Steven Nichtberger, MD
Senior Fellow, Life Sciences & Management Program
Adjunct Professor, Department of Healthcare Management
Capstone Course – LSMP 421

Vision

• Integration of business and science
• Transition from academic to real world

Objectives

• Develop & present integrated plan to finance a healthcare advance
• Understand and develop individual leadership / teamwork behaviors

Experiential and Practical Learning Process

• Groups of 5 students each form a management team
  o team diversity, trust, and transparency are key to success
  o select an opportunity that you can get excited about
  o develop and present an integrated plan to gain financing
Organization and Staffing

Course Director: Steven Nichtberger, MD
• Assistant Course Director: Joan Lau, PhD

Guest Lecturers: Leaders from healthcare industry

Four teams, with substantial support:
- Healthcare MBAs as teaching assistants - leadership / teamwork
- LSM mentors – practical advisors on process
- Scientific advisors
  ▪ Founding scientists for each team
- VC advisors
  ▪ Domain, Flagship, NEA, Osage, others
- Strategic advisors
  ▪ Pharma and biotech executives
- Functional advisors
  ▪ Market research and analysis experts; pharma; biotech; device; regulatory
Approach

Lectures
• By accomplished experts in each functional area
  o preclinical
  o clinical
  o regulatory
  o marketing
  o finance
  o banking
  o investing
  o partnering

Team meetings
• immediately following lectures with experts rotating
• additional team meetings each week as needed
Setting Expectations

• Substantial workload
  o greater in first semester (information) than second (integration)

• Experiential learning with abundant resources to support teams

• Consultations with experts and advisors will be essential
  o ‘networking is key to success’

• Feedback may be conflicting as in the real world
  o Teams will need to determine how to proceed

• Leadership / teamwork behaviors
  o 1st semester – develop conceptual framework / observation
  o 2nd semester – 360 degree feedback and coaching
  o Process
    ▪ Team 360 degree meetings with update to TA’s
    ▪ Individual emails to TAs weekly
    ▪ 1:1 meetings in November and March with TAs and director

• Learning process is iterative
  o Need to optimize and align strategic choices in functional areas
Course Objectives (1 of 2)

Develop and present integrated plan to finance a healthcare advance

1. Understand scientific basis of product – critically review literature
2. Evaluate and understand clinical unmet need that product could fill
3. Identify key attributes of product that can deliver relevant clinical advance
4. Write target product profile, clinical indication, draft development strategies

1. Evaluate the market opportunity and make strategic choices
2. Evaluate pricing and reimbursement challenges and identify drivers, barriers, and key success factors; (evaluate and describe IP strategy)
3. Create transparent assumption based revenue projections (US and ex-US)
4. Create a sound development strategy (preclinical and clinical)
5. Create a detailed clinical development plan for each regulatory phase
6. Create a financial model and develop pro forma with key sensitivities

7. Create a milestone based operating plan that links directly with optimal recommended financing plan to minimize the cost of capital
8. Develop time based valuation and evaluate exit opportunities for investors
Course Objectives (2 of 2)

Understand and develop individual leadership / teamwork behaviors

• Coaching throughout semester
  
  o TA’s are your direct ‘manager’
    ▪ Will attend Friday team meetings, other team meetings as needed, and will collect email impressions from each individual on a weekly basis.
    ▪ Will meet with each of you individually each semester to discuss leadership behaviors and provide feedback and guidance
  
  o My office hours in McNeil - by appointment
    ▪ Friday mornings; will schedule other days if necessary
    ▪ In addition to encouraging you to schedule a meeting with me whenever you feel it could be helpful, each of you will schedule a 1:1 with me after your 1:1 meetings with your TA during November and March.

  o Joan Lau, PhD, assistant course director
    ▪ Always available to provide advice and guidance
Course Overview

• August

  o 30 – Steven Nichtberger, MD
    ▪ Introductions
    ▪ Course overview – philosophy, objectives, approach, syllabus, grading

