



James E. Shepard, Founder

NORTH CAROLINA CENTRAL UNIVERSITY SCHOOL OF LAW
The Biotechnology and Pharmaceutical Law Institute and Law Review
4th Annual Symposium
Friday, March 19, 2010
North Carolina Biotechnology Center

**HOT TOPICS AND DEVELOPMENTS IN BIOTECHNOLOGY AND
PHARMACEUTICAL LAW**

AGENDA

- 8:30 – 9:00** **REGISTRATION AND BREAKFAST**
- 9:00 – 9:15** **OPENING REMARKS**
- **Kenneth R. Tindall, Ph.D.**, Senior Vice President, Science and Business Development, North Carolina Biotechnology Center
 - **Raymond C. Pierce**, Dean, North Carolina Central University School of Law
- 9:15 – 9:20** **INTRODUCTION**
- The Biotechnology and Pharmaceutical Law Review
- 9:20 – 10:05** **KEYNOTE ADDRESS**
- **David Cade**, Acting General Counsel, United States Department of Health and Human Services
- 10:05 – 10:20** **REFRESHMENT BREAK**
- 10:20 – 11:40** **PANEL DISCUSSION: PATIENT FOCUSED AND PUBLIC HEALTH PANEL**
- Mark Hall**, Professor, Wake Forest University School of Law
Harold Eustache, Sr., Managing Partner, Eustache & James LLP, Health Law Firm
Mark Shapiro, M.B.A., Director of Clinical Solutions, Clinipace
Bill Christopher, Assistant General Counsel, R&D Legal Operations, GlaxoSmithKline
- MODERATOR:** **Anne M. Akwari, M.D., J.D.**, A.M. Akwari, LLC
- 11:40 – 11:55** **REFRESHMENT BREAK**
- 11:55 – 1:05** **PANEL DISCUSSION: ISSUES RELATED TO DEVELOPMENTS WITHIN SCIENCE AND INTELLECTUAL PROPERTY**
- T. Robert Rehm**, Partner, Smith, Anderson, Blount, Dorsett, Mitchell, & Jernigan, LLP
Shawna Lemon, Ph.D., J.D., Shareholder, Myers Biegel Sibley & Sajovec, P.A.
Li-An Yeh Ph.D., Director, BRITE, North Carolina Central University
Bernard Brown II, Ph.D., Patent Agent, Womble Carlyle Sandridge & Rice, PLLC
Edward Ergenzinger, Jr., Ph.D., J.D., Director of Intellectual Property, Duke Human Vaccine Institute
- MODERATOR:** **Deborah H. Spencer**, Associate, Moore & Van Allen PLLC
- 1:05 – 1:35** **Luncheon Speaker TBA**
- 1:35 – 2:00** **CLOSING REMARKS**

PRESENTATION ABSTRACTS

PANEL 1 MEMBERS:

Mark Hall:

Paying more for clinical research than the cost of doing the work may create a conflict of interest that could lead to overzealous recruitment, putting participants and scientific integrity at risk. Thus, various policies prohibit “finder’s fees” simply for recruiting patients, but paying actual costs for research is permissible. While industry-sponsored research routinely pays for the costs of each patient enrolled, the line between reasonable and excessive costs merits further explanation.

Harold Eustache:

This presentation will provide an update on Federal Privacy and Security of Health Records; How the HITECH Amendment Modified HIPAA for the Electronic Age.

Mark Shapiro:

Innovation in biotechnology depends on the willing participation of human subjects in medical research. A global network of legal, regulatory, and ethical protections have been put into place to protect human subjects and, for the last one hundred years, these protections have evolved at an increasingly rapid pace. My goal is to: review the role of human subjects in drug development, discuss the current factors driving changes to human subject protections, and describe how these factors affect businesses performing medical research.

Bill Christopher:

The FDA Amendments Act of 2007 included significant expansions of federal requirements to make publicly available certain information on clinical trials, and established penalties for noncompliance. An overview of the requirements of FDAAA Title XIII will be provided, along with discussion of topics for future rule-making.

