

Curriculum Vitae



Joseph C. Fratantoni, MD
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Senior Clinical Consultant
Biologics Consulting Group, Inc.
Rockville, MD

EXPERIENCE

Biologics Consulting Group, Inc., *Senior Clinical Consultant*
Rockville, MD (Apr 2009 - present)

- Assists and guides developers of biologics, especially those involving blood and blood products, to create and execute regulatory strategies that lead to approval

MaxCyte, Inc., *Vice President, Medical Affairs and Clinical Development, Chief Medical Officer*, Gaithersburg, MD (1999 – 2008)

- Joined company at its inception and led technical and regulatory aspects of product development
- Brought initial product to IND and clinical trial
- Initiated and managed academic collaborations in areas of interest to MaxCyte – these were primarily related to cell-based therapies.
- Provided regulatory and clinical development support for corporate partners
- Initiated, produced and maintained Master File with CBER/FDA to document the MaxCyte technology and to support needs of partners and collaborators
- Presented MaxCyte technology to technical, regulatory and financial audiences

Uniformed Services University of the Health Sciences, *Adjunct Professor of Medicine*, Bethesda, MD (1976 – present)

- Serve as instructor in clinical medicine and related courses for medical students

C. L. McIntosh & Associates, *Vice President, Biologics*, Rockville, MD (1996 – 1999)

- Worked with clients on problems related to biologic products, especially blood products. These included:
 - Development of new products,
 - Compliance problems in blood centers and plasma establishments,
 - Design and development of complex biologic therapeutics
 - Design and management of clinical trials



CBER/FDA, Chief, Cellular Hematology Branch (1978 – 1992), *Director, Division of Hematology*, Bethesda, MD (1992 – 1996)

- Managed research and review of blood products related to transfusion,
 - Led review process for platelets and the first clinical cell separator (apheresis system)
 - Led research and review of blood substitutes
 - Conducted research and review on cellular transfusion components, plasma derivatives, coagulation products, pathogen inactivation and blood-related biotechnology products and issues.

NHLBI, Division of Blood Diseases and Resources, Program Director and Branch Chief, Bethesda, MD (1974 – 1978)

- Managed programs supported by NHLBI related to blood diseases and blood transfusion.
- Initiated and managed multicenter study of factor VIII inhibitors in hemophilia
- Assisted with initiation of federal funding of comprehensive hemophilia care centers
- Managed NHLBI interaction with transfusion industry and the American Blood Commission

NIH, Hematology Service, Clinical Center, Staff Physician, Bethesda, MD (1972 – 1974)

Georgetown University, Hematology Division, Assistant Professor of Medicine, Washington, DC (1971 – 1972)

EDUCATION

M.D. Cornell University (1965)

M.A. Chemistry, Harvard University (1961)

B.S. Chemistry, Fordham College (1959)

CLINICAL RESEARCH AND TRAINING

Intern and resident (Medicine), Fellow (Hematology),

Cornell New York Hospital

1965-67 and 1969-71

Staff Associate, NIAMD, NIH

1967-69

MEDICAL LICENSURE

- Maryland (1968 – present)

HONORS AND AWARDS

- B.S. degree *egregia cum laude* (highest honors)
- American Institute of Chemists Medal
- Woodrow Wilson Fellow
- Alpha Omega Alpha, Cornell Univ Med College
- Teagle Foundation Scholar, Cornell Univ Med College
- Accelerated promotion to CAPTAIN, USPHS
- FDA Recognition Award for patent on platelet evaluation device
- FDA Commissioner's Special Citation
- US Public Health Service Citation



- US Public Health Service Outstanding Unit Citation
- US Public Health Service Meritorious Service Medal
- US Public Health Service Unit Citation
- Distinguished Service Award, Am Assoc of Blood Banks

SPECIALTY CERTIFICATION

Diplomate (Internal Medicine), American Board of Internal Medicine, 1971

Diplomate (Hematology), American Board of Internal Medicine, 1972

Fellow of the American College of Physicians, 1975

MILITARY SERVICE

LIEUT. COMMANDER, US. Public Health Service, 1967 to 1969

COMMANDER, USPHS, 1972 to 1976

CAPTAIN, USPHS, 1976 to 1996 (retired, 1996)

