

**Challenges of Moving
Personalized Health Care Forward:
Public Policy, Regulatory, Consumers, and Payer**

Personalized Healthcare Conference
Ohio State University
Friday, October 17, 10:15-11:15

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Driving Business Advantage

Pharmacogenomics: Challenges and Opportunities

Dan M. Roden, MD; Russ B. Altman, MD, PhD; Neal L. Benowitz, MD; David A. Flockhart, MD, PhD; Kathleen M. Giacomini, PhD; Julie A. Johnson, PharmD; Ronald M. Krauss, MD; Howard L. McLeod, PharmD; Mark J. Ratain, MD; Mary V. Relling, PharmD; Huijun Z. Ring, PhD; Alan R. Shuldiner, MD; Richard M. Weinshilboum, MD; and Scott T. Weiss, MD, for the Pharmacogenetics Research Network

The outcome of drug therapy is often unpredictable, ranging from beneficial effects to lack of efficacy to serious adverse effects. Variations in single genes are 1 well-recognized cause of such unpredictability, defining the field of *pharmacogenetics* (see Glossary). Such variations may involve genes controlling drug metabolism, drug transport, disease susceptibility, or drug targets. The sequencing of the human genome and the cataloguing of variants across human genomes are the enabling resources for the nascent field of *pharmacogenomics* (see Glossary), which tests the idea that genomic variability underlies variability in drug responses. However, there are many challenges that must be overcome to apply rapidly

accumulating genomic information to understand variable drug responses, including defining candidate genes and pathways; relating disease genes to drug response genes; precisely defining drug response phenotypes; and addressing analytic, ethical, and technological issues involved in generation and management of large drug response data sets. Overcoming these challenges holds the promise of improving new drug development and ultimately individualizing the selection of appropriate drugs and dosages for individual patients.

Ann Intern Med. 2006;145:749-757.

For author affiliations, see end of text.

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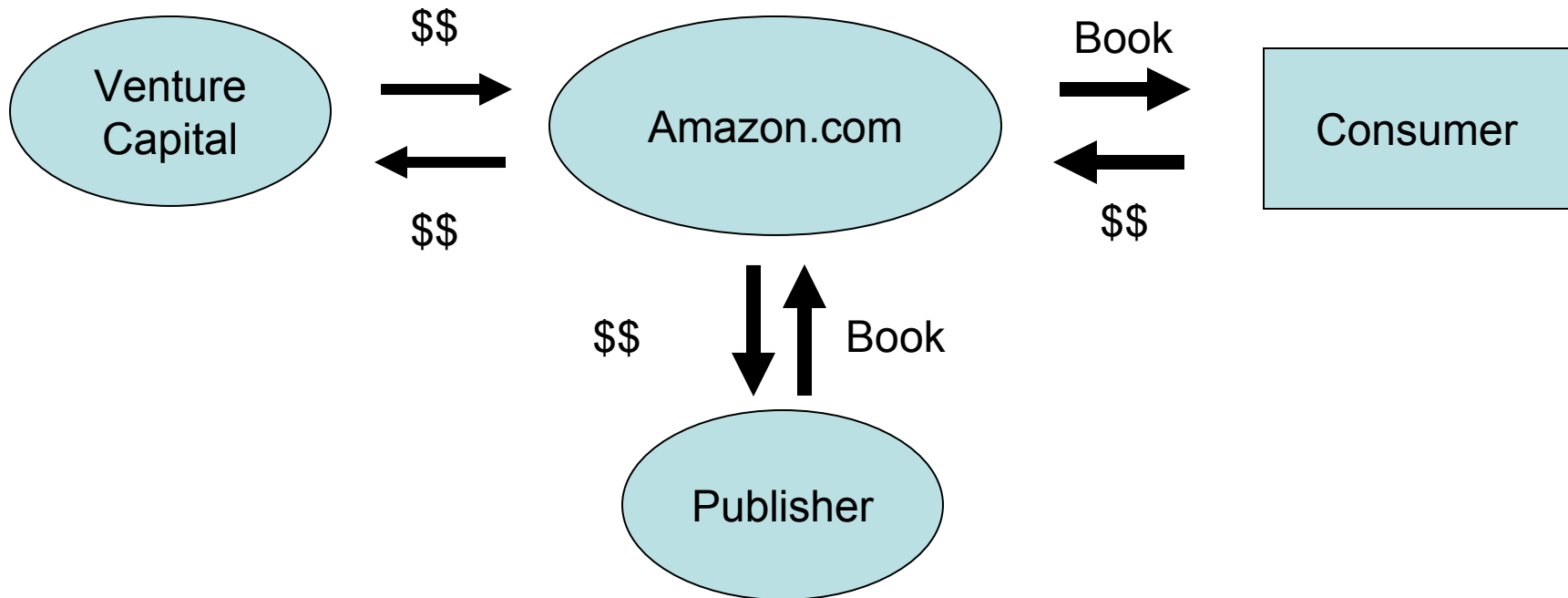
<http://www.annals.org/cgi/content/abstract/145/10/749>

