Cancer Res., 37: 1883-1891, 1977.
- Druckrey, H. Quantitative Aspects in Chemical Carcinogenesis. Pp. 60-76. In: Truhaut, R. (ed.), Potential Carcinogenic Hazards from Drugs. UICC Monograph Series, Vol. 7, Springer-Verlag, Berlin, 1967.
- Homura, T. Urethan (Ethyl Carbamate) as a Cosolvent of Drugs Commonly Used Parenterally in Humans. Cancer Res., 35: 2895-2897, 1975.

Henry C. Pitot, H.D., Ph.D. Member of Board of Directors Association of American Cancer Institutes Professor of Oncology and Director, McArdle Laboratory for Cancer Research

HCP/rb

-3-

January 26, 1978

Mr. Tom Hall OSHA Office of Consumer Affairs Room N 3635 U.S. Dept. of Labor 3rd & Constitution Ave., N.W. Washington, D.C. 20210

Dear Hr. Hall:

Enclosed please find documented the position I will take in the hearings on OSHA regulations 29 CFR Part 1990 - Identification, Classification and Regulation of Toxic Substances Posing a Potential Occupational Carcinogenic Risk - on April 4, 1978 representing the Association of American Cancer Institutes and my own member institution, The McArdle Laboratory for Cancer Research.

As you will see from the enclosed documents, I will present the scientific issues and arguments for modifications of the proposed guidelines especially as to how they relate to research laboratories.

If there is any clarification or additional information necessary, please let me know.

Sincerely yours,

Henry C. Pitot, H.D., Ph.D. Director

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Henry C. Pitot, M.D. Madison, Wisconsin

Timothy R. Talbot, Jr. M.D. Philadelphia, Pennsylvania

March 1, 1978

Dr. R. Lee Clark, President University of Texas System Cancer Center M. D. Anderson Hospital and Tumor Institute Texas Medical Center Houston, Texas 77030

Dear Dr. Clark:

I should like to have you serve again as the Liaison Representative to the UICC/CICA for the AACI for the year 1978.

Please complete the attached form and return it to the Secretary-Treasurer at your earliest convenience.

I hope you will find it possible to accept this appointment and I look forward to working with you in the coming year.

Sincerely yours,

Jorm returned Jordon Zubrok 3/8. appointment C. Gordon Zubrod, M. D. accepted

CGZ/o Attachment

association of american cancer institutes

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G. Denman Hammond, M.D. Los Angeles, California

Henry C. Pitot, M.D. Madison, Wisconsin

Alvin M. Mauer, M.D. Memphis, Tennessee

January 13, 1978

MEMO TO:	AACI Membership
FROM:	Dr. E. A. Mirand, Secretary-Treasurer
SUBJECT :	Reorganization of National Cancer Institute

Dr. Arthur Upton will be announcing an administrative reorganization of the National Cancer Institute. Of special interest to you is that the Centers Program will be moved to the Office of the Director. An Acting Director from the currect NCI staff will be in charge of the Centers Program until a permanent Director is selected. Dr. Upton assured Dr. Shingleton that the AACI will have input into the reorganization of the Centers Program.

EAM:co



Roswell Park Memorial Institute new york state department of health

Date Mailed: March 20, 1978

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For Release: Immediate

ROSWELL PARK DIRECTOR ELECTED CANCER INSTITUTES ASSOCIATION OFFICER

Dr. Gerald P. Murphy, director of Roswell Park Memorial Institute, the New York State Health Department's comprehensive cancer center in Buffalo, N.Y., has been named the vice president and president-elect of the Association of American Cancer Institutes (AACI).

The 19-year-old organization has a membership of 70 institutions and centers devoted to cancer research, treatment, education and rehabilitation. It was organized in 1959 as an outgrowth of the Association of Cancer Institute Directors.

AACI meets frequently to hear reports on the latest developments in all aspects of the cancer war and to participate in a global exchange of information with other organizations such as the National Cancer Institute, Bethesda, Md., and the International Union Against Cancer (UICC) with headquarters in Switzerland.

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For further information: Charles H. Pokrandt/Communications Dept., (716) 845-5746.