PANEL 2 MEMBERS:

Robert Rehm:

This presentation will provide (i) a brief history of the jurisprudential evolution of the Patent Statute's "written description" and "enablement" requirements, which heretofore have been considered separate requirements for securing a patent; (ii) a discussion of *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, 560 F.3d 1366 (Fed. Cir. 2009) in view of that history; and (iii) a look at the possible impact on patent prosecution and litigation practice, and inventive activity in the biopharmaceutical field, of the merging of the two requirements into a single, enablement-type requirement.

Dr. Shawna Lemon:

Patent Filing Strategies in a Down Economy: The decision regarding the subject matter upon which to file a patent application and when can be challenging under normal circumstances. This decision is particularly challenging during a down economy. This presentation will address issues that should be considered when undertaking the patenting process including technical and business concerns and aspects of U.S. and foreign patenting.

Dr. Li-An Yeh:

This presentation will provide a discussion on the unique challenges surrounding the protection and commercial development of novel technologies emerging from Institutes such as the Biomanufacturing Research Institute and Technology Enterprise (BRITE) that have dual missions of research and teaching.

Dr. Bernard Brown II:

This presentation will provide a discussion on DNA Patents with regard to the potential impacts of the currently pending case *Association for Molecular Pathology, et al. v. United States Patent and Trademark Office, et al.*, ___ F.Supp.2d ___, 2009 WL 3614434 (S.D.N.Y. 2009) (a/k/a *ACLU v. Myraid Genetics*) (order denying defendant’s motion to dismiss).

Dr. Edward Ergenzinger, Jr

This presentation will provide a discussion on developments in patent form legislation.

Keynote Address Speaker

David S. Cade

DHHS Acting General Counsel



Mr. David S. Cade was appointed Acting General Counsel of the United States Department of Health and Human Services on January 20, 2009. As Acting General Counsel, Mr. Cade serves as the highest career official in the Office of the General Counsel and chief legal advisor to the Secretary. He oversees a staff of more than 500 attorneys and staff, and provides leadership on many issues of critical importance to the Department requiring ongoing legal counsel, such as the response to the H1N1 flu outbreak, pending health care reform legislation, food and product safety and tobacco regulation, Medicare and Medicaid reform and fraud and abuse prevention. Prior to his appointment as Acting General Counsel, Mr. Cade served as Deputy General Counsel.

Mr. Cade previously served as Director of the Family & Children's Health Programs Group in the Health Care Financing Administration (HCFA), now known as the Centers for Medicare & Medicaid Services (CMS). As Director, Mr. Cade was responsible for the health care services and delivery systems serving families and children. In this capacity, he directed the activities of the Group in establishing program policies, including: Medicaid payment and eligibility policy, Medicaid managed care, 1115 demonstrations, Drug Rebate, Children's Health, hospital and health center surveys, and the Federal Clinical Laboratory Improvement Act (CLIA).

Mr. Cade has also served as Acting Deputy Director of HCFA's Medicaid Bureau, where he was responsible for personnel and financial management, policy development, legislative and regulatory activities, and budget development.

Before joining HCFA, Mr. Cade served for eleven years in the Office of the General Counsel's Health Care Financing Division where he provided legal counsel to the Secretary and the Administrator and represented the Department before Congress, the States, federal courts and other federal agencies regarding the interpretation, application and enforcement of the Medicaid and Medicare laws. Moreover, he was the primary legal advisor to HCFA and the Department on state Medicaid payments, disproportionate share hospital payments, living wills requirements, state financing and taxation, federal audits, and state health care reform issues. He also served as the General Counsel's representative to the White House Task Force on Health Care Reform, where he developed new integrated health care delivery systems and worked to modify the Federal Anti-trust rules.

Mr. Cade received his bachelor's degree from the College of William and Mary and his J.D. degree from the University of Maryland School of Law. He is a member of the Pennsylvania and District of Columbia Bars.

Panel Discussion 1: Patient Focused and Public Health

Moderator

Anne Micheaux Akwari, M.D., J.D.

A.M. Akwari, LLC



Dr. Anne Micheaux Akwari is a medical educator and coach. Her company holds conferences that teach practicing physicians communication skills for use with patients and staff. She coaches medical practitioners one-on-one, teaches at Duke Medical School, and consults with medical specialty organizations on six accepted competencies, or standards, required for medical training and practice. Anne is experienced in hematology, hematopathology (hee-MA-to-path-OL-ogy), and occupational & environmental medicine. She was a senior medical manager at IBM Corporation, then earned a law degree and predominantly litigated medical device and pharmaceutical products liability cases and mediated state and federal lawsuits.