• September

  o 6 – Steven Nichtberger, MD
    ▪ Leadership behaviors and teamwork: foundational concepts
    ▪ Example of final presentation

  o 13 – No class (Yom Kippur holiday)

  o 20 – Steven Nichtberger, MD
    ▪ ‘A sure thing is not’
      ▪ History of the industry: Project selection criteria
      ▪ Project presentations and selection; team formation

  o 27 – Laura Bessen, MD – Head US Medical, Bristol Myers Squibb
    ▪ ‘A problem well stated is half solved’
      ▪ Developing a target product profile for a new product opportunity
      ▪ Team meetings – develop target product profile; identify info gaps
Course Overview

• October

○ 3 – Assignment due – 1 page summary
  ▪ Problem statement and proposed questions to explore
  ▪ Send TA for your team a copy of your CV / resume

○ 4 – Tony Ford-Hutchinson, PhD – Retired Head Basic Rsrch, Merck
  ▪ Preclinical – targets, chemistry, PK, PD, assays, biologic effects, IP strategy, GLP safety, regulatory requirements to IND
  ▪ Team meetings – implications of talk for team project plans

○ 11 – Break

○ 18 – Keith Gottesdiener, MD – CEO, Rhythm Pharmaceuticals
  ▪ Clinical – strategic choices, trial design key elements
  ▪ Team meetings – initial plan, opportunities, challenges, and info gaps

○ 25 – Peter Honig, MD – Head, Global Regulatory AstraZeneca
  ▪ Regulatory– history, regulatory guidelines, process and risk management
  ▪ Team meetings – initial plan, opportunities, challenges, and info gaps

○ 31 – Assignment due – 2 page summary
  ▪ Technology, unmet need, clinical / regulatory paths
  ▪ Detailed review of development strategy and specific plans
Course Overview

- November
  - 1 – Jay Galeota, President Hospital & Specialty Care, Merck
    - Marketing – New product mkt assessment; Pricing / reimb; ex-US mkts
    - Revenue model – approach to development of pre-launch models
    - Team meetings –market framework, pricing / reimbursement needs, initial choices, opportunities, challenges, and information gaps
  
  - 8 – Team Consultations with Staff
    - 30 minutes discussion each team
    - Technology, unmet need, target product profile, clinical indication, strategy

  - 8 – TA’s schedule 1:1’s week of November 11 for each student
    - 1:1 meetings with course director week of November 18th

  - 15 – Team Presentations
    - 30 minutes – 20 minute presentation and 10 min evaluation / discussion
    - Technology, unmet need, target product profile, development strategy

  - 22 – Rick Kuntz, MD, Chief Medical Officer, Medtronic
    - Device development and approval process, device partnerships / M&A
    - Historic, development, and business development perspectives

  - 27 – Cross-fertilization team meetings
    - Wed class, prior to thanksgiving; share experiences; provide advice
Course Overview

• December

○ 6 – Team Presentations
  ▪ Market opportunity, strategic choices, pricing, preliminary sales forecast
  ▪ 30 minutes each – 20 min presentation and 10 min evaluation / discussion
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Grading

• Team Presentations 66%
  o Quality of preparation and evaluation
  o Persuasiveness of presentation in support of strategic choices
  o Clarity and efficiency of presentation

• Individual Leadership / Teamwork Behaviors 34%
  o Self awareness
  o Self management
  o Social awareness
  o Social skill
Additional logistics (1 of 2)

• Team presentations
  o ‘Empowered leaders’ on teams for each functional area
    ▪ Expect team engagement and collaboration in each functional area
  o Presenters will be assigned shortly before presentations
  o Provide color copies with 2 slides per page for reviewers

• Background reading and pre-class preparation
  o Invited speakers expect you to be prepared

• Projects and products selected from Penn Medicine and elsewhere
  o Non-disclosure agreements must be signed by all involved