Contact: DEPARTMENT OF MEDICAL AND SCIENTIFIC COMMUNICATIONS **ROSWELL PARK MEMORIAL INSTITUTE** 666 ELM STREET . BUFFALO . NEW YORK . 14263

TELEPHONE: A.C. 716-845--5746-7-8



THE UNIVERSITY OF TEXAS SYSTEM CANCER CENTER

Texas Medical Center Houston, Texas 77025



10.2

OFFICE OF THE PRESIDENT

March 17, 1978

Dr. Gordon Zubrod Comprehensive Cancer Center for the State of Florida P.O. Box 875, Biscayne Annex Miami, Florida 33152

Dear Gordon:

I am in receipt of your note of March 1, 1978 extending an invitation to serve again as the Liaison Representative to the American College of Surgeons for the AACI for the year 1978 (please find completed form attached), and also to serve as a member of the Membership Committee for the AACI for the year 1978 (please find completed form attached).

I am pleased to accept these invitations and will be happy to work with you in any way during your term of presidency. Again congratulations.

Very sincerely,

11th

M. Copeland, M.D. Vice President University Cancer Foundation

MMC/jp

Attachments

/ cc: Dr. R.L. Clark

M. D. ANDERSON HOSPITAL AND TUMOR INSTITUTE **EXTRAMURAL PROGRAMS DIVISION** UNIVERSITY CANCER FOUNDATION

Annes and Rehabilitation Center

Cacole :y Council-Biomedical Institutions The Anderson Mayfair

Collaborative Studies

Substations

Environmental Science Park



THE UNIVERSITY OF TEXAS SYSTEM CANCER CENTER

M. D. Anderson Hospital and Tumor Institute Texas Medical Center Houston, Texas 77030

R. Lee Clark, M. D. President

July 6, 1978 10.2

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Dr. Edwin A. Mirand Associate Institute Director Roswell Park Memorial Institute

Dear Doctor Mirand:

Following is the text of the mailgram sent by Dr. Clark today to all members of AACI. When a bill is received we will forward it to you.

As I believe you and Dr. Clark discussed by telephone, it would be most helpful and less costly in the future to send such messages by telecopier. Dr. Clark indicated you plan to ask AACI members to supply the appropriate telephone numbers to use in reaching their telecopiers, and also to encourage institutes which do not have such equipment to consider its purchase. May we have a list of the telecopier numbers after you receive them.

Thanks very much.

Sincerely,

Beverly Ross Governmental Affairs Analyst

MAILGRAM TEXT (To all AACI members, July 6, 1978)

1974 National Health Planning and Resources Development Act (PL 93-641) is to be renewed this year. Bills extending/amending the law have been passed by committees in both houses of Congress and are reacy for floor action following Congressional recess (July 10). Bills are: HR 11488 and S 2410.

It's thought that a floor amendment to HR 11488 will be offered which would effectively exempt cancer programs from HSA review/approval. The spirit of such an amendment hopefully will be that "a Health Systems Agency shall not review and approve/disapprove proposed uses within its health service area of federal funds appropriated for support of biomedical research activities which meet a nationally defined need" although specific language of amendment may vary.

It's important to contact your congressmen now to brief them on this matter and solicit support so they can be ready to respond when called on to vote for amendment. It should be stressed that exemption of cancer programs should be permitted because they are integral components of a national program approved by Congress and subject to peer and agency review procedures of national funding agencies. These procedures take many months for full evaluation and ultimate awarding of funds. HSA review/approval process could clearly add another 6 to 12 months delay in implementing new programs which could save lives.

If HR 11488 is amended on the floor the amendment can possibly be retained in House/Senate Conference.

Please contact your congressmen without delay. We will advise you when the floor amendment is to be offered so you may call them again at that time.

R. Lee Clark

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Alvin M. Mauer, M.D. Memphis, Tennessee

Henry C. Pitot, M.D. Madison, Wisconsin

Timothy R. Talbot, Jr. M.D. Philadelphia, Pennsylvania

March 1, 1978

Dr. R. Lee Clark, President University of Texas System Cancer Center M. D. Anderson Hospital and Tumor Institute Texas Medical Center Houston, Texas 77030

Dear Dr. Clark:

I should like to have you serve as the Chairman of the Policy and Programs Committee for the AACI for the year 1978.

Please complete the attached form and return it to the Secretary-Treasurer at your earliest convenience.

I trust you will be able to accept this appointment and I look forward to working with you in the coming year.

Jorn returned Sincerely yours, 3/8. appointment Gorden Zubrok accepted. Gordon Jubrod N. D.

C. Gordon Zubrod, M. D. President

CGZ/o Attachment