

WILLIAM M. WARDELL, MD PhD

Dr. Wardell is president of the consulting firm, Wardell Associates International LLC, in Jacksonville, FL. A large part of his consulting includes solving problems in Drug Development, Regulatory Approval, and Safety, for both large Pharma companies and small startups in biotech, drugs, and some devices.

His Pharmaceutical and Biotechnology industry experience includes: President, Protein Engineering Corporation (now Dyax); Senior-VP, Drug Development, Parke-Davis; VP-Medical Director, Boehringer Ingelheim Pharmaceuticals; Senior Scientific Officer at Covance, and Executive Director of the Covance Institute for Drug Development Sciences. He serves on two Corporate Boards (OrthoLogic, Inc., and PhytoCeutica, Inc.), several Scientific Advisory Boards, including the BioSeed Advisory Committee of Connecticut Innovations (a high-tech investment and advisory firm established by the CT Legislature), the BioFlorida Bioscience Founders Council, and the Biotechnology Advisory Committee of the University of Florida's Sid Martin Biotechnology Incubator, which supports 12 resident start-up biotech companies.

Prior to Industry, his academic and clinical career was mainly at the University of Rochester Medical Center, as Associate Professor of Pharmacology, Toxicology and Medicine, attending on the Clinical Pharmacology consultation service of Strong Memorial Hospital. This was the start of his career in Translational Medicine. He co-founded and directed the University's Center for the Study of Drug Development (now at Tufts).

He has testified as an expert in Drug Development in several Congressional hearings.

In addition to drug discovery and development and its contribution to medicine, his interests include medical devices, clinical pharmacology, clinical trial methodology, drug safety, regulation, biotechnology, pharmacogenomics, and botanicals -- topics on which he has published over one hundred scientific papers and four books.

Bill Wardell earned his MA, PhD (in pharmacology), and MD at the University of Oxford (UK), and was a Merck International Fellow in Clinical Pharmacology and Medicine under Dr. Louis Lasagna at the University of Rochester / Strong Memorial Hospital.

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**WILLIAM M. WARDELL, MD PhD
WARDELL ASSOCIATES INTERNATIONAL LLC**

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ONE-PAGE SUMMARY OF EXPERIENCE

CONSULTING FIRM

President, Wardell Associates International LLC (1995-96 and 2000 to date):

Consulting on Drug Development, Regulatory Approval, and Safety to the Pharmaceutical, Biotechnology, and Medical Device Industries.

CONTRACT RESEARCH ORGANIZATION

Covance, Inc. (1996-2000): **Senior VP; Senior Scientific Officer, Covance, Inc., &**

Executive Director, Covance Institute for Drug Development Sciences:

- Led most of Covance's high-level medical & regulatory drug, biotech, and device consulting projects, over 100 Internal and external projects;
- Wrote & evaluated Strategic Product Development Plans (over 100 across all therapeutic areas);
- Responsible for Global Clinical Research, Phases 1-4; liaison with Clinical Laboratories, Preclinical, & Pharmacoeconomics;
- Founded the Covance Institute for Drug Development Sciences (external & internal responsibilities);
- Led Technical Evaluations of outside firms and technologies for Corporate Business Development;
- Created and managed the Internal Career Enrichment program for Covance's physicians & scientists;
- Represented Covance Drug Development Sciences externally (>50 presentations and papers);
- Led and managed Technical Services (Medical, Regulatory, Safety, Biometrics, Training) to the Business Centers.

BIOTECH COMPANY

President: Protein Engineering Corporation, now Dyax in Cambridge, MA (1993-95):

- Development Programs & Pharmaceutical Corporate Partnering; Strategy for Discovery, Development, Regulatory, & Marketing; Proteins as therapeutics, imaging, and diagnostic agents.

TWO MULTINATIONAL PHARMA COMPANIES

Boehringer Ingelheim & Parke-Davis (1983-1992):

- **Senior VP, Drug Development, Parke-Davis:** Including Project Management and Future Pharmaceutical Markets.
- **VP- Medical & Regulatory, Boehringer Ingelheim:** Head of Medical (all functions, including Clinical Research Phases 1 - 3, Medical-Marketing Services & Phase 4, Regulatory, Biostatistics, and Drug Safety).

PHARMA INDUSTRY POLICY

- **PhRMA** Medical Committee & International Regulatory Harmonization (ICH Representative and Speaker).

