founded 1881



Sent via Email

November 18, 2009

Ms. Carolyn Jeletic Center for Food Safety and Applied Nutrition Office of Regulations, Policy, and Social Services (HFS-024) U.S. Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

Re: Nomination for a Nonvoting Member Representing Industry Interests on the CFSAN Food Advisory Committee; 74 *Fed. Reg.* 54589 – 54590 [Docket No. FDA-2009-N-0664]

Dear Ms. Jeletic:

The Consumer Healthcare Products Association (CHPA) appreciates the opportunity to nominate candidates to serve as the nonvoting industry representative for the FDA Center for Food Safety and Applied Nutrition (CFSAN) Food Advisory Committee, as noted in the *Federal Register* notice of October 22, 2009¹. CHPA, founded in 1881, is a national trade association representing manufacturers and distributors of dietary supplements and nonprescription drug products.

Members of the CHPA Dietary Supplements Committee (DSC) have products affected by issues considered by the Food Advisory Committee (FAC) and therefore nominate two candidates for the nonvoting industry representative position on the FAC. We believe both candidates, listed alphabetically, are well-qualified for the position.

Consumer Healthcare Products Association 900 19th Street, NW, Suite 700

Washington, DC 20006

т 202.429.9260 F 202.223.6835 www.chpa-info.org

¹ 74 *Fed. Reg.* 54589-54590; Request for Notification From Industry Organizations Interested in Participating in Selection Process for Nonvoting Industry Representatives on Public Advisory Committees and Request for Nominations for Nonvoting Industry Representatives on Public Advisory Committees.

Retrieved November 17, 2009, from http://edocket.access.gpo.gov/2009/pdf/E9-25407.pdf.

Adrianne Bendich, Ph.D., FACN, GlaxoSmithKline Consumer Healthcare

Adrianne Bendich, Ph.D., is the director of medical affairs at GlaxoSmithKline Consumer Healthcare (GSK). With over 100 peer-reviewed scientific publications to her credit, she is internationally recognized by industry and academia as an authority in women's health and preventative medicine. Since 1997 she has served as the series editor for *Nutrition and Health* and currently holds academic appointments at the Columbia University Institute of Nutrition, Rutgers University, and the University of Medicine and Dentistry (NJ). Dr. Bendich is a member of several professional organizations such as the American Association of Immunology, the American College of Nutrition, and American Society of Nutritional Sciences.

Dr. Bendich has also demonstrated her ability to provide leadership for novel research products and products that have the potential to optimize human health and prevent chronic disease. Having worked in industry since 1983, she was the director of new product research worldwide at GSK for 2 years (2001-2002). Dr. Bendich has provided medical support on behalf of GSK for several dietary supplement products such as Cirtucel®, FiberChoice®, Geritol®, TUMS®, and Os-Cal®.

Richard Cotter, Ph.D., Columbia University

Richard Cotter, Ph.D., recently retired as assistant vice president, global scientific affairs for Wyeth Consumer Healthcare (now Pfizer Consumer Healthcare) after more than 30 years of industry experience in the field of food and nutrition. Prior to retirement, he led the worldwide Wyeth Technical Nutrition Resources team with responsibilities in 88 countries. Based on his accomplishments in this role, Dr. Cotter assured a strong expanding technical foundation in the rapidly growing dietary supplement and functional food business.

Dr. Cotter currently holds the position of visiting research scientist at the Columbia University Institute of Nutrition. He has authored numerous scientific publications, has received several awards, and holds multiple patents. Dr. Cotter is a member of several professional societies including the American Society of Nutrition, the American Society of Clinical Nutrition, and the International Life Sciences Institutes. Ms. Carolyn Jeletic CFSAN FAC Nominations (Docket No. FDA-2009-N-0664) November 18, 2009 Page 3 of 3

Dr. Bendich and Dr. Cotter have provided current curriculum vitae (CV) as well as letters indicating their full intent to serve if selected as the nonvoting industry representative on the CFSAN Food Advisory Committee. These documents are attached as part of their nomination materials.

Thank you for your time and attention to this matter. A separate letter expressing CHPA's interest in participating in the selection of the nonvoting industry representative was previously submitted so we look forward to the next step in this process.

Sincerely,

Marcia D. Havard

Marcia D. Howard, Ph.D. Director, Regulatory & Scientific Affairs

MDH/11-06-09

ABendich_RCotter CFSAN PAC Nomination 110609.doc

Adrianne Bendich, Ph.D., FACN

Director of Medical Affairs – GlaxoSmithKline Consumer Healthcare where she is responsible for the Medical leadership for the Venture Group, and has provided Medical support for well-known Brands including TUMS, FiberChoice, Os-Cal, Geritol and Citrucel. Additionally, she served as a member of GSK's successful Advisory Committee team in support of FDA's Rx to OTC switch of alli.

Internationally recognized expert on Women's Health, calcium and vitamin D in bone health, folic acid and pregnancy outcomes, antioxidants and carotenoid effects on immune functions. Corporate representative to the Women's Health Initiative (WHI) for 9 years as GSK Consumer Healthcare provided all calcium and vitamin D supplements for the WHI study.

Member (ongoing and former): Editorial Board, Journal of Women's Health and Gender-based Medicine; Associate Editor for Nutrition, the International Journal; Chair, Corporate Advisory Committee, Society for Women's Health Research; Member of the Program Advisory Committee for Helen Keller International; Advisor to the Nutrition Department, Montclair State University; Member: Advisory Board, Current Topics in Nutraceutical Research; member ASN's Industry Board and provides support to several RIS groups.

