AUTM 2006 Educational Track Session & Networking Event

Date & Time: Thursday, March 2, 2006, 10:30 am to 5:00 pm Venue: Disney's Yacht & Beach Club Resorts, Orlando, Florida

Session Chair: Usha Balakrishnan, MIHR-USA & Founder, Technology Managers for Global Health (TMGH), an AUTM Special Interest Group TMGH Liaisons: (Co-Chair) Gennaro Gama, University of Georgia (Session Recorder) Karen Blochlinger, Seattle Biomedical Research Institute

Session Title: Licensing to global product development partnerships (PDPs)

10:35 am: Opening Remarks, Usha Balakrishnan

Overview of Global Product Development Partnerships (PDPs) 10:40 am: Charles Gardner, The Rockefeller Foundation

Panel 1: Variations in licensing approaches and deal structuring with PDPs Moderator: Sandy Shotwell, Alta Biomedical 11:00 am: Rita Khanna, Aeras Global TB Vaccine Foundation 11:15 am: Labeeb Abboud, International AIDS Vaccine Initiative 11:30 am: Linda Nyari, PATH 11:45 am: Pat Vaughan, Population Council

12:00-1:00 pm Lunch break

Panel 2: Making the "business case" to encourage product development
Moderator: Gennaro Gama, University of Georgia
1:00 pm: Katherine Woo, Institute for OneWorld Health
1:15 pm: Greg Graff, PIPRA
1:30 pm: Robert Johnston, Global Vaccines
1:45 pm: Paul Model, (attorney/consultant to) International Partnership for Microbicides

<u>Panel 3: Training Curricula, Case Studies, Regional Global Health TT Forums</u>
Moderator: Rachelle Harris, MIHR
2:00 pm: Lita Nelsen, MIT
2:15 pm: Carol Mimura, University of California at Berkeley
2:30 pm: Cale Lennon, Emory University

2:45-3:00 pm: Inviting New Ideas, Discussing Next Steps: Usha Balakrishnan

3:00-5:00 pm: Q&A, networking

Session Summary

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"Licensing to global product development partnerships (PDPs)"

Global product development partnerships (PDPs) are programs that involve public (governmental and publicly-funded international agencies) and private actors (drug development companies, and privately-funded philanthropic organizations). PDPs focus on global health challenges to development of treatments for so-called neglected diseases which are not being addressed by the usual private or public channels alone.

Since nearly half of all the PDP deals are with universities, the objective of this session is to familiarize the university technology transfer professionals with the strategies and challenges of PDPs, and how to work with them. Professionals from PDPs will provide insight from their experiences dealing with university managers and share information about their policies and procedures and resources in identifying, selecting, and assisting with the development of products for neglected diseases and other global issues. Several university managers will share their experiences and highlight some key points to appreciate and consider when working with PDPs. Information will also be provided about new initiatives being launched with financial support from private foundations to enhance the collaborative activities of PDPs and universities.

Session learning objectives

- What was the rationale for the funding and formation of PDPs?
- How are PDPs aiding in addressing drug development challenges in global health?
- What are PDPs' and universities' concerns in license agreements as they strive to increase availability, affordability, and access to new medicines for diseases afflicting millions of the poorer populations in developing countries?
- What are some of the issues encountered during deal-making between PDPs and universities, e.g. "access to the poor" provisions, royalty rates, milestones, timelines, etc.?
- What are some of the lessons from case studies and deals structured between universities and PDPs and/or consortia arrangements?
- What are some specific patent management strategies and valuations relating to PDPs' products?
- What are some ways in which university managers and PDP officials can jointly engage to raise awareness, enhance global health licensing/deal flow, and collaborate in new ways?