PROFESSIONAL SOCIETIES

American College of Physicians (Fellow)

American Society of Hematology

American Association of Blood Banks

International Society for Cellular Therapy

SELECTED COMMITTEE APPOINTMENTS

- Planning Committee for NIH/FDA workshop on hemoglobin-based oxygen carriers, 2007-2008.
- NIH SBIR Study Section (Hemoglobin blood substitutes), 2007
- Int Soc Cell Therapy, Regulatory Committee, 2005 – present
- National Academies Special Advisory Committee on Biomedical Research Proposals, May 2003
- Committee for Review of Military Blood Product Research, March, 2003
- Biotechnology Industry Organization, Regulatory Affairs Committee, 2001 – present
- Institutional Review Board, American Red Cross, 1999 – present
- Institute of Medicine (Nat Acad of Sciences) Committee on Fluid Resuscitation for Combat Casualties, Washington, September 1998
- International Advisory Panel on Safety of Plasma Products (Chairman), Vienna, June 1998
- AABB Scientific Section Coordinating Committee, 1997 - 2000
- FDA Special Committee on BSE, 1996
- Forum on Blood Safety and Availability, Inst of Medicine, 1993 - 1996
- Scientific Program Committee, Am Assoc of Blood Banks, 1993 - 1996
- Working group on blood safety of the International Society of Blood Transfusion, 1993
- FDA Working Group on PHS Senior Biomedical Research Service 1993
- Panel on Delivery of Artificial Blood, Naval Research Advisory Committee, 1992
- CBER Promotion and Tenure Review Committee, 1988-92; Chairman, 1990-92
- Canadian Red Cross Research Review Committee, 1989-present
- Advisory Panel on Erythropoietin, Congressional Office of Technology Assessment,



1989

- Data and Safety Monitoring Committee, NHLBI Trial to Reduce Alloimmunization to Platelets (TRAP), 1989 - 1996
- Special Study Section on viral inactivation in blood products, NHLBI, 1988, 1993
- Chairman, license committees, all erythropoietin applications (Amgen, Chugai, Ortho), 1987-91.
- U.S. Army Medical R&D Adv Cte, (Subcte on Blood and Blood Preservation), 1981-85
- Pheresis Committee, American National Red Cross, 1979-82
- Review Cte, Hemophilia Treatment Centers, DHEW, 1977 and 1978 (Chairman)
- Expert Panel on Anti-thrombotic therapy, American College of Physicians, 1976
- Executive Committee, Council on Thrombosis, American Heart Association, 1975-77

PATENTS

Non-invasive optical assessment of platelet viability
U.S. Patent No. 4,522,494, June 11, 1985

Measurement of platelet aggregation using a microplate reader
U.S. Patent No. 5,325,295, June 28, 1994

SELECTED INVITED PRESENTATIONS

1. Non-Viral Gene Delivery for Therapeutics. Gene Delivery Systems conference, San Diego, Nov 2003
2. Development of Platelet Substitutes: Scientific and Regulatory Considerations. 9th Int Soc of Blood Substitutes, Tokyo, March 2003
3. A Non-Viral Cell-Loading System Enabling Gene Delivery And Drug Discovery Applications. Conference on Cell and Tissue Bioprocessing, Santa Barbara, CA. Oct 2002.
4. Development And Regulation Of Red Cell Substitutes: How Did We Get Here And Where Are We Going. Advanced Technology Applications for Combat Casualty Care, St Petersburg, FL, Sept 2002.
5. Blood Substitutes: History and Overview. Conference on Oxygen Therapeutics and Transfusion Alternatives, Arlington, VA, May, 2002.
6. New Biotherapeutics: Approaching the FDA. Presented at the Center for Molecular and Cellular Therapy, Univ of Minnesota, May 1999.
7. Regulation of New Platelet Products: Lessons Learned from Red Cell Substitutes. FDA Workshop on Platelet Testing, October 1998.
8. Determining the Efficacy of Platelet Substitutes. Presented at Symposium on Current Advances in Platelet Substitutes, Am Soc Hematol Meeting, San Diego, December 1997.

