FEDERICO C.A. GAETA, Ph.D.

CONTACT INFORMATION

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PROFESSIONAL EXPERIENCE

Biotechnology Consultant	Sole Proprietor	1998-present
Geron Corp.	Program Director	1996-98
	Director of Chemistry	1994-98
Cytel Corp.	Executive Officer	1993
	Director of Chemistry	1989-93
	Director and Founder, Glytec Corporation	1990
Merck & Co., Inc.	Section Leader	1985-89
(Schering-Plough Corp.)	Principal Scientist	1983-84
	Senior Scientist	1981-83
Bristol Myers Squibb Corp.	Senior Scientist	1979-81

EDUCATION

University of California, Los Angeles, California 1977-79
Postdoctoral Advisor: Professor Donald J. Cram (1987 Nobel Laureate in Chemistry)
Research Topic: Host-Guest Chemistry, Physical Organic Chemistry

University of California, Los Angeles, California 1976-77
Postdoctoral Advisor: Professor Robert V. Stevens
Research Topic: Studies Towards the Total Synthesis of Vitamin B-12

Rice University, Houston TX 1973-76
Ph.D. (Chemistry/Organic Synthesis). Doctoral Advisor: Prof. Robert V. Stevens
Dissertation: "Camphorae: Chiral Intermediates for the Total Synthesis of Steroids"

State University of New York, Buffalo, NY 1968-72
B.A. (Chemistry). Undergraduate Advisor: Professor Fred Wudl
Research Topic: Synthesis of Chiral Crown Ethers

HONORS AND AWARDS

Schering Corporation Presidential Award for outstanding achievement, 1983
Postdoctoral Research Fellowship, UCLA, 1977-78
Stauffer Chemical Company Fellowship, 1975-76
Nettie S. Autrey Fellowship, 1974-75
Rice Graduate Fellowship, 1973-74

GRANTS

$2.4M National Cooperative Discovery and Development Grant (U19 CA67842) awarded to Geron Corporation and Memorial Sloan Kettering Cancer Research Center; Principal Investigator and Program Director, drug discovery/medicinal chemistry section (1995-99)

PUBLICATIONS AND PATENTS

99 Patents granted and/or pending and additional applications filed
49 Publications in major, peer-reviewed, scientific journals

SUMMARY OF MAJOR ACCOMPLISHMENTS AND RESPONSIBILITIES

1998-present. Independent Consultant (Mountain View, CA). Retained by broad range of biopharmaceutical companies to direct drug discovery and development programs. Strategic services provided included:

- Scientific due diligence review of potential licensing candidates
- Review regulatory dossiers, in particular chemistry, manufacturing and controls (CMC) sections of investigational new drug (IND) applications
- Identify sources, negotiate contracts, and manage external efforts in
  - Medicinal chemistry
  - Organic synthesis
  - Process chemistry
  - Formulation development
  - Manufacturing
- Management of drug discovery and development (in addition to above)
  - Assay development and high throughput screening (HTS) (biochemical & cell-based)
  - Hit-to-lead development
  - Lead optimization (medicinal chemistry, pharmacology, etc.)
  - Intellectual property protection
- Pharmaceutical development
  - Preclinical pharmacology
  - ADME and Safety evaluation
  - Regulatory affairs
- Business development and corporate partnering

Major recent successes as an independent consultant include:

- 2015-present. Formulation of DNA preservation solution, Spectrum Solutions, LLC, Draper, UT
- 2013-present. Formulation of DNA preservation solution, Ancestry.com DNA, LLC, Provo, UT
- 2004-present. Development of MN-166 (ibudilast, AV411 with MediciNova (formerly Avigen, Inc., for the treatment of Neuropathic Pain, Multiple Sclerosis, Amyotrophic Lateral Sclerosis, Opiate Dependence, Methamphetamine Dependence, Alcohol Dependence. A U.S. IND has been filed, and this drug is currently in Phase II/III clinical trials. Responsible for directing chemistry-related issues, including analytical and bio-analytical development, process development for API production, synthesis of metabolites and related substances, and formulation development. Two additional programs at earlier stages of development: MN-001 for Non-Alcoholic Steatohepatitis, Idiopathic Pulmonary Fibrosis; and MN-221 for Acute Asthma.
- 2006-2008. Discovery and development of Avigen's (now MediciNova's) second generation drug for Neuropathic Pain and other CNS indications. A new chemical entity was discovered, with improved pharmacological and biopharmaceutical properties. A manufacturing process for API has been developed.
- 2006-2008. Development of AV513 with Avigen, Inc. for the treatments of hemophilias A and B. AV513 is a form of fucoidan, a sulfated oligosaccharide extracted from brown seaweed. Significant analytical and manufacturing challenges had to be overcome for the success of this program. A process for manufacturing and formulating AV513 under cGMP has been developed, and U.S. IND submission is expected 2Q2009. This was a non-core program for Avigen, and it was sold to Baxter in December, 2008.
- 2007-2008. Discovery of new chemical entities for the treatment of neurological disorders such as Parkinson's and Alzheimer's disease. This is an on-going medicinal chemistry effort exploiting lead candidates.

- 2006-2008. Development of AV650 (tolperisone) with Avigen, Inc. for the treatment of Disabling Neuromuscular Spasm and Spasticity indications. A major manufacturing challenge to produce API had to be overcome, in order to continue U.S. development of this drug candidate. An elegant and practical solution was discovered, and this drug can benefit from new composition of matter protection. Avigen is no longer pursuing this development program and rights have been returned to Sanochemia Pharmaceutica AG.
- 2002-2005. Development of Savella® (Milnacipran) with Cypress BioScience for the indication of Fibromyalgia Syndrome (FMS). Responsible for synthesis of Milnacipran and specific stereoisomer, related substances, salt forms and formulation development. In 2004 CYPB announced a $250M partnership with Forest Laboratories to fund late stage clinical trials of Milnacipran, and a $40M public offering. This drug received US-FDA approval in January 2009, and is now a marketed product in the United States.
- 2005-present. Discovery and development with Sierra Sciences, LLC of drugs that activate human telomerase reverse transcriptase (hTERT) to retard and/or reverse this genetic component of aging. Acquired high throughput screening instrumentation including robotics and a large (~350,000) maximally diverse compound library for Sierra Sciences, Inc. Developed HTS biochemical and cell-based assays. Screening efforts to date have resulted in the identification of small molecule drugs capable of activating the hTERT gene, and established medicinal chemistry efforts to optimize selected hits.
- 1998-2001. Directed drug discovery efforts for Ciblex Corporation, where I discovered a potent inhibitor of human Macrophage Migration Inhibitory Factor (MIF), as a novel type of anti-inflammatory drug. The MIF blocker program was acquired by Avanir Pharmaceuticals/Novartis in 2006.

1994-1998. Geron Corporation (Menlo Park, CA). Program Director, Telomerase Inhibition, and Director of Chemistry reporting to President & CEO.

- Directed the efforts of 60+ medicinal chemists, biochemists, pharmacologists and immunologists, including 30 Ph.D. level scientists.
- Managed large collaborations with corporate partners Kyowa Hakko Kogyo, Ltd., ($30M) and Pharmacia & Upjohn (now Pfizer) ($57M).
- Managed collaborations with academic collaborators; Principal Investigator on $2.4M NCDDG grant from NCI.
- Sole inventor of a universal therapeutic cancer vaccine technology based on telomerase, currently being evaluated in human clinical trials.
- Discovered the first potent, small molecule, inhibitors of human telomerase. Lead compounds inhibited telomerase *in vitro* and *in vivo*, and resulted in death of human cancer cells in culture via a telomere shortening mechanism.

