

Ethical Issues in Translational Research – Paradigm or Policy Shift?

The First Indiana CTSI Symposium
on Disease and Therapeutic Modeling

Eric M. Meslin, Ph.D.

Director, IU Center for Bioethics

Associate Dean (Bioethics), IU School of Medicine

Professor of Medicine, Medical and Molecular Genetics, and Philosophy

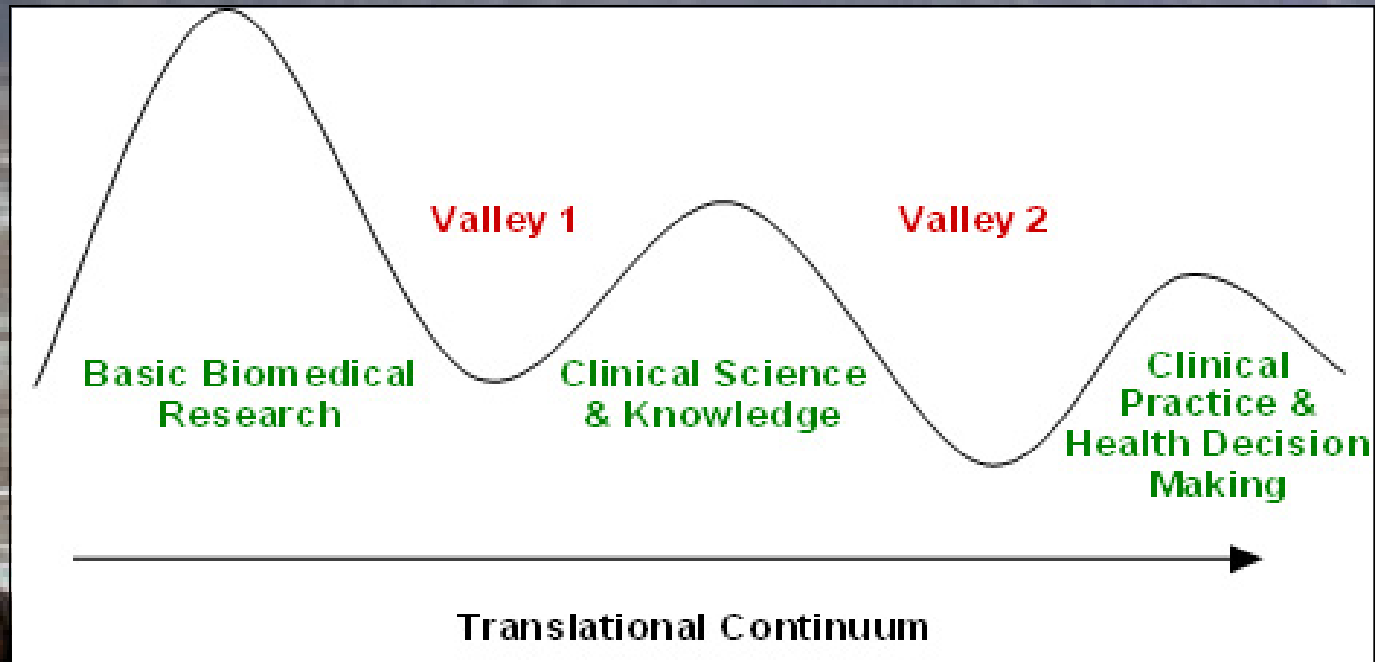
Director, Bioethics and Subject Advocacy Program, Indiana CTSI



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The ONLY Ethical Issue: Traversing the “Valley of Death”

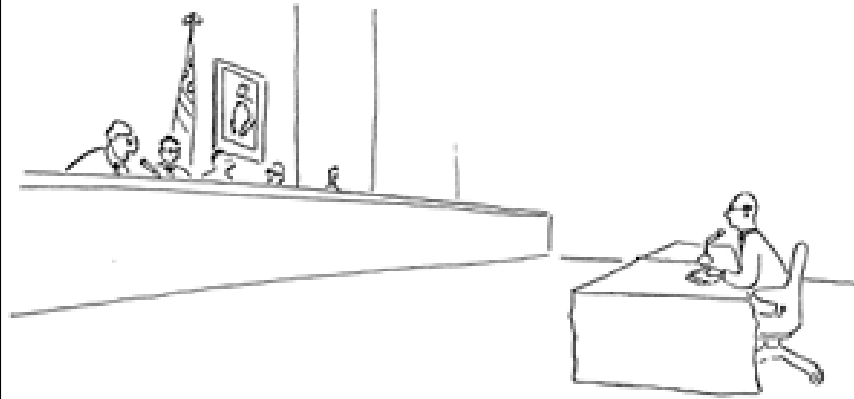


Paradigm Shifts?

