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**Curriculum Vitae**

**SIERRA PRODUCTIONS RESEARCH, LLC – Research Division**

**Irvine, CA**

*President / Research Director*

**1987 – Present**

Provides strategic biomedical communications, research coordination and medical research consulting services for medium to large multi-national pharmaceutical, nutraceutical, diagnostic, medical, and health care professional companies. Over 30 years experience in biomedical research. Currently consults on formulations, pre-clinical/clinical research and product development. Also writes, produces and directs medical educational videos & films - garnered 37 international awards. Produced internationally acclaimed therapeutic DVD, “Immuno-Imagery” – visualization and guided imagery for immune enhancement utilized in numerous clinics and by health care professionals.

**Partial list of clients:**

**APPLIED-BIORESEARCH, INC. – Research Division**

**Irvine, CA**

*Research Director*

**2010 – Present**

**• OVERSEES ALL R&D FOR NEW PRODUCTS**

- Manages all pre-clinical and clinical research
- Manages and directs outside GLP and GMP labs
- Interfaces and directs all scientific and medical consultants
- Lead supervisor of FDA consulting groups
- Writes and approves all final pre-clinical and clinical protocols
- Patent preparation, principle and inventor
- Interfaces with patent attorneys
- Fund-raising for scientific and medical research

**Naturally Plus, USA, Japan and Asia. – Main Office**

**Japan**

*Research Director*

**2014 – Present**

- Conducted original research for hydrogenized water product, Izumio
- Protocol design implementation of research studies
- Manages and directs outside GLP labs
- Wrote and published one hydrogen review article and two original research studies
- Keynote presenter at US and international seminars
- Designed international PowerPoint product presentations
- Produced major health care professional and physician video on Izumio
- Organized, presented and managed major medical conference exhibition meetings, A4M
- Assisted in corporate and product research press releases
- Recruited nine physicians as co-investigators and co-authors for research and publications

**NUTRITIONAL THERAPEUTICS, INC.**

**Commack, NY**

*Consulting Director of Clinical Research*

**1996 – Present**

- Designed protocols for clinical studies
- Coordinated major clinical research
- Developed and managed an “On-Line” internet-based, IRB approved Asthma Clinical Trial
- Instrumental in the preparation of three publications for the company
- Product profile development and marketing materials for health care professionals & pharmacies
- Published five peer-reviewed medical journal articles
- Produced educational/promotional product videos
- Coordinated 13-part product radio infomercial on KRLA radio “Healthy Advice with Dr. Gene”
- Created technical power point presentations for medical professionals
- Research and development and writing of new patents

**WORLD HEALTH PRODUCTS, LLC.**

*Consulting Manager of Clinical Research Director*

**Draper, UT**

**2003 – 2010**

- Designed and wrote protocols for clinical and preclinical studies
- Coordinated and managed major clinical prostate trials
- Designed and coordinated preclinical pharmacokinetic studies
- Developed and managed an “On-Line” internet-based, IRB approved BPH study
- Instrumental in the preparation of five publications for the company
- Wrote numerous technical and medical articles on chelation therapy and heavy metal toxicity
- Developed product profile materials for health care professionals and pharmacies
- Produced international award-winning DVD – “Living in a Toxic World”
- Coordinated 45 international medical conferences and seminars on reporting research findings
- Published four medical journal articles on original research
- Published chapter on detoxification in medical text book – “Anti-Aging Therapeutic Medicine”
- Co-author of a detoxification book for the public
- Arranged and produced medial exhibition booths and medical materials for medical trade show

**CLRS TECHNOLOGY, INC.**

*Consulting Research Director*

**Irvine, CA**

**2008 – 2010**

- Designed and conducted microbiological research assay for acne device
- Coordinated and managed FDA 510K device research to test and validate acne device
- Conducted expanded device survey research for FDA 510K approval
- Research studies resulted in full FDA 510K approval for acne device
- Wrote instruction and training manuals for the device.
- Wrote three FDA filings for the company

