**ROUTING SLIP**
**GENERATED BY: HF-40**
**DATE: NOV 07, 2001**

**FDA CONTROL NUMBER:** 01 5419 **TRACER #:** **OS #:**

**DATE OF CORRESPONDENCE:** 10/31/01 **DATE INTO FDA:** 11/07/01

**TO:** BERNARD A SCHWETZ HF-1
JOSEPH A LEVITT HFS-1
ALAN M RULIS HFS-200
LAURA M TARANTINO HFS-206

**FROM:** ANDREW KIMBRELL, CENTER FOR FOOD SAFETY
WENONAH HAUTER, PUBLIC CITIZEN

**SYNOPSIS:** SUBMITS NEW EVIDENCE REGARDING DOCKET NO. 99F-4372, FOOD ADDITIVE PETITION (REF. TRAC # 012565): SWORN AFFIDAVIT PROVIDING THE OPINION OF DR. WILLIAM AU, A PROFESSOR IN THE DIVISION OF ENVIRONMENTAL TOXICOLOGY AT THE UNIVERSITY OF TEXAS.

**LEAD OFFICE:** HFA-305 **HOME OFFICE:** HF-40

**CONTACT/PHONE#:** KELLY M MALONE 301-827-4437

**COPIES:** GENERAL DISTRIBUTION
HF-40 LAJUANA D CALDWELL
HF-40 ANNE B CRAWFORD
HF-40 INDYA P GORDON
HF-40 KRISTINE M MORAN
HFS-1 JOSEPH A LEVITT
HFS-200 ALAN M RULIS
HF-1 BERNARD A SCHWETZ
HF-10 LINDA A SUYDAM

**COORDINATION:**

**SIGNATURE REQUIRED:**

**REFERRALS FROM HF-40**

| ASSIGNED TO | ACTION | DUE DATE |
|---|---|---|
| HFA-305 | NECESSARY ACTION | |

THE CENTER FOR FOOD SAFETY

Public Citizen 30 YEARS
*Protecting Health, Safety & Democracy*

October 31, 2001

Dr. Bernard Schwetz
U.S. Food and Drug Administration
14-71 Parklawn Building
5600 Fishers Lane
Rockville, MD 20857

Mr. Joseph Levitt
U.S. Food and Drug Administration
CFSAN
200 C St. SW
Washington, DC 20204

Dr. Alan Rulis
U.S. Food and Drug Administration
CFSAN
200 C St. SW
Washington, DC 20204

Dr. Laura Tarantino
U.S. Food and Drug Administration
CFSAN
200 C St. SW
Washington, DC 20204

**Re: Food Additive Petition 9M4697, Use of ionizing radiation for pre-processed meat and poultry; both raw and pre-processed vegetables, fruits and other agricultural products of plant origin; and certain multi-ingredient food products; Food Additive Petition 1M4727, Use of ionizing radiation for control of foodborne pathogens in crustaceans and processed crustaceans; Food Additive Petition 9M4682, Ionizing radiation for the control of Vibrio and other foodborne pathogens in fresh or frozen molluscan shellfish; Food Additive Petition 9M4695, Use of ionizing radiation to treat unrefrigerated (as well as refrigerated) uncooked meat, meat products, and certain meat food products; and Food Additive Petition 9M4696, Increase the maximum dose of ionizing radiation permitted in the treatment of poultry products**

Greetings,

The FDA is considering the five above-referenced food additive petitions to irradiate a much greater portion of the food supply, such as ready-to-eat foods, including some food items regulated by the USDA Food Safety and Inspection Service. On May 16, our organizations filed comments opposing these petitions on grounds of serious safety issues stemming from scientific studies indicating that certain irradiated foods may cause mutagenic and cytotoxic effects in lab animals as well as in humans.[1]

On behalf of the more than 100,000 consumer members of our two organizations, this is to request you to fully consider the enclosed new evidence: a sworn affidavit providing the opinion of Dr. William Au, a Professor in the Division of Environmental Toxicology at the University of Texas. Dr. Au is an internationally recognized expert on the toxicological mechanisms for the induction of human disease. This new evidence supplements our previous comments in



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opposition to the pending petitions and is being submitted to the appropriate dockets. Dr. Au's expert opinion provides independent support for our opposition. He states:

> *Radiolytic products are formed during the irradiation of food. Their potential health hazards have not been adequately evaluated. An emphasis should be placed on the products that are unique to the irradiation process and that are potentially mutagenic, e.g. 2-DCB. The quality and quantity of these radiolytic products may be different from one food type to another. Without conclusive evidence regarding the safety of these products, the safety of irradiated food cannot be assured. Conclusive evidence of safety of these products can be derived from in vivo studies published in peer-reviewed journals.*

FDA simply cannot ignore an eminent toxicologist's sworn opinion that the safety of a proposed food additive has "*not been adequately evaluated.*" We emphasize that Dr. Au is not alone. As stated in our earlier comments, 26 medical experts and many other prominent individuals endorsed a detailed warning published in a health journal on the dangers of food irradiation.

