

Vera S. Byers, M.D., Ph.D.

CURRICULUM VITAE

Clinical Immunologist
Medical Toxicologist
Internist

SUMMARY OF PROFESSIONAL EXPERTISE

Disease Expertise: Autoimmune diseases such as rheumatoid arthritis and psoriasis diabetes, ulcerative colitis, multiple sclerosis; cancer immunology and oncology such as solid tumors, leukemia/lymphoma. Designed and ran trials in atopic dermatitis, bone marrow transplantation, cancer immunology and oncology: principally GI (colon), breast cancer, renal cell cancer, malignant melanoma, leukemia/lymphoma; autoimmune diseases, HIV and multiple sclerosis.

Drug Expertise: primarily in biologics, monoclonal antibodies, cytokines, peptide vaccines and herbal medicines. Developed a large number of monoclonal antibodies with specificity ranging from tumor antigens to allergens. Supervised preclinical development of >50 of them, filed INDs on about 15 different drugs.

Toxic Chemical Expertise: with human disease caused by a wide variety of chemicals including TCE, PCE, Dioxin, Benzene, Formaldehyde, hexavalent chromium. Design supervise and run epidemiologic studies on populations exposed to such chemicals.

Environmental and Pharmaceutical Toxicology: Evaluating human safety of both experimental and licensed drugs as well as herbal medicines. Also assessing patients exposed to pesticides, herbicides, other environmental toxins and carcinogens for immunotoxicity and cancer.

Preclinical and Clinical Consulting Medical Director: to biotechnology companies, supervising experiments to validate IND submissions. Design Phase I, II, III clinical trials in autoimmune diseases and cancer.

Principal Medical Witness: in over 20 multi-plaintiff cases requiring assessment of medical damages, affidavits, depositions and court testimony.

Holds United States Patent in Ribosomal Inhibiting Protein-Immunoglobulin Conjugates with Specificity for Tumor Cell Surface Antigens, and Mixtures Thereof.

Holds European Patent in Hepatic Blocking Agents.

Serves with the National Institutes of Health Review Board Study Sections Evaluating

Vaccine Cases for the United States Court of Federal Claims, Office of the Special Masters.

CAREER POSITIONS

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO – 2008 - PRESENT

Consultant in Orthopedic Oncology
Immunotherapy in Osteogenic Sarcoma

HUTCHISON MEDIPHARMA 2001-2012

Analyzed Chinese clinical trial for the TNF inhibitor Andogaphis in Crohn's Disease. Submitted results to Chinese FDA. Designed and supervised bridging studies and Phase II trials for Crohn's disease and Ulcerative Colitis in the U.S. Defended Phase II results in Ulcerative Colitis before the U.S. F.D.A. Obtained approval for a Phase III study.

ICOS/ELI LILLY 2000-2001

Served as Consulting Medical Director and designed and ran one of the 20 trials resulting in FDA approval of Cialis.

IMMUNEX 1997-2000

Served as part of the medical team directing clinical trials resulting in approval of Enbrel (fusion protein with anti-TNF fused to constant region of IgG) for rheumatoid arthritis and psoriasis; also analyzed clinical trials of GM-CSF as flu vaccine adjuvant.

CONNECTIVE THERAPUTICS 1994-1997

Consulting Medical Director. Directed clinical trials of vaccines for multiple sclerosis and IFN-gamma for atopic dermatitis.

ALLERGENE CORP 1991-1994

Invented and directed preclinical development of monoclonal antibodies against allergens such as poison oak, dust mite etc. for use in desensitization.

POSITIVE ACTION HEALTHCARE 1986-1991

Director/Physician HIV Clinic, Largest HIV clinic in California
Supervised Clinical Trial on AIDS
Designed and ran HIV Clinical Trial - FDA Fast Track drug approval.

NOTTINGHAM UNIVERSITY SCHOOL OF MEDICINE 1984-1998

Director of Immunotoxin Research 1984-1986

Special Lecturer in Tumor Immunology
Nottingham University Faculty of Medicine
Nottingham, England 1986 to 1998

XOMA CORP 1984-1991

Director of Clinical Immunology:

Invented four immunotoxins. Supervised their preclinical and clinical development.
Defended the INDs before the FDA. Filed the PLA for use of one of them in graft
vs. host disease which was approved by FDA Scientific Advisory Board

IMMUNOLOGY INCORPORATED MEDICAL GROUP 1983 - 2003

Director/Physician: Allergy, Immunology, Rheumatology, Oncology Clinic
San Francisco, CA

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO 1971- 2008

Adjunct Professor of Immunodermatology
San Francisco, CA
1974 – 2008

Fellow Clinical and Tumor Immunology
Department of Medicine
1971-1974

ABBOTT LABORATORIES 1969-1971

Bench protein chemistry investigation of structure/function
relationship of Cytochrome C.