Recipient of Burroughs-Wellcome Fund Professorship and Roche Research Award; Listed in Who's Who of American Women Scientists and many other Who's Who volumes; recipient of the CRN Apple Award for contributions to the science of vitamin and mineral supplements.

Author of more than 100 peer-reviewed publications; Series Editor of "Nutrition and Health" for Springer/Humana Press which includes 32 volumes such as "Preventive Nutrition", "Handbook of Clinical Nutrition and Aging", "Diet and Human Immune Functions", "Handbook of Drug-Nutrient Interactions" and other reference volumes for health professionals.

Adrianne Bendich, Ph.D. Director of Medical Affairs

GlaxoSmithKline Consumer Healthcare 1500 Littleton Road Parsippany, New Jersey 07054-3884 (973) 889-2407; FAX (973) 889-2460 e-mail: adrianne.4.bendich@gsk.com

SUMMARY

Internationally recognized authority by both industry and academia in Women's Health and preventive medicine

Proven leader of novel research projects and products that have the potential to optimize human health and prevent chronic disease

EDUCATION

B.S.	City College of New York	Zoology
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M.S. Iowa State University Ph.D. Rutgers University Physiology Immunology

RECENT POSITIONS:

GlaxoSmithKline 2001-2002 Director, New Product Research Worldwide SmithKline Beecham 1998-2001 Associate Director, New Product Research Hoffmann-LaRoche Inc. 1995-1998: Assistant Director, Human Nutrition Research 1983-1995: Clinical Research Scientist AWARDS 2008 - Council for Responsible Nutrition's Apple Award 2001 - Best research paper published in Journal of the American College of Nutrition 2000 - Burroughs Wellcome Visiting Professor 1996 - NJ Spina Bifida "Powerful Women with a Powerful Message" Honoree 1995 - Tribute to Women in Industry Award 1992 - Roche Research and Development Prize

ACADEMIC APPOINTMENTS

Adjunct Full Professor	University of Medicine and Dentistry, NJ
Adjunct Professor	Institute of Nutrition, Columbia University School of Physicians and Surgeons, NY
Adjunct Research Professor	Rutgers University, Newark Campus

PROFESSIONAL ACTIVITIES

Editorial Board, Journal of Women's Health and Gender-based Medicine, 2001 - 2007 Chair: Corporate Advisory Committee, Society for Women's Health Research, 2000 Strategic Decision Making and Critical Thinking Program – Cornell University, 1999 Editorial Board: Women's Health Alternative Medicine Report, 1998 - 2003 Associate Editor, Journal of Nutritional Immunology, 1992 – 1998 Associate Editor, Nutrition, The International Journal, 1998 – 2006 Member, Editorial Board, Free Radical Biology and Medicine, 1992-1998 Member, American Association of Immunology, 1983-present Fellow, American College of Nutrition, 1994-present Member, American Society of Nutritional Sciences, 1983-present Member, NIH Nutrition Study Section, 1994 Member, Editorial Board, Journal of Nutrition, 1990-1994

PUBLICATIONS

Author or co-author of over 100 scientific papers

Series Editor 1997-present:Nutrition and Health, Springer/Humana Press

32 volumes including:

Nutrition and Metabolism	2009
Probiotics in Pediatric Medicine	2009
Nutrition and Rheumatic Diseases	2008
Handbook of Nutrition and Pregnancy	2008
Nutrition in Kidney Disease	2008
Handbook of Nutrition and Ophthalmology	2007
Adipose Tissue and Adipokines in Health and Disease	2007
Nutritional Health, Second Edition	2006
Nutrients, Stress and Medical Disorders	2006

Calcium in Human Health	2006
Preventive Nutrition, Third Edition	2005
The Management of Eating Disorders and Obesity	2005
Nutrition and Oral Medicine	2005
IGF and Nutrition in Health and Disease	2005
Epilepsy and the Ketogenic Diet	2004
Handbook of Drug-Nutrient Interactions	2004
Nutrition and Bone Health	2004
Beverages in Nutrition and Health	2004
Diet and Human Immune Function	2004
Handbook of Clinical Nutrition and Aging	2004
Nutrition and Bone Health	2004
Handbook of Drug-Nutrient Interactions	2004
Fatty Acids	2001
Nutrition and Health in Developing Countries	2001
Nutritional Health	2001
Preventive Nutrition, Second Edition	2001
Primary and Secondary Preventive Nutrition	2000
Clinical Nutrition of the Essential Trace Elements and Minerals	2000
The Management of Eating Disorders and Obesity	1999
Vitamin D	1998
Preventive Nutrition	1997

Co-author or co-editor of eleven books including:

Preventive Nutrition: Fourth Edition, in press	2009
Preventive Nutrition: Third Edition	2005
Diet and Human Immune Function	2004
Primary and Secondary Preventive Nutrition	2001
Preventive Nutrition: Second Edition	2000
Preventive Nutrition: The Comprehensive Guide	1997
Maternal Nutrition and Pregnancy Outcome	1993
Micronutrients in Health and in Disease Prevention	1992
Vitamin Intake and Health: A Scientific Rationale	1991
Micronutrients and Immune Functions	1990
Antioxidant Nutrients and Immune Functions	1990

Journal Volume Editor: Beyond Deficiency: New Roles for Vitamins and Other Bioactive Molecules –A Memorial Tribute to Lawrence J. Machlin, Ph.D., FACN; Nutrition, volume 17, number 10, October, 2001.