• All classes Huntsman F50 from 2:00-5:00pm, unless noted
  o Lunch with speakers can usually be arranged - interest
  o TAs and LSM mentors invited to join
  o Each team must reserve a GSR room from 3:30-5:00 each week
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Additional logistics (2 of 2)

• Class attendance is required and participation noted
  o E-mail director in advance if absence unavoidable
  o Impact on team dynamics

• Cross fertilization teams
  o Class time scheduled to meet

• CWiC support for presentations (communication within curriculum)
  o Advisors will provide feedback on late draft presentations

• Wharton Spike Video
  o All classes recorded, including team presentations

• After class LSM senior / staff gatherings
  o Twice per semester, after class
  o Student organized, LSM budget covers costs
Assistant Course Director

Dr. Joan Lau, Ph.D., MBA serves as Chief Executive Officer and President of Azelon Pharmaceuticals, Inc. and Ansaris, Inc. Dr. Lau served as Chief Operating Officer and President of Locus Pharmaceuticals, Inc. Dr. Lau worked in the pharmaceuticals and device industry for over 10 years. Prior to Ansaris, Dr. Lau served at Merck & Co. where she served roles of increasing responsibility in R&D Project Management, Portfolio Management, and Business Development. During this period, she played significant roles in leading preclinical and early clinical programs and managing the neuroscience drug development portfolio. She managed global business development activities for the Merck Vaccines and Infectious Diseases division. She was responsible to scientific integration in the Office of the President, Merck Research Laboratories. Dr. Lau worked in medical device development at Zimmer, Inc. She serves as a Director of Ansaris, Inc. Dr. Lau has MBA from the Wharton School of Business. She also has a PhD in Medical Neuroscience and a BS degree in Bioengineering from the University of Pennsylvania.
Invited Speakers

Laura Bessen, M.D.

Head of U.S. Medical

Bristol-Myers Squibb

Dr. Laura Bessen is Vice President, Head of U.S. Medical, Bristol-Myers Squibb where she is responsible for the successful launches of medicines and driving value creation and decision making within the U.S. Medical organization. Her career has spanned both industry and time as a practicing physician which brings a patient centered approach to her work.

Laura has held a number of cross-functional leadership and management roles in her 11 year career with Bristol Myers Squibb which started when she joined as part of the DuPont acquisition. During this time she co-led the lifecycle management team for Sustiva and then additionally Reyataz. In 2004, she was promoted to Vice President, Global Medical Affairs, with responsibility for marketed HIV and hepatitis B compounds. She played an integral role in the co-development with Gilead Pharmaceuticals of Atripla. Subsequent to the launch of Atripla, Laura formed the Global Medical Affairs Immunology therapeutic area focusing on the expanded development of BMS’ biologic compounds including, Ocrevus for Rheumatoid arthritis and other autoimmune diseases as well as belatacept, (under development for solid organ transplantation). In 2008, Laura took on additional responsibility for Global Medical Affairs Immunology and Oncology responsible for medical strategic planning and lifecycle management for products in these therapeutic areas post DP 4.5. Prior to being promoted to the Head of U.S. Medical in late 2012, Laura led the Immunoscience and Neuroscience therapeutic areas within U.S. Medical. As well as carrying out Global Development and Medical Affairs responsibilities, Laura was involved in many organizational activities partnering with commercial colleagues in designing product commercialization systems, life cycle flexing resourcing principles, market access strategies and defining roles and responsibilities of commercial and medical throughout the stages of drug development.

Laura holds an M.D. degree from New York University School of Medicine. She completed her clinical training in internal medicine at Mount Sinai Medical Center and finished her fellowship in Infectious Diseases at Albert Einstein College of Medicine. After her medical training, she became Physician-in-Charge for the AIDS Clinical Trial Unit at Beth Israel Medical Center where she carried out both industry and NIH sponsored clinical trials and was an Assistant Professor of Medicine at the Albert Einstein College of Medicine.
Anthony W. Ford-Hutchinson,
Independent Consultant to the Pharmaceutical Industry

Tony obtained his BSc in biochemistry from the University of Birmingham, a master's in molecular enzymology from the University of Warwick, and a Ph.D. in biochemistry from the University of London. Prior to coming to Merck, he performed research in the field of leukotrienes and prostaglandins at Kings College Hospital Medical School in London and was a lecturer in its Chemical Pathology Department.