Healthcare and Innovation: Any Uneasy Partnership



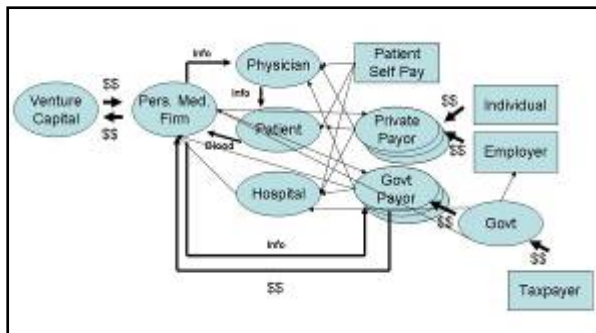
- The healthcare industry triggers two competing and opposite viewpoints on innovation.
- In one viewpoint, medical technology runs wild in the system, drives unsustainable cost inflation, loads each disease subcategory with laundry lists of me-too drugs that require \$800M apiece to develop, and puts more MRI centers in Cleveland than in Canada.
- But in the contrasting viewpoint, any company is doomed if it depends on
 - altering physician practices, or
 - requiring forward-looking thinking by insurers or Medicare, or
 - displacing locked-in perverse incentives (e.g. more surgery, more therapy), while
 - the operations of a physician office and healthcare system have remained largely untouched by technology and IT.

A Regular Industry



The position "venture capital" could be any investor; public markets, loans, internal R&D, etc.

Industry structure → fundamental economics problem



- **FIRST LAW:**
 - INNOVATION requires prices above marginal cost, to repay development

- **SECOND LAW:**
 - Prices above marginal cost drive “over utilization” in health care

➤ **RESULT ONE:**

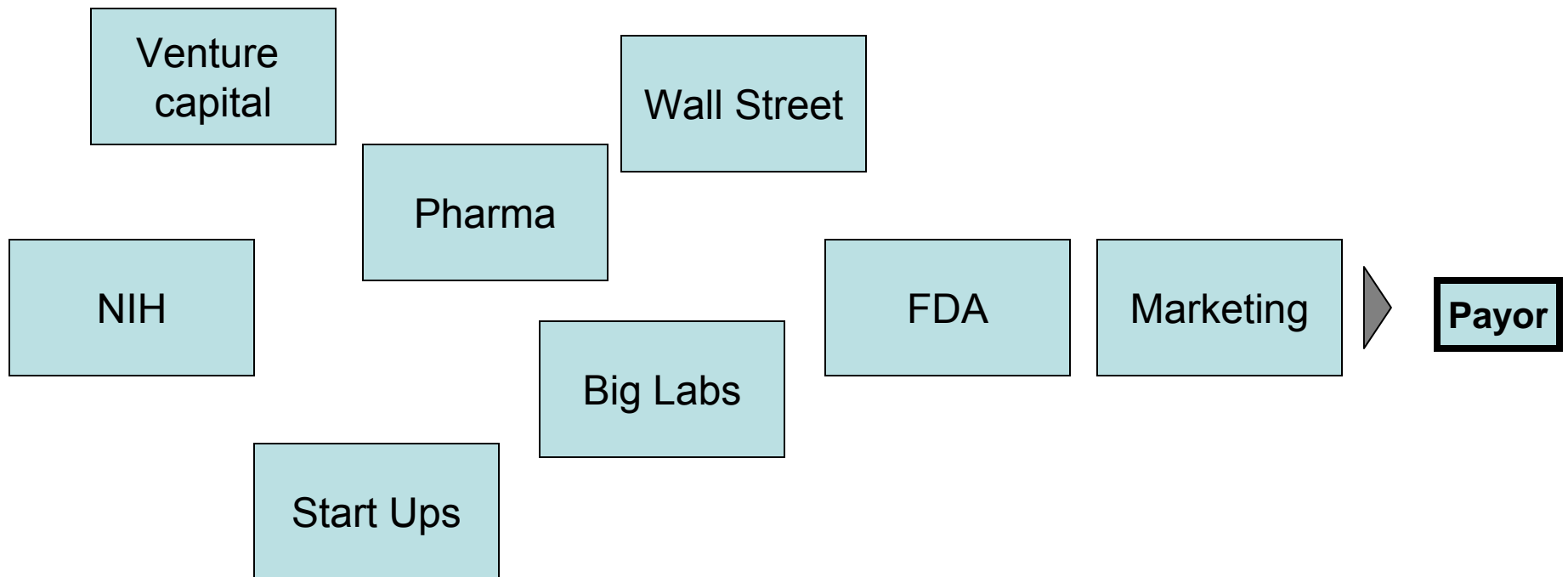
- Government tries to drive prices to marginal cost as fast as possible
 - Particularly acute in laboratory tests
 - Payor tries to pay nothing (non coverage decision)