Annals of the New York Academy of Sciences Volume Editor:

Volume 587: Micronutrients and Immune Function, 1990 Volume 678: Maternal Nutrition and Pregnancy Outcome, 1993

Adrianne Bendich, Ph.D., FACN: Scientific Publications

- 1. Bendich, A., Belisle, E.H., Strausser, H.R. Immune system modulation and its effects on the blood pressure of the spontaneously hypertensive male and female rat. *Biochem. Biophys. Res. Comm.* 99: 600-607, 1981.
- Bendich, A., Belisle, E.H., Strausser, H.R. Immune responses of rats chronically fed subclinical doses of lead. *Clin. Exp. Immunol.* 43: 189-194, 1981.
- 3. **Bendich, A.**, Kafkewitz, D., Abuchowski, A., Davis, F.F. Immunological effects of native and polyethylene glycol-modified asparaginases from Vibrio succinogenes and Escherichia coli in tumor bearing mice. *Clin. Exp. Immunol.* 48: 273-278, 1982.
- 4. Bendich, A., Kafkewitz, D., Abuchowski, A., Davis, F.F. Immunosuppressive effects of polyethylene glycol-modified asparaginases. *Annals, N.Y. Academy of Sciences*. 392: 379, 1982
- 5. **Bendich, A.**, Gabriel, E., Machlin, L.J. Effect of dietary level of vitamin E on the immune system of the spontaneously hypertensive (SHR) and the normotensive Wistar Kyoto (W/K) rat. *J. Nutr.* 113: 1920-1926, 1983.
- 6. Bendich, A., Gabriel, E., Machlin, L.J. Low concentrations of vitamin E in the tissues of the spontaneously hypertensive rat (SHR). *Proc. Soc. Exp. Biol. Med.* 172: 297-300, 1983.
- 7. **Bendich, A.**, Kafkewitz, D., Abuchowski, A., Davis, F.F. Inhibition of blastogenesis by native and polyethylene glycol-modified asparaginases of E. coli and V. succinogenes. *Immunol. Comm.* 12: 273-284, 1983.
- 8. Kafkewitz, D. and **Bendich, A.** Enzyme induced asparagine and glutamine depletion and immune system function. *Am. J. Clin. Nutr.* 37: 1025-1030, 1983.
- 9. Bendich, A., D'Apolito, P., Gabriel, E., Machlin, L.J. Interaction of dietary vitamin C and vitamin E on guinea pig immune responses to mitogens. J. Nutr. 114: 1588-1593, 1984.
- 10. Gabriel, E., **Bendich, A.**, Machlin, L.J. Strain differences in testes degeneration, myopathy, and the lymphocyte mitogen response in vitamin E deficient rats. *Proc. Soc. Exp. Biol. Med.* 176: 378-383, 1984.
- 11. Kafkewitz, D. and **Bendich, A.** The inhibition of lymphocyte mitogenesis by asparaginase: A still unexplained phenomenon. *Experientia* 40: 173-177, 1984.
- 12. Bendich, A., Gabriel, E., Machlin, L.J. Depression of rat and guinea pig lymphocyte blastogenic responses by vitamin E deficiency: A new model for reproducible immune modulation. *Annals, NY Academy of Sciences.* 435: 382-384, 1984.
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- 15. Bendich, A. & Shapiro, S.S. Effect of beta carotene and canthaxanthin on immune responses of the rat. *J. Nutr.* 116:2254-2262, 1986.
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- 23. Bendich, A. A role for carotenoids in immune function. Clin. Nutr. 7: 113-117, 1988.
- 24. Bendich, A. The safety of beta carotene. Nutr. and Cancer 11: 207-214, 1988.
- 25. Bendich, A. & Machlin, L.J. Safety of oral intake of vitamin E. Am. J. Clin. Nutr. 48: 612-619, 1988.
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- Bendich, A. Antioxidant vitamins and immune responses. In: *Nutrition and Immunology*, ed: R.K. Chandra, Alan Liss, Inc., NY, 1988, pp. 125-148.
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Recent Abstracts

- 113. Heaney, R.P., Dowell, S., **Bendich, A.** Bioavailability and the optimization of calcium supplementation. *Osteoporosis Int.* 11:S7, 2000.
- 114. Bendich, A., Heaney, R.P., Dowell, S., Hale, C.A. Bioavailability and cost effectiveness of calcium supplementation. *FASEB J.* 15(5):A1095, 2001.
- 115. Heaney, R.P., Dowell, S., Bierman, J., Hale, C.A., **Bendich, A.** The magnitude of the PTH response to calcium supplementation. *Bone* 28:5232, 2001.
- 116. Heaney, R.P., Bendich, A. Effects of vitamin D status on calcium absorptive performance in elderly women. J. Am. Coll. Nutr. 21(5): 478, 2002.
- 117. Bendich, A., Hale, C.A., Heaney, R.P. Vitamin D status affects calcium absorptive performance in postmenopausal women. *FASEB J*. 17(4):A704, 2003.
- 118. Bendich, A. Secondary osteoporosis and other complications in end stage renal disease (ESRD) patients. J. Am. Coll. Nutr. 23(5): 454, 2004.
- 119. **Bendich, A.** Calcium: Chemistry and biology. American Chemical Society annual meeting, March 2005, San Diego, CA

CURRICULUM VITAE (Rev. 5/09)

RICHARD COTTER, Ph.D. dcnutrition@gmail.com

9 Cooper Road Mendham, NJ 07945 (973) 543-0028 Wyeth Consumer Healthcare 5 Giralda Farms Madison, NJ 07940 (973) 660-6257