ACADEMIC MEDICINE, CLIN. PHARMACOLOGY, DRUG DEVT & PHARMACEUTICAL POLICY (1971-1992)

- Clinical Professor of Medicine, University of Connecticut Health Sciences Center.
- Medicine, Pharmacology, and Clinical Pharmacology/Therapeutics (Univ. of Rochester & Strong Memorial Hospital).
- Founding Director, Center for the Study of Drug Development (now at Tufts University).
- Pharmaceutical, Regulatory, and Drug Development Sciences; Pharmaceutical Public Policy.

BOOKS, PUBLICATIONS, INVITED PRESENTATIONS IN CLINICAL PHARMACOLOGY, DRUG DEVELOPMENT & USE: 4 Books & 110 papers.

CORPORATE BOARDS

OrthoLogic, Inc. 2006-- (Chair, Clinical & Regulatory Review Board). Center for Orphan Drug Devt of the University of Minnesota 2006-- (Advisory Board). Orphan Medical, Minneapolis, 1995-2005 (Chair, Regulatory Oversight Committee). PhytoCeutica, New Haven (Board Member since inception, 1999). Biotech Advisory Committee of U of Florida Sid Martin Biotech Incubator. BioFlorida Bioscience Founders Council. BioSeed Advisory Committee of Connecticut Innovations. PharMetrics, Boston, 1998-2003 (Chair, SAB). Eleos, Omaha, SAB. Protea, Morgantown, WV, SAB.

DETAILS OF PHARMACEUTICAL & BIOTECHNOLOGY COMPANY EXPERIENCE

CONSULTING FIRM

PRESIDENT, Wardell Associates International LLC, Princeton, NJ 1995-6; 2000 to date
A large network of industry-experienced experts to provide product-development and product-support for pharmaceutical, biotech, and medical device firms in the US and abroad, to get products approved faster and support them in the market. The right experts at the right time.

CONTRACT RESEARCH ORGANIZATION

Covance, Inc, Princeton, NJ (formerly Corning Besselaar, CBI / CPS) 1996 – 2000

Covance is one of the largest Global Contract Drug Development organizations. I joined it in an operational role when it was part of Corning Pharmaceutical Services, Inc., and after the spinoff as Covance in 1/97, I had combined operational and corporate roles.

- **SENIOR SCIENTIFIC OFFICER, Clinical & Periapproval Services, COVANCE**
Led most of Covance's high-level drug, biotech, and device consulting projects (>100) for North America;
Responsible for Global Clinical Research, Phases 1-4;
Led Technical Evaluations for Corp Business Devt
Directed Covance's Training program & Internal Medical / Scientific Career Enrichment program.
- **EXECUTIVE DIRECTOR, Covance Institute for Drug Development Sciences**
Co-founded this Institute (a partnership between Covance's Drug Development Services Depts and the Marketing Dept) to develop and highlight Covance's leading position in the Drug Development Sciences. In addition to formalizing and extending scientific knowledge for our business, the Institute provided both our external representation and our internal educational and career-enrichment opportunities for scientists throughout Covance worldwide. Responsible for starting Covance's Knowledge-Bases and moving the consulting to higher strategic levels. Represented Covance externally in national and international technical forums. (For example, personally gave >25 presentations at external meetings in '99 alone.)
- **SENIOR VP, Corning Besselaar, Inc., & Director, Center for Strategic Product Development**
Responsible for worldwide integration of Pharmaceutical Development Services across the former Corning Besselaar US, Corning Besselaar Europe, and its PACT Divisions.
I joined Corning Besselaar full-time in 1/96, from the position of consultant to CBI, when a major reorganization created the Business Centers and with them the need for central provision of technical services. I was the first head of the Covance Strategic Product Development group, responsible for providing all Central Scientific & Technical Services (Medical, Clinical Drug Safety, Biometrics, Programming, Data Management, Information Resources, Training & Best Practices, Project Feasibility, and Investigator Services) to CBI's Business Centers.
- **HEAD OF REGULATORY AFFAIRS, Corning Besselaar, Inc. (1996).**
The head of Regulatory had left CBI just before I joined, so I also headed the Regulatory Affairs Dept until I recruited a VP of Regulatory, who joined us in late 1996. Subsequently I continued to work very closely with Regulatory at Covance, particularly in Covance's consulting work.