**AMERICAN NUTRACEUTICAL ASSOCIATION**

*Senior Consulting Vice President, Member of Board of Director*

**Birmingham, AL**

**1996 – 2009**

- Coordination and organization pre-clinical and clinical research with major research institutions
- Developed produced of bio-medical multi-media educational programs
- Direct liaison for new and existing clients in the nutraceutical industry
- New business development & project supervision with physicians, nurses, pharmacists
- Interface with nutraceutical manufacturers, scientific and technical advisors, formulators, distributors consultants and pharmacies for new and existing business development
- Co-managed 35 ANA Nutraceuticals in Medicine Conference throughout the country

**LANE LABORATORIES**

*Consultant*

**Allendale, NJ**

**2003 – 2005**

- Designed protocol and carried out in-vitro research for anti-infective agents
- Published research findings in JANA 2003
- Presented at American Academy for Anti-Aging Medicine conference in 2004
- Targeted research to supported launch of product

**INSTITUTE FOR MOLECULAR MEDICINE**

*Consultant*

**Huntington Beach, CA**

**1999 – 2012**

- Elected and participating member of Investigational Review Board (IRB)
- Review and approval determination for clinical research submissions
- Acquired three clinical trial for the Institute
- Organized, wrote protocols, coordinated and managed and published clinical trials
- Consultant to Founder and Principal Investigator of IMM, Dr. Garth Nicolson

**M. PRODUCT GROUP**

*Consultant*

**Scottsdale, AZ**

**2002 – 2006**

- Wrote protocol, IRB submission and Informed Consent for AIDS clinical trial
- Successful approval at Raritan Bay Medical Center for study
- Coordinated physicians, nurses and staff
- Responsible liaison between client and research institution

**DAVSTAR, INC.**  
*Consultant*

**Costa Mesa, CA**  
**1994 – 2000**

- Concept, development research of clinical diagnostic product for urinalysis “Censlide”
- Wrote protocols, coordinated, managed clinical laboratory research
- Published key study in conjunction with UCI MC
- Published research in conjunction with UCLA
- Presented and demonstrated product to diagnostic centers and hospitals in 25 states
- Presented and demonstrated product to diagnostic centers and hospitals in seven countries
- Successfully launched product in US and international markets

**NEWPORT PHARMACEUTICALS**  
*Director Biological Research*

**Newport Beach, CA**  
**1975 – 1986**

- Responsible for biomedical research and development of immunological products
- Designed tissue culture and animal research laboratory facilities
- Coordinated compilation of New Drug Application (NDA) for FDA submission
- Research led to approvals drug approvals in 80 countries
- Published 21 scientific articles in viral immunology and related fields in medical journals
- Assisted in protocol design, monitoring, and final publication of multi-center clinical trials
- Developed time-lapse cinemicrophotographic films - cancer target cell destruction by human cells
- Designed and produced numerous international technical slide presentations on Pharma products
- Produced technical and marketing brochures for international licensees
- Production of educational films on immunology - garnered 21 international film awards

**EDUCATION**

Master of Science, Emphasis, Microbiology & Immunology, Cum Laude 1978 California State University

**HONORS AND AWARDS**

Alpha Chi National Honorary Society • Biology Book Award for Outstanding Achievement in Biology  
• American Medical Writer's Association, Finalist Award • International Scientific and Technical Film Award  
• John Muir Medical Film Festival, Gold Leaf Award • Chicago Int'l Film Award 2nd place • US Industrial Film Festival, Creative Excellence Award • American Association for the Advancement of Science, Silver Film Award • Houston International Film Festival, Gold & Silver Award • Bill Mackey Award, Outstanding Ski Industry Representative • National Educational Festival, Silver • IFPA, Gold Cindy

**PATENTS**

**PHOSPHOLIPID COMPOSITIONS AND USE THEREOF TO ENHANCE SPERMATOZOA MOTILITY AND VIABILITY**

Inventors: Garth Nicolson, Gonzalo Ferreira de Mattos, Robert Settineri Patent # US9861656B2

