

# Ed Carmines, Ph.D.

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**Summary** A proven leader with the ability to merge science and business. Extensive experience with the Center for Tobacco Products at the FDA. Proven track record with Premarket Tobacco Applications, Modified Risk Tobacco applications, Substantial Equivalence, and Exemptions Requests. Detailed knowledge of the technical aspects of all types of e-cigarettes, oral tobacco, tobacco leaf free oral products, cigars, and cigarettes. Expert on flavor ingredients and food GRAS panels. Demonstrated ability to manage complex large scale, long term projects. Ability to understand complex scientific problems and to develop business relevant solutions.

**Professional Experience** **Board of Directors** **2022 - Present**  
**Charlies Holdings Inc.**

- Independent board member for Charlies Holdings (CHUC), a publicly traded e-cigarette company

**Chief Scientific Officer** **2019 - Present**  
**Chemular, Inc**

- Design and direct scientific and regulatory programs for Premarket Tobacco Applications

**Advisory Board Member** **2016 - Present**  
**Sparq Life, Inc**

- Provide advice on the science of inhalation of non-tobacco products

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

- Consultant to the regulated tobacco 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 (Altria Client Services, Inc)**

- 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

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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
- Directed \$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

## **Director, Product Safety and Regulatory Affairs**

**1993 - 1996**

**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

## **Director, Product Safety**

**1992 - 1993**

**1996 - 2009**

### **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**

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**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
- Presentations to the FDA

**Manager, Agricultural Products Toxicology**

**1985 - 1989**

**Hoechst-Roussel Agri-Vet, Inc.**

- 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
- Presentations to the EPA

**Study Director, Drug Safety**

**1981 - 1985**

**Hoechst-Roussel Pharmaceuticals, Inc**

- Managed small animal testing laboratory
- Prepared drug safety sections of IND and NDAs
- Contracted animal toxicology and mutagenicity studies
- Made presentations to the FDA

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## **Publications and Patents**

Application of Rapid in vitro Toxicological Screening Using ToxTracker to Determine the Effect of Flavors in Oral Tobacco Products. Carmines, E.; Misra, M.; Oh, S.; Hendrik, G.; Coffa, B.; Aleksa, K.; TSRC, Tob. Sci. Res. Conf., 2023, 76, Poster 99.

Youth Underestimate the Health and Addiction Risks of Tobacco Products. Carmines, E.; Fraissinet, L.; Steele, A.; TSRC, Tob. Sci. Res. Conf., 2023, 76, Poster 97.

A Relatively Low Nicotine Strength E-Liquid that Reduces the Urge to Smoke as much as Cigarettes. Carmines, E.; Carmines, K.; Fraissinet, L.; Levy-Cooperman, N; TSRC, Tob. Sci. Res. Conf., 2023, 76, Poster 96.

Evaluation of the Potential Extractables from a Chubby Gorilla E-liquid Bottle. Carmines, E.; Fraissinet, L.; Barrett, T.; TSRC, Tob. Sci. Res. Conf., 2023, 76, Poster 8.

Potential Environmental Impact of Use and Disposal of a Modern Oral Nicotine Pouch Product. Carmines, E.; TSRC, Tob. Sci. Res. Conf., 2023, 76, Poster 7.

Imotine™: A Novel Non-nicotine Compound with CNS Activity. Carmines, E.; Misra, M.; Benaim, S.; TSRC, Tob. Sci. Res. Conf., 2023, 76, Poster 6.

A Black Buffalo Novel Nicotine Pouch Product is Bioequivalent to 4 mg Nicorette Gum. Carmines E.; Carmines K.; Fraissinet L.; Levy-Cooperman N.; Seltzer, R., TSRC, Tob. Sci. Res. Conf., 2022, 75, Poster 19.

Salt vs. Free-base Nicotine in E-Liquids Does Not Impact Nicotine Plasma Levels. Ed Carmines, Karen Carmines, Lise Fraissinet, Naama Levy-Cooperman. TSRC, Tob. Sci. Res. Conf., 2022, 75, Poster 73.

Actual User Testing of E-Cigarette Age Gating Technology. Ed Carmines, Lise Fraissinet, Azure Steele. TSRC, Tob. Sci. Res. Conf., 2022, 75, Poster 74.

Simulated User Testing of E-Cigarette Age Gating Technology. Ed Carmines, Lise Fraissinet, Azure Steele. TSRC, Tob. Sci. Res. Conf., 2022, 75, Poster 75.