He has spent 30 years at Merck, starting in 1981 when he joined Merck Frosst Canada in Montreal, where he spent 17 years moving from Director of Pharmacology to Senior Vice President and Site Head.

During his time in Canada, the laboratories there developed novel drugs for the treatment of human diseases. This included the development of Singulair®, for the treatment of adult and pediatric asthma and allergic rhinitis, and the discovery of selective COX-2 inhibitors for the treatment of osteoarthritis and pain.

In 1998, Tony moved to Pennsylvania to head the basic research effort in the USA and worldwide, covering all therapeutic areas. As an Executive Vice President he became responsible for franchise strategies in multiple disease areas, including Vaccines and Infectious Diseases. After 30 years at Merck, Tony retired in February 2012 and is currently a member of several biotech and not-for-profit boards.
Invited Speakers

Keith Gottesdiener, M.D., is Chief Executive Officer of Rhythm Pharmaceuticals, Inc., a Boston based biotech company that specializes in the development of peptide therapeutics for the treatment of metabolic diseases, such as diabetes, obesity and functional GI disorders. Rhythm currently has two compounds in Proof of Concept studies, RM-131 (ghrelin agonist) for the treatment of diabetic gastroparesis, and RM-493 (melanocortin-4 receptor agonist) for the treatment of obesity.

Dr. Gottesdiener brings great depth and breadth of experience in pharmaceutical development to his leadership role at Rhythm. Previously, he spent 16 years at Merck Research Laboratories in positions of increasing responsibility. He joined Merck as an associate director in early clinical development in 1995, and in that role he helped transition compounds from the bench to the bedside and through to proof of concept. During the next 10 years at Merck, he rapidly moved to the leadership role in early clinical development/clinical pharmacology at Merck from 2001 through early 2006. From 2006-2008, he was leader of the Clinical Infectious Diseases and Vaccines area, overseeing the development of Merck's infectious diseases and vaccine products from early clinical studies through late clinical development, registration, and life cycle management. He was responsible for more than 40 clinical programs and products, including Gardasil™ (HPV Vaccine), Rotateq™ (rotavirus vaccine), Zostavax™ (zoster vaccine) and Isentress™ (HIV integrase inhibitor), among others. In 2008, Dr. Gottesdiener was appointed Late Stage Therapeutic Group Leader for Merck & Co., Inc., and in that role led the late stage clinical development efforts of Merck Research Laboratories. This included responsibility for clinical research programs in infectious diseases and vaccines; cardiovascular diseases; diabetes and obesity; neurosciences; oncology; bone, respiratory, allergic, gastrointestinal, and endocrine diseases; immunology; arthritis; analgesia; and urology. After the merger with Schering Plough in 2009, he was appointed co-lead of late development, with responsibility for four of the main therapeutic areas including infectious disease, vaccines, cardiovascular and diabetes/obesity.

Dr. Gottesdiener received his B.A. from Harvard College and his M.D. from the University of Pennsylvania. He completed his residency in internal medicine at the Brigham and Women's Hospital of Harvard Medical School. He also completed an infectious diseases fellowship at the combined Brigham and Women's Hospital-Beth Israel Medical Center-Dana Farber Cancer Institute Children’s Hospital program. After his fellowship, Dr. Gottesdiener did post-doctoral research in the laboratory of Dr. Jack Strominger at Dana Farber Cancer Institute working on the molecular immunology of the T-cell receptor. In 1986, he joined the faculty as an assistant professor at Columbia University, and continued a research post-doc in the laboratory of Dr. Lex Van der Ploeg, working on gene transcriptional control in parasites. He started his independent laboratory at Columbia in 1991 with NIH RO-1 funding, focusing on gene transcription. In 1995, before leaving for MRL, Dr. Gottesdiener was appointed Associate Clinical Professor of Medicine at Columbia University.
Peter K Honig, M.D., M.P.H.