➤ **RESULT TWO:**

- Innovators complain that system is blind to value-based reimbursement

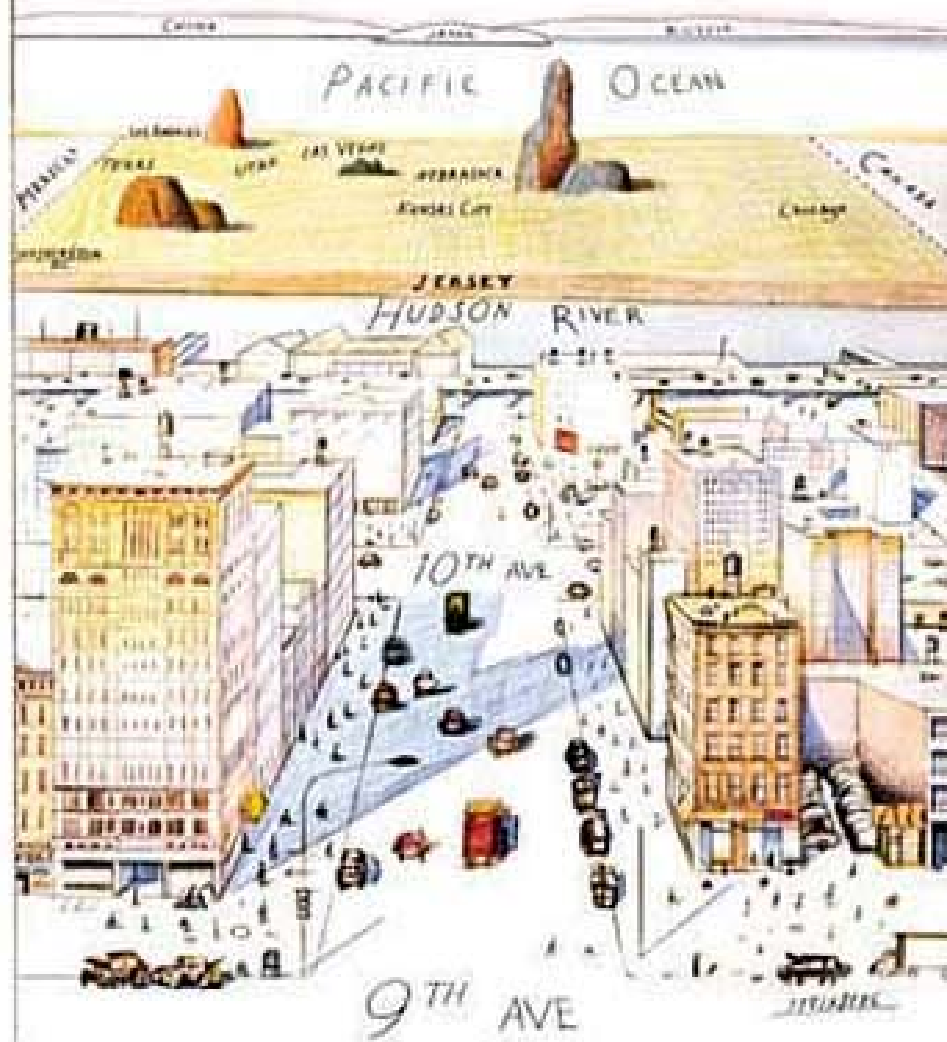
An industry-based workshop participant asserted,
"There is a substantial **market failure** on the payor
side."