BIOTECH COMPANY**PRESIDENT, Protein Engineering Corporation (now Dyax Corp.), Cambridge, MA 1993 - 1995**

I was president of Protein Engineering Corporation (PEC) from January 1993 until its merger with Biotage to form DYAX Corporation in September 1995. DYAX Corp. is a publicly-held biotechnology company with a leading proprietary position in surface remodeling of protein structures by molecular evolution using phage display. It creates novel ligand molecules for use as receptor antagonists, enzyme inhibitors, diagnostic markers, and other actions of pharmaceutical and industrial value, including the creation of very large combinatorial diversity libraries. I created the Development programs for its currently active-development compounds.

My responsibilities included:

- Strategy for all uses of engineered proteins, including therapeutics, imaging, and diagnostics;
- The Business Plan for managing Discovery, Development, Regulatory, and Marketing;
- All Development Programs; Pharmaceutical Corporate Partnering; Business Development (contacted 200 companies worldwide and obtained Japanese and European corporate partners);
- Any other needs that arose (classic small-company environment!).

MULTINATIONAL PHARMA COMPANIES**SENIOR VICE-PRESIDENT, Parke-Davis Pharmaceutical Research Division,
Warner Lambert Company, Ann Arbor, MI**

1991 - 1992

- **Senior VP, Drug Development**

Responsible for Project Mgmt, Strategic Planning, Portfolio Management, & Pharmacoeconomics; Managed 4 VPs plus staff of 20+ in the Drug Development Department, with responsibility for project management of all 40 Drug Development projects in the Research Division; Rationalized project management by combining two Departments into one, and instituted formal Strategic Drug Development Plans (with signoff from all involved Departments) for all compounds in Development.

- **Senior VP, Pharmaceutical Research & Healthcare**

Initiated and set up (with representatives from the Managed Care Marketing and Drug Epidemiology Departments) the Corporate Health Economics Committee, to enable the Corporation to respond to the future healthcare market demands;

Through this committee, incorporated health economics and outcome analysis into the clinical development programs of the IND, to meet Marketing's needs.

V-P, - MEDICAL DIRECTOR, Boehringer Ingelheim Pharma, Inc., Ridgefield, CT 1983 - 91

- Directed development and implementation of all US medical functions, including Clinical Research and Regulatory Affairs;
- Managed six departments and 190 professionals: departments included

Clinical Research (Phase 1 to 3)	Drug Regulatory Affairs
Clinical Investigation (Phase 4)	Medical Research Administration
Clinical Drug Safety	Medical Data Services & Statistics
- International responsibility for worldwide research, development, clinical, and regulatory programs through seat on German parent's International Steering and Medical Committees.
- Rejuvenated and built up a sagging medical department into a first-class team that became a model for the corporation worldwide and for visiting benchmarking teams from other companies;
- Retrieved and rescued an NDA from a previous negative advisory committee review;
- Designed and performed first-rate IND/NDA programs on over 20 compounds;
- Built a high reputation for the company at FDA in Review Divisions, Safety and Post-Marketing areas;
- Obtained timely NDA approval on all feasible NDAs (total of 10 at Boehringer);
- Handled a drug safety crisis and was publicly commended by FDA.

SELECTION OF DRUGS NOW MARKETED THAT I'VE HAD A ROLE IN DEVELOPING

as Pharma Department Head, Consultant, Clinical Investigator, or Board Member:
OMI = Orphan Medical Inc., P-D = Parke Davis, B-I = Boehringer Ingelheim,
U-R = University of Rochester)