Based on this new evidence, plus the scientific documentation we submitted in our earlier comments, we strongly urge you to **deny** the above-referenced petitions. Approving them in the absence of thorough, food-specific, published studies of 2-DCB and other potentially toxic unique radiolytic products plainly would constitute arbitrary and capricious actions on your part due to the serious public health risks raised. If you would like further information, please contact Mark Worth of Public Citizen at 202.547.5123; email: mworth@citizen.org; or Peter Jenkins of the Center for Food Safety (tel: 202.547.9359 x13; email: peterjenkins@icta.org).

Sincerely,

Andrew Kimbrell, Executive Director
Center for Food Safety

Wenonah Hauter, Director
Public Citizen, Critical Mass Energy and Environment Program

Center for Food Safety
660 Pennsylvania Ave., S.E.
Suite 302
Washington, DC 20003

Public Citizen
215 Pennsylvania Ave., S.E.
Third Floor
Washington, DC 20003

Enclosures

Cc: FDA Food Additive Petition Docket No.s: 99F-5522; 01F-0047; 99F-4372; 99F-5321; 99F-5322
Secretary Ann Veneman, USDA
Mr. Thomas Billy, Administrator, USDA Food Safety Inspection Service

[1] Copies of these past comments are available on request or they can be accessed on the CFS website at www.centerforfoodsafety.org under Legal Initiatives.

In the Matter of Food Irradiation Petitions )
Pending before the United States )
Food and Drug Administration )

## Expert Affidavit on Safety of Irradiated Food

By William W. Au, Ph.D.

William Au, being duly sworn, hereby deposes and says:

A. My address is: Division of Environmental Toxicology, Department of Preventive Medicine and Community Health, Ewing Hall, 700 Harborside Drive, University of Texas Medical Branch, Galveston, Texas 77555-1110, where I have been employed as a Professor since 1991. My Curriculum Vitae is attached hereto indicating my professional qualifications as an environmental toxicologist. My primary research interest is in conducting molecular and cellular studies to elucidate toxicological mechanisms for the induction of human disease. Since obtaining my Ph.D. from the University of Cincinnati, I have more than 20 years of experience teaching, conducting and publishing peer-reviewed research, consulting and speaking internationally, editing professional publications, and serving on numerous expert committees. I am a member of the major scientific societies related to environmental toxicology and have received approximately one dozen awards recognizing my professional contributions. I have delivered more than 35 invited lectures internationally and published or co-published more than 100 articles in peer-reviewed scientific journals.

B. I submit this Affidavit on the food irradiation petitions pending before the United States Food and Drug Administration, most specifically FAP 9M4697 (Docket No. 99F-5522), addressing "ready-to-eat foods," however, the conclusions herein also apply generally to other past and pending irradiation petitions.

C. I submit this Affidavit on behalf of two Washington, DC, non-profit groups, the Center for Food Safety and Public Citizen, who have retained me as a consulting expert. Prior to this consultation I had no prior involvement with those or any other non-profit groups involved in food irradiation issues.

D. In formulating my opinion, I have reviewed relevant documents and studies that were provided by my clients and conducted independent research including several publications that I have selected from the literature.

E. My opinion, based on a reasonable degree of scientific certainty, is as follows:

1) Ionizing radiation is a well-documented teratogen, mutagen and carcinogen whereas some other procedures for food decontamination/sterilization such as heat and steam are not. Ionizing radiation interacts with cellular macromolecules that are also present in food products to generate toxic products. Therefore, the use of radiation to decontaminate/sterilize foods that are destined for human consumption should be evaluated for health concerns very carefully. Whenever other processing methods or combination of methods that are equally effective in reducing the risk of food borne disease are available, the use of the radiation procedure should be avoided. Therefore, it is surprising to learn from the Food and Agriculture Organization/International Atomic Energy Agency/World Health Organization report (1999) that those agencies gave a blanket statement of approval in the conclusion section "the study group concluded that no upper dose limit need be imposed." (p. 161). This decision can lead to misuse of the procedure in processing food for human consumption.

2) Some reports in the peer-reviewed literature on mutagenic activities of irradiated foods were not considered in the 1999 FAO/IAEA/WHO report (Bhaskaram and Sadasivan, 1975; Vijayalaxmi, 1975, 1976, 1978; Vijayalaxmi and Sadasivan, 1975; Vijayalaxmi and Rao, 1976). Although the observations from these studies are not confirmed by some publications in the literature, the positive findings have support from other publications (Bugyaki et al, 1968; Moutschen-Dahmen, et al., 1970; Anderson et al., 1980; Maier et al., 1993). Furthermore, repeated observations of activities that have significant public health implications such as polyploidy in somatic cells, genetic alterations in germ cells and reproductive toxicity should not be ignored, but should be considered seriously and explicitly by FDA with respect to the pending food irradiation petitions.