9. Viral Inactivation of Blood Products, An Overview. Presented at Symposium on Viral Inactivation, Am Assoc of Blood Banks Annual Meeting, Denver, October 1997 (repeated, November 1998).
10. Thoughts on the Future of Human Blood Resources. Presented at Int Symp on Alternative Approaches to Human Blood Resources, Groningen, Netherlands, October 1997.
11. Red Cell Substitutes: Evolution to Approaches for Demonstrating Efficacy. Presented at VIIth Int Symposium on Blood Substitutes, Tokyo, September 1997.
12. Transmissible Spongiform Encephalopathies: Policies in the U.S. Presented at Int Conference on Virological Safety of Plasma Derivatives, Bethesda, November 1996.
13. Criteria for evaluation of platelet products: testing algorithms and clinical trial endpoints. Presented at Workshop on Platelets and Platelet Transfusion, Bethesda, March 1996.
14. Future prospects for management of threats of unknown agents in plasma products. Presented at Meeting of the European Plasma Fractionation Association, Brussels, October 1995.
15. Demonstration of the efficacy of a therapeutic agent. Presented at the meeting Fibrin Sealant: Characteristics and Clinical Use. Bethesda, December 1994.
16. Clinical Development of Blood Substitutes: Role of the FDA. Presented at inaugural meeting of Japan Society of Blood Substitutes, Tokyo, December 1993.
17. Hemoglobin-based red cell substitutes. Workshop program at the Annual Meeting of the American Association of Blood Banks, Miami, October 1993
18. Evaluating platelets for transfusion: research overview. Int Soc for Blood Transfusion, Barcelona, Spain, June 1993.
19. Clinical Development of Blood Substitutes: the FDA Perspective. Presented at Annual Meeting of Amer Assoc for Advancement of Science, Boston, February 1993
20. Alternatives to Transfusion (chairman and organizer of session), College of American Pathologists, Boston, April 1992.
21. Perfluorocarbons as Red Cell Substitutes. Education Program of the Annual Meeting of the American Society of Hematology, Denver, December 1991.
22. Hemoglobin-based red cell substitutes: establishing preclinical safety standards.
23. IVth International Symposium on Blood Substitutes, Montreal, August 22, 1991.
24. Viral Inactivation of Blood Products: Regulatory Considerations. American Society for Photobiology. San Antonio, June 24, 1991.
25. Stroma-free Hemoglobin - The toxicity problem: establishing preclinical safety standards. Update in Transfusion Medicine, Harvard Medical School, April 26-27, 1991.
26. The Platelet Storage Lesion: Role of Membrane Plasticizer. Symposium on the Cellular and Molecular Basis of the Platelet Storage Lesion, Bethesda, April 9-10, 1991.



27. Alternatives to transfusion of cellular components. Presented at Institute of Medicine meeting, "The Nation's blood supply: is absolute safety achievable." 1 November 1989.
28. Inactivation of viral contaminants in blood products: an overview. Presented at Scientific Symposium, 1989 Annual Am. Assoc. of Blood Banks Meeting, 25 October 1989.

SCIENCE MANAGEMENT AND REGULATORY SCIENCE: HIGHLIGHTS AND ACCOMPLISHMENTS

As V.P., Medical Affairs and Clinical Development, MaxCyte, Inc. (formerly TheraMed, a subsidiary of EntreMed, Inc)

1999 - present: Developed clinical applications and provide scientific direction for a series of potential products based on new cell-loading technology developed by MaxCyte.

- 2000-2001. Directed successful IND application and phase I trial of a red blood cell-based product
- 2001-2002. Developed and submitted to FDA Master File for gene loading. This has been referenced by partners for clinical trials.
- 2002-2003. Worked with academic and corporate collaborators and partners in development and execution of projects. Two INDs submitted, one study ready to proceed; preclinical work with other partners leading to clinical trials in near future.
- 2003-present. Work with business development staff to present technical and regulatory aspects of MaxCyte technology to potential partners. Participate in alliance management with established partners.