New Technology Stakeholders



His assertion was, Payors are in a pivotal position in the entire system but drastically under-resourced and/or dealing with fuzzy tools, vague guidelines, and creating uncertainty across all the other (earlier) stakeholders in achieving improved patient care.

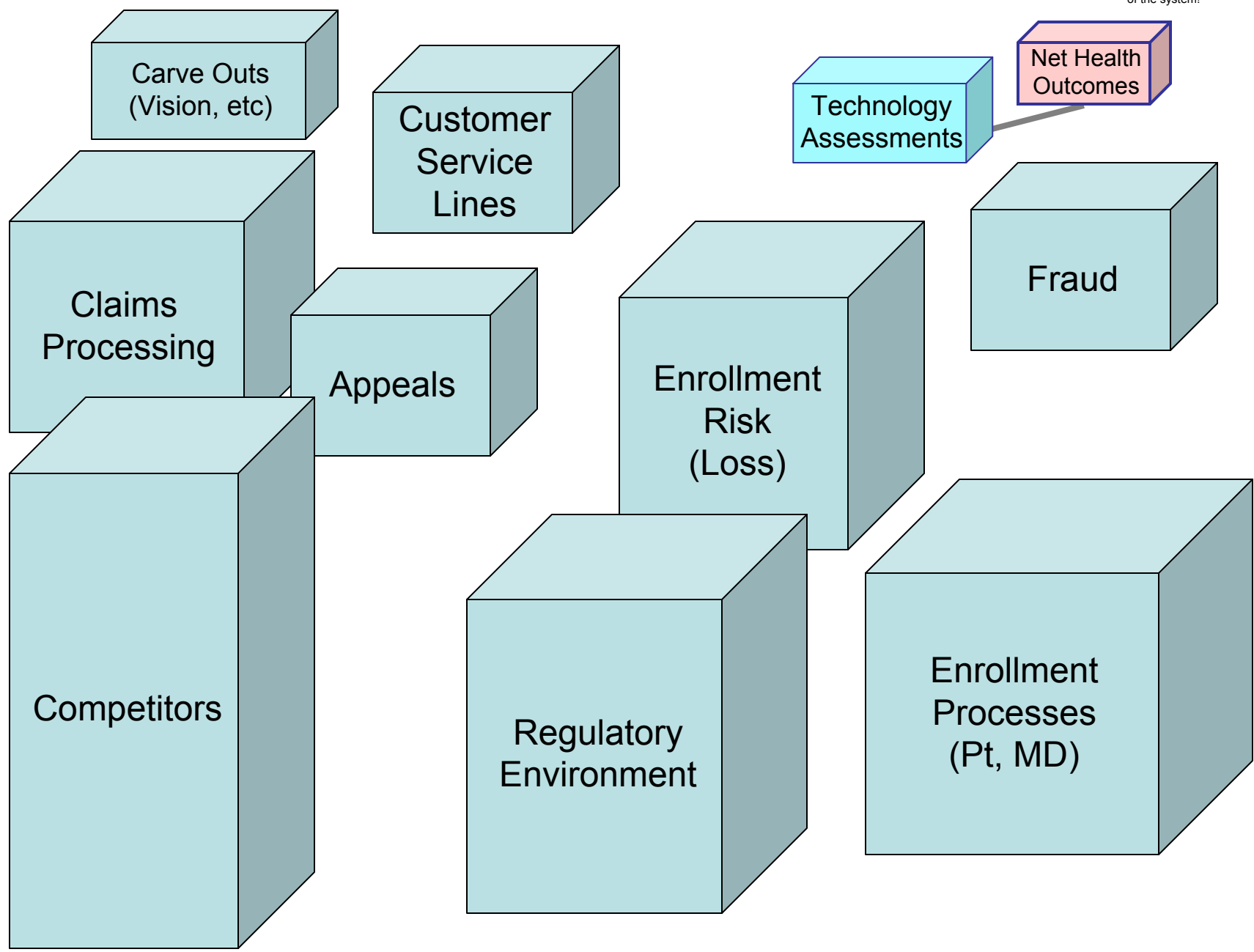
THE NEW YORKER



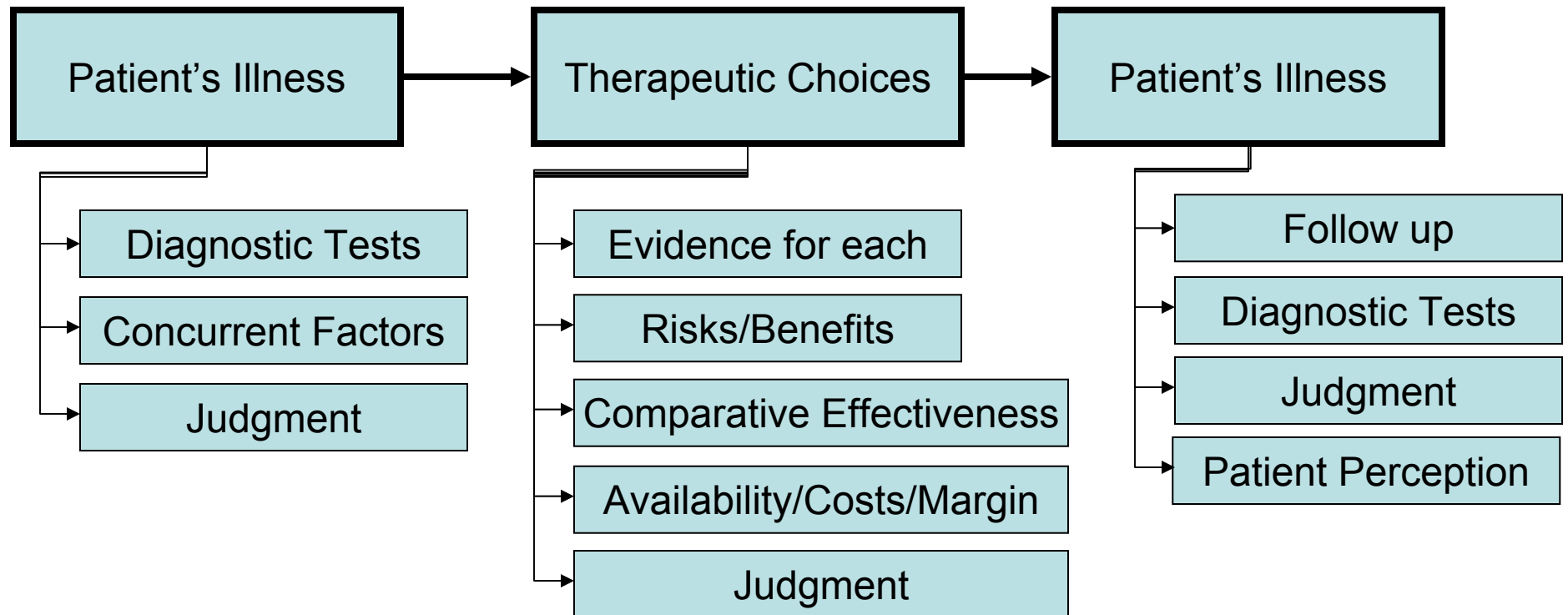
New Yorker's View of the World
March 29, 1976
Saul Steinberg

Payor's View of Health Care (Apologies to Steinberg)

↓
Net health outcomes
might seem to be the
most important aspect
of the system!