3) Radiolytic products are formed during the irradiation of food (Schubert, 1969). Their potential health hazards have not been adequately evaluated. An emphasis should be placed on the products that are unique to the irradiation process and that are potentially mutagenic, e.g. 2-dodecylcyclobutanone (Delincee and Pool-Zobel, 1998; Delincee et al., 1998). The quality and quantity of these radiolytic products may be different from one food type to another. Without conclusive evidence regarding the safety of these products, the safety of irradiated food cannot be assured. Conclusive evidence of safety of these products can be derived from *in vivo* studies published in peer-reviewed journals.

4) The formation of hazardous free radicals in irradiated food that can cause DNA damage is of serious concern. For food with high water content, the free radicals are rapidly degraded after irradiation. Therefore, human exposure to the free radicals through the food chain is minimal. For food with low water content, the Food and Drug Administration stated that "irradiated dry spices and seasonings are examples of foods in which free radicals are known to persist for long periods of time." (FDA, 1986, p. 13379). However, the FDA concluded that this should not be of concern based on the manner in which these foods are used. On the other hand, the concerns for other dry foods that are consumed without further cooking and that are consumed in large

quantities, such as dried fruits and nuts, are not considered. This possibility should be evaluated to determine the potential for exposing consumers to free radicals. This concern should be included in the FDA's analysis of the "ready-to-eat food" irradiation petition, FAP 9M4697.

Dated this 10 day of October, 2001, at Houston, Texas.

Signature

State of Texas

County of Harris :ss.

Subscribed and sworn to before me this 10 day of October, 2001.

Notary Public

JOSIE JONES
Notary Public, State of Texas
My Comm. Expires Nov. 10, 2001

C.V. attached

References Cited:

Anderson, D., Clapp, M.J.L., Hodge, M.C.E., Weight, T.M. Irradiated laboratory animal diets – dominant lethal studies in the mouse. Mutat. Res. 80, 333-345, 1981.

Bhaskaram, C., Sadasivan, G. Effects of feeding irradiated wheat to malnourished children. Am. J. Clin. Nutri. 28:130-135,1975.

Bugyaki, L., Deschreider, A.R., Moutschen, J., Moutschen-Dahmen, M., Thijs, A., Lafontaine, A. Do irradiated foodstuffs have a radiomimetic effect? II. Trials with mice fed wheat meal irradiated at 5 Mrad. *Atompraxis* 14:112-118, 1968.

Delincee, H., Pool-Zobel, B.L. Genotoxic properties of 2-dodecylcyclobutanone, a compound formed on irradiation of food containing fat. Radiat. Phy. Chem. 52:39-42,1998.

Delincee, H., Pool-Zobel, B.L., Rechkemmer, G. Genotoxicity of 2-dodecylcyclobutanone. Food Irradiation: Fifth German Conference, Report EFE-R-99-01, Federal Nutrition Research Institute, Karlsruhe, Germany, 1998.

FAO/IAEA/WHO report. High dose irradiation: wholesomeness of food irradiated with doses above 10 kGy. World Health Organization, Geneva, 1999.

Food and Drug Administration. Final Rule, Irradiation in the Production, Processing, and Handling of Food, 51 Fed. Reg. 13376, Fri. Apr. 18, 1986.

Maier, P., Wenk-Siefer, I., Schawalder, H.P., Zehnder, H., Schlatters, J. Cell-cycle and ploidy analysis in bone marrow and liver cells of rats after long-term consumption of irradiated wheat. Fd. Chem. Toxic. 31:395-405, 1993.

Moutschen-Dahmen, M., Moutschen, J., Ehrenberg, L. Pre-implantation death of mouse eggs caused by irradiated food. Internat. J. Rad. Biol. 18: 201-216, 1970.

Schubert, J. Mutagenicity and cytotoxicity of irradiated foods and food components. Bull. Wld. Hlth. Org. 41:873-904,1969.

Vijayalaxmi. Cytogenetic studies in rats fed irradiated wheat. Int. J. Radiat. Biol. 7:283-285,1975.

Vijayalaxmi. Genetic effects of feeding irradiated wheat to mice. Canad. J. Genet. Cyto. 18:231-238,1976.

Vijayalaxmi. Cytogenetic studies in monkeys fed irradiated wheat. Toxicology 9:181-184,1978.

Vijayalaxmi and Sadasivan, G. Chromosome aberrations in rats fed irradiated wheat. Int. J. Radiat. Biol. 27:135-142,1975.

Vijayalaxmi and Rao, K.V. Dominant lethal mutations in rats fed on irradiated wheat. Int. J. Radiat. Biol. 29:93-98,1976.

**CURRICULUM VITAE**

NAME: William Wingkam Au, Ph.D. DATE: September, 2001.