Aptivus (tipranivir) – AIDS (B-I)
Xyrem (sodium oxybate) – narcolepsy (OMI)
Naprosyn (naproxen) – NSAID (U-R)
Antizol (fomepizole) – antidote for methanol and ethylene glycol poisoning (OMI)
Cystadane (betaine anhydrous) – homocystinuria (OMI)
Busulfex (busulfan) – conditioning agent for bone or marrow transplantation (OMI)
Elliotts B Solution - diluent for intrathecal oncology drug delivery (OMI)
Sucraid (sacrosidase) – enzyme therapy for sucrase deficiency (OMI)
Vesicare (solifenacin) – urinary urgency (Covance)
Actos (pioglitazone) – type 2 diabetes (Covance)
Velcade (bortezomib) – cancer treatment (Covance)
Lipitor (atorvastatin) – hypolipidemic (P-D)
Neurontin (gabapentin) – refractory epilepsy, partial epileptic seizures, post-herpetic neuralgia (P-D)
Cognex (tacrine) – the first drug for Alzheimer's disease (P-D)
Cerebyx (fosphenytoin) – epilepsy – intravenous form of Dilantin (P-D)
Nipent (pentostatin) – treatment of hairy cell leukemia (P-D)
Combivent MDI (fixed combination of ipratropium+albuterol) - for COPD (B-I)
Atrovent Nasal Solution (ipratropium bromide) – rhinitis (B-I)
Atrovent MDI (ipratropium bromide) – 1st anticholinergic bronchodilator, for COPD (B-I)
Thalitone (chlorthalidone) - low-dose formulation for hypertension (B-I)
Persantine I.V. (dipyridamole) – thallium-imaging diagnosis of myocardial ischemia (B-I)
Alupent Solution (metaproterenol) asthma - pediatric indications (B-I)
Persantine (dipyridamole) - prevention of heart-valve thromboembolism (B-I)
Aggrenox (aspirin/dipyridamole) – reduction of ischemic stroke risk (B-I)
Mexitil (mexiletine) for cardiac antiarrhythmias (B-I)
Catapres TTS (clonidine) - first weekly antihypertensive transdermal patch (B-I)
Mirapex / Sifrol (pramipexole) - Parkinson's disease (B-I)
Viramune (nevirapine) – AIDS (B-I)
Mobic (meloxicam) – NSAID (B-I)

plus numerous consultations on > 30 other compounds in development or on the market

THERAPEUTIC AREAS: DRUG DEVELOPMENT & MARKET SUPPORT EXPERIENCE

- Protein therapeutics and diagnostic imaging: inhibitors of elastase, plasmin, and kallikrein
- Antibiotics and cancer chemotherapy
- Atherosclerosis: 3 lipid-regulating drugs
- Endocrine/Metabolism: Contraceptives, Estrogen Replacement, Diabetes
- HIV Infection, AIDS
- Immune System, Allergy, Cell Adhesion: Organ Transplantation, Asthma, Rhinitis, Sjogren's
- PAF (Platelet Activating Factor) Antagonists: Asthma, Rhinitis
- Coronary Mortality, Heart Failure, Hypertension, Arrhythmias, Angina
- Asthma, COPD, Respiratory Mucus, Rhinorrhea Inhibition
- Alzheimer's, Epilepsy, CNS Dopamine Systems (Parkinson's, Schizophrenia)
- Analgesics (Non-steroidals, Opiate Agonists) Hypnotics
- Peptic Ulcer
- Statistical Methodology, Pharmacoepidemiology, and Adverse Drug Reactions
- Health Economics studies and methodology
- Worldwide reorganization of Corporate Drug Development structure and function
- Worldwide Corporate Drug Safety System; Responses to 2 worldwide drug-safety problems

**ACADEMIC MEDICINE, CLINICAL PHARMACOLOGY,
AND PHARMACEUTICAL PUBLIC POLICY**

University of Connecticut Health Sciences Center Clinical Professor of Medicine	1983 - 1992
University of Rochester Medical Center, Rochester, NY Strong Memorial Hospital Associate Professor of Pharmacology and Toxicology (tenured) Assistant Professor of Medicine Associate Physician, Strong Memorial Hospital (Clinical Pharmacology Service) Director (Co-founder), Center for the Study of Drug Development (now at Tufts) Merck International Fellow in Clinical Pharmacology and Medicine	1971 - 1983
Otago University Medical School, Dunedin, New Zealand Dunedin Hospital Lecturer - Pharmacology and Clinical Pharmacology (Pharmacology Dept, Medical School) Clinical Assistant, Dunedin Hospital Medical Research Officer, NZ-MRC Clinical Pharmacology & Toxicology Research Unit Staff Physician, National Adverse Drug Reaction Center & National Poisons Center Intern in Medicine and Surgery	1968 - 1970