CONTENT OF HEALTH CARE

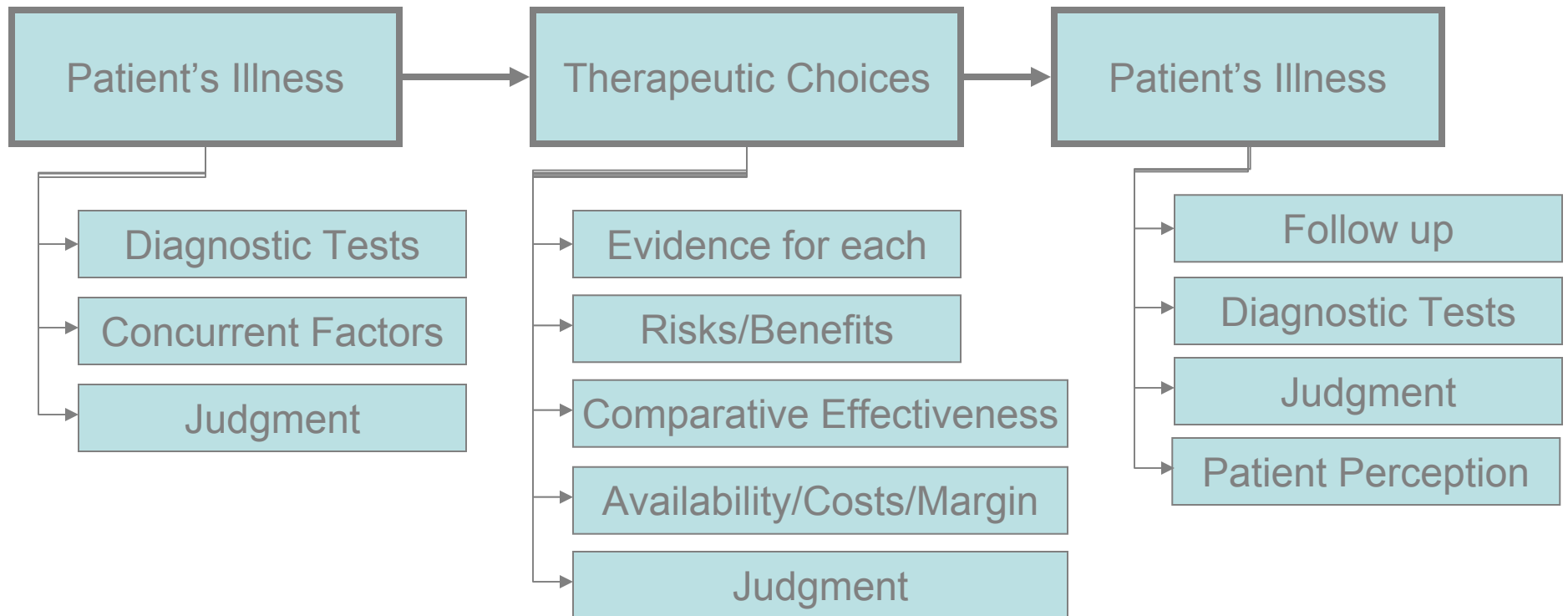


Arrow K (1963) Uncertainty and the welfare economics of medical care. American Economic Review 53:941.

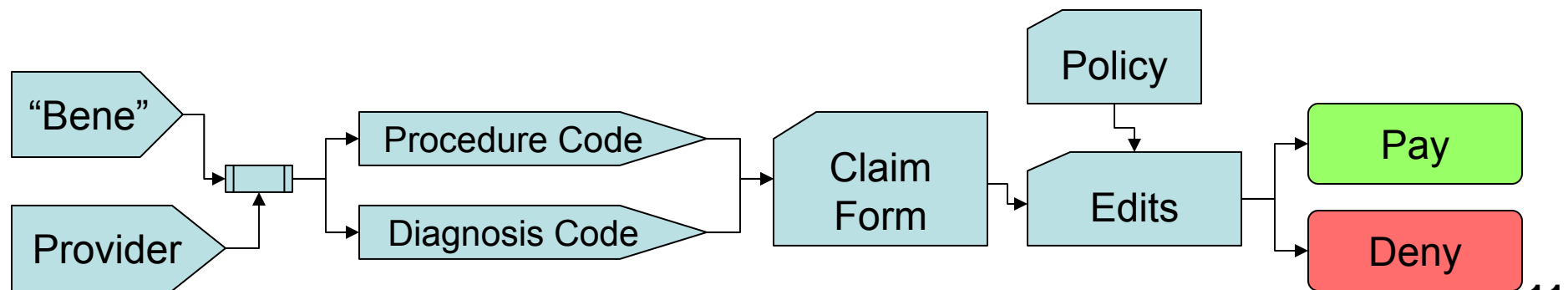
Also: Hammer PJ (ed; 2003) Uncertain times: Kenneth Arrow and the changing economics of health care. Duke Univ Press.