1989-1994. Cytel Corporation (San Diego, CA). Executive officer reporting to the President & CEO. Cytel branched out into two different companies: Epimune and Glytec (acquired by Neose). Principal areas of research: Immunology, Carbohydrate Chemistry and Biochemistry, Enzyme Catalyzed Carbohydrate Synthesis, Peptide Synthesis, Design of Peptidomimetics

- Directed a group of 33 chemists, biochemists, and pharmacologists, including 18 Ph.D. level scientists.
- Co-founder of a spin-off company, Glytec Corporation in 1989, to exploit advances in carbohydrate biology, biochemistry and synthesis methodology. Glytec was merged back into Cytel nine months later, and became the principal focus of a successful IPO in 1991 ($30M), follow-on ($20M) and major corporate partnership ($57M).
- Managed large collaborations with Sandoz (now Novartis) ($31M) and Sumitomo Pharmaceuticals ($47M).

- Discovered blockers of class II Major Histocompatibility Complex (MHC) to treat autoimmune diseases. Peptidomimetic compound advanced to preclinical development.
- Discovered peptide binding motifs for class I MHC to design therapeutic vaccines. Several products entered clinical trials for various indications, including Theradigm-HBV™ (for chronic hepatitis B).
- Identified the ligand for E- and P-selectins
- Discovered Cylexin™, an analog of the carbohydrate sialyl-Lewis X, as a blocker of intercellular adhesion. Cylexin™ advanced to Phase II human clinical trials
- Discovered small molecule, high affinity, blockers of VLA-4/CS-1 mediated intercellular adhesion for use in chronic inflammation therapy. Peptidomimetic compound advanced to preclinical development

1981-1989. Schering-Plough Corporation (Kenilworth, NJ). Section Leader Medicinal Chemistry. Principal Scientist. Senior Staff Scientist. Principal areas of research: CNS, Cardiovascular, Immunology, Enzyme Inhibition, Peptide Synthesis, Design of Peptidomimetics, Process Development

- Directed a group of 12 chemists, including 5 Ph.D. level scientists
- Inhibitors of neutral endopeptidase (NEP). Two compounds reached clinical trials for analgesia and cardiovascular indications
- Discovered dual acting inhibitors of Angiotensin Converting Enzyme (ACE) and Neutral Endopeptidase (NEP)
- Discovered combination ACE inhibitors with diuretic properties
- Discovered ACE inhibitors as anti-glaucoma agents
- Initiated and directed program in the areas of inhibition of cyclic nucleotide phosphodiesterases
- Initiated and directed program in the areas of inhibition of kinases
- Directed peptide synthesis operations
- Epitope mapping of lymphokines

1979-1981. Bristol-Myers Squibb Corporation (Wallingford, CT and Princeton, NJ). Senior Staff Scientist. Principal areas of research: β-Lactam Antibiotics, Antibiotic Resistance, Enzyme Inhibition, Enzyme Isolation

- Synthesis of β-lactam antibiotics
- Biosynthesis of β-lactam antibiotics
- Isolation of renal dipeptidase, a carbapenem β-lactam antibiotic degrading enzyme from mammalian kidney
- Synthesis of inhibitors of renal dipeptidase for use in urinary tract infection indications

PUBLICATIONS

1. F. Wudl and F.C.A. Gaeta, "A Versatile Synthesis of Chiral Crown Amino-ethers", *J. Chem. Soc., Chem. Commun.,* 107 (1972).

2. F.C.A. Gaeta, "Camphorae: Chiral Intermediates for the Total Synthesis of Steroids", Rice University Ph.D. dissertation, *Diss. Abstr. Int. B*, **38**(3), 1206 (1977).

3. R.V. Stevens and F.C.A. Gaeta (1977), "Camphorae: Chiral Intermediates for the Total Synthesis of Steroids", *J. Am. Chem. Soc.*, **99**, 6105-6106 (1977).