PRESENT POSITION

- 7/09 -- Visiting Research Scientist, Columbia University, Institute of Nutrition
- 7/96 9/08 Assistant Vice President, Global Scientific Affairs Wyeth Consumer Healthcare, Madison NJ. This position is responsible for leadership of the Technical Nutrition Resources of the Corporation on a worldwide basis (88 Countries). This responsibility covers Current and New Product Development, strategical planning, budgeting, and technical management of New Business Development. This position assures the company a strong expanding technical base in the rapidly growing dietary supplement/functional food business.
- 2/95 7/96 Corporate Vice President Research & Development (Product Development, Food Safety, Science and Technology) Gerber Products Company, Fremont, MI, Division of Novartis Corporation, Basel, Switzerland. This position is the chief technical position in the senior management team. This position is responsible for management of all the technical areas of Gerber and for synergistic technical initiatives of Gerber/Novartis. This necessitates the strategic planning, managing, budgeting and planning for all technical areas of Gerber and for all Gerber/Novartis synergies. This position assures the corporation a strong technical and scientific base that allows for safe efficient innovative products that satisfy consumer needs.
- 4/92 2/95 Corporate Director Research & Development (Product Development, Quality Assurance, Food Safety & Regulatory Affairs) Gerber Products Company, Fremont, MI. This position is responsible for the management, direction, and focus of the short and long term strategic plans of Gerber. These responsibilities necessitate the strategic management, budgeting, and planning of these technical Research & Development resources. In addition, this position ensures that all required food safety, toxicology, technical, and regulatory affairs issues are managed for the corporation.
- 6/90 4/92 Corporate Director of Research & Development (Nutrition and Quality Assurance Food Safety), Gerber Products Company, Fremont, MI.
 This position encompasses all of the described responsibilities of the Director of Nutrition (see below). In addition, this position is responsible for the management of quality at the corporate level at Gerber and familiarity with state-of-the-art quality approaches for industry. This position is accountable for the integration of Quality Control into Manufacturing, and has both corporate and manufacturing responsibility. This responsibility encompasses Gerber food plants, co-packers, and Gerber Baby Care manufacturing. This position assures the corporation of the quality, nutrition and safety of all Gerber products.

1/89 - 6/90 Corporate Director of Nutrition - Research & Development, Gerber Products Company, Fremont, MI.
 Administration of existing as well as all new product nutrition research and development. Participates in the formulation and execution of all existing and new product development strategies. These strategies cover the areas of infant formula, cereal, food and juices; toddler products including cereals and complete meals; and also adult foods (up to 60 products per year). Advanced technologies are monitored for potential Gerber applications. This position acts in a regulatory capacity with government agencies to plan and execute clinical trials and research studies. Joint ventures with U.S. and European companies are evaluated and coordinated under this responsibility. This position initiates and executes strategies from product concept, through development, to final product.

EDUCATION

1976	Post Doctoral Training, Vitamin B12 Metabolism, New York Medical College, New York, NY.		
1974	Ph.D. St. John's University, New York, NY		
	Major concentration in biochemistry, cellular and vertebrate physiology, and nutrition.		
	Thesis: Studies were conducted to monitor the interrelationship of the amino acids, tryptophan		
	and tyrosine, in gluconeogenesis in the diabetic under physiological stress.		
1969	M.S. Adelphi University, Garden City, NY.		
	Major concentration in endocrinology, physiology, physiological and developmental cellular		
	biology and genetics.		
	Thesis: Dealt with DNA replication and organ regeneration.		
1967	A.A. and B.S. St. John's University, New York, NY		
	Major: Biology Minor: Chemistry		
	Course concentration in cellular and vertebrate biology.		

PROFESSIONAL EXPERIENCE

- 10/86 12/88 Associate Director, Clintec Nutrition Research & Development, Baxter Healthcare Corporation, Deerfield, IL/Nestle S.A., Vevey, Switzerland.
 Administration of new product research, development and clinical trials in the area of clinical nutrition. Formulate new and existing product research and development strategies; utilize the R&D resources of Baxter Healthcare Corporation, Nestle S.A., and KabiVitrum; and execute these strategies from product concept, through development, to final product.
- 11/84 10/86 Associate Director, Corporate Research Travenol Laboratories, Inc.; Round Lake, IL.

Administration of three laboratory sections, Biochemistry and Nutritional Sciences, Immunochemistry, and Hematology Research. Directed approximately 20 research and development scientists from B.S. to Ph.D. level in widely diverse corporate projects. The Biochemistry and Nutritional Sciences section conducted studies in the areas of the general biochemistry and nutrition of proteins, carbohydrates and lipids; metabolism in injury and repair, organ preservation; cardiovascular disease; gerontology; prostaglandins and leukotriene biochemistry. The Immunochemistry section conducted studies in the areas of general biochemistry of protein and nucleic acids, immunochemistry, immunobiology, monoclonal antibody production, immunoadsorption technology, recombinant DNA technology, and macrotechnology including fermentation and cell culture. The Hematology Research section

conducted studies in the areas of blood coagulation factors and their role in hemostasis.

Program Management:

Acted as a Corporate Research program manager in various major corporate programs. Allocated departmental resources for the execution of preclinical biochemical, nutritional, and toxicological studies.

PROFESSIONAL EXPERIENCE (Cont'd)

New Business Development:

Evaluation and Development of over twenty-five new business opportunities and acquisitions per year for Wyeth (1996-present). Leader Wyeth Global Nutrition Product Team 1996 - 2002 Acquisition Solgar vitamins, minerals and herbals company 1998. Probotics in nutritional products Herbal, botanical and bioactive ingredients. Infant Nutrition and Development - Gerber Products Company. Evaluating the areas of immunity and biotechnology for potential new paradigm shifting food and feeding concepts to concrete new business opportunities. Food products for older Americans. Food products designed to help in childhood diarrhea. R&D's Chief Technical Officer on the Gerber/Novartis Merger Team.