Handouts to be distributed at the session

- Biosketches of moderators and speakers
- Copy of presenters' slide presentations, including accompanying literature
- Rockefeller Fndn report: Partnering to Develop Products for Diseases of Poverty
- MIHR Handbook of Licensing Practices (CD)
- Summary of results of 2005 Global Health & TT survey of AUTM members
- List of references on topics relating to global health and technology transfer

SPEAKER BIOSKETCHES

AUTM 2006 Educational Track Workshop titled Licensing to Global Product Development Partnerships

Labeeb Abboud is the General Counsel for the International AIDS Vaccine Initiative (IAVI), headquartered in New York. IAVI (www.iavi.org) is a global not-for-profit organization working to speed the search for a vaccine to prevent HIV infection and AIDS. Founded in 1996 and operational in 23 countries, IAVI and its network of partners research and develop vaccine candidates. IAVI also advocates for a vaccine to be a global priority and works to assure that a future vaccine will be accessible to all who need it. IAVI's major financial supporters include the Bill & Melinda Gates Foundation; the Rockefeller, Starr and Sloan foundations; the World Bank; BD (Becton, Dickinson & Co.); the European Union; and the governments of Canada, Denmark, Ireland, the Netherlands, Norway, Sweden, the UK and the US.

Labeeb joined IAVI with a wide range of experience in the private and non-profit sectors. Prior to joining IAVI, Labeeb served as General Counsel to Atriax, a London-based electronic marketplace for foreign exchange products and related services. Previously he was Group Counsel to American Express Bank, Ltd., where he was responsible for supporting the international private bank and asset management divisions, as well as a wide range of transactional and regulatory work. He also worked as a corporate attorney with Shearman & Sterling, and with Curtis, Mallet-Prevost, Colt & Mosle, in New York. In the non-profit sector, Labeeb has worked as a legal and business consultant, primarily in the areas of the environment and microfinance, and has also provided *pro bono* legal support to a wide range of non-profit organizations. He is currently Vice Chairman of the Rainforest Alliance, a director of Shackleton Schools, and a member of the Council on Foreign Relations. He is a graduate of Wesleyan University and Georgetown University Law Center.

<u>Usha Balakrishnan</u> is a Founding Board Member and the first Executive Director of MIHR-USA (www.mihr-usa.org), a 501 c 3 nonprofit entity incorporated in Iowa City, Iowa in August 2005. MIHR-USA represents the US operational base of MIHR (www.mihr.org), a global nonprofit headquartered in Oxford, United Kingdom.

Usha and a rapidly increasing number of colleagues are involved in reaching out to and mobilizing technology managers and other professionals in a variety of sectors to find new ways to promote the development of health product innovations that address needs of poorer populations in developing countries. Her efforts as a founder of the Technology Managers for Global Health (www.tmgh.org), a special interest group within AUTM, were accelerated with a Rockefeller Foundation grant in 2004. Usha has introduced global healthrelated academic tech transfer sessions at key conferences: AUTM (since 2003), Biotechnology Industry Organization (2005), Licensing Executive Society (2005), and Global Health Council (2006). Through her presentations on these topics, she has spurred dialog and seminars on a number of campuses in the US and abroad. Usha's diverse interests - in fostering interdisciplinary connections between the health and engineering sciences, social sciences, and humanities to address emerging societal issues -- arise from her 15 years of progressively responsible professional work at the University of Iowa (most recently as Director of Corporate Partnerships) and her past service on numerous boards including the Iowa Economic Development Board (gubernatorial appointee, 2001-2005), the Iowa Biotechnology Association Board and the Iowa Business Council's Deputy group. Usha has conceptualized and launched complex multi-sector alliances; initiated an eclectic set of research collaborations with university faculty in the US and abroad; designed US-India bilateral exchanges and symposia; evaluated hundreds of academic discoveries for patentability and commercial potential; negotiated patent licenses with pharmaceutical and biotechnology companies; and advised small business owners and high-technology entrepreneurs. Usha currently serves on the AAAS (American Association for the Advancement of Science) Committee on Scientific Freedom and Responsibility; and the University of Iowa Global Health Studies Steering Committee. She is on the Board of Directors of the Community Foundation of Johnson County. Usha received her MBA (1988) from the University of Iowa and her Bachelors in Commerce (1985) from Bombay University, India.

Karen Blöchlinger is patent counsel at the Seattle Biomedical Research Institute (SBRI). SBRI (www.sbri.org) is the largest independent, non-profit organization in the United States focused solely on infectious disease research. The mission of SBRI's nearly 200 employees is to eliminate the world's most devastating infectious diseases through leadership in scientific discovery. Founded in 1976, SBRI's research targets the world's most underserved populations: the 14 million people who die each year from diseases such as malaria, HIV/AIDS and tuberculosis as well as other lesser known, but equally deadly diseases, including African sleeping sickness, Chagas disease and leishmaniasis. SBRI's discoveries are the basis for new diagnostics, drugs and vaccines that provide long-term solutions to the world's biggest health problems.

