



THE NATIONAL ACADEMIES

Building The Ohio Innovation Economy
Biomedical Growth Opportunities
Biomedical Research and the Health Care Industry

Frank L. Douglas Ph.D., M.D.
April 26, 2011

The GAPS



- Conceptual Gaps: Illness vs Wellness, One Size Fits All, Reductionism vs Integration
- Specific Gaps: Tradition and Culture, Basic Science, Clinic, Technology, Education and Science, Funding, Commerce, Reimbursement, Government & Law, Communication & Media, Patients and Consumers

From: *The Personalized Health Project; D. E. Duncan, with F. L. Douglas, L. Molnar and S.P. Spielberg, Ewing Marion Kauffman Foundation, Jan. 2011.*

Basic Science/Technology Gaps



- Biological/Chemical space mismatch
- Pathway/Pathophysiology Maps
- Epidemiology/natural course of disease
- Biomarkers of Failures
- Predictive Models of Disease

Approaches to address

- Chemical Biology Platforms
- Translational Medicine Platforms



Is the Biopharmaceutical Industry Ready for a Black Swan Event

Frank L. Douglas Ph.D., M.D.

Drug Discovery and Technology Conference
Feb 2007

Black Swan Scenario: Internal Forces

Large Pharma will focus on:

- Strategic Discovery Clusters
- New Role for Alliance Manager
- Commercial / R & D Spend: 2:1 
- Approvals after Ph 2b
- A Changed IP Space
- Safe Haven and Precompetitive Space

Black Swan Scenario for BioPharm

- 3-4 Top Tier Large Pharma as integrators
- Many small specialty players
- Venture Capital firms as research translators
- Virtuality becomes a Reality
- Strategic Global Sourcing
- Academia/Government/Industry Collaborations

Black Swan Scenario for BioPharm: External Forces

- On few conditions, e.g. Alzheimers, some cancers, orphan disease
- Mandatory use of generics by drug class
- Identification of susceptibility to efficacy and side effects required for approval and marketing of all non-generics
- Preventive Health measures are preferentially reimbursed
- Approval after Ph 2b, Large scale/Ph 111 (normal use) for confirmation or relabeling
- Price controls!!!