Clinical Nutrition - Clintec Nutrition Company. Acted as a corporate liaison evaluating the potential for successful formation of a new clinical nutrition company (Clintec Nutrition). This company combined the vast resources of Baxter Healthcare Corporation, Nestle, and the KabiVitrum companies in the area of clinical nutrition.

Veterinary Medicine - Baxter Alternate Care Division. One of the original three people who conceptualized, evaluated, and executed a business in this area.

Biomedical Opportunities in Space. Evaluated this area for Baxter at the request of NASA for future product development opportunities.

Industrial Expertise:

Cost center management including strategic budgetary, program, and manpower assignments. Knowledge of FDA, IND, and NDA & USDA requirements, Nutrition Labeling and Education Act (NLEA); Dietary Supplement Health and Education Act (DSHEA) familiarity with operating under FDA Good Laboratory Practices. Experience acting as internal corporate liaison between sales, marketing, advertising and research and development areas in regard to new and existing product development; experience as a project manager in taking products from developmental stages through pilot plant to final product production operations, marketing and sales. Over twenty five years of R&D management experience.

Research and Technical Expertise:

Knowledge and technical expertise in: Whole animal and human nutrition and metabolism studies; product evaluation, clinical trials; plasma and tissue analysis of metabolites; histochemical, immunological and enzymatic techniques; radioimmunoassay; protein iodination; autoradiography; separation, identification, and quantification of proteins, carbohydrates, and lipids; radioisotope handling; gamma and liquid scintillation counting techniques; electrophoresis; electrofocusing; high and low pressure liquid chromatography separations; spectrophotometric methods; gas chromatography; pharmacokinetics; bioavailability and toxicological evaluation; computer applications; skill in the preparation of written protocols, technical reports, and their oral presentation. Familiarity with food and dietary supplement labeling and dietary application of supplements and food products both medical, consumer and dietary supplement/functional food products.

PROFESSIONAL EXPERIENCE (Cont'd.)

06/77 - 11/84	 Manager, Biochemistry and Nutrition Section Department of Life Sciences, Travenol Laboratories, Inc., Morton Grove, IL 60053 Directed seven to ten scientists having bachelor to Ph.D. degrees in various research and development projects. Studies were conducted in the following areas: IND and NDA biochemical and toxicological studies. New product development. In-depth studies in the area of lipid carbohydrate and protein nutrition. Pharmacokinetics of intravenous products. Bioavailability studies. Biochemistry of endotoxins and their biological activities. Models and metabolism of the critically ill. Chronic renal failure. Endocrinology.
10/76 - 06/77	Assistant Professor, New York Medical College, New York, NY
06/74 - 10/76	Research Instructor, Post-Doctoral Training New York Medical College, New York, NY Conducted research on the physiological mechanisms of absorption and transport of vitamin B12 in normal and pathological states. Emphasis being placed on the isolation and purification of vitamin-binding and transport proteins. The development of radio and radioimmunoassays for these proteins and the use of these assays to elucidate the physiological mechanism of vitamin absorption, transport, and function within mammalian systems. First to identify, isolate and purify the vitamin B12 Ileal receptor which had been hypothesized to exist for over 25 years.
09/73 - 06/74	Graduate Teaching Fellowship St. John's University, Jamaica, NY Direction and teaching of physiology laboratories.
09/71 - 09/73	Graduate Teaching Assistantship St. John's University, Jamaica, NY Preparation and teaching of biology and physiology laboratories.
06/69 - 09/71	U.S. Army Research Institute of Environmental Medicine Natick, MA Working in the Biochemistry Pharmacology Department, I took part in numerous studies on the effects of physiological stress, such as heat, cold, high altitude, nutritional, and sleep deprivation on the metabolism of various research animals as well as human test subjects.
06/68 - 06/69	Graduate Teaching Assistantship Adelphi University, Garden City, NY Preparation and teaching of college biology laboratories.
06/67 - 09/67	Research Scientist. New York State Health Department. Veterinary Science Division, Albany, NY Participated in studies working with all types of wildlife and domestic animals. Laboratory work involved the isolation and identification of viruses from these animals.

MEMBERSHIPS IN SOCIETIES

American Association for the Advancement of Science American Society of Nutrition ASN Sustaining (Industrial Members) Chair and Executive Board Representative The American Society of Clinical Nutrition American Physiology Society Society for Complex Carbohydrates American Society of Parenteral and Enteral Nutrition Society of Toxicology, Midwest Regional Chapter American Society of Quality Control International Life Sciences Institutes (North American , Board Member) International Food Technologists

BUSINESS ASSOCIATIONS

National Food Processors - Chairman, Regulatory & Scientific Affairs Council Grocery Manufactures of America Member, International Life Sciences - Board of Trustees Food Research Institute – Board of Advisors Member, Gerber Foundation - Board of Trustees Council of Responsible Nutrition – Board Member Consumer Health Products Association – Chairmen Vitamin and Mineral Task Group

AWARDS

- 1. Patent Award, Travenol Laboratories, 1981.
- 2. Award for Contribution to Nutritional Product Development, Travenol Laboratories, 1982.
- 3. Technical Achievement Award for Nutritional Biochemistry, Travenol Laboratories, 1983 and 1984.
- 4. Patent Award, Travenol Laboratories, January 1984.
- 5. Three Patent Awards, Baxter Healthcare Corporation, 1988.
- 6. Milestone Inventive Award, Baxter Healthcare Corporation, 1988.
- 7. Wyeth Global Technical Achievement Award, 2008

