Jonathan S. Stamler, M.D.

*Director, UH Harrington Discovery Institute*
*University Hospitals Case Medical Center and*
*Case Western Reserve University School of Medicine*

Baiju R. Shah

*Chief Executive Officer,*
*BioMotiv*
Intersecting Challenges in American Medicine

• Drug development
• Physician-scientist role
“More than 100 million Americans suffer from diseases for which there are still no cures, or even meaningful therapeutic options. To conquer disease and relieve suffering, we must have a medical innovation pipeline that is as strong and robust as possible.”

-Margaret Anderson (FasterCures)
Defining Great Academic Medical Centers

- Deliver highest level of care
- Advance standard of care
The Mission of Physician-Scientists

To transform new knowledge into therapies that will save lives
Physician-Scientists are Dedicated to Finding New Cures

Link scientific inquiry with patient-based experience

- Edward Jenner
- Jonas Salk
- Joseph Lister
- Marie Curie
- Louis Pasteur
Academic-Commercial Pipeline Model is Broken

Academic Medical Enterprise

[

Unsustainable

]

Venture Capital/Biopharma

[

Shift to Later-stage

]
The number of new medicines approved each year is at near historic low point
Applications for approval have continued to trend downward.

**New US FDA Drug Approvals**

- 56 approvals in 1996
- 45 approvals in 1997
- 37 approvals in 1998
- 38 approvals in 1999
- 29 approvals in 2000
- 29 approvals in 2001
- 24 approvals in 2002
- 27 approvals in 2003
- 36 approvals in 2004
- 20 approvals in 2005
- 22 approvals in 2006
- 18 approvals in 2007
- 24 approvals in 2008
- 26 approvals in 2009
- 21 approvals in 2010
The Consequences for Human Health Are Severe and Long-term

- Unrealized potential of discoveries
- Struggle of institutions to meet societal obligation
- Environment suboptimal for physician-scientist participation in drug development
“There’s never been a time where we’ve had a greater outpouring of discoveries about the nature of disease. And yet paradoxically, the ability to turn that information into clinical applications seems to have slowed down. If there was ever a time when we need to figure out how to take this wonderful scientific opportunity and apply the most bold, audacious principles of innovation to make those products happen, it is now.”

--Dr. Francis Collins, NIH Director
We have a unique **opportunity**

**to influence the model construct:**

**ensure solution is aligned**

**with our mission**
A national model uniting academic medical centers, physician-scientists, and commercial partners to maximize conversion of discoveries into novel, life-saving therapeutics.
Our Solution: The Harrington Project

$250 Million National Project
Mission: Accelerating Breakthrough Discoveries into Medicines

- UH Harrington Discovery Institute
- Innovation Support Center
- National Consortium of Academic Medical Centers
- BioMotiv
- National bio-accelerator to promote commercialization and entrepreneurship in medicine

Nonprofit
For-Profit

Breakthrough Medicines
National Programs for Physician-Scientists

- Harrington Scholar-Innovator Awards
- Foundation Scholar Award
- National Prize for Innovation in Medicine
The Harrington Project for Discovery & Development
Internationally Renowned Scientific Advisory Board

Jonathan Stamler, MD
Director of UH Harrington Discovery Institute and the Robert S. and Sylvia K. Reitman Distinguished Chair in Cardiovascular Innovation at UH Case Medical Center and Case Western Reserve University School of Medicine

Irwin Fridovich, PhD
James B. Duke Professor Emeritus, Biochemistry, Duke University

David Ginsburg, MD
James V. Neel Distinguished University Professor of Internal Medicine and Human Genetics; Warner-Lambert/Parke-Davis Professor of Medicine; Member of the Life Sciences Institute, University of Michigan Medical School; Howard Hughes Medical Institute Investigator

William George Kaelin, MD
Professor of Medicine, Harvard Medical School; Howard Hughes Medical Institute Investigator, Dana-Farber Cancer Institute; Senior Physician, Medicine, Brigham and Women’s Hospital

Andrew R. Marks, MD
Chairman, Department of Physiology and Cellular Biophysics, Columbia University Medical Center; Founding Director, Wu Center for Molecular Cardiology; Professor, Physiology and Cellular Biophysics, Columbia University Medical Center

Charles Sawyers, MD
Marie-Josée and Henry R. Kravis Chair and Chairman, Human Oncology and Pathogenesis Program, Memorial Sloan-Kettering Cancer Center, Howard Hughes Medical Institute Investigator

Solomon H. Snyder MD, DSc, D.Phil
Distinguished Service Professor of Neuroscience, Pharmacology and Psychiatry, Johns Hopkins University

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Director of UH Harrington Discovery Institute and the Robert S. and Sylvia K. Reitman Distinguished Chair in Cardiovascular Innovation at UH Case Medical Center and Case Western Reserve University School of Medicine