PRESENT POSITION AND ADDRESS:

**Professor**
Division of Environmental Toxicology
Department of Preventive Medicine and Community Health
2.102 Ewing Hall
700 Harborside Drive
The University of Texas Medical Branch
Galveston, Texas 77555-1110
USA

Office Phone: 409/772-1545; 772-1803
Telefax: 409/772-9108
E-mail: william.au@utmb.edu

**Director**
International Science Outreach Program
Sealy Center for Environmental Health and Medicine
University of Texas Medical Branch

**Editor**
International Journal of Hygiene and Environmental Health

**Chairman**
Alexander Hollaender Fund for International Programs

BIOGRAPHICAL:

| | |
|---|---|
| Date of Birth: | October 30, 1946 |
| Place of Birth: | Hong Kong |
| Citizenship: | United States of America |
| Marital Status: | Married, one child |

Social Security Number: xxx-xx-xxxx

EDUCATION:

| | | | |
|---|---|---|---|
| 1972 | Biology | B.A. | University of North Carolina<br>Greensboro, North Carolina |
| 1977 | Developmental Biology | Ph.D. | University of Cincinnati<br>Cincinnati, Ohio |

PROFESSIONAL AND TEACHING EXPERIENCE:

| | | |
|---|---|---|
| 1991-present | Professor | Division of Environmental Toxicology, Department of Preventive Medicine and Community Health, Univeristy of Texas Medical Branch, Galveston, TX |
| 1988-present | Graduate Faculty | Human Genetics and Cell Biology Program, Graduate School of Biomedical Sciences, UTMB, Galveston, TX |
| 1985-1990 | Associate Professor | Division of Environmental Toxi cology, Department of Preventive Medicine and Community Health, UTMB, Galveston, TX |
| 1985-present | Graduate Faculty | Preventive Medicine Medicine and Community Health Program, Graduate School of Biomedical Sciences, UTMB, Galveston, TX |
| 1984-1985 | Assistant Professor | Division of Environmental Toxicology, Department of Preventive Medicine and Community Health, UTMB, Galveston, TX |

| | | |
|---|---|---|
| 1980-1984 | Staff Scientist | Biology Division, Oak Ridge National Laboratory, Oak Ridge, TN |
| 1979-1980 | Research Associate | Department of Cell Biology, The University of Texas System Cancer Center, M.D. Anderson Hospital and Tumor Institute, Houston, TX |
| 1977-1979 | Post-doctoral fellow | Department of Biology, The University of Texas System Cancer Center, M.D. Anderson Hospital and Tumor Institute, Houston, TX |

RESEARCH ACTIVITIES AND FUNDING HISTORY:

Dr. William Au's research interest is in conducting molecular and cellular studies to elucidate toxicological mechanisms for the induction of human disease. The working hypothesis is that individuals who have inherited variant metabolic and DNA repair gene alleles are susceptible to the induction of chromosome aberrations/gene mutations and thus have increased health risk from exposure to toxicants. Cancer patients are used as a model to document which susceptible versions of polymorphic genes are significantly associated with the disease. Cigarette smokers and workers with occupational exposure to toxicants are studied to demonstrate the toxicological mechanisms in support of the association. Besides using human volunteers, experimental animal and cells in culture are also used to conduct mechanistic studies under well controlled exposure conditions. Molecular techniques and cytogenetic assays (e.g. FISH) are used for the investigations. These studies provide data for understanding the etiology of disease, the toxicological mechanisms for development of disease, risk assessment and prevention of disease.

COMMITTEE RESPONSIBILITIES:

1. International

Project officer for U.S.-Egyptian Cytogenetic Program, 1985 - 1987.

Organizer - Participation of US scientists to present papers at the Second Southeast Asian Workshop on Short-Term Assays to Detect Environmental Mutagens, Carcinogens and Teratogens. Bankok, Thailand, Feb. 6-17, 1989.

Co-Chairman: First International Conference on Environmental Mutagenesis on Human Populations at Risk, Cairo, Egypt, January 20-25, 1992.

Co-Chairman: International Conference on Exposure to Carcinogens and Mutagens in the Industrial and Ambient Environment. Jerusalem, Israel, January 29-30, 1992.

Member-Organizing and Scientific Committee, Satellite Meeting of the International Union of Toxicology, Bologna, Italy, June 4-6, 1992.

Member-Advisory Board of Latin American Environmental Mutagen Society, 1990-present

Member-International Advisory Board Pan African Environmental Mutagen Society, 1992-present

Co-Chairman: Second International Conference on Environmental Mutagens in Human Populations, Prague, Czech Republic, August, 1995.

Co-Chairman: Third International Conference on Environmental Mutagens in Human Populations, Bangkok, Thailand, December, 1998.

Councilor: International Association of Environmental Mutagen Societies, August, 1997 - July, 2001.

Member-Program Committee: 8th International Conference on Environmental Mutagens, Shizuoka, Japan, October 21 - 26, 2001

2. National

Consultant for Food and Drug Administration (1981-present)

Gene-Tox Committee Member of the Environmental Protection Agency (1979-1980)

Member - Membership Committee of Environmental Mutagen Society (1987-1988)

Member - Program Planning Committee of Southwest Environmental Mutagen Society (1987-1988)

Member - Awards and Honors Committee of the Environmental Mutagen Society (1988-1989)

Member - Advisory Panel for the Texas Air Control Board (1989-1994)

Member - Peer Review Panel for Assessment of Radon Research Program for Department of Energy (1990)

Member - Peer Review Panel on DNA Repair and Genetics for Department of Energy (1990; 1991)

Member - Sub-committee on Anesthetic and Life Support Drugs, Food and Drug Administration (1990)

Member - Peer Review Panel for Medical Research and Development Command, United States Army (1993-present)

Organizer - Expert Panel on the Use of Genetic Monitoring for Risk Assessment in Communities Exposed to Hazardous Chemicals. US EPA, February 7-8, 1994.