Before going to law school, Karen was a member of the Basic Sciences Division at the Fred Hutchinson Cancer Research Center studying the development of the nervous system using fruit flies as a model system. After law school, she worked at Christensen, O'Conner, Johnson & Kindness before joining SBRI.

Gennaro Gama is a Technology Manager with the University of Georgia Research Foundation, Inc. (UGARF) a non-profit organization charged with protecting and commercializing technologies developed at The University of Georgia. Prior to joining UGARF, Gennaro was a Technology Manager at the University of Pennsylvania's Center for Technology Transfer, where he managed a portfolio comprised of nanotechnologies and materials. Gennaro obtained a B.Sc. (Chemistry) from the Universidade Federal de Minas Gerais (Brazil) and a Ph.D. in Chemistry from Indiana University-Bloomington. He was a postdoctoral fellow at Georgetown University in Washington, DC where he worked on lanthanide and actinide chemistry with a goal on nuclear waste remediation and at the University of Pennsylvania where he worked on the synthesis of chiral catalysts. His current duties include the management of technologies developed at UGA's Center for Tropical and Emerging Global Diseases and Center for Infectious Diseases. Gennaro is a member of AUTM, LES, American Chemical Society, and Georgia Bio.

Charles Gardner is an Associate Director at the Rockefeller Foundation (www.rockfound.org). He manages a program within the Health Equity division that has provided "social venture capital" to create and support public-private partnerships (PPPs) to accelerate the development of drugs and vaccines against diseases of the poor. The program now focuses on (1) sustainability of product development PPPs, and (2) ensuring product availability and adoption within disease endemic countries. From 1998 to 2003, Chad served as the Official Representative of the U.S. Department of Health and Human Services to South Asia with the title of Science Attaché at the U.S. Embassy in New Delhi. Prior to 1998, he was the Program Officer for Africa, the Middle East and South Asia at the Fogarty International Center, U.S. National Institutes of Health. He also taught bioethics as an Assistant Professor at Howard University, Washington DC. From 1991 to 1992, Chad served on the staff of the House Government Operations Committee, U.S. Congress, with fellowship support from the American Society for Microbiology under the Congressional Science Fellowship program managed by the American Association for the Advancement of Science. Chad received his Ph.D. in Cell, Developmental and Neurobiology from the University of Michigan in 1991; his dissertation focused on gene expression and pattern formation in the early embryo.

<u>Gregory Graff</u> helped to create the Public Intellectual Property Resource for Agriculture (PIPRA), a consortium of 33 agricultural research universities dedicated to mobilizing its members' technologies globally for the genetic improvement of 'orphan' crops through the collaborative management of intellectual property. PIPRA (www.pipra.org) is an initiative by universities, foundations and non-profit research institutions to make agricultural technologies more easily available for development and distribution of subsistence crops for humanitarian purposes in the developing world and specialty crops in the developed world. PIPRA is headquartered at the University of California at Davis.

Greg currently manages research projects for PIPRA at UC Davis and has taught as a university lecturer at both UC Berkeley and UC Davis. He has published widely on the economics and policy of innovation, entrepreneurship, intellectual property, and technology transfer in the Review of Economics and Statistics, the California Management Review, and Nature Biotechnology. Greg has a Ph.D. from UC Berkeley (2002), an M.A. from Ohio State University (1995), and a B.S. from Cornell University (1992).

Rachelle Harris is Business Development and Research Manager for MIHR (www.mihr.org). She is also Programme Director of the MIHR Programme for Health Innovation (MPHI), working to build capacity in intellectual property (IP) management in health innovation in developing countries. MIHR is an independent Charity registered in the United Kingdom and headquartered in Oxford. MIHR was initiated by the Rockefeller Foundation in 2002 to promote the strategic management of intellectual property to encourage innovation and bring needed health products to the poor in developing countries. MIHR seeks to find constructive ways to promote collaboration among all sectors involved in improving access to needed drugs, vaccines, diagnostics and other important health technologies. With active working partnerships in a number of developing countries, MIHR has undertaken in-country IP management capacity-building programs in Egypt, South Africa, India, East Africa, and Southeast Asia.