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Distinguished Service Professor of Neuroscience, Pharmacology and Psychiatry, Johns Hopkins University
AMYOTROPHIC LATERAL SCLEROSIS (ALS)
MULTIPLE MYELOMA
WOUND HEALING
PULMONARY HTN
LIVER REGENERATION
ALZHEIMERS DISEASE
TUBERCULOSIS
DIABETES
PAIN CONTROL
MYOCARDIAL INFARCTION
CANCER X 2
PAIN CONTROL
Innovation Support Center: Translating Discoveries into Products

• Bridge to Commercial Environment
• Expert guidance & mentoring
• Optimize development and establish proof-of-concept
• Strengthen IP positions
• Additional funding for promising initiatives
The Harrington Project for Discovery & Development

- New For-profit Model for Drug Development
  - Mission-aligned with non-profits
  - Evergreen
  - Portfolio approach
  - High-caliber team to diligence and develop
  - Experienced, national advisory board
  - Scaled for efficiency and financial returns

Accelerating Products to Market
Capable, Connected Team

Baiju R. Shah, Chief Executive Officer
• President & CEO of BioEnterprise
• McKinsey & Company
• Board of Directors, Invacare (NYSE: IVC)

David C. U’Prichard, Ph.D., Chief Scientific Officer
Chairman, Scientific Advisory Board
• Chair, Global R&D, SmithKline Beecham, and ICI/Zeneca; CEO of 3-D Pharmaceuticals (sold to J&J)
• Venture Partner for several biotech venture groups
• Board of Directors, Life Technologies (NASDAQ:LIFE), Cyclacel (NASDAQ: CYCC)

Thomas Facklam, Ph.D., Senior Vice President
• Senior Executive, Serono, DSM, BioMira, Creative Biomolecules, J&J
• R&D, business development, strategic management

Al Hawkins, Vice President, Business Development
• Co-founder of several early-stage biotech companies
• Director, New Ventures, Boston University, BU Venture Fund
### Experienced Advisory Board

<table>
<thead>
<tr>
<th>Name</th>
<th>Position and Company</th>
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<tbody>
<tr>
<td><strong>David C. U’ Prichard, Ph.D.</strong>, Chairman</td>
<td>Chair, Global R&amp;D SmithKline Beecham, ICI/Zeneca, CEO of 3-D Pharmaceuticals, Venture Partner at Apex, Care Capital, Red Abbey</td>
</tr>
<tr>
<td><strong>Perry Molinoff, M.D.</strong></td>
<td>Vice Provost, Research, University of Pennsylvania, VP, Neuroscience and Genitourinary Drug Discovery, Bristol Myers Squibb</td>
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<tr>
<td><strong>Christine Debouck, Ph.D.</strong></td>
<td>Former SVP, Genomic &amp; Proteomic Sciences, GlaxoSmithKline, Gates Foundation, Scientific Advisory Board</td>
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<tr>
<td><strong>Lawrence Olanoff, M.D., Ph.D.</strong>, President and COO, Forest Pharmaceuticals</td>
<td>President &amp; CEO, Celsion, SVP, Sandoz, Corporate Vice President, Upjohn</td>
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<tr>
<td><strong>Frank Douglas, M.D., Ph.D.</strong></td>
<td>CEO, Austen BioInnovation Institute in Akron, Founding CEO of MIT Center for Biomedical Innovation, EVP, CSO, Aventis, Chief Scientific Adviser, Bayer Healthcare</td>
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<td><strong>Srinivas Rao, M.D., Ph.D.</strong></td>
<td>CEO, Kyalin Biosciences, CSO, Sova Biopharmaceuticals, CSO, Cypress Bioscience</td>
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<tr>
<td><strong>Diane Jorkasky, M.D.</strong></td>
<td>CMO, Endo Pharmaceuticals, CMO, Aileron Therapeutics, VP, Global Clinical Research, Pfizer, Director, Tengion.</td>
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**Note:** The list above includes a variety of professionals with expertise in various fields such as research, pharmaceuticals, and biotechnology. Each individual brings unique experience and contributions to the advisory board, reflecting a broad range of capabilities and contributions to the field of medicine and biotechnology.
Focused on Greatest Opportunity

Basic Discovery → Late Discovery → Pre-Clinical → Phase 1 → Phase 2 → Phase 3

Stage 1: Basic Discovery & Late Discovery
Stage 2: Pre-Clinical, Phase 1, Phase 2, Phase 3

Strategic/Financial Partnering

BioMotiv
Translating Promising Innovations Into Products ...and Profits

Case Study: New Cancer Therapeutic

UH Harrington Discovery Institute
Innovation Support Center
BioMotiv
Breakthrough Medicines
The Harrington Project: Aims for Transformational Outcomes

• Accelerate innovation by physician-scientists

• Transform innovation into novel therapeutics

• Commercialize therapeutics to save lives
Partnerships & Pipeline

• Academic Medical Centers
  – Consortium Partners
• Disease Foundations
  – Opportunities to Partner for Development
  – Foundation-Scholar Partners
• Industry
  – Strategic Partners