

Ed Carmines, Ph.D.

Summary A proven toxicologist with an appreciation for science and business. Regulatory experience with the FDA, EPA, and CPSC. Wide consumer product experience ranging from foods, pharmaceuticals, over the counter drugs, pesticides, veterinary products, paints, personal care, household cleaners to cigarettes. Demonstrated ability to manage complex large scale, long term projects. Ability to understand complex scientific problems and to develop business relevant solutions.

Professional Experience **Principal** **2011 - Present**
Carmines Consulting LLC

- Consultant to the consumer product industry in the field of toxicology and regulatory affairs.

Scientist **2011**

R.J Reynolds Tobacco Co.

- Managed the safety of novel and oral tobacco products.

Principal **2009 – 2011**

Carmines Consulting LLC

- Consultant to the consumer product industry in the field of toxicology and regulatory affairs.

Principal Scientist **1996 - 2009**

Philip Morris USA Richmond, VA

- Developed guidelines for safety testing of cigarette ingredients and components based on the FDA Red Book
- Conceived and engaged the Life Sciences Research Office, Inc. (LSRO) to independently evaluate the health risks associated with the nontobacco ingredients of cigarettes resulting in two monograph publications:
“Review of Ingredients Added to Cigarettes. Phase One: The Feasibility of Testing Ingredients Added to Cigarettes”
“Review of Ingredients Added to Cigarettes. Phase Two: Scientific Criteria for the Evaluation of Ingredients Added to Cigarettes”
- Engaged the Life Sciences Research Office, Inc. (LSRO) to provide an independent, comprehensive evaluation of the science base necessary to determine if there is sufficient scientific evidence to characterize the relative risks of using smokeless tobacco products compared to cigarette smoking and the relative risks posed to users of various categories of smokeless tobacco products. This resulted in publication of a monograph: “Exposure Assessment in the Evaluation of Potential Reduced-Risk Tobacco Products”
- Set-up and validated laboratories to perform in vitro, smoke chemistry and animal toxicology studies
- Managed \$100M product testing program evaluating 150 cigarette ingredients over 7 years
- Prepared over 100 cigarette ingredient monographs for submission to governments around the world
- Developed Open Innovation Program to source new technologies and products externally
- Managed development of new technologies

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- Product Types: Cigarettes, Oral Tobacco Products, Cigars, New Non-Tobacco Product Categories

Director, Product Safety and Regulatory Affairs **1993 - 1996**

The Dial Corp Scottsdale, AZ

- Directed safety programs for EPA, FDA, and CPSC regulated products
- Directed regulatory activities for EPA and FDA registrations
- Chairman, Antimicrobials Division of the Chemical Specialties Manufacturers Association
- Lead an industry task force for antimicrobial pesticide registration reform. Drafted and lobbied Congress in support of proposed changes to FIFRA. The proposed legislation was incorporated at Title II: Antimicrobial Pesticide Registration Reform of the Food Quality Protection Act became law (P.L. 104-170) in 1996
- Contracted human clinical safety and efficacy studies
- Developed product label warning and safety statements
- Developed automated MSDS writing program
- Set up and managed poison control system
- Product Types: Disinfectants, Laundry Detergents, Fabric Softeners, Antibacterial Soaps, Antiperspirants, Floor Cleaners, Dish Detergents, Foods

Director, Product Safety **1992 - 1993**

Lehn and Fink Products Montvale, NJ

- Directed safety programs for EPA, FDA, and CPSC regulated products
- Managed Quality Assurance Unit
- Managed rodenticide research and product development program
- Developed product label warning and safety statements
- Contracted animal toxicology, human clinical safety and efficacy studies
- Set up and managed poison control system
- Product Types: Disinfectants, Baby Care, Hair Care, Topical Creams, Floor Cleaners, Rug Cleaners, Rodenticides, Paints and Stains, Bleach

Manager, Veterinary Business Development **1989 - 1992**

Hoechst-Roussel Agri-Vet Bridgewater, NJ

- Strategic guidance of business units
- Financial analysis of licensing and divestiture opportunities
- Set up and managed poison control system
- Managed insecticide research and product development program
- Managed safety testing of veterinary products
- Contracted animal toxicology studies
- Prepared reviews of all studies and submissions for FDA registrations
- Made presentations to the FDA

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- Product Types: Antibiotics, Antifungals, Insecticides, Vaccines, Antibiotic Food Additives, Growth Promoting Hormones, Diuretics

Manager, Agricultural Products Toxicology **1985 - 1989**

Hoechst-Roussel Agri-Vet, Inc. Bridgewater, NJ

- Managed pesticide research and product development programs
- Lead Industry Task Forces for product re-registration
- Managed product chemistry and safety testing of insecticides and herbicides
- Set up and managed poison control system
- Contracted animal toxicology, environmental and human exposure studies
- Prepared reviews of all studies and submissions for EPA registrations
- Made presentations to the EPA
- Product Types: Herbicides, Insecticides

Study Director, Drug Safety **1981 - 1985**

Hoechst-Roussel Pharmaceuticals, Inc. Bridgewater, NJ

- Managed small animal testing laboratory
- Prepared drug safety sections of IND and NDAs
- Contracted animal toxicology and mutagenicity studies
- Made presentations to the FDA
- Product Types: Antibiotics, Antifungals, Diuretics, Ace Inhibitors, Alzheimer's, Anti-depressants, Anti-hypertensive's

Education

Intern **1980 - 1981**
International Research and Development Corp. Mattawan, MI

Ph.D. Pharmacology/Toxicology **1976 - 1980**
Medical College of Virginia, Virginia Commonwealth University Richmond, VA

B.S. Chemistry **1972 - 1976**
Hampden-Sydney College Hampden-Sydney, VA

Publications and Patents

Safety assessment of AGPC as a food ingredient. Brownawell AM, Carmines EL, Montesano F. Food Chem Toxicol. 2011 Jun;49(6):1303-15.