Panel Members

Mark Hall

Professor, Wake Forest University School of Law



Professor Mark Hall is one of the nation's leading scholars in the areas of health care law and policy and medical and bioethics. The author or editor of fifteen books, including *Making Medical Spending Decisions* (Oxford University Press), and *Health Care Law and Ethics* (Aspen), he is currently engaged in research in the areas of consumer-driven health care, doctor/patient trust, insurance regulation, and genetics. Professor Hall has published scholarship in the law reviews at Berkeley, Chicago, Duke, Michigan, Pennsylvania, and Stanford, and his articles have been reprinted in a dozen casebooks and anthologies. Additionally, he teaches in the MBA program at the Babcock School and is on the research faculty at Wake Forest's Medical School. Professor Hall regularly consults with government officials, foundations and think tanks about health care public policy issues.

Harold Eustache, Sr.

Managing Partner, Eustache & James LLP, Health Law Firm



Mr. Harold Eustache, Sr., a native of Cap-Haitien, Haiti, has over 25 years of direct business experience in the pharmaceutical industry, healthcare consulting and business management. He worked in Marketing and Distribution for the Baby Products Division of Johnson & Johnson, in Pharmaceutical Sales and Account Management for Wyeth, Bristol-Myers Squibb and IVAX pharmaceuticals. For 5 years, Mr. Eustache taught a post-graduate continuing education course in pharmaceutical sales at several large universities such as the University of North Carolina at Charlotte, North Carolina State University in Raleigh, and the University of Texas at Austin. Mr. Eustache returned to school at the age of 50 years to earn a law degree from the North Carolina Central University School of Law in July 2007. He was admitted to the Maryland Bar in December 2007 and immediately began practicing in his field of experience and expertise, healthcare/pharmaceuticals.

Mr. Eustache is married with three adult children one of whom is also an attorney with the law firm of Hunton & Williams in Charlotte, North Carolina. Mr. Eustache has published in the *Maryland Bar Journal* on health law issues (Nov. 2009) and has been the keynote speaker at Charlotte, North Carolina at the naturalization ceremonies five times in the mid 1990's. He was also a frequent editorial contributor for The Charlotte Post, one of the oldest African-American Newspapers in the State of North Carolina.

Mark Shapiro, M.B.A.

Director of Clinical Solutions, Clinipace



Mr. Mark Shapiro has worked in drug development for more than fourteen years. Beginning as a pharmacologist in an NIH-sponsored Doctoral Training Program in Biomolecular Pharmacology, his experience spans virtually all aspects of drug development including: program planning, management of all phases of pre-clinical and clinical research, development of briefing materials and regulatory submissions, and presentations to advisory committees and regulatory agency officials. Immediately prior to joining Clinipace, Mr. Shapiro was a management consultant specializing in pharmaceutical R&D process improvement at Campbell Alliance. Mark received an MBA from the Fuqua School of Business at Duke University. Prior to business school, he led the operations of a drug safety research center at the Duke University School of Medicine.

Bill Christopher

Assistant General Counsel, R&D Legal Operations, GlaxoSmithKline



Mr. Bill Christopher is Assistant General Counsel, R&D Legal Operations at GlaxoSmithKline. Mr. Christopher supports GlaxoSmithKline's global R&D organization on major areas of regulatory operations and business concerns, including issues such as FDA financial disclosure, data transparency, clinical trial regulations, human subject protection regulations, privacy, anti-kickback law, and R&D contracts.

Mr. Christopher joined GlaxoSmithKline in 1996 following private practice in the health care law field. He has a Bachelor of Science degree in Chemistry from Northwest Missouri State University (1984), and worked in the pharmaceutical industry for six years as a medicinal chemist. He received his Juris Doctor degree from the University of North Carolina at Chapel Hill in 1993.

