

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

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## 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.

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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.
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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. Gotlieb, ed. Springer-Verlog, New York, 1974.
10. Fudenberg, H.H., Levin, A.S., Spitler, L.E., Wybran, J.E., and Byers, V.S.: Therapeutic uses of transfer factor. *Hospital Practice* 9:2, 1974.
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.
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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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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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