PATENTS

- 1. Method for Determining Endotoxin Concentration. U.S. Patent #4,221,866 (1980).
- 2. Biological Extracts and Method for Making Same. U.S. Patent #4,376,819 (1983).
- 3. Methods and Composition for Parenteral Nutrition of Patients with Liver Disease. U.S. Patent #4,703,062 (1987).
- 4. Method for Directed Visceral Metabolism of Medium-Chain Triglycerides. U.S. Patent #4,678,807 (1987).
- 5. Intravenous Emulsions of Omega-3 Fatty Acid Esters. U.S. Patent #4,678,808 (1987).
- 6. Oral and Intravenous Diets for Cardiac Patients. U.S. Patent #4,920,098 (1991).
- 7. Use of Short Chain Fatty Acid Containing Lipids to Maintain Gastrointestinal Integrity and Function in Patients. U.S. Patent # 5919822 (1999).
- 8. Multivitamin/mineral formulation for cholesterol lowering and the prevention of cardiovascular disease. Patent Applied for 2006
- 9. Calcium sustained release mechanism of action, invention record 2007.
- 10. A dietary Supplement formulation to provide biochemical support to prevent or restore skin from photo ageing, Invention record 2008.
- 11. A multivitamin/mineral formulation to combat the effects of environmental stress on various physiological systems while addressing vitamin and mineral deficiencies. U.S. Patent application filed, 2009.
- 12. Nutritional supplement for the 50+ individual to improve vitality and support various physiological organ functions. U.S. patent applications filed 2009.

HONORS

1.	Invited speaker:	National Conference on the Metabolism of Structured Lipids, National Institute of Health, Nov., 1984.
2.	Invited speaker:	International Symposium of Pediatric Pharmacology, Ahmedabad, India, Jan. 21-22, 1985. (Feeding the Premature Infant).
3.	Invited speaker:	Conference on the Health Effects of Polyunsaturated Fatty Acids in Seafoods. National Institutes of Health, Jun. 24-26, 1985.
4.	Invited speaker:	Association of Primate Veterinarians, Annual Meeting, Oct. 3-5, 1986. (Total Parenteral Nutrition)
5.	Invited speaker:	Conference on the Use of Nutrition in Critical Care Medicine, Jan. 1988.
6.	Invited speaker:	European Society of Enteral and Parenteral Nutrition, Aug. 1988. (Medium Chain Triglycerides)
7.	Invited speaker:	Cornell University, February 12, 1990. (Feeding the Elderly)
8.	Invited speaker	University of Tennessee, 1993
		(Industrial/Science)
9.	Invited speaker:	Child Health Foundation (Oral Rehydration)
10	Invited speaker	NFPA/USDA, Middle East Symposium
		November, 1994
		(Shelf Life & Food Safety)
11.	Invited speaker	Philippine Pediatric Association, 1994
10	Invited an appen	(Infant Nutrition & Development)
12.	Invited speaker	Perinatal Society of Singapore, 1994 (Infant Nutrition & Development)
13.	Requested reviewer:	American Journal of Clinical Nutrition, 1987-1990.
14.	Requested reviewer:	Metabolism 1988
15.	Requested reviewer:	Nutrition 1988-1996
16.	Editorial Advisory Board:	Journal of International Nutrition, 1993 – 1996
17.	Publication Committee:	Journal of Nutrition 1992-1993
18.	Invited Speaker.	Presidential Council of Science &
		Technology of Korea (Infant Development &
		Eating Readiness A Current View)
19.	Invited Speaker.	Johns Hopkins University School of
		Public Health, Research to Promote
		Childhood Nutrition Corporate-
20.	Invited Speeker	University Partnerships, 1995
∠0.	Invited Speaker.	University of Maryland School of Medicine, Research to Promote
		Childhood Nutrition Corporate
		University Partnerships, 1995

21.	Invited Speaker.	Institute of Food Technologists (IFT) (How World Class Companies Enter New Markets, 1995)
22.	Invited Speaker	National Institute of Health - National Eye Institute (Nutrition's Role in Eye Disease of the Aging Population) 1998.
23.	Invited Speaker	GMA 1999 (The future of Dietary Supplements, Science and Policy)
24.	Invited speaker	Nutrition 2000 (Nutrition Role in Eye Health)
25.	Invited speaker	Nutrition 2002 (Scientific Support for Product Claims)
26.	Invited Speaker	Experimental Biology 2003 (Carotenoids An Industrial Perspective)
27.	Requested Reviewer	Journal of Parenteral and Enteral Nutrition, 2001-
28	Requested Member	Friends of Tufts University. School of Nutrition