Member - Peer Review Panel for National Institute of Environmental Health Sciences (1995 - present)

Member - Environmental Mutagen Society Diversity Committee (1995 - 1998).

Member - Program Planning Committee of the Environmental Mutagen Society (1996).

Member - Environmental Health Sciences Panel, National Institutes of Health, (1997 to 2001).

Chairman - Alexander Hollaender Fund for International Programs, (1997 to present).

Councilor - U.S. Environmental Mutagen Society (1999- 2003).

Member – Board of Scientific Counselors, Agency for Toxic Substances and Disease

Registry (May, 1999 - April, 2003).
Chairman - Community and Tribal Subcommittee, Board of Scientific Counselors, Agency for Toxic Substances and Disease Registry (May, 2000 - present).

3. University

Member - University Curriculum Committee (1989-1991)
Member - University Chemical Safety Committee (1990-1994)
Member - Curriculum Committee, NIEHS - Toxicology Training Program (1994-1999)
Member - Seminar Committee, NIEHS - Toxicology Training Program (1994-1999)
Member - Internal Advisory Committee - Center for Environmental Toxicology (1997-8)
Member - Committee in Support of Science Education (1997 - present).
Presentation Judge - Undergraduate Research symposium (1996 - present).
Member - Radiation Safety Committee (1998-2001).
Member - Radioactive Drug Safety Committee (1998 - 2001)
Member - Chancellor's councilor, The University of Texas System (1995 to present).
Member - Admissions Committee, School of Medicine (1999 - 2002).
Chairman - Credential Committee, Graduate Program of the Department of Biological Chemistry and Genetics (2000 to present)
Member - Recruitment Committee, Graduate Program of the Department of Biological Chemistry and Genetics (2000 to 2001)
Member - Curriculum Committee, Graduate School of Biomedical Sciences (2000 - present)

4. Departmental

Chairman - Budget Committee - Graduate school program of the Department of Preventive Medicine and Community Health (1986-1987)
Member, Long-Range Planning Committee for the Department of Preventive Medicine and Community Health (1987-present)
Member, PMCH Residency Planning Committee (1987-1988)
Member, Steering Committee for departmental review. (1989-1990)
Member, Appointment, Promotion and Tenure Committee (1990-1993)
Member, Admissions Committee, Department of Human Biological Chemistry and Genetics (1991-1994)
Member, Seminar Committee, Department of Preventive Medicine and Community Health (1994-present)
Member and then Chairman - Advisory Committee, Graduate Prograam for Department of Human Biological Chemistry and Genetics (1994-1997)
Member - Long Range Planning Committee, Cell Biology Graduate Program (1997-2001)
Chairman - Credential Committee, Graduate Program for Dapartment of Human

Biological Chemistry and Genetics (2000 – present).
Member – Admission and Recruitment Committee, Cell Biology Graduate Program (1999 – 2001).
Member – Graduate Policy Committee, Preventive Medicine and Community Health (1999 - 2001).
Member – MPH course review committee, Preventive Medicine and Community Health (1999 – present)

TEACHING RESPONSIBILITIES AT UTMB:

Chairman - Dissertation Committee for Kanokporn Rithidech (1984-1987)
Chairman - Dissertation Committee for Hasnaa Shafik (1984-1987)
Member - Dissertation Committee for Glen Talaska (1984-1987)
Chairman - Dissertation Committee for Mary Lowery (1984-1987)
Chairman - Dissertation Committee for Renate MacLaren (1984-1988)
Member - Dissertation Committee for Pamela Harris of The University of Texas Health Science Center in Houston (1987-1989)
Chairman - Dissertation Committee for Elie Hanania (1989-1992)
Member - Dissertation Committee for Zhidong Xu (1989-1992)
Chairman - Dissertation Committee for Treetip Chiewchanwit (1993-1996)
Chairman - Dissertation Committee for Lance Hallberg (1992-1997)
Chairman - Dissertation Committee for Randa El-Zein (1992-1998)
Course Director - Cytogenetics HGCB 6221, 1987-88.
Lecturer - Somatic Cell Genetics HGCB 6222, 1987-88.
Lecturer - Cell-Gene Course for the Medical School (1987-1992)
Lecturer - Preventive Medicine and Community Health for Medical School. (1990-1999)
Lecturer - Genetic Toxicology, PMCH 6325 (1987-1998)
Supervisor - Research project of a medical student, Miss Georgina Loya, 1992-1993
Lecturer - Principles of Drug Action (1994- 1998).
Lecturer - Cell Biology (1995- 1998).
Lecturer - Experimental Design (1995 - 1998).
Director - Environmental Health and Toxicology course for Preventive Medicine Residents and Graduate Students (1996-present)
Lecturer - Issues in Preventive Medicine (1998 - 1998).
Lecturer – Oncogene course (1999 – 1998).
Lecturer – Environmental and Genetic Toxicology, for 4th year medical students, School of Medicine (1999 to present).
Moderator – Practice of Medicine, School of Medicine (1999 – 2001)
Lecturer – Practice of Medicine, School of Medicine (1999 – 2001)
Lecturer – Cell Biology basic science course, Graduate School of Biomedical Sciences (1999 – 2000)
Lecturer – Gene, Evironment and Disease course, Graduate School of Biomedical

Sciences (2000 - present)
Tutor – Interactive Learning Track, School of Medicine (2000 to present)
Training – Advanced Facilitator Training Workshop, 2000.