Rachelle received an MSc in Technology and Innovation Management at SPRU, University of Sussex, UK, where she focused on issues surrounding pharmaceutical innovation systems, 'neglected diseases', product development partnerships, technology transfer and issues relating to economic development and knowledge flows to the developing world. She has completed two years of work on a PhD thesis at London School of Hygiene and Tropical Medicine, and her research interests continue to lie in the relationship between technology transfer in health R&D and technological upgrading in emerging economies. Prior to joining MIHR, Rachelle has worked in business development and publications management in the charity sector and at the United Nations Information Centre (UNIC), London. In 2004, she was an intern at the US NIH Office of Technology Transfer. She has consulted to Rolls Royce Plc and British Technology Group Plc, where she participated in patent portfolio analyses and evaluation of commercialization routes and infringements. Rachelle has also consulted to the Intellectual Property Institute (IPI), London.

Robert Johnston is the Executive Director of Global Vaccines, a nonprofit organization based in North Carolina. Global Vaccines (www.globalvaccines.org) was established by a group of successful vaccine researchers and biotechnology entrepreneurs to address the lack of progress against the disease burden of the developing world. Global Vaccines is a not-for-profit company established to provide a new generation of vaccines for diseases prevalent among people who live in poor countries. This company is technology based, seeking to leverage newly discovered vaccine technologies into a self-sustaining, not-for-profit business enterprise. The initial product focus will be on human immunodeficiency virus and dengue fever virus with expansion to other vaccine targets.

Bob is also a professor of microbiology and Director of University of North Carolina-Chapel Hill's Carolina Vaccine Institute. He is an internationally recognized expert in viral genetic and vaccine development, having worked notably on the modification of alphaviruses for use as vaccine vectors. In 1997 he was a co-founder of AlphaVax, a biotechnology company devoted to developing vaccines based on vectors, which he and others derived from the Venezuelan Equine Encephalitis virus. A prototype vaccine against HIV based on this technology is currently undergoing Phase I testing in the USA and South Africa. He served as CEO and Chairman of the Board and as a consultant to the company, resigning in 2001 to establish GVI. Bob is on the editorial board of Virology, and he shared the 2001 World Technology Award for Health and Medicine. **<u>Rita Khanna</u>** is currently the Legal Counsel for Aeras Global TB Vaccine Foundation and head of International Technology Transfer Management Consulting based in Maryland, USA. Aeras (www.aeras.org) was founded in 1997 to help develop new concepts and tools to control the global TB epidemic. Today the organization focuses solely on developing new vaccines against TB and ensuring their availability to all who need them. In February 2004, Aeras received a 5-year US\$82.9 million grant from the <u>Bill & Melinda Gates</u> Foundation for new TB vaccine development and recently received funding from the U.S. Centers for Disease Control and Prevention and the Government of Denmark. It is the goal of Aeras to develop, test, characterize, license, manufacture and distribute at least one new TB vaccine within 10 years.

Prior to joining Aeras, Rita was the Director of Technology Transfer at the University of Maryland Biotechnology Institute (UMBI) where she was responsible for management and licensing of intellectual property, assessment of the commercial potential of inventions, negotiation of IP related agreements, and start up initiatives. Before coming to UMBI, Rita worked at the National Institutes of Health (NIH) where she was involved in the assessment of inventions for their commercial potential and strategic licensing, and was involved in processing and negotiation of a wide range of agreements between NIH and pharmaceutical companies, universities and foreign governments. During this period she also engaged in the negotiation of agreements for procuring natural products from foreign countries/institutions and for distribution of these materials to interested parties. Before coming to NIH, Rita worked at the law firm of Venable, Baetjer and Howard where she was involved with patent prosecution, trademarks and copyrights. In addition to her technology transfer and legal experience, she has many years of research experience in both academia and private industry. Rita received her Ph.D. in Biology from the University of Illinois, her J.D. from the University of Maryland Law School and is a member of the Maryland Bar. She has published many articles in peer-reviewed journals. She has received many professional awards, was a member of various committees and has been an invited speaker at many national and international conferences. She was Co-Chair of the first Gordon Conference on technology transfer titled "Global Aspects of Technology Transfer: Biotechnology."