4. S.C. Peacock, L. Domeier, F.C.A. Gaeta, R.C. Helgeson, J.M. Timko, and D.J. Cram, "Host-Guest Complexation. 13. High Chiral Recognition of Amino Esters by Dilocular Hosts Containing Extended Steric Barriers", *J. Am. Chem. Soc.*, **100**, 8190-8202 (1978).

5. S.C. Peacock, D.M. Walba, F.C.A. Gaeta, R.C. Helgeson, and D.J. Cram, "Host-Guest Complexation. 22. Reciprocal Chiral Recognition between Amino Acids and Dilocular Systems", *J. Am. Chem. Soc.*, **102**, 2043-2052 (1980).

6. S.P. Brundidge, F.C.A. Gaeta, D.J. Hook, C. Sapino, R.P. Elander, and R.B. Morin, "Association of 6-Oxo-piperidine-2-carboxylic Acid with Penicillin-V Production in *Penicillium Chrysogenum* Fermentations", *J. Antibiotics*, **33**, 1348-1351 (1980).

7. D.J. Phelps and F.C.A. Gaeta, "A Convenient Synthesis of Glycyl-(β-aryl)-dehydroalanines", *Synthesis*, 234-235 (1982).

8. R.V. Stevens, F.C.A. Gaeta, and D.S. Lawrence, "Camphorae: Chiral Intermediates for the Enantiospecific Total Synthesis of Steroids. 1.", *J. Am. Chem. Soc.*, **105**, 7713-7719 (1983).

9. T.P. Kogan and F.C.A. Gaeta, "A Convenient Synthesis of Alkyl 2-Nitrovinyl Ethers – Conjugate Addition of an Alkoxide to Give a Nitroacetaldehyde Mixed Acetal", *Synthesis*, 706-707 (1988).

10. R.E. Chipkin and F.C.A. Gaeta, "Analgesics", *Annual Rep. Med. Chem.*, **23**, 11-18 (1988).

11. C.B. Knobler, F.C.A. Gaeta, and D.J. Cram, "Source of Chiral Recognition in Coraplexes with Phenylglycine as Guest", *J. Chem. Soc., Chem. Commun.*, 330-333 (1988).

12. T. Swenson, A. Tall, C. Hesler, M. Brown, E. Quinet, P. Trotta, M. Haslanger, F.C.A. Gaeta, Y. Marcel, and R. Milne, "Mechanism of Cholesteryl Ester Transfer Protein (CETP) Inhibition by Neutralizing Monoclonal Antibodies (Mabs)", *Arteriosclerosis*, **8**, 593A (1988).

13. M. Czarniecki, C. Foster, F.C.A. Gaeta, T.P. Kogan, L.S. Lehman, and Y.-S. Or, "Small Peptide Inhibitors of Smooth Muscle Myosin Light Chain Kinase", *FASEB J.*, **2**(4), 208 (1988).

14. C.J. Foster and F.C.A. Gaeta, "The Calmodulin Binding Domain of Chicken Gizzard Myosin Light-Chain Kinase Contains Two Non-overlapping Active Site-directed Inhibitory Sequences", *Biophys. J.*, **53**(2), 182A (1988).

15. T.L. Swenson, C.B. Hesler, M.L. Brown, E. Quinet, P.P. Trotta, M.F. Haslanger, F.C.A. Gaeta, Y.L. Marcel, R.W. Milne, and A.R. Tall, "Mechanism of Cholesteryl Ester Transfer Protein Inhibition by a Neutralizing Monoclonal Antibody and Mapping of the Monoclonal Antibody Epitope", *J. Biol. Chem.*, **264**, 14318-14326 (1989).

16. F.C.A. Gaeta, L.S. Lehman De Gaeta, T.P. Kogan, Y.-S. Or, C. Foster, and M. Czarniecki, "Small Peptide Inhibitors of Smooth Muscle Myosin Light Chain Kinase", *J. Med. Chem.*, **33**, 964-972 (1990).