**CHEWABLE LIPID SUPPLEMENTS FOR TREATING PAIN AND FIBROMYALGIA**

Inventor: Robert Settineri Patent # US20170319608A1

**CHEWABLE LIPID SUPPLEMENTS CONTAINING CAFFEINE FOR INCREASING ALERTNESS, FOCUS AND ENERGY**

Inventor: Robert Settineri Patent # US9717734B2

**FLAVORED CHEWABLE LIPID SUPPLEMENTS FOR MAINTAINING HEALTH AND THE TREATMENT OF ACUTE AND CHRONIC DISORDERS**

Inventor: Robert Settineri Patent # US9468668B2

**LIPID SUPPLEMENTS FOR MAINTAINING HEALTH AND THE TREATMENT OF ACUTE AND CHRONIC DISORDERS**

Inventors: Robert Settineri, James F. Palmer Patent # China-Cert ZL 2011 8 0039539.2

**LIPID SUPPLEMENTS FOR MAINTAINING HEALTH AND THE TREATMENT OF ACUTE AND CHRONIC DISORDERS**

Inventors: Robert Settineri, James F. Palmer Patent # Australia 2011289846

CHEWABLE WAFERS CONTAINING LIPID SUPPLEMENTS FOR MAINTAINING HEALTH AND THE TREATMENT OF ACUTE AND CHRONIC DISORDERS

Inventor: Robert Settineri Patent # US9095507B2

CHEWABLE WAFERS CONTAINING LIPID SUPPLEMENTS FOR MAINTAINING HEALTH AND THE TREATMENT OF ACUTE AND CHRONIC DISORDERS

Inventor: Robert Settineri Patent # US8877239B2

NATURAL MEMBRANE PHOSPHOLIPID SUPPLEMENTS FOR CELLULAR REPAIR, THE TREATMENT OF ACUTE AND CHRONIC ILLNESSES, FATIGUING ILLNESSES AND MITOCHONDRIAL DISORDERS

Inventors: Robert Settineri EP 2603090 A1

AN EDTA COMPOSITION AND METHOD OF ADMINISTERING EDTA COMPLEXES

Inventor: Robert Settineri Provisional application

PRO-DRUG FOR ADMINISTRATION OF EDTA

Inventor: Robert Settineri Provisional application

### INTERESTS AND HOBBIES

Skiing, sailing, cycling, tennis

### PUBLICATIONS

1. Settineri, R., Zhou, J., Ji, J., Ellithorpe, R., Rosenblatt, S., Jimenez, A., Ohta, S., Ferreira, G., and Nicolson, G.L. Hydrogenized Water Effects on Protection of Brain Cells from Oxidative Stress and Glutamate Toxicity. *American Journal of Food and Nutrition*, 6(1):9-13 (2018)
2. Nicolson, G.L., Rosenblatt, S., Ferreira de Mattos, G., Settineri, R., Breeding, P.C., Ellithorpe, R., and Ash, M.E. Clinical Uses of Membrane Lipid Replacement Supplements in Restoring Membrane Function and Reducing Fatigue in Chronic Diseases and Cancer. *Discoveries*, 4(1) (2016)
3. Settineri, R., Ji, J., Luo, C., Ellithorpe, R., Ferreira de Mattos, G., Rosenblatt, S., LaValle, J., Jimenez, A., Ohta, S., and Nicolson, G.L. Effects of Hydrogenized Water on Intracellular Biomarkers for Antioxidants, Glucose Uptake, Insulin Signaling and SIRT 1 and Telomerase Activity. *American Journal of Food and Nutrition*, 4(6):161-168 (2016)
4. Nicolson, G.L., Rosenblatt, S., Ferreira de Mattos, G., Settineri, R., Breeding, P.C., Ellithorpe, R., and Ash, M.E. Clinical Uses of Membrane Lipid Replacement Supplements in Restoring Membrane Function and Reducing Fatigue in Chronic Diseases and Cancer *Discoveries 2016*, 4(1) (2016)
5. Nicolson, G.L., Ferreira de Mattos, G., Settineri, R., Costa, C., Ellithorpe, R., Rosenblatt, S., La Valle, J., Jimenez, A., and Ohta, S. Clinical Effects of Hydrogen Administration: From Animal and Human Diseases to Exercise Medicine. *International Journal of Clinical Medicine*, 7 :32-76 (2016)
6. Ellithorpe, R., Settineri R., Ellithorpe, T., and Nicolson, G.L. Blood homocysteine and fasting insulin levels are reduced and erythrocyte sedimentation rates increased with a glycopospholipid-vitamin formulation: a retrospective study in older subjects. *Functional Foods in Health and Disease*, 5(4):126-135 (2015)
7. Nicolson, G.L., Settineri, R. and Ellithorpe, R. Neurodegenerative and fatiguing Illnesses, infections and mitochondrial dysfunction: use of natural supplements to improve mitochondrial function. *Funct. Foods Health Dis.*, 4(1):23-65 (2014)