THERMOFORMABLE MULTILAYER FILMS AND BLISTER PACKS PRODUCED THEREFROM. Stephen J. Bellamah Ed Carmines and Rangaraj S. Sundar USPA 20110049003

Palladium alters cigarette smoke toxicological profile, but accumulates in the lungs of rats during inhalation exposure. Gaworski CL, Coggins CR, and Carmines EL. Inhal Toxicol. 2008 Jan;20(2):167-82.

Evidence for carbon monoxide as the major factor contributing to lower fetal weights in rats exposed to cigarette smoke. Carmines EL and Rajendran N. Toxicol Sci. 2008 Apr;102(2):383-91.

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Detection of Nitrates from tobacco for correlation with the amount of tobacco specific nitrosamines with in the tobacco. Deevi SC and Carmines EL. USPA US2008/0094625 A1 2008 Apr 24.

Toxicological evaluation of potassium sorbate added to cigarette tobacco. Gaworski CL, Lemus-Olalde R, and Carmines EL. Food Chem Toxicol. 2008 Jan;46(1):339-51.

Toxicological comparisons of cigarettes containing different amounts of vanillin. Lemus R, Carmines EL, Van Miert E, Coggins CR, Anskeit E, Gerstenberg B, Meisgen TJ, Schramke H, Stabbert R, Völkel H, Terpstra PM. Inhal Toxicol. 2007 Jun;19(8):683-99.

Toxicological evaluation of glycerin as a cigarette ingredient. Carmines EL and Gaworski CL. Food Chem Toxicol. 2005 Oct;43(10):1521-39.

Toxicologic evaluation of licorice extract as a cigarette ingredient. Carmines EL, Lemus R, and Gaworski CL. Food Chem Toxicol. 2005 Sep;43(9):1303-22.

In utero and lactation exposure of rats to 1R4F reference cigarette mainstream smoke: effect on prenatal and postnatal development. Gaworski CL, Carmines EL, Faqi AS, and Rajendran N. Toxicol Sci. 2004 May;79(1):157-69.

In utero exposure to 1R4F reference cigarette smoke: evaluation of developmental toxicity. Carmines EL, Gaworski CL, Faqi AS, and Rajendran N. Toxicol Sci. 2003 Sep;75(1):134-47

Evaluation of the potential effects of ingredients added to cigarettes. Part 1: cigarette design, testing approach, and review of results. Carmines EL. Food Chem Toxicol. 2002 Jan;40(1):77-91.

Evaluation of the potential effects of ingredients added to cigarettes. Part 2: chemical composition of mainstream smoke. Rustemeier K, Stabbert R, Haussmann HJ, Roemer E, and Carmines EL. Food Chem Toxicol. 2002 Jan;40(1):93-104.

Evaluation of the potential effects of ingredients added to cigarettes. Part 3: in vitro genotoxicity and cytotoxicity. Roemer E, Tewes FJ, Meisgen TJ, Veltel DJ, and Carmines EL. Food Chem Toxicol. 2002 Jan;40(1):105-11.

Evaluation of the potential effects of ingredients added to cigarettes. Part 4: subchronic inhalation toxicity. Vanscheeuwijck PM, Teredesai A, Terpstra PM, Verbeeck J, Kuhl P, Gerstenberg B, Gebel S, and Carmines EL. Food Chem Toxicol. 2002 Jan;40(1):113-31.

Investigations into the mechanism of paraquat toxicity utilizing a cell culture system. Carmines EL, Carchman RA, and Borzelleca JF. Toxicol Appl Pharmacol. 1981 May;58(3):353-62.

A method for the evaluation of dose-effect data utilizing a programmable calculator. Carmines EL, Carchman RA, and Borzelleca JF. J Environ Pathol

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Toxicol. 1980 Aug;4(1):23-30.

New Drug Evaluation: Safety Assessment. Borzeleca JF and Carmines EL. In "Research Frontiers in Fertility Research". GL Zatushni, MH Labbok and JJ Sciarra, editors. 1980. Harper and Row, publishers.

Kepone: cellular sites of action. Carmines EL, Carchman RA, and Borzelleca JF. Toxicol Appl Pharmacol. 1979 Jul;49(3):543-50.

The effect of corticotropin on phospholipid metabolism in isolated adrenocortical cells. Laychock SG, Shen JC, Carmines EL, and Rubin RP. Biochim Biophys Acta. 1978 Mar 30;528(3):355-63.