17. F.C.A. Gaeta, L.B. Slater, B.R. Sunday, J.R. Miller, C.L. Ramsaur, L. Ghibaudi, and M. Chatterjee, "Synthesis and Characterization of Porcine Endothelin and Big Endothelin," in "Peptides: Chemistry, Structure and Biology," J.E. Rivier, and G. Marshall, eds., 264-266 (1990).

18. C.J. Foster, S.A. Johnston, B. Sunday, and F.C.A. Gaeta, "Potent Peptide Inhibitors of Smooth Muscle Myosin Light Chain Kinase: Mapping of the Pseudo Substrate and Calmodulin Binding Domains", *Arch. Biochem. Biophys.*, **280**, 397-404 (1990).

19. M.L. Phillips, E. Nudelman, F.C.A. Gaeta, M. Perez, A.K. Singhal, S.-I. Hakomori, and J. C. Paulson, "ELAM-1 Mediates Cell Adhesion by Recognition of a Carbohydrate Ligand, Sialyl-Le^X," *Science*, **250**, 1130-1132 (1990).

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21. M.F. Powell, H.M. Grey, F.C.A. Gaeta, A. Sette, and S. Colón, "Peptide Stability in Drug Development: A Comparison of Peptide Reactivity in Different Biological Media," *J. Pharm. Sci.*, **81**, 731 (1992).

22. G.Y. Ishioka, A.G. Lamont, D. Thomson, N. Bulbow, F.C.A. Gaeta, A. Sette, and H.M. Grey, "MHC Interaction and T Cell Recognition of Carbohydrates and Glycopeptides," *J. Immunol.*, **148**, 2446-2451 (1992).

23. A. Sette, D. O'Sullivan, J. Sidney, F.C.A. Gaeta, T. Arrhenius, S.M. Colón, E. Appella, and H.M. Grey, "Multiple Amino Acid Substitutions as a Strategy to Improve Class II Binding Capacity of Peptide Molecules," *J. Immunol. Res.*, **4**, 56-60 (1992).

24. C.-H. Wong, T. Krach, C. Gautheron-Le Narvor, Y. Ichikawa, G.C. Look, F. Gaeta, D. Thomson, and K.C. Nicolaou, "Synthesis of Novel Disaccharides Based on Glycosyltransferases: β1,4Galactosyltransferase," *Tetrahedron Letters*, **32**, 4867-4870 (1991).

25. D. O'Sullivan, T. Arrhenius, J. Sidney, M.-F. Del Guercio, M. Albertson, M. Wall, C. Oseroff, S. Southwood, S.M. Colón, F.C.A. Gaeta, and A. Sette, "On the Interaction of Promiscuous Antigenic Peptides with Different DR Alleles. The Identification of Common Structural Motifs," *J. Immunol.*, **147**, 2663-2669 (1991).

26. A. Sette, S. Southwood, D. O'Sullivan, F.C.A. Gaeta, J. Sidney, and H.M. Grey, "Effect of pH on MHC Class II-Peptide Interactions," *J. Immunol.* , **148**, 844-851 (1992).

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29. M. Wall, S. Southwood, J. Sidney, C. Oseroff, M.-F. Del Guercio, A. Lamont, S.M. Colón, T. Arrhenius, F.C.A. Gaeta, and A. Sette, "High Affinity for Class II Molecules as a Necessary But Not Sufficient Characteristic of Encephalitogenic Determinants," *Int. Immunology*, **4**, 773-777 (1992).

30. A. Sette, J. Sidney, F.C.A. Gaeta, E. Apella, S.M. Colón, M.-F. Del Guercio, J.-C. Guéry, and L. Adorini, "MHC Class II Molecules Bind Indiscriminately Self and Non-self Peptide Homologs: Effect on the Immunogenicity of Non-self Peptides," *Int. Immunol.*, **5**, 631-638 (1993).