8. Ellithorpe, R., Calpp, L, Jimenez, T., Jacques, B., Settineri, R., Dyck, H. and Nicolson, G.L. Antimicrobial plus CaNa<sub>2</sub>EDTA chelation suppository therapy for chronic prostatitis/chronic pelvic pain syndrome: preliminary study. *Revised* (2013)
9. Nicolson, G.L., Settineri, R. and Ellithorpe, E. Lipid Replacement Therapy with a Glycophospholipid Formulation, NADH and CoQ10 Significantly Reduces Fatigue and Improves Mood and Cognition in Intractable Fatiguing Illnesses and Chronic Lyme Disease. *Townsend Lett.*, 347(6):58-61 (2012)
10. Nicolson, G.L., Settineri, R. and Ellithorpe, E. Glycophospholipid formulation with NADH and CoQ10 significantly reduces intractable fatigue in chronic Lyme disease patients: preliminary report. *Funct. Food Health Dis.*, 2(3):35-47 (2012)
11. Ellithorpe, R., Settineri R., Ellithorpe, T. and Nicolson, G.L. G.L. Blood homocysteine and fasting insulin levels are reduced and erythrocyte sedimentation rates are increased with a glycophospholipid-vitamin formulation: a retrospective study in older subjects. *Funct. Food Health Dis.*, (2013)
12. Ash, M., Settineri R. and Nicolson, G.L. Fatigue, Immunity and Inflammation: their resolution using natural medicine. *Townsend Lett.*, 352(10):48-51 (2012)
13. Nicolson, G.L., Settineri, R. and Ellithorpe, E. Lipid Replacement Therapy with a glycophospholipid formulation with NADH and CoQ10 significantly reduces fatigue in intractable chronic fatiguing illnesses and chronic Lyme disease. *Int. J. Clin. Med.*, 3(3):164-170 (2012)
14. Ellithorpe, R.A., Settineri, R., Jacques, B. and Nicolson, G.L. Lipid Replacement Therapy functional food with NT Factor for reducing weight, girth, body mass, appetite, cravings for foods and fatigue while improving blood lipid profiles. *Funct. Food Health Dis.*, 2(1):11-24 (2012)
15. Ellithorpe, R.A., Settineri, R., Mitchell, C.A., Jacques, B., Ellithorpe, E. and Nicolson, G.L. Lipid replacement therapy drink containing a glycophospholipid formulation rapidly and significantly reduces fatigue while improving energy and mental clarity. *Funct. Food Health Dis.*, 1(8):245-254 (2011)
16. Nicolson, G.L. and Settineri, R. Lipid Replacement Therapy: a functional food approach with new formulations for reducing cellular oxidative damage, cancer-associated fatigue and the adverse effects of cancer therapy. *J. Funct. Food Health Dis.*, 1(4):135-160 (2011)
17. Nicolson, G.L., Ellithorpe, R., Ayson-Mitchell, C., Jacques, B., and Settineri, R. Lipid Replacement Therapy with a Glycophospholipid-Antioxidant-Vitamin Formulation Significantly Reduces Fatigue Within One Week. *JANA*, 13(1):10-14 (2010)
18. Ellithorpe, R., Jimenez, T., Jacques, B., Settineri, R., Clapp, L. and Nicolson, G.L. Calcium disodium EDTA chelation suppositories: a novel approach for removing heavy metal toxins in clinical practice. In: *Anti-Aging Therapeutics. American Academy of Anti-Aging Medicine*, : 107-118 (2009)
19. Ellithorpe, R., Settineri, R. "Detox Outside the Box" *Sierra Productions* (2009)
20. Nicolson, G.L., Ellithorpe, R., and Settineri, R. Dietary supplement Healthy Curb for reducing weight, girth, body mass, appetite and fatigue while improving blood lipid values with NT Factor Lipid Replacement Therapy. *Invest Myalgic Encephalomyelitis*, 3(1):39-48 (2009)
21. Ellithorpe, R., Clapp, L., Jimenez, T., Jacques, B., Settineri R., Nicolson, G. The Effects of an Anti-Microbial plus CaNa<sub>2</sub> EDTA Chelation Suppository Therapy on Prostate Conditions/ Prostatism. *J. Complementary and Alternative Medicine*, (2008)
22. Reynolds, J., Hamill, R., Ellithorpe, R., Settineri, R. Retarding Cognitive Decline with Sciencebased Nutraceuticals. *JANA*, 11(1):19-27 (2008)