- individual researchers replaced by teams;
- multiple institutions collaborating with international partners;
- blurring the prevailing division of labor between universities and the private sector;
- funders emphasizing impact over knowledge



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"Please pay attention, as the ethics have changed."

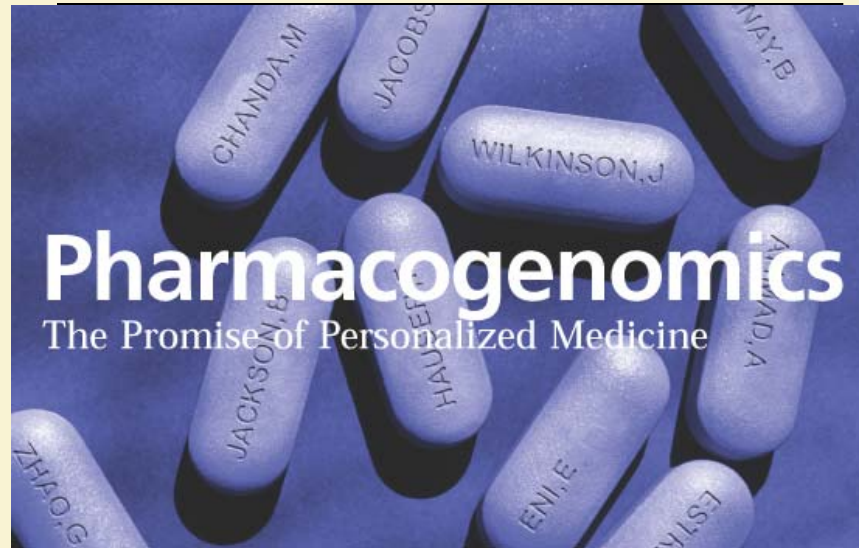


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Research Ethics Paradigm Shifts?

- increasing emphasis on access to trials, especially involving women and children;
- arguments about the scope of permission, especially to broaden consent for biobanking;
- greater involvement of communities in planning studies;
- increased ethical scrutiny about financial and commercial arrangements
- Clinical trials gold standard → genetic exceptionalis

Paradigm Shift?





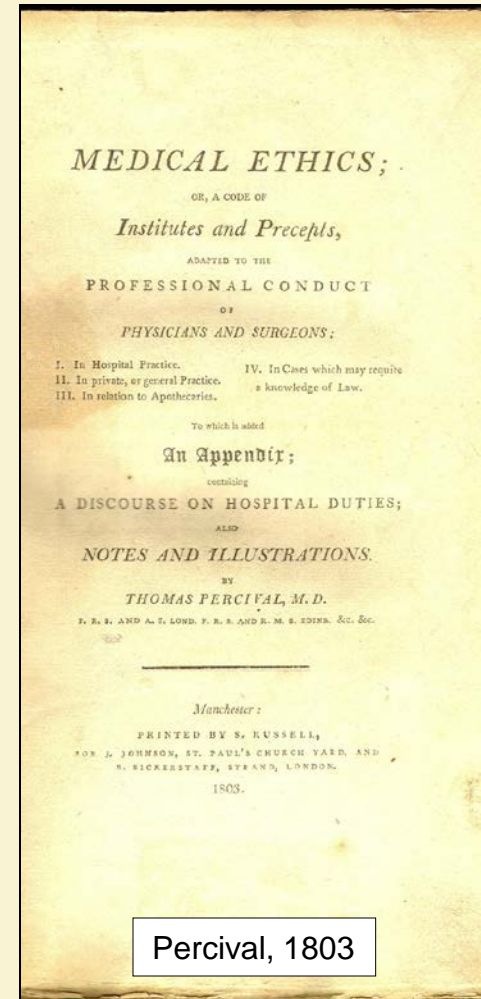
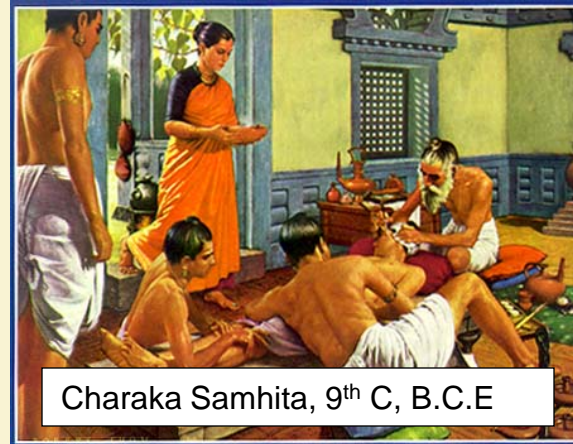
If it were not for the great variability among individuals, medicine might as well be a science and not an art.