31. A. Sette, J. Sidney, C. Oseroff, M.-F. Del Guercio, S. Southwood, T. Arrhenius, M.F. Powell, S.M. Colón, F.C.A. Gaeta, and H.M. Grey, "HLA DR4w4-Binding Motifs Illustrate the Biochemical Basis of Degeneracy and Specificity in Peptide-DR Interactions," *J. Immunol.*, **151**, 3163-3170 (1993).

32. G.Y. Ishioka, A.G. Lamont, D. Thomson, N. Bulbow, F.C.A. Gaeta, A. Sette, and H.M. Grey, "Major Histocompatibility Complex Class II Association and Induction of T Cell Responses by Carbohydrates and Glycopeptides," *Springer Seminars in Immunopathology*, **15**, 293-302 (1993).

33. G.F. Herrmann, Y. Ichikawa, C. Wandrey, F.C.A. Gaeta, J.C. Paulson, and C.-H. Wong, "A New Multi-Enzyme System for a One-Pot Synthesis of Sialyl-Oligosaccharides: Combined Use of β-Galactosidase and α(2,6)-Sialyltransferase Coupled with *in situ* Regeneration of CMP-Sialic Acid," *Tetrahedron Letters*, **34**, 3091-3094 (1993).

34. M.F. Powell, T. Stewart, L. Otvos, L. Urge, F.C.A. Gaeta, A. Sette, T. Arrhenius, D. Thomson, K. Soda, and S.M. Colón, "Peptide Stability in Drug Development. II. Effect of Single Amino Acid Substitution and Glycosylation on Peptide Reactivity in Human Serum," *Pharm. Res.*, **10**, 1268-1273 (1993).

35. T.W. Kuijpers, E.P.J. Mul, M. Blom, N.L. Kovach, F.C.A. Gaeta, V. Tollefson, M.J. Elices, and J.M. Harlan, "Freezing Adhesion Molecules in a State of High-Avidity Binding Blocks Eosinophil Migration," *J. Exp. Med.*, **178**, 279-284 (1993).

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37. G. Siuzdak, Z.-L. Zheng, J.R. Ramphal, Y. Ichikawa, K.C. Nicolaou, F.C.A. Gaeta, K.S. Chatman, and C.H. Wong, "Examination of the Sialyl Lewis X-Calcium Complex by Electrospray Mass Spectrometry," *Bioorganic & Medicinal Chemistry Letters*,, **4** (24), 2863-2866 (1994).

38. J.R. Ramphal, Z. Zheng, S. DeFrees L. Walker, and F.C.A. Gaeta, "Structure-Activity Relationships of Sialyl Lewis X Containing Oligosaccharides. 1. Effect of Modifications of the Fucose Moiety," *J. Med. Chem.*, **37**, 3459-3463 (1994).

39. M. Buerke, A.S. Weyrich, X.-L. Ma, Z. Zheng, F.C.A. Gaeta, M.J. Forrest, and A.M. Lefer, "Sialyl Lewis X-Containing Oligosaccharide Attenuates Myocardial Reperfusion Injury in Cats, *J. Clin. Invest.* , **93** (3), 1140-1148 (1994).

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47. E.A. Kraynack, J.E. Dalgard, and F.C.A. Gaeta, "An Improved Procedure for the Regiospecific Synthesis of 4- and 6-Substituted Isatins," *Tetrahedron Letters*, **39**(42), 7679-7682 (1998).

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PATENTS

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2. D.R. Andrews and F.C.A. Gaeta (1985). Antihypertensive Compounds Having both Diuretic and Angiotensin Converting Enzyme Inhibitory Activity. United States Patent No. 4,556,655, December 5, 1985.

3. D.R. Andrews and F.C.A. Gaeta (1987). Antiglaucoma Agents. United States Patent No. 4,634,698, January 6, 1987.

4. D.R. Andrews and F.C.A. Gaeta (1989). Antihypertensive Compounds. United States Patent No. 4,826,816, May 2, 1989.

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