<u>Cale Lennon</u> is currently the Assistant Director at Emory University's Office of Technology Transfer. Prior to joining Emory, he was in the Office of Technology Transfer and Business Development at Tulane University in New Orleans. During his tenure at Tulane, he held positions as senior licensing associate, associate director, and interim executive director. While at Tulane, Cale organized and obtained funding for the Technology Innovation Gap Fund a seed fund to support prototyping and proof-of-principle for early stage technologies. He earned his Ph.D. in genetics and molecular biology in 1999 from Emory University where he investigated *in vivo* transcription elongation. Cale holds a bachelor in science in aerospace engineering from the University of Virginia. He was previously a mechanical design engineer at United Technologies Pratt & Whitney where he designed jet engine hardware for the F/A 22 Raptor fighter.

Carol Mimura is the Assistant Vice Chancellor for Intellectual Property & Industry Research Alliances (IPIRA) at the University of California, Berkeley and the immediate past Executive Director of U.C. Berkeley's Office of Technology Licensing. IPIRA is the portal to Berkeley for industry access to Berkeley's preeminent faculty and research capabilities. Carol has a B.S. degree from Yale University in Molecular Biophysics and Biochemistry and a Ph.D. in Biology (biochemistry & microbiology concentration) from Boston University. She was an NIH-sponsored postdoctoral fellow and research scientist at U.C. Berkeley in Biochemistry and in Chemical Biodynamics. She is a Director of the Children's Hospital Research Institute in Oakland and served as a board member (the Chancellor's alternate) of BayBio, the regional voice of biotechnology in Northern California. She is an advisory board member of a USDA-funded initiative on "University-Industry Relationships" and a steering committee member of PharmaSTART, a drug development consortium at SRI International founded by four California-based research universities, including UC Berkeley. Prior to her positions at Berkeley, Carol was an analyst at Technology Forecasters, a consultant to Cor Therapeutics and Genomyx, and wrote for the Genetic Engineering News.

Paul Model is an attorney in private practice in New York City. Paul has extensive experience in the fields of drug development, medical technology, and the formation and financing of companies in the fields of pharmaceuticals, biotechnology, and medical devices. His clients include the International Partnership for Microbicides. Paul is a graduate of Hampshire College and Harvard Law School. He is a member of the New York bar.

Lita Nelsen is the Director of the Technology Licensing Office at the Massachusetts Institute of Technology, where she has been since 1986. This office manages over 400 new inventions per year from M.I.T., the Whitehead Institute, and Lincoln Laboratory. Lita earned B.S. and M.S. degrees in Chemical Engineering from M.I.T. and an M.S. in Management from M.I.T. as a Sloan Fellow. Prior to joining the M.I.T. Technology Licensing Office, Lita spent 20 years in industry, primarily in the fields of membrane separations, medical devices, and biotechnology, at such companies as Amicon, Millipore, Arthur D. Little, Inc., and Applied Biotechnology. Lita was the 1992 President of the Association of University Technology Managers and serves on the boards of directors of the State of Massachusetts Technology Development Corporation, the Massachusetts Biotechnology Council, the Mount Auburn Hospital, and the Scientific Advisory Board of the Children's Hospital Oakland Research Foundation. She has served as advisor to the NIH, the National Academy of Sciences and the Office of Technology Assessment, and currently serves as the intellectual property advisor to the International AIDS Vaccine Initiative and serves on the Board of Trustees of the Centre for the Management of Intellectual Property in Health R&D (MIHR). She is a co-founder, with David Secher of the University of Cambridge, of Praxis Courses Ltd, the UK university technology transfer program. Lita is widely published in the field of technology transfer and university/industry collaborations was a CMI Fellow at the University of Cambridge WIT Institute studying university/industry/government partnerships in technology transfer and local economic development.

Linda J. Nyari is the Director of Legal Affairs and Division Director, AFH for PATH. PATH (www.path.org) is an international, nonprofit organization that creates sustainable, culturally relevant solutions that enable communities worldwide to break longstanding cycles of poor health. By collaborating with diverse public- and private-sector partners, PATH helps provide appropriate health technologies and vital strategies that change the way people think and act.