As V.P., Biologics, C.L. McIntosh & Associates

1996 - 1999: Assisted a variety of clients with problems ranging from development of blood products, compliance problems in blood centers and plasma establishments, design and development of complex biologic therapeutics and the design and management of clinical trials.

1978 - 1996, with FDA

1980-82: Streamlined the review process for platelets, platelet storage procedures and plateletpheresis devices, permitting expeditious approval of improved products.

1980-83: Directed the controversial and sensitive review of the NDA for a blood substitute (Fluosol) to the benefit and satisfaction of all. At a later time, completed review (as committee chairman) of Fluosol for use in cardiac angioplasty.

1986-1990: Directed research efforts of platelet biology group to investigate possibility of inactivating contaminating viruses within platelets for transfusion with minimal damage to the product. The scientists involved were required to redirect their efforts in order to accomplish the goals.



1987-1992 Chairman of review committees for three license applications for erythropoietin. Completed review and successfully recommended approval for the first of these.

1988-1992: Served as a key participant in policy formulation related to application of the Orphan Drug Act to biological macromolecules in general and erythropoietin in particular.

1989-90: Organized a special meeting of an advisory committee to discuss the toxicity of hemoglobin-based blood substitutes. Formed and led an internal working group that developed output from this meeting into Points to Consider for use by interested parties. Obtained approval for Points and initiated distribution and publication within six months from the original advisory meeting.

1991-92: Helped U.S. Navy Research Advisory Committee organize a Panel on Delivery of Artificial Blood (mandated by Congress) and served on this committee. The report from this committee helped to determine federal policy in this area.

1993-1996: Served as FDA representative to the Forum on Blood Safety and Availability, a forum conducted by the Institute of Medicine to evaluate critical issues related to the national blood supply and the functioning of the blood industry.

1994: Developed consensus among investigators on efficacy parameters for blood substitutes. Organized workshop to present and discuss this. Wrote, distributed and published Points to Consider on the subject.

1994-1996: Played central role in development and evolution of FDA policy on donor deferral related to Creutzfeldt-Jakob Disease. Organized international workshop to assist industry scientists in the design of critical studies.

1995-1996: Developed and implemented modified approach to evaluation of fibrin sealant products. This was done by reconsideration of required clinical trial endpoints, examination of the complexities of these trials and successful presentation of existing problems to senior FDA officials.

1995-1996: Worked with members of the relevant scientific community to plan strategy for preclinical and clinical evaluation of platelet substitutes. A major workshop (sponsored by U.S. Army, U.S. Navy, FDA, NIH) has been held and other meetings and issuance of written FDA guidance are planned.

1995-1996: Worked with representatives of FDA and the blood industry to evaluate a successor to the Forum on Blood Safety and Availability. The need perceived was a mechanism to allow the stakeholders to identify their problems and regain public confidence, since the loss of confidence was responsible for many policy problems.

1974 - 1978, with Division of Blood Diseases and Resources, NHLBI

1974-75: Organized and managed a multicenter study designed to evaluate the efficacy of various antithrombotic regimens for the prophylaxis of deep vein thrombosis in patients undergoing surgical hip replacement.

1974-77: Initiated, designed and organized a multicenter project to study the biology and the natural history of inhibitors to Factor VIII in patients with hemophilia. Activities included initial laboratory standards, center recruitment, peer review, funding, regular meetings with participants.

1976-77: Served as advisor and reviewer in development of new federal program to support comprehensive medical care of patients with hemophilia.

1977-78: Served as a principal liaison with the American Blood Commission, which was chartered to facilitate implementation of the National Blood Policy using NHLBI funding. This very delicate situation was at least a partial success and restrictive federal legislation was not necessary.