Peter Honig is currently Head, Global Regulatory Affairs, Patient Safety and Quality Assurance at AstraZeneca. Dr. Honig received his baccalaureate, medical and public health degrees from Columbia University in New York. He has postgraduate training and is board-certified in internal medicine and clinical pharmacology and has authored numerous peer reviewed publications and book chapters. He has held senior leadership positions at US Food and Drug administration and Merck Research Laboratories. He is and has been the PhRMA representative to the International Conference on Harmonization (ICH) Steering Committee since 2002 and a past co-chair of the ICH Global Cooperation Group (GCG) whose mission it is to promote regulatory harmonization in non-ICH countries and regions. Dr. Honig is an Associate Editor of Nature Clinical Pharmacology and Therapeutics.
James J. Galeota, Jr. (Jay)

President, Hospital and Specialty Care

Merck Global Human Health

Jay Galeota is president of the hospital and specialty care customer business line for Merck Global Human Health (GHH), which includes immunology, oncology, hepatitis, HIV, neuroscience, ophthalmology, antibiotic, antifungal, thrombosis, anesthetic and antiarrhythmic products. The hospital and specialty care business represents close to $11 billion in worldwide revenues for Merck.

Previously, Mr. Galeota served as senior vice president of GHH strategy and business development, and he continues to lead this group. Strategy and business development is responsible for identifying new models and business development opportunities that broaden the GHH portfolio and establish leadership in Merck’s franchises and markets.

Since joining Merck in 1988 as a sales representative, Mr. Galeota has assumed a variety of U.S. and global roles with increasing leadership responsibility. In Merck’s U.S. division, he managed promotion of the anti-ulcer drug PRILOSEC and VASOTEC for high blood pressure. He also served as product manager for ZOCOR and marketing director and senior director in Merck’s osteoporosis business group during the launch of FOSAMAX.

As U.S. senior business director, Mr. Galeota led Merck's highest revenue U.S. sales region. He later assumed roles as vice president of worldwide marketing for the atherosclerosis and diabetes franchise; general manager of the global commercialization team for JANUVIA, where he led the launches of JANUVIA and JANUMET; and senior vice president and general manager of the diabetes and obesity franchise. After the merger of Merck and Schering-Plough in 2009, Mr. Galeota led the integration of the global pharmaceutical and vaccine businesses.

Mr. Galeota holds a Bachelor of Science degree in biology from Villanova University and is a graduate of Harvard Business School's Advanced Management Program.

He currently serves on the boards of JFK Health System, Inc., Global Health Innovation Fund LLC, the New Jersey Symphony Orchestra, and the Metuchen Edison Woodbridge YMCA.

Mr. Galeota is married and has three children. In addition to business, his interests include sailing, skiing, flying, automobiles and music.
Richard E. Kuntz, M.D., M.Sc.
Sr. Vice President and Chief Scientific, Clinical and Regulatory Officer

Dr. Rick Kuntz is Senior Vice President and Chief Scientific, Clinical and Regulatory Officer of Medtronic, Inc. In this role, which he assumed in August 2009, Kuntz oversees the company’s global regulatory affairs, health policy and reimbursement, clinical research, ventures and new therapies and innovation functions.

Kuntz joined Medtronic in October 2005, as Senior Vice President and President of Medtronic Neuromodulation, which encompasses the company’s products and therapies used in the treatment of chronic pain, movement disorders, spasticity, overactive bladder and urinary retention, benign prostatic hyperplasia, and gastroparesis. In this role he was responsible for the research, development, operations and product sales and marketing for each of these therapeutic areas worldwide.