HONORS AND AWARDS

1994 Henry Elliott Award for Distinguished Service, American Society for Clinical Pharmacology and Therapeutics
 Founding Director, Center for the Study of Drug Development
 Merck International Fellowship in Clinical Pharmacology
 University of Oxford: Commonwealth Medical Scholarship
 University of Oxford: Christopher Welch Scholarship in Biology
 University of Oxford: Radcliffe Prize for Research in Medical Science
 Otago University Medical School: John Malcolm Memorial Prize in Physiology

STATEMENTS BEFORE U.S. CONGRESSIONAL COMMITTEE; STATEMENTS OR PARTICIPATION IN OTHER GOVERNMENT PANELS, AND OTHER NATIONAL ACTIVITIES

Statement representing ASCPT on the Drug Approval Process for the Final Report of the National Committee to Review Current Procedures for the Approval of New Drugs for Cancer and AIDS. President's Cancer Panel ("Lasagna Committee"), organized by the National Cancer Institute

Subcommittee on Investigations and Oversight of the Committee on Science and Technology: Hearings on "Pharmaceutical Patent Life and Innovation"

Commission on the Federal Drug Approval Process: "Current Trends and State of New Drug Development in the United States"

Member of the Pharmaceutical Panel of the Committee on Technology and International Economic and Trade Issues, National Academy of Engineering/National Academy of Sciences

Library of Congress Congressional Research Service, Science Policy Research Division, Workshop on Biotechnology for the House Committee on Science and Technology: "Legislative and Regulatory

U.S. House Science, Research and Technology Subcommittee: “FDA’s New-Drug Approval Process”
(review of the General Accounting Office Drug Lag study)

House Health Subcommittee: Statements on Sections 108e, g, h, and Section 185 of the Drug Regulation Reform Act

U.S. House Health Subcommittee: Testimony of the Drug Regulation Reform Act of 1978 (H.R. 12980) as Chairman of the Drug Regulatory Committee of the American Society for Clinical Pharmacology and Therapeutics (jointly with Dr. Arthur Hayes)

AMA Delegate to the National Council on Drugs

Food and Drug Administration: Testimony as Chairman of the Drug Regulatory Committee (ASCPT) on the Drug Regulation Reform Act

Subcommittee on Regulation, Advisory Group on Contributions of Technology to Economic Strength (National Science Foundation): “Regulation and Pharmaceutical Innovation: A Review of the Relationship Between Government [Safety] Regulation and Innovation Leading to Medically Useful Drugs”

HHS Review Panel on New Drug Regulation: “Role of Regulations in Drug Development and Therapeutics”

Consultant, Federal Trade Commission

Member, Scholarly Adjunct to the Special Study Panel, National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

PROFESSIONAL AFFILIATIONS AND SERVICE (current and former)

American Society for Clinical Pharmacology and Therapeutics (ASCPT):

Vice President, Board of Directors. Committees: Government Affairs, Long-Range Planning, Certification in Clinical Pharmacology, Clinical Trials Methodology (Chairman), Publications (Vice Chairman), Membership.

PhRMA: Commissioner, Commission on Orphan Drugs; Member, Medical Section

Steering Committee; International Committee on Harmonization (ICH): Member of US Delegation and Speaker, ICH-1; Chairman, Subcommittee on ICH-2 (Efficacy Expert Working Group; Dose-Response Panel).

American Medical Association - ASCPT Section Council on Clinical Pharmacology and Therapeutics (Chairman).

American Society of Pharmacology and Experimental Therapeutics (ASPET).

American Board of Clinical Pharmacology (Board Member).

American Association of Pharmaceutical Physicians.

Australasian Society of Clinical and Experimental Pharmacology (ASCEP).

EDUCATION, LICENSURE, FAMILY

MD Medicine, **PhD** Pharmacology, **MA** Physiology & Biochemistry: all from Oxford University, England

Medical Licensure: New York State [and formerly New Zealand and UK]

Board Certification: American Board of Clinical Pharmacology

US citizen, born in Christchurch, New Zealand; married with two adult sons

ACADEMIC AND PROFESSIONAL APPOINTMENTS

Adjunct Professor of Pharmacology and Therapeutics, Tufts University Medical School

Co-founder and Lecturer, Rochester, then Tufts Univ. Postgrad. Course in Clinical Pharmacol, Drug Development, and Regulation

Faculty, Pharmaceutical Development course, Drexel University MBA Program in Pharmaceutical Management

Founder/Director, Boehringer Ingelheim Fellowship Program in Clinical Pharmacology

National Sjogren's Syndrome Foundation, Board of Directors

National Organization of Rare Diseases (NORD), Member, Research Advisory Board

Connecticut Academy of Science and Engineering, Member

RECENT INVITED PRESENTATIONS (grouped by topic)

Drug Development (General), including Outsourcing and Regulatory Reform

Navigating the FDA: Obtaining Approval, Navigating Post-Approval Hurdles, and Perspectives on Safety, BioFlorida Annual Conference, Weston, FL, 10/17/07.