BIBLIOGRAPHY

Abstracts

1. Askari and J. C. Fratantoni. Presence of sodium- and potassium- activated adenylic kinase in human erythrocyte membrane preparations. *Fed Proc* 22: 212, 1963.
2. J. C. Fratantoni. Effect of sodium and potassium on the ATPase and calcium binding of skeletal muscle microsomes. *Fed Proc* 23: 569, 1964.
3. J. C. Fratantoni and E. F. Neufeld. Correction of the biochemical defect in Hurler and Hunter syndromes by diffusible factors. *J Clin Invest* 48: 26a, 1969.
4. L. E. Kun, R. E. Johnson, J. Whang-Peng and J. C. Fratantoni. Acute myeloproliferative disorders in 3 long-term survivors of non-Hodgkins lymphoma. *Clin Res* 22: 491a, 1974.
5. P. Farrell, J. C. Fratantoni, R. E. Wood, V. W. Fischer and J. Bieri. Effects of vitamin E deficiency on red blood cells. *Fed Proc* 33: 672, 1974.
6. J. C. Fratantoni and B. J. Poindexter. Dimethyl sulfoxide and platelet function. *Transfusion* 20: 624, 1980.
7. J. C. Fratantoni, B. J. Poindexter, P. Smith and R. F. Bonner. A new device for evaluation of platelets for transfusion. *Transfusion* 21: 620, 1981.
8. F. Schott, M. C. Mihm, J. C. Fratantoni, et al. A Wiscott-Aldrich-like syndrome in a congenitally athymic CBA/N mouse. *Fed Proc* 41: 425, 1982.
9. K. N. Prodouz, B. J. Poindexter and J. C. Fratantoni. Ouabain affects platelet reactivity as measured in vitro. *Fed Proc* 45: 1494, 1986.

10. R. A. Devine, B. J. Poindexter and J. C. Fratantoni. Effect of inoculum size, storage time and container on the numbers of Staphylococci recovered from platelets stored at 22 C. Presented at Am Soc Microbiol Annual Meeting, March 3, 1987.
11. K. N. Prodouz, P. Albrecht, R. F. Bonner and J. C. Fratantoni. Viral inactivation with UV in blood products. Fed Proc 46: 424, 1987.
12. J. N. Kuritsky, J. C. Fratantoni, M.W. Dreis and D.J. Graham. Characteristics of EIA- and Western Blot-Positive Blood Donors in a Multicenter Study. Proc of IIIrd Int Conf on AIDS, June, 1987.
13. K. N. Prodouz, R. F. Bonner and J. C. Fratantoni. Use of laser-UV to inactivate virus in platelets for transfusion. Proc of IIIrd Int Conf on AIDS, June, 1987.
14. J. C. Fratantoni and K.N. Prodouz. Inactivation of viral contaminants in blood products: an overview. Transfusion 29: 4S, 1989.
15. K.N. Proudouz, C.D. Lytle, A.P. Budacz, E.A. Keville and J.C. Fratantoni. Albumin reduces the effects of merocyanine 540 on platelets and viruses. Presented to International Photobiology Association, July 1990
16. K.N. Prodouz, C.D. Lytle, R.F. Bonner and J.C. Fratantoni. Effects of two viral inactivation methods on platelets: Laser-UV radiation and merocyanine 540-mediated photoinactivation. Photochem and Photobiol 53: 58S, 1991.
17. A.I. Alayash and J.C. Fratantoni. Hypothermic conditions and the oxygen-carrying capacity of crosslinked hemoglobins. Proceedings of IVth International Symposium on Blood Substitutes, Montreal, August, 1991.
18. A.I. Alayash, B.A. Brockner Ryan and J.C. Fratantoni. Hemoglobin-based oxygen carriers: structural alterations that affect free radical formation. Proceedings of IVth International Symposium on Blood Substitutes, Montreal, August, 1991.
19. A.I. Alayash, J.C. Fratantoni and R. Cashion. The kinetics of nitric oxide reaction with hemoglobin-based red cell substitutes. NIH Research Day, 1992.
20. J.G. Vostal and J.C. Fratantoni. Econazole and prostaglandin E1 block platelet store-regulated calcium influx by different mechanisms. NIH Research Day, 1992.
21. A.I. Alayash, B.A. Brockner Ryan and J.C. Fratantoni. Formation of ferrylhemoglobin by the reaction of diaspirin cross-linked hemoglobins with hydrogen peroxide. Proceedings of Vth International Symposium on Blood Substitutes, San Diego, March 1993.
22. A.I. Alayash, J.C. Fratantoni, C. Bonaventura, et al. Interdimeric cross linking of human hemoglobin alters the reaction kinetics of its ferric form with nitric oxide. Proceedings of Vth International Symposium on Blood Substitutes, San Diego, March 1993.
23. J.G. Vostal and J.C. Fratantoni. Econazole inhibits thapsigargin-induced calcium influx by mechanisms other than cytochrome p450 inhibition. NIH Research Festival, Sept. 1993.
24. J.G. Vostal, E.A. Keville, D.A. Terle and J.C. Fratantoni. Cyclic AMP inhibits platelet tyrosine phosphorylation by preventing cytosolic calcium elevation. ASH Meeting, December 1993.