23. Ellithorpe, R., Mazur, P., Glenwood, G., Button, G., Le, J., Pfadenhauer, E., Settineri, R., Nicolson, G. Comparison of the Absorption, Brain and Prostate Distribution, and Elimination of CaNa<sub>2</sub> EDTA of Rectal Chelation Suppositories to Intravenous Administration. *JANA*, 10(2): 38-44 (2007)
24. Ellithorpe, R., Settineri, R., Nicolson, G. Pilot Study: Reduction of Fatigue by Use of a Dietary Supplement Containing Glycophospholipids. *JANA*, 6(1):40-46 (2003)
25. Agadjanyan, M., Vasilevko, V., Ghochikyan, A., Berns, P., Kesslak, P., Settineri, R., Nicolson, G. Nutritional supplement (NT Factor) restores mitochondrial function and reduces moderately severe fatigue in aged subjects. *J. Chronic Fatigue Syndr.*, 11(3):23-36 (2003)
26. Settineri, R., Krassner, S. Antimicrobial Effects of Plant-Derived Essential Oil Formulations on Pathogenic Bacteria. *JANA*, 7(2) (2003)
27. Lenani, C., Settineri, R., Garrison, R., Fu, P. Immune Function and the Role of Keratin. *JANA*, 3(3) (2003)
28. Lenani, C., Settineri, R., Garrison, R., Fu, P. Urinary Sediment: Evaluation of Cen-Slide 1500 and KOVA Methods. *Harbor UCLA. American Association of Clinical Chemists. Abstract*, (1995)
29. Tipper, P., Yang, G., Nichols, L., Settineri, R. Comparison of Cen-Slide and Standard Methodology for Microscopic Urinalysis. *Diagnostic and Clinical Testing*, (1993)
30. Settineri, R. The Evasive Invader (Film Brochure). *Newport Pharmaceuticals International Inc.*, (1985)
31. Settineri, R. Inosiplex: The Immunostimulant (Film Brochure). *Newport Pharmaceuticals International Inc.*, (1984)
32. Settineri, R. The Immune Response (Film Brochure). *Newport Pharmaceuticals International Inc.*, (1982)
33. Hadden J., Hadden, E., Spira, T., Settineri, R. Effects of NPT 15392 In Vitro on Human Leukocyte Function. *Int. J. Immunopharmac*, 4 :235-242 (1982)
34. Simon, L., Maxwell, K., Ginsberg, T., Settineri, R. Immunomodulation by Synthetic Purine Derivatives. *American Chemical Society Book of Abstracts*, (1981)
35. Simon, L., Settineri, R., Pfadenhauer, E. NPT 15329: A Pharmacologic and Toxicologic Profile. *Intl. J. Immunopharmac*, (1st Intl. Conf. on Immunopharma.) 2 (1980)
36. Simon, L., Settineri, R., Coats, H., Glasky, A. Isoprinosine: Studies on Mechanism of Anti-Influenza activity. *Annual Meeting of the American Society for Microbiology*, (1978)
37. Simon, L., Settineri, R., Coats, H., Glasky, A. Isoprinosine: Integration of the Antiviral and Immunoproliferative Effects. *Current Chemotherapy (10th Intl. Congress of Chemotherapy)*, 1 :366-368 (1977)
38. Settineri, R., Simon, L., Coats, H., Glasky, A. Immunopotential of Mitogen-Induced Murine Lymphocyte Proliferation by Isoprinosine. *77th Annual Meeting of the American Society for Microbiology*, (1977)
39. Glasky, A., Settineri, R., Coats, H., Simon, L. Immunopotential of Mitogen Induced Murine Lymphocyte Proliferation by Isoprinosine. *Intl. Congress on Immunology*, (1977)
40. Settineri, R., Rothman, A., Ginsberg, T., Glasky, A. Application of Several Tissue Culture Methods to the Evaluation of Antiviral Action of a New Drug: Inosiplex. *8th Symposium of California Branch of the Tissue Culture Association*, 1(1976)
41. Ginsberg, T., Settineri, R., Glasky, A. In Vitro and In Vivo Effects of Inosiplex in Experimental Influenza. *Sixteenth Interscience Conference Antimicrobial Agents and Chemotherapy*, (1976)