PUBLICATIONS

ARTICLES

- 1. Starvation and Refeeding: Effects on the Periodicity of Tryptophan and Tyrosine Metabolism in Mice. Ralph Francisconi, Richard Cotter, and Milton Mager. The Journal of Nutrition 102: 597, 1972.
- Solubilization, Partial Purification and Radioassay for the Intrinsic Factor Receptor from the Ileal Richard Cotter and Sheldon P. Rothenberg. British Journal of Hematology 34: 477, 1976.
- 3. Purification of the Intestinal Receptor for the Intrinsic Factor by Affinity Chromatography. Richard Cotter, Sheldon P. Rothenberg, and J.P. Weiss. Biochemica et Biophysics Acta 490: 19, 1977.
- 4. Alteration of Human Intrinsic Factor During Affinity Chromatography Purification Using Concentrated Guanidine. J.P. Weiss, S.P. Rothenberg, and R. Cotter. FEBS Letters 78(2): 275-278, 1977.
- Formation of Transcobalamin II Vitamin B12 Complex by Guinea Pig Ileal Mucosa in Organ Culture after <u>In</u> <u>vivo</u> Incubation with Intrinsic Factor Vitamin B12. Sheldon P. Rothenberg, J.P. Weiss, and Richard Cotter. British Journal of Hematology 40: 401, 1978.
- Disassociation of the Intrinsic Factor Vitamin B12 Complex by Bile: Contributing Factor to B12 Malabsorption of Pancreatic Insufficiency. Richard Cotter, Sheldon P. Rothenberg, and J.P. Weiss. Scandinavian Journal of Gastroenterology 14(5): 545-550, 1979.
- Nonlinear Kinetic Analysis of the Elimination of Lipid Emulsion Administered Intravenously to Dogs.
 R. Cotter, L. Martis, F. Cosmas, H. Sargent, C.A. Taylor, W. Remis, S.K. Young, W.B. Rowe, and E.P. Woods. Journal of Parenteral and Enteral Nutrition 7(3): 244-250, 1983.
- Comparison of the Elimination and Metabolism of 10% Travamulsion and 10% Intralipid Emulsion in the Dog. R. Cotter, L. Martis, F. Cosmas, H. Sargent, C.A. Taylor, S.K. Young, W.B. Rowe, and E.F. Woods. Journal of Parenteral and Enteral Nutrition 8(2): 140-145, 1984.

- Comparison of the Elimination of 10 and 20% Travamulsion Lipid Emulsion from the Blood of Beagle Dogs. R. Cotter, L. Martis, F. Cosmas, C.A. Taylor, S.K. Young, W.B. Rowe, and R.C. Johnson. The American Journal of Clinical Nutrition 41(5): 994-1001, 1985.
- Dietary Supplementation of Undernourished Rats with Soy or Safflower Oil: Effects of Myelin Polyunsaturated Fatty Acids. P. Divakaran, Thomas Pavlina, Robert C. Johnson, Richard Cotter, David Madsen, and Richard Wiggins. Metabolic Brain Disease 1(2): 157-164, 1986.
- 11. A Metabolic Comparison of a Pure Long Chain Triglyceride Lipid Emulsion (LCT) and Various Medium Chain Triglyceride (MCT)-LCT Combination Emulsions. R. Cotter, C.A. Taylor, R.C. Johnson, and W.B. Rowe. The American Journal of Clinical Nutrition 45: 927-939, 1987.
- Fatty Acid Profiles in Response to Soybean Oil Lipid Emulsion Infusions in Essential Fatty Acid Deficient Miniature Swine. R. Cotter, R.C. Johnson, M. Tumbelson, J. Dexter, S.K. Young, C.A. Taylor, F. Cosmas, W.B. Rowe, and L. Lin. Journal of Parenteral and Enteral Nutrition 12(2): 121-126, 1988.
- Competitive Effects of Long-Chain Triglyceride Emulsion on the Metabolism of Medium-Chain Triglyceride Emulsions. R. Cotter, R.C. Johnson, S.K. Young, L.I. Lin, and W.B. Rowe. The American Journal of Clinical Nutrition 50: 794-800, 1989.
- 14. Fasting Plasma Amino Acids in Elderly Men. D. Rudman, D.E. Mattson, A.G. Feller, R. Cotter, and R.C. Johnson. The American Journal of Clinical Nutrition 49: 559-566, 1989.
- 15. Utilization and Distribution of Medium-Chain Triglyceride Lipid Emulsions. R.C. Johnson, S.K. Young, R. Cotter, L.I. Lin, and W.B. Rowe. The American Journal of Clinical Nutrition 50: 794-800, 1989.
- Medium-Chain Triglyceride Lipid Emulsion: Metabolism and Tissue Distribution. R.C. Johnson, S.K. Young, R. Cotter, L.I. Lin, and W.B. Rowe. American Journal of Clinical Nutrition 52:502-508, 1990.
- Infant Development and Eating Readiness, A Current View. B.R. Carrath, J. Skinner, S.E. Morris, K. Houck, F. Coletta, M. McLeod and R. Cotter. Proceedings of the 2nd International Symposium on Infant Nutrition, 36-53, 1995.
- Effect of Fruit Juices Supplemented with Soluable Fiber on Serum Lipids and Lipoproteins Among Hypercholesterolomic Subjects: A Randomized Double-Blind, Placebo Controlled Dose Ranging Study, Journal of Nutrition 128: 1927-1932, 1999.

BOOK CHAPTERS, REVIEWS, EDITORIALS, AND SYMPOSIA

- Comparative Dose Effects of Tritiated Thymidine on Cell Cycle Time in <u>Triturus viridesceus</u>. Richard Cotter. MS Thesis, Adelphi University, New York, 1969.
- 2. The Effect of Chronic Stress on the Circadiant Rhythms of Selected Liver Enzymes in the Diabetic and Nondiabetic Mouse. Richard Cotter. Ph.D. Thesis. St. Johns University, New York, 1974.
- 3. Nutrient Deficiencies in Man: Vitamin B12. Sheldon P. Rothenberg and Richard Cotter. Handbook Series in Nutrition and Food. M. Rechcigl, ed. The Chemical Rubber Company, Cleveland, OH, p. 69, 1978.
- 4. Quantitative Detection of Endotoxin by Nephelometry. Proceedings of the Symposium on "Biomedical Applications of Limulus Polyphemus." John A. Dubczak, Richard Cotter, and Frank R. Dastoli. Alan R. Liss, Inc., New York 29: 403-414, 1979.
- The Stability and Comparative Clearance of TPN Mixtures with Lipid. G. Hardy, R. Cotter, and R. Dawe. In: Advances in Clinical Nutrition, Proceedings of the 2nd International Symposium, I.D.A. Johnston, ed. M & P Press Limited, Lancaster, England, p. 241, 1983.
- Metabolism of Medium-Chain Lipid Emulsion. Robert C. Johnson and Richard Cotter. Nutrition International 2(3): 150-158, 1986.

