



**SmithKline Beecham**  
*Pharmaceuticals*

MEMORANDUM

20 September, 2000

Docket No. 00N-930  
Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, rm. 1061  
Rockville, MD 20852

1355 00 SEP 29 10:32

RE: Self-nomination for Working Group to develop biomarkers and/or other evolving molecular technologies to identify or predict drug-induced vasculitis.

To Whom It May Concern:

Please consider this self-nomination to participate on the working group focussed on drug-induced vasculitis. Having been involved with preclinical drug development for approaching two decades, I appreciated the need for an organized, multidisciplinary advancement in this arena. Attached please find a brief biographical overview and recent publications. If selected, I am certainly willing to participate with this working group.

Sincerely,

Lester W. Schwartz DVM, PhD  
Group Director, Clinical, Cellular and  
Biochemical Pathology.

00N-0930

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## **Biographical Material**

### **Name**

**LESTER W. SCHWARTZ**

### **Address**

**Work:** SmithKline Beecham Pharmaceuticals  
Safety Assessment - US  
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### **Education**

1974	Ph.D.	University of California Davis, CA
1972	Diplomate	American College of Veterinary Pathologists
1970	Resident	Armed Forces Institute of Pathology Washington, D.C.
1967	D.V.M.	Purdue University West Lafayette, IN
1963		University of Wisconsin Madison, WI

### **Professional Positions**

1999-Present	Group Director, Clinical, Cellular & Biochemical Pathology SmithKline Beecham Pharmaceuticals
1995-1999	Director, General Toxicology and Morphologic Pathology SmithKline Beecham Pharmaceuticals
1991-1995	Director, Morphologic Pathology, and Histotechnology SmithKline Beecham Pharmaceuticals
1982-1991	Associate Director, Pathology

- 1983-1991 Adjunct Associate Professor of Pathology, Department of Pathobiology, School of Veterinary Medicine, University of Pennsylvania, Philadelphia, PA
- 1977-1982 Associate Professor, Department of Pathology, School of Veterinary Medicine, and Associate Research Pathologist, California Primate Research Center, University of California, Davis
- 1975-1977 Assistant Professor, Department of Pathology, School of Veterinary Medicine and California Primate Research Center, University of California, Davis
- 1973-1975 Adjunct Assistant Professor, California Primate Research Center, and Department of Pathology, School of Veterinary Medicine, University of California, Davis
- 1970-1974 Graduate trainee in Comparative Pathology, School of Veterinary Medicine, University of California, Davis
- 1967-1970 Resident in Veterinary Pathology, Veterinary Pathology Division, Armed Forces Institute of Pathology, Washington, D.C.

**Research Interests/Areas of Specialization**

1. Drug Development/Hazard Identification/Safety Assessment
2. Toxicologic Pathology/Molecular Pathology
3. Respiratory Diseases
4. Inflammatory Response

**Pharmaceutical Development Experience**

Principal Discovery/Development interface for clinical development of leukotriene receptor antagonists advancing 3 molecules into Phase II clinical programs and 1 to completion of Phase III clinical efficacy; Principal Discovery/Development interface of novel antiinflammatory molecules advancing 2 molecules to Phase I clinical tolerability studies; Active principal in the registration of an angiotensin receptor antagonists (Teveten); Provided principal preclinical interface for an inlicensed clinical restenosis project (Tranilast); Managed preclinical development and regulatory interface of novel therapies for chronic respiratory disease one of which (Ariflo, a selective PDE inhibitor) is approaching worldwide registration; Provide Safety Assessment support for several monoclonal antibodies and peptide therapeutics. Established molecular pathology investigative support for safety assessment. Management responsibility for diverse pathology and toxicology professional and technical staff which provided technical study support for product registration.