AS MENTOR TO DOCTORAL STUDENTS

Marilyn Aardema (1986)
Kanokpoon Rithidech (1987)
Hasnaa Shafik (1987)
Mary Lowery (1987)
Renate MacLaren (1988)
Elie Hanania (1992)
Treetip Chiewchanwit (1995)
Lance Hallberg (1997)
Randa El Zein (1998)
Marc McConnell (1999)
Hernan Sierra-Torres (1997 - present)
Nohelia Cajas (1997 - present)
Salama Salama (1998 - present)

ADVISORY ACTIVITIES TO OTHER STUDENTS:

Sasaly AbuBakar, (1991 – 1995, Ph.D.)
Dennis Sawyer, (1997 – 1999, Ph.D.)
Jeff Hill (1998 - present)
Jeff Jones, M.D., (1998 – 1999, M.S.)
Robert Cox (1997 - present)
Marc Madsen (1999 - 2000)
Philip Kovoor, medical student (2000)
Barbara Bowerstock, medical student (2000)
Boris Oberheitman, Germany (1998 – 2000)

VISITING SCIENTISTS/POST-DOCTORAL FELLOWS:

Dr. Wagida Anwar - Fogarty International Fellow, Ain Shams University, Cairo, Egypt (May 1987-April 1988; August 1990-October, 1990)
Dr. Sawsan El-Ghazali - Peace Fellow, Ain Shams University, Cairo, Egypt (September 1989-January 1990).
Dr. Moon-Young Heo - University Fellow, Kangweon National University, Chuncheon, Korea (December 1989-November 1990).
Dr.. Randa El Zein - Alexandria University, Alexandria, Egypt (January 1990-December 1990).

Professor Luz Stella Hoyos - University of Antioquia, Colombia, South America (September, 1990-August, 1991)

Dr. Csilla Kormos, National Research Institute for Radiobiology and Radiohygiene, Budapest, Hungary (November, 1990-October, 1991)

Dr. Hongbao Ma, Tianjin Medical College, Tianjin, P.R. China (January, 1991-December 1992).

Dr. Shende Li, Chinese Academy of Medical Sciences, Beijing, P.R. China (April, 1991-July, 1992)

Dr. Shimin Cao, Chinese Academy of Medical Sciences, Beijing, P.R. China (March 1992-September, 1992).

Dr. Fatma Mohammed, Ain Shams University, Egypt (October, 1994- September, 1995)

Dr. Nivea Conforti Froes, University of San Paolo, Brazil (July, 1995-June, 1996)

Lecturer Mila Serrana, Miriam College Foundation, Manila, The Philippines (May, 1997 - April, 1998).

Lecturer Suparp Kietthebthew, Prince of Songkla University, Songkla, Thailand, October 1 - November 10, 1997.

Dr. Hyeong Oh, Director, Division of Genetic Toxicology, National Institute of Toxicological Research, Korean Food and Drug Administration, Seoul, Korea, December 26, 1998 - March 12, 1999.

Lecturer Suparp Kietthubthew, Prince of Songkla University, Songkla, Thailand, March 20 - June 10, 1999.

Professor Moon Heo, Kwangeon National University, Korea, December 20, 1999 to January 27, 2001.

Dr. Concepcion Arrastia, Clinical Fellow, Department of Obstetrics and Gynecology, The University of Texas Medical Branch, Galveston, Texas, March, 2000 to 2001.

Dr. Osama Badary, Department of Pharmacology and Toxicology, Al-Azhar University, Nasr City, Cairo, Egypt, July 1 – December 10, 2000.

Dr. Boris Oberheitmann, University of Bremen, Bremen, Germany, April 1 – 30, 2001.

Dr. Salama A. Salama, Department of Pharmacology and Toxicology, Al-Azhar University, Nasr City, Cairo, Egypt, October 1, 2001 – September 30, 2002.

Dr. Carsten Harms, University of Bremen, Bremen, Germany, November 15, 2001 – February 28, 2002.

MEMBERSHIPS IN SCIENTIFIC SOCIETIES:

American Association for the Advancement of Science (1985- present)
Environmental Mutagen Society (1979-present)
Sigma Xi (1981-present)
Southwest Environmental Mutagen Society (1986-present)
Society for Risk Analysis (1990-present)

CONSULTATION

Corporate consultant - Molecular Epidemiology; Simultec, Meilen/Zurich, Switzerland.