- Rapid Changes in Hemostasis and Fatty Acid Profiles After Intravenous Infusion of a Marine Oil Lipid Emulsion to Various Animal Species. M. Ward, T. Pavlina, R. Butchin, R. Johnson, and R. Cotter. In: Proceedings of the AOCS Short Course on Polyunsaturated Fatty Acids and Eicosanoids, W.E.M. Lands, ed. American Oil Chemists' Society, Champaign, IL, pp. 372-377, 1987.
- 8. Nutrition, Fluid Balance, and Physical Performance. R. Cotter. In: Drugs, Athletes, and Physical Performance, J.A. Thomas, ed. Plenum Publishing Corporation, New York, London, pp. 31-38, 1988.
- 9. The Evolution of Clinical Nutrition in the Critical Care of the Neonate. R. Cotter. Equine Veterinary Journal, Supp. 5: 17-18, 1988.
- Medium-Chain Triglycerides: A Preclinical Perspective. R. Cotter and C. D'Alleinne. In: Perspectives in Clinical Nutrition, J. M. Kinney and P.R. Borum eds. Urban and Schwarzenberg, Baltimore-Munich, pp. 393-403, 1989.
- 11. Commercial Medium-Chain Triglyceride Emulsions: Where Are They? R. Cotter. Nutrition 6: 122, 1990.
- 12. The Evolving Story of Lipids as a Caloric Source. R. Cotter. Nutrition 8: 370, 1992.
- 13. Infant Feeding: Professional Recommendations vs. Parental Practices. R. Cotter. Pediatric Basics 60: 1, 1992.
- 14. Agents to Improve Gastrointestinal Integrity. R. Cotter. Current Opinions in Therapeutic Patents, 3: 359-365, 1993.
- 15. Solid Food Introduction and Food Allergy. R. Cotter. Pediatric Basics, 65:1,1993.
- Osteoporosis (in) Encyclopedia of Food Science, 2nd Edition, (Ed) Fredrick J. Francis; R. Cotter, S. Trimbo, C. Dominguez, 1999.
- 17. Drug Nutrient Interactions in the Critically Ill. J.A. Thomas, W.W. Stargel and R. Cotter In: Nutrient Support in the ICU, Pichard, C and Kudsk, K.A. eds. Springer, pp 151-165, 2000.
- Interactions Between Foods Nutritional Supplements and Drugs. J. Thomas and R. Cotter in: Nutrition Toxicology, F.N. Kotsonis and Maureen Mackey ed. Taylor Francis, London and New York. Pp. 155 – 172, 2002.
- 19. Potential Benefits for the use of Minerals and Vitamin Supplements. R. Cotter, J. Morienes, L. Ellenbogen. In: Hand Book of Nutrition, Carolyn D.Berdanier ed. July 2007.
- 20. Nutrition and Eye Disease, J. Moreines, R. Cotter, L. Ellenbogen. In: Handbook of Nutrition, Carolyn Berdanier ed. July 2007.

ABSTRACTS

- 1. Changes in Serum Triglycerides, Cholesterol and Glucose in Normal and Diabetic Rats During Hyperthermia. Daniel Frascella, Richard Cotter, and Ingo Kampa. American Zoologist 12: 669, 1976.
- 2. Partial Purification and Properties of Intrinsic Factor-Binding Receptor from Guinea Pig Ileum. Richard Cotter and Sheldon P. Rothenberg. Federation Proceedings 34: 475, 1975.
- 3. Purification of the Receptor for Intrinsic Factor from Guinea Pig Ileum using Affinity Chromatography. Richard Cotter, Sheldon P. Rothenberg, and J.P. Weiss. Clinical Research 24: 432, 1976.
- The Demonstration that Intrinsic Factor (IF) Vitamin B12 (B12) Complex Undergoes Transition to Free B12 During Absorption Using an <u>In vivo-In vitro</u> Culture System. Sheldon P. Rothenberg, J.P. Weiss, and Richard Cotter. Clinical Research 25: 516, 1977.
- 5. Effect of Pancreatic Enzymes and Pepsin on B12 Binding Proteins in Bile. Richard Cotter, Sheldon P. Rothenberg, and J.P. Weiss. Federation Proceedings 36: 594, 1977.

- 6. Nonlinear Elimination Kinetics of Intravenously Administered Lipid Emulsion in the Dog. Richard Cotter, Leo Martis, Frances Cosmas, and Harold Sargent. Federation Proceedings 38: 895, 1979.
- Kinetic Analysis of the Elimination of an IV 10% Fat Emulsion from the Blood Stream of Cynomolgus Monkeys. Richard Cotter, Leo Martis, Frances Cosmas, Susan Young, Daniel Dalgard, Harold Sargent, and Eugene F. Woods. Physiologist 22: 23, 1979.
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Supported Studies:

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- 3) NIH Physicians Health Study II 2000 the present
- 4) NIH Age Related Eye Disease Study (AREDS I) 2000 2004
- 5) NIH AREDS II 2005 the present
- 6) NIH Italian Eye Study 2000 completed 2008