Panel Discussion 2: Issues Related To Developments Within Science & Intellectual Property

Moderator

Deborah “Debby” H. Spencer

Associate, Moore & Van Allen



Debby Spencer currently concentrates her practice in intellectual property with a focus on patent drafting and prosecution. She has significant patent experience and is registered before the United States Patent and Trademark Office. Ms. Spencer’s patent practice spans a broad spectrum of technologies, including the biotechnology, bioinformatics, medical device, mechanical, and computer software arts as well as the business method arts.

Prior to law school, Ms. Spencer worked as a research scientist at the University of Virginia, University of North Carolina at Chapel Hill, Glaxo Wellcome, and at a start-up biotechnology company in Research Triangle Park, NC. While at the start-up biotechnology company, Ms. Spencer implemented a novel system for utilizing robotic technology to create a fully automated genetic screening assay for plants. Ms. Spencer additionally worked as a patent agent at the start-up biotechnology company, where she specialized in drafting and prosecuting patents in the biotechnology, bioinformatics, bioagriculture, imaging technology, computer software and business method arts.

Panel Members

T. Robert Rehm, Jr.

Partner, Smith, Anderson, Blount, Dorsett, Mitchell, & Jernigan, LLP



Mr. T. Robert Rehm, Jr. is a partner at Smith Anderson and practices primarily in the areas of technology licensing and commercialization and the acquisition, licensing, and protection of intellectual property rights. An important part of his practice involves helping health care clients integrate software-based technologies, including those directed to electronic health records, into their respective practices and counseling such clients in connection with privacy and HIPAA-related issues. Mr. Rehm’s experience includes drafting and negotiating a wide variety of license, assignment, confidentiality, joint venture, alliance, and other types of collaborative agreements directed to technology commercialization; prosecution of trademark and copyright registration applications before the United States Patent and Trademark Office and United States Copyright Office, respectively; counseling in connection with patent-related matters and the intellectual property and privacy law aspects of mergers, acquisitions, development of pharmaceutical and medical devices and products, and other commercial transactions; and counseling in connection with issues relating to the legal/engineering interface in construction-related transactions and disputes. Prior to joining Smith Anderson, Mr. Rehm practiced in the Washington, D.C. area at two international law firms, Hogan & Hartson LLP and Steptoe & Johnson LLP, in the areas of patent, trademark, copyright, and antitrust law with particular emphasis on technology licensing and commercialization, patent litigation and licensing, and intellectual property counseling. Mr. Rehm was a practicing electrical engineer for sixteen years prior to embarking on a legal career.

Mr. Rehm received his J.D. from Cumberland School of Law of Samford University in 1993 and graduated magna cum laude. He received his M.B.A in 1990 from the University of Alabama at Birmingham. Mr. Rehm received his B.S from the University of Notre Dame in 1971 and graduated summa cum laude.

Shawna C. Lemon, Ph.D., J.D.

Shareholder, Myers Biegel Sibley & Sajovec, P.A



Dr. Shawna C. Lemon is a shareholder with Myers Bigel Sibley & Sajovec, PA in Raleigh, NC where she is also the chairperson of the Chemistry/Biotechnology practice group. Dr. Lemon received her Bachelor of Science Degree in Biology from Wofford College and her Doctorate in Biomedical Sciences (with a concentration in pharmacology) from the University of South Carolina School of Medicine. Additionally, she received her Juris Doctor Degree from the University of North Carolina at Chapel Hill, and has been practicing patent law since 2001. Dr. Lemon is co-author of several publications regarding the possible regulatory role in exocytosis of a novel G protein-activated potassium current in bovine adrenal chromaffin cells (*Molecular Pharmacology*, 1996, 1994 and *Neuroscience Abstracts*, 1994). Prior to her legal career, Dr. Lemon worked in pharmaceutical market development at Merck & Co., Inc.

Dr. Lemon is a member of the North Carolina Bar. She focuses her practice on the preparation and prosecution of patent applications and due diligence in the pharmaceutical and biotechnological fields as well as provides counseling in trademark protection. Moreover, Dr. Lemon served as Co-chair of the Biotechnology and Chemical Patent Practice Subcommittee of the Intellectual Property ("IP") Section of the North Carolina Bar Association, 2004-2005 and 2006-2007.

Li-An Yeh, Ph.D.