Dangers of Overcompliance: Preserving the Future of Drug Development, Grand Rounds, Leukemia Department, University of Texas MD Anderson Cancer Center, Houston, TX, 6/7/06.

Approaching Sources of Funding for Product Development, First International Symposium on Translational Clinical Research for Inherited and Orphan Diseases, sponsored by the National Neurovision Research Institute, 11/04.

How To Avoid Clinical Failure in Small-Company and Biotech Drug Development, First International Symposium on Translational Clinical Research for Inherited and Orphan Diseases, sponsored by the National Neurovision Research Institute, 11/04.

Regulatory Capture in Reverse: Overcompliance Is Strangling Drug Development, AAPP, 11th Annual Meeting, Atlanta, 11/04.

Molecular Diagnostics and Therapeutic Drugs: Understanding and Validating the Clinical Claims and the Evidence Needed To Support Them, Molecular Diagnostics Symposium, Center for Business Intelligence, Arlington, VA, 11/04.

Expedited Drug Approval Pathways: Do they substantially expedite Drug Development and Approval? In: "Expedited Drug Approval Pathways: Strategic Planning, Implementing and Achieving Faster Product Approval." Barnett International Symposium, Phila (Wardell: Speaker & Session Chair), 11/03.

The "New" Drug Approval / Utilization System: Do we have it already? Will it speed Drug Development and Approval while maintaining Safety? ASCPT Annual Meeting (Wardell: Speaker and Session Chair), 3/02.

Strategic Global Drug Development: A CRO Perspective. In: Key Issues In Pharmaceutical R&D Management: Managing a Global Submission & Developing an Integrated Global Strategy, Tufts CSDD Workshop, Phila, 11/99.

Accelerating Phase III Trials a) Strategically; b) Tactically / Operationally, IIR Pre-Conference Workshop with Dr Larry Meinert, Phila, 11/99.

Accelerating Clinical Drug Development: Strategically & Tactically. NJ Association of Pharmaceutical Licensing Executives, Basking Ridge, 11/99.

Strategic Global Drug Development: A CRO Perspective. In: Key Issues In Pharmaceutical R&D Management: Managing a Global Submission & Developing an Integrated Global Strategy, Tufts CSDD Workshop, Phila, 11/99.

Accelerating Clinical Development: "Standards of Evidence for Approval / Is There a 'Silver Standard'?" (Panel Debate with Dr Robert Temple, FDA), DIA Annual Meeting, 6/99.

Use of Metrics in Improving Clinical Trials, DIA Annual Meeting, 6/99.

Accelerating Clinical Trials: Increasing Success Rates, Earlier Approvals, DIA Annual Meeting, 6/99.

Developing the Portfolio: Clinical Development and Regulatory Approval; & Optimizing the Process: How problems in the Drug Development process are being addressed"
Both given at: Wharton - Windhover Pharmaceutical Executive MBA course, 4/99.

The Strategic Product Development Plan: Use of the SPDP in Business Development: Creating the initial SPDP for a compound in early development. Innovations symposium: Phila, 3/99.

Evaluating Botanicals by Modern Standards: Principles and lessons: in: Nutritional Supplements in Managed Care. DIA, Washington, DC, 3/99.

The FDA as a Consulting Firm: A Comparative View Across Products, Companies and Agencies / Continents" In Tufts CSDD workshop on "Seeking FDA Advice To Speed New Drug Development." In: The Role of FDA/Sponsor Mtgs," Phila, 2/99.

Rationale for facilitated early human study of drug candidates in the US. PhRMA / FDA DRUSAFE. DC, 9/96.

Plan for Reforming Regulation of the US Drug and Device Development Process. PFF, Washington, DC, 2/96 - presentation at launch of book.

Approval Standards for Drug Efficacy in the Future: PhRMA Clinical/Regulatory Annual Update, DC, 4/95.