— Sir William Osler (1892)

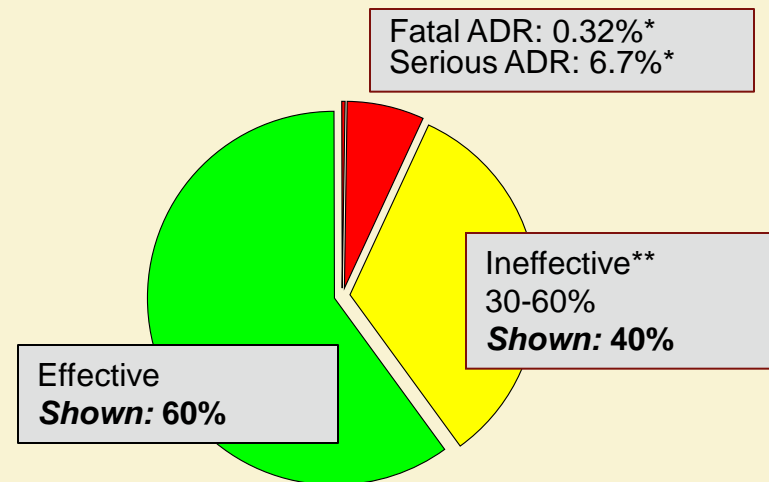


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Some Historical Origins of “Personalized” Medicine



- Dramatically re-adjust the benefit-risk profile on medicines (increase benefit, minimize harm)
- Improve targeting of therapies (right drug for them)
- Potential to lower out-of-pocket payment for patients



* Lazarou *et al*, JAMA (1998)

** Peakman & Arlington, Drug Discovery World (2001)



Overcoming the Valley: Differing Paradigms

1. Basic/clinical researchers and clinicians each use somewhat different paradigms – they see the world differently
2. Ethical foundations of clinical care are not identical to the ethical foundations of research
3. Genetic research is different from clinical trials