EDUCATION

COLLEGE:

University of California at Los Angeles
B.A. in Bacteriology, January 1965

GRADUATE SCHOOL:

University of California at Los Angeles
M.A. in Microbiology, January 1967
PH.D. in Immunology, December 1969

POSTDOCTORAL FELLOWSHIP

Abbott Labs, North Chicago
Dr. E. Margoliash
Protein Chemistry
1970-1971

POSTDOCTORAL FELLOWSHIP

University of California at San Francisco
Dr. H. Fudenberg
1971-1974

FACULTY

Adjunct Professor
Department of Dermatology
University of California at San Francisco
1974 -2008

MEDICAL SCHOOL:

University of California at San Francisco
August 1977 - June 1981
M.D., June 1981

RESIDENCY:

Internal Medicine, University of California San Francisco
1981-1984

BOARD CERTIFICATION:

Diplomate, American Board of Internal Medicine
1984

PROFESSIONAL MEMBERSHIPS

American Academy of Allergy Asthma and Immunology- Fellow
American Society for Cancer Research – Member
American Association of Immunologists – Member
American Medical Association – Former Member
California Medical Society – Former Member
Clinical Immunology Society – Member
San Francisco Medical Society – Former Member
Society of Toxicology – Member

EDITORIAL BOARDS

Cancer Immunology and Immunotherapy, March 1983 - 2004
Cancer Drugs, 1991 – present

REVIEW BOARDS

(Analyzes grant applications to determine who receives funds)

Small Business Innovative Research, NCI review panel
Oncology Clinical Trials, NCI review panel

PATENTS

Ribosomal Inhibiting Protein-Immunoglobulin Conjugates with Specificity for Tumor Cell Surface Antigens, and Mixtures Thereof. P.J. Scannon, R.W. Baldwin, V.S. Byers. United States Patent 4,916,213; April 10, 1990.

Hepatic Blocking Agents. V.S. Byers, R.W. Baldwin.
European Patent, 889,062,972; December 12, 1990.

Novel Methods for treatment of retroviral infections. U.S. Pat Docket No. L018-1
June 2, 1992.

BIBLIOGRAPHY OF VERA S. BYERS, M.D., PH.D.

1. Sercarz, E.E. and Byers, V.S.: The XYZ scheme of immunocyte maturation. III. Early memory and the nature of the memory cell. *J. Immunol.* 98:886, 1967.
2. Byers, V.S. and Sercarz, E.E.: The XYZ scheme of immunocyte maturation. IV. Exhaustion of memory cells. *J. Exp. Med.* 127: 307, 1968.
3. Byers, V.S. and Sercarz, E.E.: The XYZ scheme of immunocyte maturation. Paralysis of memory cells. *J. Exp. Med.* 128:715, 1968.
4. Byers, V.S. and Sercarz, E.E.: In vitro unresponsiveness induced by antibody or antigen; sequence of sensitive events. *In* Prague Symposium, Developmental Aspects of Immunity. 1969.
5. Byers, V.S. and Sercarz, E.E.: Induction and reversal of immune paralysis in vitro. *J. Exp. Med.* 132:845, 1970.
6. Margoliash, E., Barlow, G.H., and Byers, V.S.: Differential binding properties of cytochrome c; possible relevance for mitochondrial ion transport. *Nature* 228:723, 1970.
7. Byers, V.S., Lamberth, D., Lardy, H.A., and Margoliash, E.: Independence of electron transport and primary structure of cytochrome c and eucaryotic species. *Fed. Proc.* #3, Part 2, 1971.
8. Goodman, J.W., Roelants, G., and Byers, V.S.: RNA-antigen complexes and the testing of a possible mode of action. *Ann. Rev. N.Y. Acad. Sci.* 1972.
9. Fudenberg, H.H., Byers, V.S., Levin, A.S., and Hackett, A.J.: Additional evidence for viral etiology of certain human tumors. *In* Fundamental Aspects of Neoplasia, A.A. Gottleib, ed. Springer-Verlog, New York, 1974.
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11. Levin, A.S., Spitler, L.E., Fudenberg, H.H., Byers, V.S., and Wybran, J.E.: Transfer factor therapy: current status. *So. Med. J.* (invited review), 1974.
12. Fudenberg, H.H., Byers, V.S., Levin, A.S., and Hackett, A.J.: Immunologic evidence for a viral etiology of certain malignant tumors. *Ann. N.Y. Acad. Sci.* 1974.