Kuntz brings to Medtronic a broad background and expertise in many different areas of healthcare. Prior to Medtronic he was the Founder and Chief Scientific Officer of the Harvard Clinical Research Institute (HCRI), a university-based contract research organization which coordinates National Institutes of Health (NIH) and industry clinical trials with the United States Food and Drug Administration (FDA). Kuntz has directed over 100 multicenter clinical trials and has authored more than 200 original publications. His major interests are traditional and alternative clinical trial design and biostatistics.

Kuntz also served as Associate Professor of Medicine at Harvard Medical School, Chief of the Division of Clinical Biometrics, and an interventional cardiologist in the division of cardiovascular diseases at the Brigham and Women’s Hospital in Boston, MA.

Kuntz graduated from Miami University, and received his medical degree from Case Western Reserve University School of Medicine. He completed his residency in internal medicine at the University of Texas Southwestern Medical School, and then completed fellowships in cardiovascular diseases and interventional cardiology at the Beth Israel Hospital and Harvard Medical School, Boston. Kuntz received his master’s of science in biostatistics from the Harvard School of Public Health.
Mrs. Fuller is Executive Chairman of Millennium prevention, a start-up in the health and wellness space. Previously, she was President of Decision Resources Inc., a leading research and advisory firm focusing in health care. The company is best known for its therapeutically-focused analyses of global pharmaceutical, biotechnology and medical device markets and for its research on the U.S. managed care industry and global market access. During her 35 years at Decision Resources, she has served 26 years as its president.

Previously, Mrs. Fuller was a Vice President at Arthur D. Little, Inc., from which she and Sam Fleming led a buy-out in 1990. As of July, 2007, Providence Equity Partners are the majority shareholders.

Mrs. Fuller serves on the Board of Trustees, the SAS Overseers and its Executive Committee. She is also a member of the Huntsman and Life Sciences and Management advisory boards at the University of Pennsylvania. In addition, she is the Chairman of Cultural Survival, a non-profit that promotes the vision, rights and voice of indigenous people and a Trustee at Plimoth Plantation. Mrs. Fuller holds a B.A. from the University of Pennsylvania and an A.M. from Harvard University.
Course Advisors

Ms. Barbara Schilberg has more than 30 years of experience working with academic technologies and start-up companies in the life sciences sector. Under her leadership as CEO, BioAdvance has committed $22.6 million to 32 seed-stage companies and 24 pre-seed projects focusing in areas including Alzheimer’s disease, cancer, diabetes, obesity and infectious diseases. The BioAdvance portfolio companies have leveraged $1.5 billion in subsequent capital from venture capital, grants, collaborations, M&A activity and product revenues. Seven portfolio companies have been acquired, one company has completed an initial public offering, and one exited through a refinancing.

Before joining BioAdvance, Ms. Schilberg served in senior management of four emerging life sciences companies. She joined Cephalon in 1994 as Senior Vice President and General Counsel and as a member of the executive committee. As part of her responsibilities, she led a multi-disciplinary team charged with completing Phase III clinical trials and preparing a new drug application for PROVIGIL® (modafinil), which was approved by the FDA in December 1999. She then served at Incara Pharmaceuticals in 1998 as Executive Vice President, where she managed a research operation in Princeton, NJ engaged in discovering new antibacterial therapeutics. She continued in that capacity after the operation’s acquisition by Advanced Medicine (now Theravance) in 2000. Ms. Schilberg also served as Vice President of Locus Discovery, Inc., an emerging pharmaceutical company in Blue Bell, PA engaged in computational drug design.

Before joining industry, Ms. Schilberg specialized in representing biopharmaceutical companies and research institutions in the commercialization of technology, as a partner in the Philadelphia office of Morgan, Lewis & Bockius. Ms. Schilberg received a J.D. from the University of Virginia and clerked with the Honorable Edward R. Becker, now Senior Judge of the U.S. Court of Appeals for the Third Circuit.
Questions