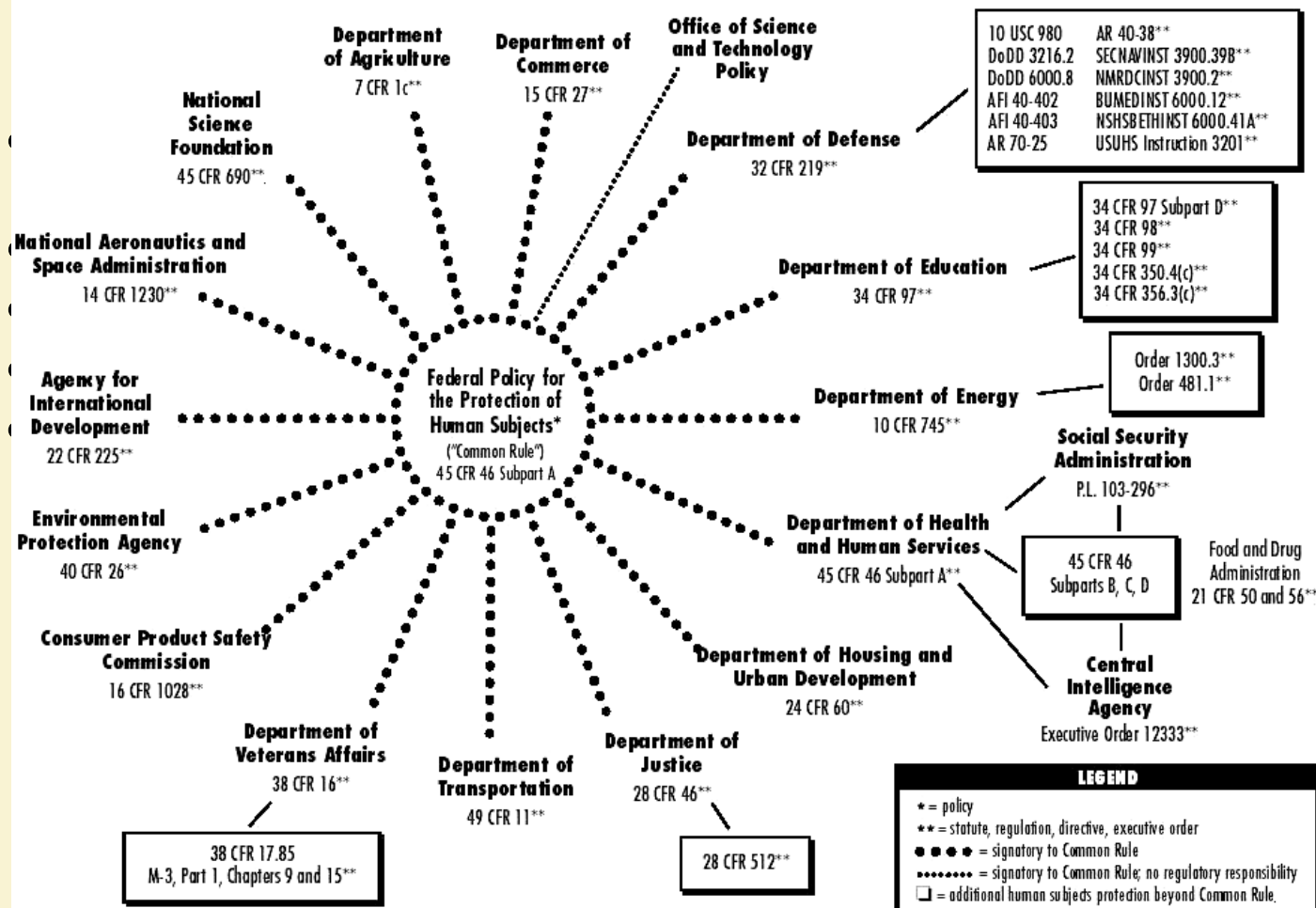


The Translational Policy Valley of Death



Personalized Medical Research is Assured Through Regulation and Oversight

Figure C-1: Common Rule and Agency-Specific Human Research Protection Regulations



The World of Biobanking

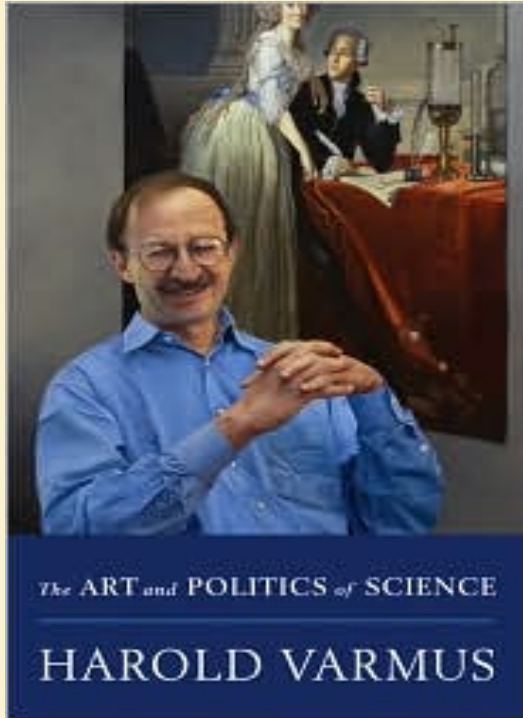


Lost in Translation

- Policy researchers and policy makers do not interact
- policy researchers think about direct applications of their work, they are not always empowered to implement;
- Differing regulatory philosophies by elected officials
- Variable funding mechanisms