Comparison of CNT Synthetic and Tobacco Derived Nicotine. Ed Carmines, Bryan Burd, Kevin Burd. TSRC, Tob. Sci. Res. Conf., 2021, 75, Poster 76.

Comparative Aerosol HPHC Evaluation of Seven Flavors of a Temperature-Regulated Nicotine Salt-Based Connected ENDS Product with Combustible Tobacco Cigarettes Manoj Misra, Ed Carmines, Lise Fraissinet, TSRC, Tob. Sci. Res. Conf., 2021, 75, Poster 20.

Comparative Aerosol HPHC Evaluation of Seven Flavors of a Temperature-Regulated Nicotine Salt-Based Connected ENDS Product with Market Standard ENDS. Manoj Misra, Ed Carmines, Lise Fraissinet, TSRC, Tob. Sci. Res. Conf., 2021, 75, Poster 21.

In Vitro Toxicity Evaluation of Aerosol from Seven Flavors from a Temperature Regulated Nicotine Salt-Based Connected ENDS Product. Manoj Misra, Ed Carmines, Lise Fraissinet, TSRC, Tob. Sci. Res. Conf., 2021, 75, Poster 22.

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Resolution of micronucleus induction genotoxicity in ends: in vitro and in vivo testing. Misra, M.; Carmines E.; Scian M.; McCormick D., TSRC, Tob. Sci. Res. Conf., 2021, 74, abstr. 61.

Toxicological and chemical evaluation of a line of novel non-tobacco smokeless products. Misra M.; Carmines E.; Fraissinet L.; Hansom M., TSRC, Tob. Sci. Res. Conf., 2021, 74, abstr. 62.

Nicotine tobacco product hazard assessment. F Fraissinet L.; Misra M.; Carmines E.; Burd K., TSRC, Tob. Sci. Res. Conf., 2021, 74, abstr. 63.

There is more to ends safety evaluation than HPHCs – a wholistic approach Carmines E.; Misra M.; Fraissinet L.; Burd B.; Burd K., TSRC, Tob. Sci. Res. Conf., 2021, 74, abstr. 64.

Dissolution testing of a novel non-tobacco long cut and pouch nicotine product. Carmines E.; Fraissinet L.; Martin A.; Hansom M., TSRC, Tob. Sci. Res. Conf., 2021, 74, abstr. 65.

Evaluation of the abuse liability of a novel non-tobacco smokeless pouch product. Carmines E.1); Carmines K.; Fraissinet L.; Levy-Cooperman N.; Bader Z., TSRC, Tob. Sci. Res. Conf., 2021, 74, abstr. 66.

Evaluation of the abuse liability of a novel non-tobacco long cut smokeless product. Carmines E.; Carmines K.; Fraissinet L.; Levy-Cooperman N.; Bader Z.; Hanson M., TSRC, Tob. Sci. Res. Conf., 2021, 74, abstr. 67.

Abuse liability of very low nicotine content cigarettes with characterization of nicotine exposure profiles in adult smokers. Levy-Cooperman N.; Shram M.J.; Kelsh D.; Vince B.; Carmines E., TSRC, Tob. Sci. Res. Conf., 2019, 73, abstr. 044.

Comparison of the yield of very low nicotine content cigarettes to the top 100 United States brand styles. Ed Carmines and I. Gene Gillman. Beitrage zur Tabakforschung. 2019. Aug;28(6); 253-266.

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. SundarUSPA 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.

Detection of nitrates from tobacco for correlation with the amount of tobacco specific nitrosamines within 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

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

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

Kepona: 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

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cells. Laychock SG, Shen JC, Carmines EL, and Rubin RP. *Biochim Biophys Acta*. 1978 Mar 30;528(3):355-63.

## **GRAS Expert Panels**

Comprehensive GRAS assessment for AlphaSize® Alpha-glycerol phosphoryl choline ( $\alpha$ -GPC); LSRO, 2010.

A COMPREHENSIVE GRAS ASSESSMENT OF ORAC-15,000™ GRAPE EXTRACT; LSRO, 2011

DOSSIER IN SUPPORT OF THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF HIGH-OLEIC ALGAL OIL FROM A MODIFIED STRAIN OF *P. MORIFORMIS* AS A FOOD INGREDIENT; Burdock Group, 2011.

REPORT OF THE EXPERT PANEL ON THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF PS 60, PS 65, AND PS 80; LSRO SOLUTIONS, 2012.