25. J.G. Vostal, D.A. Terle and J.C. Fratantoni. Cyclic AMP inhibits platelet tyrosine phosphorylation by preventing cytosolic calcium elevation. NIH Research Festival, Sept 1994.
26. J.C. Fratantoni. Regulatory implications of leukoreduction performed as part of blood product manufacture. Proceedings of meeting on Leukoreduction of Blood Components: Implications for Transfusion Medicine; Boston, September 1995.
27. J.C. Fratantoni. Future prospects for management of threats of unknown agents in plasma products. Report on the Meeting of the European Plasma Fractionation Association, October 1995 (Brussels).
28. S.M Dzekunov, I. Abdoul-Massih, V. Singh and J.C. Fratantoni. Oxyhemoglobin dissociation curves: Combining Adair model with optical properties of hemoglobin. Blood 96: 24b, 2000.
29. L.H. Li, S. Wang, M. Wood, V. Singh, J.C. Fratantoni and L.N. Liu. Non-viral gene transfer into resting primary lymphocytes: small and large volume. Molec Ther 2001 3 (5): S69.
30. Lin-Hong Li, Maria Wood, Rama Shivakumar, Stephanie Feller, Sarah Wang, Vin Singh, John Holaday, Joseph Fratantoni, Linda N. Liu. High-flow Electroporation: a Novel Approach for *ex vivo* Gene Therapy. Blood 98: 425a, 2001
31. Sergey M. Dzekunov, Lilian Abdoul-Massih, Maria A. Wood, Vininder Singh, Douglas A. Doerfler, John W. Holaday, Joseph C. Fratantoni. Nonclinical Studies of IHP-Loaded Red Blood Cells (IHP-RBC) Prepared by Flow Electroporation. Blood 98: 21b, 2001
32. Li LH, Biagi E, Weiss J, Shivakumar R, Dzekunov S, Feller S, Fratantoni JC, Brenner , Liu LN. Efficient Non-viral Transfection of CLL-B cells with Human CD40 Ligand. Molec Ther 5(5): S117, 2002
33. Li LH, Feller S, Fratantoni JC, Blaese RM, Liu LN. Single Base Gene Conversion by Single Strand DNA Oligo Delivered by Electroporation. Molec Ther 5(5): S334, 2002
34. Li LH, Feller S, Zhang L, Dzekunov S, Shivakumar R, Holaday J, Fratantoni JC, Mazda O, Liu LN. A Novel Approach for *ex vivo* Non-viral Gene Delivery . Molec Ther 5(5): S333, 2002
35. Weiss JM, Shivakumar R, Feller S, Li L-H, Fogler W.E., Sim KL, Holaday J, Fratantoni JC, Liu LN. Rapid, In Vivo Evaluation Of Antiangiogenic And Antineoplastic Gene Products By Electroporation-Based Transfection Of Tumor Cells. Presented at AACR , 2003
36. Weiss JM, Shivakumar R, Allen C, Li L-H,, Fratantoni JC, Liu LN. An Improved Method for Loading Dendritic Cells with Tumor Lysate. Presented at ISCT, 2003
37. Jonathan M Weiss, Rama Shivakumar, Cornell Allen, Lin-Hong Li, Joseph C Fratantoni, Linda N Liu. Efficient generation of a cancer vaccine: Electroloading dendritic cells with whole tumor lysate. Presented at Am Assoc Cancer Res, Orlando, March 2004.
38. N. Chopas, S. Feller, R. Shivakumar, C. Allen, J.M. Weiss, J.C. Fratantoni, S. Dzekunov. A Non-viral Gene Delivery System Adapted for Very Large Scale Applications. Presented at Int Soc Cell Ther, Dublin, May 2004.