Therapeutics and Culture. Drug Information Association Annual Meeting, San Diego, CA, 6/92.

What Information is Needed To Support a Dose for Registration? ICH-1 & 2, PhRMA representative and speaker on Efficacy Expert Working Group, Dose-Response topic. Also given at DIA Annual Mtg, Workshop on Integrated Safety Assessment and Benefit/Risk Evaluation, Arlington, VA, 7/92.

Statement before the Committee on the Approval Process for Drugs for Cancer and AIDS ("Lasagna Committee"), 4/90 (representing ASCPT at DHHS).

Biotechnology and Emerging / Small Companies

Australasian Small Companies in the US Environment: Planning the Most Efficient Drug Development Program, for the BioRelationships 2006 Conference of the American Australian Association, Boston, MA, 4/5/06.

The Small-Company Model in Early-Phase Drug Development: What Small Companies Must Do To Survive, for the Association of Clinical Pharmacology Units, Bethesda, MD, 10/18/05.

Decisions Emerging Companies Must Make: What We Can Learn About Success and Failure Factors from Small-Company Development Experience, & Writing Product Development Plans, Seminar for Drexel University Executive MBA program in Drug Development, Philadelphia, October 2004 and 2005.

Avoiding Drug-Development Failures in Biotech and Emerging Companies, Harvard Business School Club: Seminar, NYC Chapter, 11/02.

Setting the Strategic Path: Decisions Emerging Companies Must Make. In: Session on "Strategy & Outsourcing for Small Companies," DIA Annual Meeting, 6/02.

Translating Pharmacogenomic Claims into Drug Labeling & Market Advantage: Clinical Methodologies and Issues; also Panel Discussion **"Impact of Pharmacogenomics – an Industry Perspective."** in PHARMACOGENOMICS IMPACT Mtg: Center for Business Intelligence, San Francisco 12/99.

Pharmacogenomics: "What is the Unmet Need for the Drug Industry?" In: Applying Genetics in Drug Development to Maximize Success and Market Potential of New Pharmaceuticals, IBC, Boston, 7/99.

Optimizing Success, Failure & Attrition in Drug Development: What have we learned from the Biotech experience to date?" Hoffman La Roche, Nutley, NJ; Clin. Pharmacol. Drug Devt Seminar Series; 1/99.

Predicting Success Rates in Biotechnology Drug Development: ASCPT Annual Meeting, and co-chair of session on "Novel Approaches to Drug Discovery," Orlando, 3/96.

Contribution of Biotechnology to the Pharmaceutical Pipeline: Biotechnology Drugs Meet Regulatory Reality - What Happened? Why? American College of Clinical Pharmacology Annual Meeting, Boston, 10/94.

Clinical Drug Development in Biotechnology: Reconciling Scientific Realities with Investor Needs, IBC, Phila, 9/94.

Clinical Drug Development in Biotech Companies vs Pharmaceutical Companies: IRB perspective. PRM&R / Tufts, Boston, 10/93.

Medical Device Development and Regulation

Lessons from Drug and Device Development: What can each learn from the other? BioWest, 11/95; BioEast, 1/96; IBC, 6/96.

Technology Assessment of New Devices: What evidence should be required to admit novel devices to the market? 2nd Annual Conference on Health Services Research in Radiology, U. Penn, 9/95.

Responsible Reform of US Regulation of Development and Approval of Drugs & Devices: AEI, DC, 3/95.

Pharmacogenomics

Personalized Medicine: Where Are the Real Opportunities? TiECON East 2007 (The Indus Entrepreneurs' East Coast Annual Conference), Moderator, Hynes Convention Center, Boston, 6/15/07.

The Zen of Theranostics: Can Pharmacogenetics Deliver the Goods? Medical History Society of NJ, Princeton, NJ, 5/23/07.

Genomics: Can Pharmacogenomics Deliver on Its Extravagant Claims? Understanding the Realities of Therapeutics, for SCBA/BioPharm 2005 Annual conference: "Tackling the Challenges in Drug Research, Development and Commercialization", Rutgers University, Piscataway, NJ, 12/4/05. Rutgers University,

Implementing the Claims of Pharmacogenomics in the Real World of Graded Dose/Exposure-Response Relationships. In: "Optimizing Dose & Exposure Response Studies," Barnett International, Philadelphia, 4/04.