42. Glasky, A., Friebertshauer, G., Holker, J., Settineri, R., Ginsberg, T. The Role of Cell Mediated Immunity in the Therapeutic Action of Viral Disease Processes. *9th International Cong of Chemotherapy*, 6 :235-238 (1975)
43. Settineri, R. Development of Methods to Study Antiviral Drug Activity and the Testing of a New Drug: Isoprinosine. *Thesis-Cal State Fullerton* (1975)
44. Glasky, A., Pfadenhauer, F., Settineri, R., Ginsberg, T. Isoprinosine, a Purine Derivative; Metabolic, Immunological and Antiviral Effects. Combined Immunodeficiency Disease and Adenosine Deaminase Deficiency, A Molecular Defect. *A Molecular Defect. Academic Press*, : 157-172 (1975)
45. Settineri, R., Friebertshauer, G., Pfadenhauer, E., Ginsberg, T. Analysis of Antiviral Effects of Isoprinosine in Tissue Culture Animals and Man. *Publications of the 1974 Pacific Slope Biochemical Conference*, (1974)
46. Friebertshauer, G., Settineri, R., Ginsberg, T., Glasky, A. Relationships Between Molecular Biochemical Effects of Isoprinosine and Immunological Phenomena. *Publication of the 1974 Pacific Slope Biochemical Conference*, (1974)
47. Ginsberg, T., Settineri, R., Pfadenhauer, E., Glasky, A. Isoprinosine: Suppression of Cytopathic Effects (CPE) of Influenza A2 and Rhinovirus in Tissue Culture. *73rd Annual Meeting, American Society for Microbiology*, (1973)
48. Glasky, A., Settineri, R., Lynes, T. Isoprinosine: Therapeutic Antiviral Activity Action Against Influenza A2 in the Mouse. *7th International Congress on Chemotherapy*, 1:19 (1972)
49. Glasky, A., Settineri, R., Lynes, T. Isoprinosine: Therapeutic Antiviral Action against Influenza A2 in the Mouse. *Advances in Antimicrobial and Antineoplastic Chemotherapy*, :319-320 (1972)
50. Lynes, T., Anderson, M., Settineri, R. The Interaction of Isoprinosine and Some Immunosuppressive Agents and Chemotherapy. (1972)