39. Linhong Li, Cornell Allen, Rama Shivakumar, Jonathan M. Weiss, Linda N. Liu . Efficient Non-viral Gene Delivery to Primary, Leukemia B Cells by mRNA Transfection. Presented at Am Soc Gene Ther, Minneapolis, June 2004.
40. Linda N. Liu, Jeffrey J. Essner, Rama Shivakumar, Linhong Li, Shannon A. Wadman, Karl J. Clark, Aidas Nasevicius, Joseph C. Fratantoni, R. Scott McIvor, and Perry B. Hackett. Non-viral, long-term gene expression in hematopoietic cells using the *Sleeping Beauty* transposon system. *Cytotherapy* 7 (Supp 1): 11, 2005.
41. Fratantoni JC, Li LH, Liu LN, Peshwa MV, Brenner M, MD, Yvon E, Carrum G, and Biagi E. A Practical Approach For Achieving Clinical Immunotherapy of CLL with hCD40L- and hIL-2 Expressing Autologous Tumor Cells. *Blood* 106: 136a, 2005.
42. Linhong Li, Cornell Allen, Stephanie Feller, Larry Wolfraim, Angelia Viley, Joseph C. Fratantoni, Linda N. Liu. An Improved, Non-viral Approach for Production of hCD40L+ B-CLL Cells for Cancer Immunotherapy. *Blood* 108 (2006 ASH meeting)
43. L. Li, R. Shivakumar, C. Allen, S. Feller, J. C. Fratantoni, M. V. Peshwa, L. N. Liu. Engineering Stem Cell Products For Enhanced Potency And Biological Function. *Cytotherapy* 8: 77, 2006
44. Linhong Li, Joshua Brody, Stephanie Feller, Cornell Allen, Rama Shivakumar, Madhusudan V. Peshwa, Joseph C. Fratantoni, Ronald Levy, Linda N. Liu. Development of Immunotherapeutics for Mantle Cell Lymphoma. *Blood* 110 (2007 ASH meeting)
45. Linhong Li, Cornell Allen, Rama Shivakumar, Hiroyuki Fujisaki, Dario Campana, Madhusudan V. Peshwa, Joseph C. Fratantoni, Peripheral Blood Mononuclear Cells Engineered with mRNA Encoding Chimeric Tumor Antigen Receptor for Cancer Therapy. *Transfusion* 48:18A, 2008
46. Sergey Dzekunov, Cornell Allen, Irina Bakaltcheva, Madusudan Peshwa and Joseph C. Fratantoni. Use of Platelets As Therapeutic Delivery Vehicles. *Transfusion* 48: 172A, 2008
47. Linhong Li, Lawrence Wolfraim, Cornell Allen, Angelia Viley, Hiroyuki Fujisaki, Dario Campana, Joseph C. Fratantoni, Madhusudan V. Peshwa. A Highly Efficient, Clinically Applicable Transfection Method to Redirect the Specificity of Immune Cells and Enhance Their Anti-Tumor Capacity *Blood* 112 (2008 ASH meeting).
48. Fatma V Okur, Eric Yvon, Gianpietro Dotti, George Carrum, Helen E. Heslop, Malcolm K Brenner, Joseph C. Fratantoni, Madhusudan V Peshwa and Linhong Li. Vaccination Strategies for Patients with B-CLL. *Blood* 112 (2008 ASH meeting)

Books

1. J. C. Fratantoni and S. Wessler (eds). Prophylactic therapy of deep vein thrombosis and pulmonary embolism. U. S. Govt. Printing Office (DHEW pub no (NIH)76-866), 1975.
2. D. L. Aronson and J. C. Fratantoni (eds). Unsolved therapeutic problems in hemophilia. U. S. Govt. Printing Office (DHEW Pub No (NIH) 77-1089), 1976.