Linda's experience of more than twenty-five years in the biotechnology and pharma industry combines a unique blend of law, business and science. Linda's practice has included the representation of clients in the life sciences focusing on corporate transactional matters and intellectual property. Her many years of practice as in-house counsel emphasized intellectual property, including patent preparation and prosecution, technology licensing and general corporate business law representing both small biotechnology companies as well as the large global pharmaceutical companies. Prior to joining PATH, Linda was the Director of Legal Affairs for the Chiroscience Group plc group of companies and VP & General Counsel for US operations. Linda managed extensive patent portfolios, negotiated and managed all corporate transaction matters and advised senior management on general business law. She has held positions of increasing authority in the in-house legal groups of SmithKline Beecham (now GSK), Roche and Syntex and has served as associate general counsel at Abgenix. She has also represented life science and high tech clients as of counsel in the firms of Orrick Herrington & Sutcliffe and Perkins Coie. Linda is admitted to practice in California and Washington and before the USPTO.

Sandra L. Shotwell is Founder and Managing Partner, Alta Biomedical Group (www.altabiomedical.com). Sandy is a senior business consultant with 20 years of experience in technology commercialization, management, regional economic development and spinout company formation. She established and led the National Institutes of Health Technology Licensing Branch, which included responsibility for the Centers for Disease Control and the Food and Drug Administration. She directed the Oregon Health Science University Office of Technology Research and Collaborations, spinning out half a dozen companies. Sandy also served as Technology Licensing Associate for Stanford's Office of Technology Licensing, and worked as an internal technology management advisor to the Director General of the European Union's Joint Research Centre. She co-founded Alta Biomedical Group in 2000, and has worked on a variety of consulting projects for public and private clients in the U.S. and internationally. A former board member for Virogenomics, Inc. and the Association of University Technology Managers, Sandy currently serves on the board of directors of the Stanford OTL Gap Fund, the Oregon Bioscience Association, and the International Sustainable Development Foundation. She did neuroscience research as an undergraduate, graduate and postdoctoral fellow at Princeton University, Caltech and Stanford University.

Patricia C. Vaughan has been the general counsel of the Population Council since November 1997. The Population Council (www.populationcouncil.org) is an international, nonprofit research organization that seeks to improve the well-being and reproductive heath of current and future generations around the world and to help achieve a humane, equitable, and sustainable balance between people and resources. Established in 1952, the Council conducts biomedical, social science, and public health research and helps to build research capacities in developing countries.

Pat is responsible for the legal affairs of the Council's U.S. and overseas operations and is involved in the business and legal aspects of licensing and managing the Council's intellectual properties (IP). Her IP work has included the completion of out-license arrangements with major German, Finnish, Swedish, and U.S. pharmaceutical companies; the sale of intellectual assets; joint research, product development, manufacturing, and in-license agreements with U.S., French, Australian, and Italian companies. She is currently working on projects that involve South African and Indian pharmaceutical companies. A key aspect of her work is ensuring that Population Council drug products and medical devices reach people in the developing world. Pat received her A.B. from Princeton University where she concentrated in the Woodrow Wilson School of Public and International Affairs. She received her J.D. from Columbia University Law School and a business management certification from New York University. Pat is admitted to the New York and New Jersey bars. She is a member of the American Bar Association's Section on IP and Section on Science & Technology, the Association of the Bar of the City of New York, the Licensing Executive Society, and AUTM. Pat is a trustee of the South Mountain Animal Rehabilitation Center and a member of the board of directors of Literacy Volunteers of Westchester County, New York. She is an adjunct lecturer at the State University of New York at Purchase.

<u>Katherine Woo</u> is the Director of Scientific Affairs of The Institute for OneWorld Health (iOWH) which is a nonprofit organization that helps develop safe, effective and affordable new medicines for people with infectious diseases in the developing world. iOWH (www.oneworldhealth.org) is a recipient of funding from donors such as Bill and Melinda Gates Foundation, Skoll Foundation, Chiron Foundation and Vital Spark Foundation. Current programs include activities related to visceral leishmaniasis, diarrheal disease, malaria and Chagas disease.

Katherine evaluates drug leads and technologies submitted to iOWH by universities and companies for potential partnership opportunities. She has more than ten years of experience in biomedical research and research management that spans the fields of development neuroscience, addiction, infectious diseases and entrepreneurship. Most recently, she developed an initiative to encourage public-private collaboration in the rapid translation of research into new HIV therapeutics. Katherine received her Ph.D. from the California Institute of Technology, and Master's and Bachelor's degrees from Cornell University.