13. Levin, A.S., Byers, V.S., Fudenberg, H.H., and Wybran, J.E.: Immunologic parameters for monitoring immunotherapy with tumor-specific transfer factor. *Trans. Assoc. Am. Phys.* 87:153, 1975.
14. Carter, J.B., Ponce, B., Byers, V.S., Levin, A.S., and Fudenberg, H.H.: Circadian rhythms of human lymphocytes. *J. Allergy and Infect. Dis.* 56:191, 1975.
15. Byers, V.S., Levin, A.S., Hackett, A.J., and Fudenberg, H.H.: Tumor Specific cell-mediated immunity in household contacts of cancer patients. *J. Clin. Invest.* 55:500, 1975.
16. Levin, A.S., Byers, V.S., Fudenberg, H.H., Hackett, A.J., Johnston, J.O. and Wybran, J.E.: Osteogenic Sarcoma: Immunologic parameters before and during therapy with tumor specific transfer factor. *J. Clin. Invest.* 55:487, 1975.
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21. Fisher, G.L., Byers, V.S., Shifrine, M., and Levin, A.S.: Copper and zinc levels in serum from human patients with sarcomas. *Cancer* 37:356, 1976.
22. Dollbaum, C.M., Smith, H.S., and Byers, V.: In-vitro characterization of human tumor cell lines. *J. Cell. Biol.* 70:329, 1976.
23. Kaplan, M.A., Byers, V.S., Levin, A.S., German, D., Fudenberg, H.H., and LeCam, L.M.: Circadian rhythm of stimulated lymphocyte blastogenesis. A 24 hour cycle in the mixed leukocyte culture reaction and SKSD stimulation. *J. Allergy Clin. Immunol.* 58:180, 1976.

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35. Epstein, W.L. and Byers, V.S.: Transfer of contact sensitivity to beryllium using dialysable leukocyte extracts (transfer factor). *J. Allergy Clin. Immunol.* 63:111, 1979.
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49. Baldwin, R.W., Byers, V.S., Hanant, D., Jones, J.A., Pimm, M.V., and Price M.R.: Specific and non-specific cellular interactions modulating host resistance to tumours. *In* Prospects of manipulation of host- tumor relationship for cancer therapy. INSERM, 97:271, 1981.
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62. Epstein, W.L. and Byers, V.S.: Poison oak hypersensitivity. USDA Forestry Service Publication. 1982.
63. Dunn, I.S., Liberato, D.J. Castagnoli, N., and Byers, V.S.: Induction of suppressor cells for lymphnode cell proliferation after contact sensitization of mice with 3-heptadecylcatechol. *Ann. N.Y. Acad. Sci.* 392:384, 1982.
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69. Baldwin, R.W. and Byers, V.S. (eds): *Monoclonal Antibodies for Cancer Detection and Therapy*. Academic Press. London, 1985.
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71. Baldwin, R.W., and Byers, V.S.: Les immunodrogues: des médicaments a tete chercheuse (Monoclonal antibody drug targeting in cancer treatment). *Biofutur* (March):53, 1986.
72. Baldwin, R.W., and Byers, V.S.: Monoclonal antibodies for drug targeting in cancer therapy. The influence of new technology on medical practice. *Strathclyde Bioengineering Seminar*. 1986.
73. Baldwin, R.W., and Byers, V.S.: Monoclonal antibodies in cancer treatment. *Lancet* 8481:603, 1986.
74. Baldwin, R.W., and Byers, V.S.: Monoclonal antibodies in drug targeting. *Research Monographs in Immunology*, Utrecht Meeting 1986.
75. Baldwin, R.W., and Byers, V.S.: Monoclonal antibody-drug conjugates in cancer treatment. *Trends in Pharmacological Sciences*. 1986.
76. Baldwin, R.W., and Byers, V.S.: Monoclonal antibody targeting of anti-cancer agents. *Springer Semin. Immunopath.* 9:39, 1986.
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87. Byers, V.S., and Baldwin, R.W. (eds): *Immunology of Malignant Diseases*. MTP Press Ltd., 1987.
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95. Baldwin, R.W., and Byers, V.S.: Monoclonal Antibody Immunoconjugates for Cancer Treatment. *Cancer Chemotherapy Biological Response Modifiers* pp. 409-431, 1987.
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