AWARDS AND HONORS:

1. International Cancer Research Technology Transfer Fellowship (1986) from the International Union Against Cancer

2. Visiting Professor, University of Bologna, Italy (1987)

3. Visiting Professor, Ain Shams University, Cairo, Egypt (1988-1991).

4. Chairman - First International Conference on Environmental Mutagenesis on Human Populations at Risk. Cairo, Egypt, January 20-25, 1992.

5. Chairman: International Conference on Exposure to Carcinogens and Mutagens in the Industrial and Ambient Environment. Jerusalem, Israel, January 29-30, 1992.

6. Chairman: Second International Conference on Environmental Mutagens on Human Populations, Prague, Czech Republic, August, 1995.

7. Symposium organizer: Genetic Susceptibility. Symposium for the US Environmental Mutagen Society, Minneapolis, Minnesota, April, 1997.

8. Chairman: Third International Conference on Environmental Toxicants on Human Populations. Bankok, Thailand, December, 1998.

9. Distinguished lecturer: Presented by the Commissioner, Korean Food and Drug Adminsitration, Seoul, Korea, June 16, 1999.

10. Recognition for Significant Contribution to the NATO (North Atlantic Treaty Organization) Conference, Turkey, September 23 – October 3, 1999, from the Director of the NATO Advanced Study Institute.

11. Award from the Environmental Mutagen Society for outstanding international education, research and services, in the Annual Conference, New Orleans, Louisiana, April, 2000.

12: Award from the University of Hong Kong as the Keynote Speaker in the 7th International Cancer Congress, 7 – 9 December, 2000.

EDITORIAL BOARD:

Member: Mutation Research (1990-present)

Member: Toxicology and Industrial Health, An International Journal (1990-present)
Associate Editor: Environmental Epidemiology and Toxicology (1998 to 2000)
Editor: International Journal of Hygiene and Environmental Health (2001 - present)

ADDITIONAL INFORMATION:

Reviewer for Human Genetics
Reviewer for Mutation Research
Reviewer for Environmental and Molecular Mutagenesis
Reviewer for Radiation Research
Reviewer for Toxicology and Industrial Health
Reviewer for Environmental Health Perspectives
Co-Editor for Environmental Health Perspectives, vol. 103, supplement 3, 1993.
Co-Editor for Environmental Environmental Health Perspectives, 1996.
Co-Editor for Mutation Research, 1999.

INVITED LECTURES AND WORKSHOP PRESENTATIONS (Selected Since 1991):

1. Seminar Speaker, Prediction of Potential Health Risks Using Short Term Cytogenetic Assays, The Upjohn Company, Kalamazoo, Michigan, January 21, 1991.

2. Symposium Speaker, Population Monitoring in First Latin American Workshop on Mutagenesis, Carcinogenesis and Teratogenesis. May 26-29, 1991, Caxambu, Brazil.

3. Symposium Speaker, Cytogenetics and Related Genetic Endpoints for Detection of Problems from Exposure to Hazardous Waste Chemicals. World Congress on Cell and Tissue Culture. Anaheim, CA, June 16-20, 1991.

4. Symposium Speaker, Abnormal Chromosome Repair and Risk to Develop Cancer. First International Conference on Environmental Mutagenesis in Human Populations at Risk, January 20-25, 1992, Cairo, Egypt.

5. Symposium Speaker, Identification of Potential Health Risk from Exposure to Occupational and Environmental Agents. Hebrew University, Jerusalem, Israel, January 29-30, 1992.

6. Symposium Speaker, Cytogenetic Approach to Document Factors that Contribute to the Development of Cancer. World Conference on Cell and Tissue Culture. Washington, D.C., June 20-25, 1992.

7. Symposium Speaker, Sensitivity and Application of Cytogenetic Assays for Detecting Biological Effects and for Prediction of Potential Health Risk. IV European ISSX Meeting, Bologna, Italy, July 3-6, 1992.

8. Course Director and Lecturer, Strategies for the Control of Mutagenic and Carcinogenic Risk. Sao Paolo State University. Sao Jose du Rio Preto, Brazil, August 12-22, 1992.

9. Invited symposium speaker on Environmental Mutagenesis and Carcinogenesis. National Biological Sciences Conference in Colombia, Papayan, Colombia, October 2-12, 1992.

10. Seminar Speaker, Cytogenetics and Molecular Biomarkers for Exposure to Toxicants and for Potential Health Risk. U.S. Environmental Protection Agency, Environ-mental Criteria and Assessment Office, Cincinnati, Ohio, March 8, 1993.

11. Seminar speaker and class lecturer, Prediction of potential health risk from exposure to hazardous agents. University of Texas at El Paso, February 24-25, 1994.

12. Symposium speaker, International Symposium on Health Hazards of Glycol Ethers, Nancy, France, April 19-21, 1994.

13. Member, Site Visit Team to Kazakhstan, Russia, to review radioactive contamination problems, July 29-August 9, 1994.

14. Symposium speaker, Induction of Abnormal DNA Repair Response from Exposure to Environmental Toxicants, 2nd Latin American Conference on Environmental Mutagenesis, Puerto Vallarta, Mexico, September 25-30, 1994.