DOSSIER IN SUPPORT OF THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF TA-65® AS A FOOD INGREDIENT; Burdock Group, 2014.

DOSSIER IN SUPPORT OF THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF HIGH-OLEIC ALGAL OIL FROM A MODIFIED STRAIN OF *P. MORIFORMIS* AS A FOOD INGREDIENT; Burdock Group, 2014.

DOSSIER IN SUPPORT OF THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF YUCCA EXTRACT AS A FOOD INGREDIENT IN CARBONATED SOFT DRINKS AND SEMI-FROZEN BEVERAGES; Burdock Group, 2015.

DOSSIER IN SUPPORT OF THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF AN INGREDIENT CONTAINING DHA ALGAL AND HIGH OLEIC SUNFLOWER OILS (*Life'sDHA™* S35-0400) AS A FOOD INGREDIENT; Burdock Group, 2015.

DOSSIER IN SUPPORT OF THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF YELLOW BEESWAX AS A FOOD INGREDIENT; Burdock Group, 2016.

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AMENDMENT TO THE DOSSIER IN SUPPORT OF THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF HIGH-OLEIC ALGAL OIL FROM A MODIFIED STRAIN (S6697) OF *PROTOTHECA MORIFORMIS* AS A FOOD INGREDIENT; Burdock Group, 2016.

DOSSIER IN SUPPORT OF THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF D-MANNITOL AS A FOOD INGREDIENT; Burdock Group, 2016.

DOSSIER IN SUPPORT OF THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF KONJAC AS A FOOD INGREDIENT; Burdock Group, 2016.

COMPREHENSIVE GRAS ASSESSMENT of 2'-O-FUCOSYLLACTOSE Infant Formula Food Usage Conditions for General Recognition of Safety; LSRO Solutions, 2017.

DOSSIER IN SUPPORT OF THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS FOR GREEN TEA EXTRACT WITH ADDED CAFFEINE AS A FOOD INGREDIENT; Burdock Group, 2017.

COMPREHENSIVE GRAS ASSESSMENT of Phosphatidylserine Derived From Sunflower; LSRO Solutions, 2018.

DOSSIER IN SUPPORT OF THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF KALGAE™ (*Klebsormidium flaccidum* var. ZIVO) AS A FOOD INGREDIENT; Burdock Group, 2018,

COMPREHENSIVE GRAS ASSESSMENT of Palmitoylethanolamide (RePea®); LSRO Solutions, 2019.

DOSSIER IN SUPPORT OF THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF ALOE VERA PURIFIED LEAF POWDER AS A FOOD INGREDIENT; Burdock Group, 2021.

DOSSIER IN SUPPORT OF THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF ALOE VERA INNER LEAF POWDER AS A FOOD INGREDIENT; Burdock Group, 2021

DOSSIER IN SUPPORT OF THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF DEACTIVATED ALKALINE SERINE PROTEASE (DASP) ENZYME AS A FOOD INGREDIENT UNDER THE CONDITIONS OF USE CITED HEREIN; Burdock Group, 2021.

Independent Conclusion of GRAS Status of Dihydroberberine. LSRO Solutions, 2022.

DOSSIER IN SUPPORT OF THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF THE BIOGARD PRODUCT LINE; Burdock Group, 2022.

DOSSIER IN SUPPORT OF THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF SODIUM AND POTASSIUM BISULFATES AS FRUIT/VEGETABLE WASH WATER INGREDIENTS; Burdock Group, 2022.



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DOSSIER IN SUPPORT OF THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF A GREEN Coffee BEAN extract (GCBE) CONTAINING 98.5% CAFFEINE, AS A FOOD INGREDIENT ACCORDING TO THE CONDITIONS OF USE CITED HEREIN, Burdock Group, 2023.

DOSSIER IN SUPPORT OF THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF PANAX GINSENG ROOT POWDER EXTRACT PREPARATIONS AS FOOD INGREDIENTS ACCORDING TO THE CONDITIONS OF USE CITED HEREIN; Burdock Group, 2023.

DOSSIER IN SUPPORT OF THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF ENERGIS SOLUTIONS' AQUEOUS CHLORINE DIOXIDE (EACLO<sub>2</sub>) AS AN ANTIMICROBIAL AGENT IN FOODS FOR HUMAN CONSUMPTION ACCORDING TO THE CONDITIONS OF USE CITED HEREIN; Burdock Group, 2023.