'Personalized Medicines' and 'Individualized Therapeutics': Scrutinizing the Extraordinary Claims of Pharmacogenomics. Medical Rounds, Hackensack Hospital, 3/04.

Validating and Implementing Pharmacogenomic Hypotheses: How shall we recognize, prove, and develop a feasible clinical claim? Session on: Commercializing Pharmacogenomics, DIA Annual Meeting, San Antonio, 6/03.

Pharmacogenomics in Clinical Development, Therapeutics, and the Market: Key Issues, with Reference to Pulmonary Examples. In: "Drug Development in Pulmonary Diseases," PERI, Baltimore, 6/02.

Converting Pharmacogenomic Knowledge into Therapeutic Advances and Market Success: Pharmacogenomics in the Real World, 12/01 and 11 prior presentations in various venues, including FDA and AAPS.

Where's the "Pharm" in Pharmacogenomics? US Food & Drug Administration, Rockville, 8/01.

What Clinical Information Is Needed To Place Pharmacogenomic Claims into a Drug Label? Conference on: SNPs for Disease Association & Drug Response: Creating Medical Value Through SNPs. Global Business Research, San Diego, 3/00.

Translating Pharmacogenomic Claims into Drug Labeling & Market Advantage: Clinical Methodologies & Issues. (Also Panel Discussion "Impact of Pharmacogenomics - an Industry Perspective.") PHARMACOGENOMICS IMPACT Meeting: Center for Business Intelligence, San Francisco, 12/99.

Pharmacogenomics: "What is the unmet need for the Drug Industry?" In: Applying Genetics in Drug Development to Maximize Success & Market Potential of New Pharmaceuticals. IBC, Boston, 7/99.

Developing Botanical Medicines to US IND / NDA Standards

Scrutinizing Herbal Medicines: What have we learned in the last millennium, century, and decade? Princeton Medical History Society, 5/04.

Experiences and Lessons-Learned in Developing Botanical TCM Products to FDA's IND-NDA Standards. Bio-2001: US-Taiwanese Scientists Annual Meeting, Newark, 11/01.

Alternative Medicine & Herbal Remedies: Can they be developed to modern evidentiary standards? American Academy of Pharmaceutical Physicians (AAPP), Regional Meeting at SmithKline Beecham, Philadelphia, 9/99.

Developing Herbal Medicines up to Modern Pharmaceutical Standards of Evidence. (Part of Covance Laboratories Workshop), Nutracon: Annual Meeting, Las Vegas, 7/99.

Evaluating Botanicals by Modern Standards: Principles & Lessons: in: Nutritional Supplements in Managed Care. DIA, Washington, DC, 3/99.

RECENT PAPERS, BOOK CHAPTERS

Wardell William, Vodra William, Jones Judith K, and Spivey Richard, **Evolution and Future Prospects of Pharmaceutical Industry Regulation.** Chapter 12 in: **Handbook of Pharmaceutical Public Policy,** Thomas R. Fulda and Albert I. Wertheimer (Editors). Pharmaceutical Products Press, Binghamton, NY, 2007.

Wardell William, Baumbauer Eberhard, [Review of] Arthur A. Daemmrch, **Pharmacopolitics: Drug Regulation in the United States and Germany**. In *The International History Review*, XXVIII, 2, June 2006.

Spivey Richard N, Jones Judith K, Wardell William, Vodra William. **The US FDA in the Drug Development, Evaluation and Approval Process**. Chapter 21 in: *The Textbook of Pharmaceutical Medicine 5th Edition*, Griffin John P, O'Grady John (Editors), BMJ Books, London, 2006.

Wardell William, Vodra William, Jones Judith K, Spivey Richard N. **Past Evolution and Future Prospects of the Pharmaceutical Industry and Its Regulation in the USA**. Chapter 22 in: *The Textbook of Pharmaceutical Medicine 5th Edition*, Griffin John P, O'Grady John (Editors), BMJ Books, London, 2006.

Wardell, William, **Approaching Sources of Funding for Product Development, & How To Avoid Clinical Failure in Small Company and Biotech Drug Development**, First International Symposium on Translational Clinical Research for Inherited and Orphan Diseases, sponsored by the National Neurovision Research Institute, **Supplement to RETINA**, 2005

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