Director, BRITE, North Carolina Central University



Dr. Li-An Yeh received her Ph.D. degree at Purdue University in Biochemistry in 1980. She then gained three years of post-doctoral experience at Harvard University. Dr. Yeh started her drug discovery research career in R&D at Pfizer Central Research in 1984. From 1992 to 2001, she worked as a scientific director for three biotechnology companies including OsteoArthritis Science, Phytera, Inc., and NEN-Life Science. In 2001, Dr. Yeh joined the Laboratory for Drug Discovery in Neurodegeneration (LDDN) as the Director of Lead Discovery at Brigham and Women's Hospital, a teaching affiliate of Harvard Medical School. In 2004, she was recruited by Eli Lilly as a Research Advisor in Lead Generation Biology. In June 2005, Dr. Yeh became the Director of BRITE (Biomanufacturing Research Institute and Technology Enterprise) and Professor of Pharmaceutical Sciences at North Carolina Central University.

Dr. Yeh's research experience in drug discovery included neurodegeneration, diabetes, anti-ulcer, osteoporosis, osteoarthritis, infectious diseases (anti-viral, anti-fungal and anti-microbial), and cancer. Her current research focuses on drug discovery in diseases related to neurodegeneration. Dr. Yeh is currently establishing a new academic program at BRITE. The mission of this program is to educate students to have scientific competence to work in the pharmaceutical and biomanufacturing industries at the undergraduate, graduate, and eventually doctoral levels. The BRITE center also has an established research program in drug discovery and drug biomanufacturing. Additionally, Dr. Yeh has published forty papers in peer review journals and held several patents.

Bernard A. Brown II, Ph.D.

Patent Agent, Womble Carlyle Sandridge & Rice, PLLC



Dr. Bernard Brown is a registered patent agent in the Biotechnology, Chemical, and Pharmaceutical Patent practice group of Womble Carlyle's Winston-Salem office. His practice includes preparing and prosecuting U.S. and foreign patent applications, reexaminations, freedom to operate analyses, invalidity, and non-infringement opinions. Dr. Brown's technical expertise is in biochemistry, immunology, molecular biology, and chemistry related to biotechnological, chemical, and pharmaceutical technologies. Moreover, Dr. Brown received his bachelor and doctoral degrees from North Carolina State University. His doctoral thesis involved generating monoclonal antibodies that recognized multi-stranded DNA complexes. Dr. Brown received a patent based on this research, which prompted his interest in patent law. As a postdoctoral fellow at the Massachusetts Institute of Technology, he investigated proteins that recognized left-handed "Z-DNA" and "Z-RNA" using biophysical methods and X-ray crystallography.

Prior to entering the legal field, Dr. Brown was an Assistant Professor of Biochemistry and Chemistry in the Chemistry department at Wake Forest University. In addition to teaching undergraduate and graduate biochemistry and chemistry, Dr. Brown managed a research lab that was funded by the National Institutes of Health and the American Cancer Society. He and his research associates used a variety of biochemical techniques and X-ray crystallography to investigate protein-RNA interactions in ribosomal RNA modification and ribosome assembly. Dr. Brown has published over 20 scientific articles and given many oral and poster presentations. He is currently a 3L at Elon University School of Law and Business Editor of the *Elon Law Review*. Additionally, Dr. Brown continues to be active in scientific research as a Senior Scientist in the Department of Molecular and Structural Biochemistry at North Carolina State University.

Edward Ergenzinger, Jr., Ph.D., J.D.

Director of Intellectual Property, Duke Human Vaccine Institute



Dr. Edward Ergenzinger is Director of Intellectual Property for the Duke Human Vaccine Institute (DHVI) at Duke University School of Medicine. His responsibilities include managing DHVI's patent matters, material transfer agreements, licensing agreements, and collaborative agreements.

Dr. Ergenzinger received a J.D. in 2002, a Ph.D. in Neuroscience in 1999, and a B.A. in Biology & Psychology in 1994, all from Wake Forest University. He has worked in the intellectual property field for over ten years, focusing on issues relating to biotechnology and pharmaceuticals. Dr. Ergenzinger is lead author or co-author on numerous scientific and legal publications in such venues as *Nature Neuroscience*, *Legal Times*, *The Scientist*, and *Stanford Technology Law Review*. He has also served as an adjunct professor at Wake Forest University School of Law and has taught a number CLE courses on patent law topics.