3. A. Rene and J. C. Fratantoni (eds). Management and logistics of blood banking. U. S. Govt. Printing Office (DHEW Pub No (NIH) 78-1471), 1978.
4. J. C. Fratantoni and J. Mischler (eds). Laboratory Evaluation of Platelets for Transfusion. *Vox Sang* 40: Supp 1, 1981.

Publications

1. Liu LN, Shivakumar R, Allen C, Fratantoni JC. Delivery of whole tumor lysate into dendritic cells for cancer vaccination. *Methods Mol Biol.* 423:139-53, 2008
2. Li L-H, Biagi E, Allen C, Shivakumar R, Weiss JM, Feller S, Yvon E, Fratantoni JC, and Liu LN. Rapid and Efficient Non-viral Gene Delivery of CD154 to Primary Chronic Lymphocytic Leukemia Cells. *Canc Gene Ther* 13: 215-24, 2006.
3. Fratantoni JC, Dzekunov S, Wang S and Liu LN. A scalable cell-loading system for non-viral gene delivery and other applications. *Bioprocessing J* 3 (Nov-Dec): 49-54, 2004.
4. Weiss JM, Shivakumar R, Feller S, Li LH, Hanson A, Fogler WE, Fratantoni JC, Liu LN.. Rapid, in vivo, evaluation of anti-angiogenic and anti-neoplastic gene products by non-viral transfection of tumor cells. *Cancer Gene Therapy* 11: 346–353, 2004.
5. Fratantoni JC, Dzekunov S, Singh V, Liu LN. A Non-Viral Gene Delivery System Designed for Clinical Use. *Cytotherapy* 5: 208-210, 2003.
6. Richman E, Liu L and Fratantoni, JC. Loading bioactive molecules into living cells. *Genetic Engineering News* 22: Nov 1 (19); 50-51, 2002.
7. Li L-H, Shivakumar R, Feller S, Allen C, Weiss JM, Dzekunov S, Singh V, Holaday J, Fratantoni JC, Liu L. Highly efficient, large volume flow electroporation. *Technol Cancer Res Treatment* 1: 341-350, 2002
8. T. Lynch and J.C. Fratantoni. Viral inactivation of blood products, in: *Scientific Basis of Transfusion Medicine*, 2nd Edition, P. Ness and K. Anderson (Eds), W.B. Saunders, Philadelphia, 2000, pp599-617.
9. J.C. Fratantoni. The IND: What is it and who needs it? *Transfusion* 39: 341-342, 1999 (Editorial).
10. J.C. Fratantoni. Red Blood Cell Substitutes: Evolution of Approaches to Demonstrating Efficacy, *Art Cells, Blood Subs, and Immob Biotech* 27: 1-9, 1999.
11. J.C. Fratantoni. When efficacy is difficult to define: Lessons learned from development of blood substitutes. *RA Focus*, August 1998.
12. J.C. Fratantoni. Creutzfeldt-Jakob Disease and Blood Products: FDA Policy.
13. J.C. Fratantoni. The future of human blood resources, in *Alternative Approaches to Human Blood Resources in Clinical Practice*, ed by C.Th. Smit Sibinga, P.C. Das and J.C. Fratantoni, Kluwer, Dordrecht, 1998.

14. J.C. Fratantoni. Red cell substitutes: Evolution of approaches for determining efficacy, in Present and Future Perspectives of Blood Substitutes, ed by E. Tsuchida, Elsevier, Tokyo, 1998, p 33.
15. B.M. Alving, T.J. Reid, J.C. Fratantoni, J.S. Finlayson. Frozen platelets and platelet substitutes in transfusion medicine. *Transfusion* 37: 866-876, 1997.
16. J.C. Fratantoni. Regulatory Changes for Specified Biotechnology and Specified Synthetic Biological Products (formerly Well Characterized Products). *RA Focus*, April 1997.
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