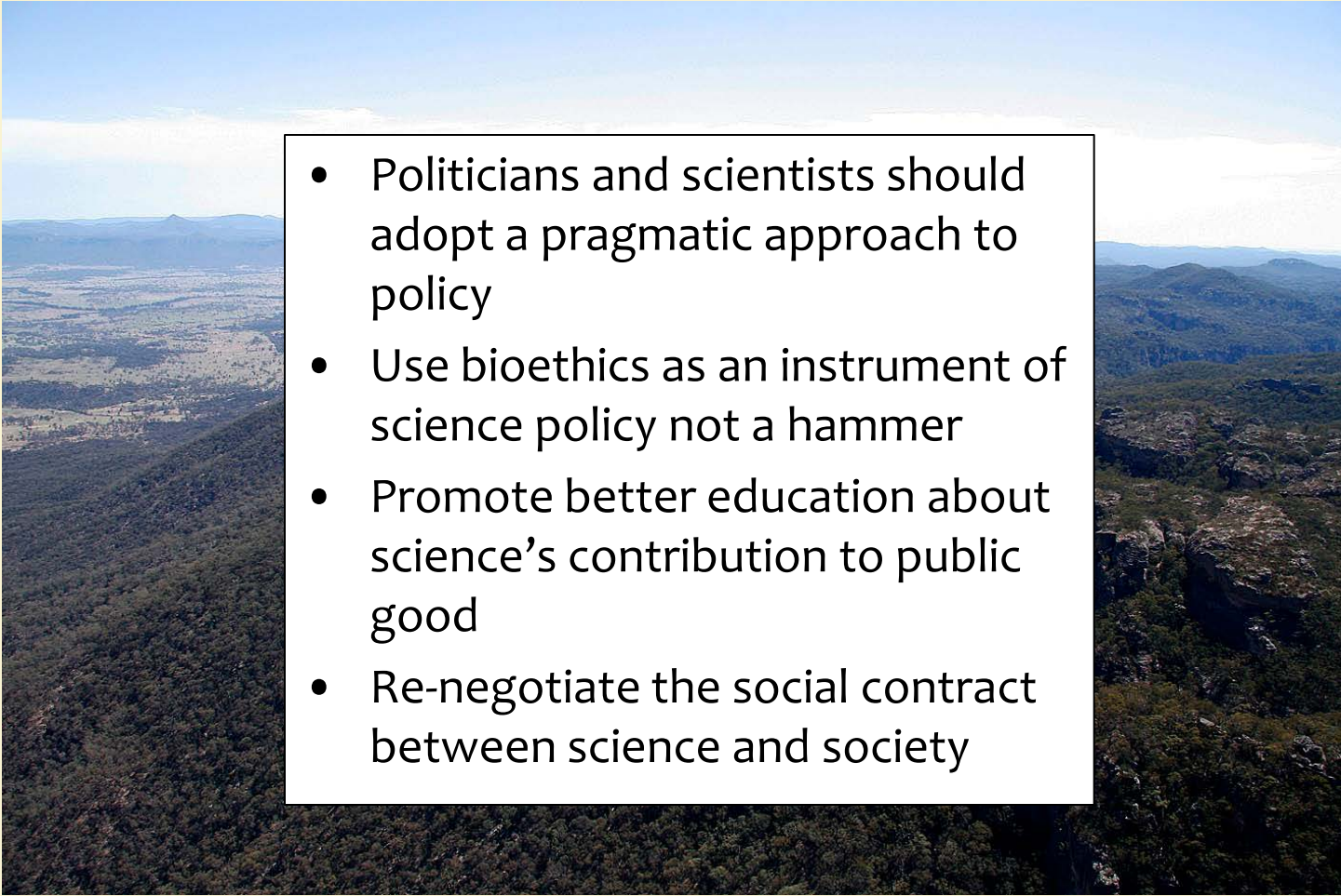
The Politics of Science Policy



“Until the mid 1980s, when I was in my mid-forties, I paid relatively little attention to the intersection of politics and science. This did not mean I was apolitical. I followed political events closely and had strong—largely left-liberal—opinions about them. Nor was I oblivious to the potential for engagement between politics and science.....”



Traversing the Translational Policy Valley of Death

- 
- Politicians and scientists should adopt a pragmatic approach to policy
 - Use bioethics as an instrument of science policy not a hammer
 - Promote better education about science's contribution to public good
 - Re-negotiate the social contract between science and society

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BOTH



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INDIANA UNIVERSITY

CENTER FOR BIOETHICS

410 West 10th Street, Suite 3100
Indianapolis, Indiana
USA 46202-3002
Tel: (317) 278-4034
Fax: (317) 278-4050
www.bioethics.iu.edu