15. Symposium speaker, Repair Deficiency in Cancer Susceptibility, Second InternationalConference on Environmental Mutagens in Human Populations, Prague, Czech Republic, August 20-25, 1995.

16. Keynote speaker, genetic predicposition for development of cancer. Colombian National Scientific Conference, Bogota, October 9-11, 1995; monitoring exposed populations for prediction of health risk. Workshop at University of Cauca, Popayan, Colombia, October 12-17, 1995.

17. Keynote speaker, Approaches in Using Standard and Molecular Biomarkers for Health Risk. Conference for the Pan African Environmental Mutagen Society,Cape
Town, South Africa, January 23-25, 1996.

18. Seminar speaker, Genetic factors for predisposition to development of cancer, University of Texas MD Anderson Cancer Center, September 9, 1996.

19. Symposium speaker, Cancer risk assessment based on inheritance of polymorphic genes and exposure to environmental toxicants. Korean Environmental Mutagen Society Conference, Seoul, Korea, October 9-11, 1996.

20. Symposium speaker, IV Conference of the Asociacion Latinoamericana de Mutagenesis, Carcinogenesis y Teratogenesis Ambiental, Vina del Mar, Chile, November 3 - 7, 1996.

21. Symposium speaker, Princess Chulabhorn Conference on Environmental and Industrial Toxicology, Bangkok, Thailand, November 9 - 13, 1996.

22. Invited speaker, Conference on Cancer and Genetic Risk Assessment: Low Dose -Effect Studies. Heidelberg, Germany, September 4-6, 1997.

23. Invited Worshop faculty, 4th Alexander hollaender Training Course in Genetic Toxicology. Cairo, Egypt, September 15 - 18, 1997.

24. Invited speaker to the 5th Latinamerican Environmental Mutagen, Carcinogen and Teratogen Society Conference, Curitiba, Brazil, November 15 - 18, 1998.

25. Invited speaker to the 3rd International Conference on Environmental Mutagens in Human Populations. Bangkok, Thailand, November 28- Decemeber 4, 1998.

26. Invited speaker to the International Conference "Current Status and International Strategy on Endocrine Disrupters", Korean Food and Drug Administration, Seoul, Korea, June 16 – 19, 1999. Presentation title: Genetic Susceptibility and Environmental Disease.

27. Invited by the Minister of Health and the Yang Ming University, Taiwain to Present lectures, Taipei, Taiwan, June 21 – 26, 1999. Lecture title: Use of Biomarkers for Exposure to Genotoxic Agents and for Health Risk Assessment.

28. Invited by the Osaka University Medical School to give lecture in the program "Research for the Future", Osaka, Japan, June 26 – July 1, 1999. Lecture title: A New Technology to Evaluate the Risk of Environmental Toxic Agents to Human.

29. Invited by the National Cancer Center Research Institute to give a lecture entitled "Genetic Variations in Metabolism of Environmental Toxicants and in Development of Environmental Disease", Tokyo, Japan, July 1 – July 3, 1999.

30. Invited by the NATO Advanced Study Institute to be a lecturer in the course entitled "Human Monitoring after Environmental and Occupational Exposure to Chemical and Physical Agents, September 23 - October 3, 1999, Antalya, Turkey.

31. Invited by the Brazilian Association for Environmental Mutagenesis, Carcinogenesis and Teratogenesis for a symposium lecture "Genetic Susceptibility to Environmental Disease", Aquas de Sao Pedro, Brazil, December 5 - 8, 1999.

32. Invited by the Colombian National Congress of Genetics and the Hollaneder course to give a lecture on "Genetic Susceptibility on the Quality of Life", Popayan, Colombia, February 23 - 25, 2000.

33. Invited by the 6th International Symposium on Pharmaceutical Sciences to present a lecture on "Metabolic Susceptibility on Environmental Disease and Response to Medication", Ankara, Turkey, June 27 - 29, 2000.

34. Invited by the 30th Annual Meeting of the European Society for Radiation Biology to give a lecture on "Inherited and Acquired Susceptibility on Environmental Disease", Warszawa, Poland, August 27 - 31, 2000.

35. Invited lecturer, "Life style factors and acquired susceptibility to environmental disease" in the conference on Biomarkers for Genetic and Acquired Susceptibility to Disease, Bremen, Germany, August 31 - September 1, 2000.

36. Keynote Speaker, Hong Kong International Cancer Congress, on "Genetic Susceptibility to Environmental Cancer." Hong Kong, December 6 - 9, 2000.

37. Invited speaker: 8th International Conference on Environmental Mutagens, on "Acquired biological effects from exposure to environmental toxicants." Shizuoka, Japan, October 21 - 26, 2001.

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A. Peer-Reviewed Articles in Journals

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3. McAllister, R.M., Isascs, H., Rongey, R., Peer, M., **Au, W.W.** Establishment of a Human Medulloblastoma Cell Line. Int. J. Cancer 20: 206-212: 1977.

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