### **Academic Affiliations**

1984-1988	Armed Forces Institute of Pathology Comparative Pathology of the Respiratory System
1984-1986	University of Pennsylvania Respiratory Disease Pathology Lecture and Laboratory
1983-1984	University of Pennsylvania Core Pathology, Inflammation and Repair
1975-1982	University of California General Pathology, Cardiovascular abnormal

### **Professional Organizations Membership/Licensing & Certification**

American College of Veterinary Pathologists (ACVP), Diplomate  
Society of Toxicologic Pathologists (STP)  
Society of Toxicology (SOT)  
ILSI/HESI Assembly of Members  
American Society for Investigative Pathology  
Federation of American Societies for Experimental Biology  
American Thoracic Society  
Inflammation Research Association (IRA)  
American Association for the Advancement of Science  
Licensed Veterinarian, State of California, 1970 - Present

### **Outside Activities**

#### **Consultantships**

NIEHS	Special Grant Study Section, 1995, 1996, 1997, 1999
AFIP/RTPA	Advisor Committee, 1995 - Present
AFIP	Respiratory Disease Panel, 1994-1995
Purdue University	Toxicologic Pathology Steering Committee, 1993-1994
USDA	Competition Grants Study Section, 1992, 1993, 1997
NCI	Special Study Section, 1991
CIIT	Scientific Advisor Panel, Ad Hoc Member, 1988
NIH - NTP	Pathology Working Group, 1983
HEI	Proposal Review Panel, 1982
NIH - NIEHS	Special Study Section, 1980
NIH - NHLB	SCOR-grant Site Visit, 1981
Veterinary Disease Laboratory, San Jose, California, Consulting Pathologist	1979 - 1982

### Professional Organization Responsibilities

1999 - Present	STP, Educational Endowment Fund Committee
1995 - Present	STP, Advisory Committee
1992 - 2000	SOT, Editorial Board, Toxicological Sciences
1989 - Present	STP, SSNDC Lung Sub-committee
1995 - 1998	STP, Educational Standards Committee, Chairperson
1996 - 1998	STP, Strategic Planning Committee
1995 - 1996	ACVP, Ad Hoc Examination Committee
1991 - 1995	ACVP, Editorial Board, Veterinary Pathology
1991 - 1992	STP, Chairperson, Executive Committee
1991	STP, Education Committee Chairman, Respiratory Diseases
1990 - 1994	STP, Executive Committee
1989	ACVP, Publications Study Committee
1988	IRA, Session Co-chair, Drugs for Arthritis
1987	STP, Poster Session/Young Investigator Committee
1986	ACVP, Nomination Committee
1984	ACVP, Industrial Pathology Program Committee
1981	ACVP, Education Committee, Respiratory Diseases

### Most Recent Publications

56. Tryphonas, L., Schwartz, L.W., Levin, S. and Haschek, W.M. Commentary, Toxicologic pathology: Modern challenges and the need for a new educational strategy. *Vet Pathol* 32: 208-210, 1995.
57. Short, B.G., Zimmerman, D.M. and Schwartz, L.W. Automated double labeling of proliferation and apoptosis in glutathione s-transferase positive hepatocytes in rats. *J Histochem Cytochem*, 45: 1299-1305, 1997.
58. Louden, C.S., Nambi, P., Pullen, M.A., Thomas, R.A., Tierney, L.A., Solleveld, H.A. and Schwartz, L.W. Endothelin receptor subtype distribution predisposes coronary arteries to damage. *AJP*, 157: 123-134, 2000.
59. Newsholme, S.J., Thudium, D.T., Gossett, K.A., Watson, E.S. and Schwartz, L.W. Evaluation of plasma von Willebrand factor as a biomarker for acute arterial damage in rats. In Press, *Toxicol Pathol*, 2000.
60. Newsholme, S.J., Maleeff, B.E. Steiner, S., Anderson, N.L. and Schwartz, L.W. Two-dimensional electrophoresis of liver proteins: characterization of a drug-induced hepatomegaly in rats. *Electrophoresis*, 21: 2122-2128, 2000.
61. Dungworth, D.L., Rittinghausen, S., Schwartz, L., Harkema, J.R., Hayashi, Y., Kittel, B., Lewis, D., Miller, R.A., Mohr, U., Morgan, K.T., Rehm, S. and Slayter, M.V. Respiratory system and

mesothelium. In: International Classification of Rodent Tumors, Part 2: The Mouse. In Press, WHO/IARC Scientific Publication, 2000.



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Pharmaceuticals

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NAME S. Newsholme

MAIL CODE UE0364

Docket No. 00N-09390  
Dockets Management Branch (HFA-305)  
Food and Drug Administration  
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