Kernick D (2004) Complexity and Healthcare Organization. Radcliffe.

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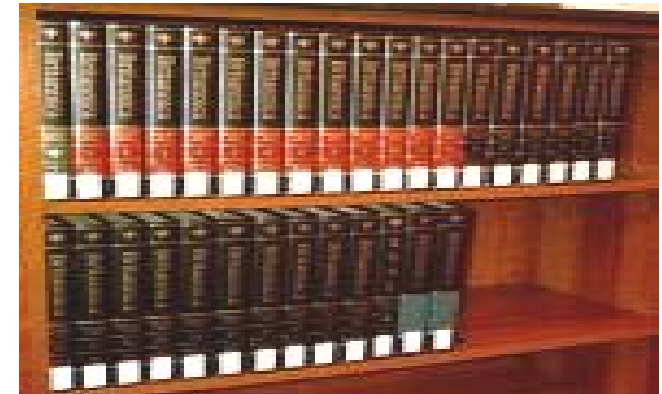
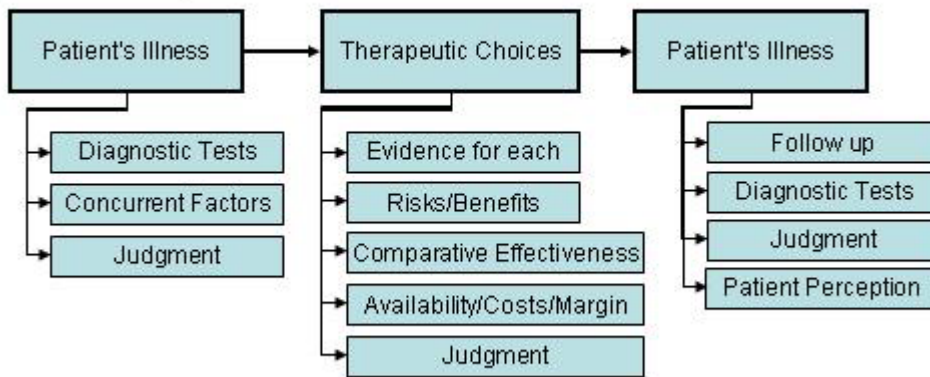


PROCESS OF HEALTH CARE REIMBURSEMENT

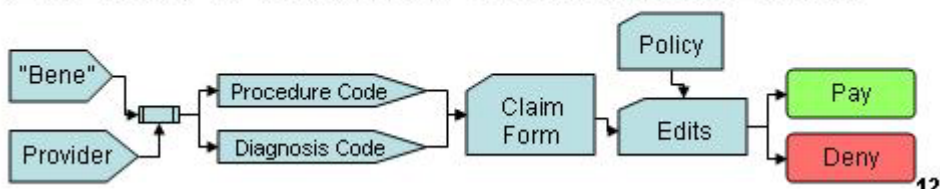


Mismatch

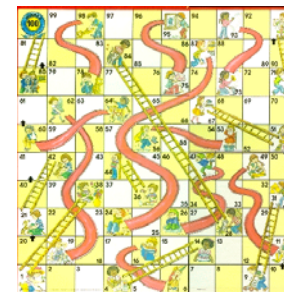
CONTENT OF HEALTH CARE



PROCESS OF HEALTH CARE REIMBURSEMENT



Some twists and turns in the road



Ethics of trial after strong pilot data	Hypothetical: 100 lung cancer patients got Drug X, 20 responded. Those 20 had gene Y. Can we do an RCT of patients with and without Gene Y?
FDA, insurers look to prospective trials	“The credible mechanism...a prospective trial that recruits all patients.” (FDA; Wang 2007).
Economics of lab tests	Medicare and some private payors may enforce “code stacking” reimbursement that assigns generic prices (e.g. \$20 per gene analyzed) to molecular tests (Schoonmaker, 2007; Lee 2008) Medicare lab specimen rules could try to bundle \$500 genetic test to \$400 biopsy service. Generic genes / “Lock-in” between pharma and lab for proprietary technology / Risks of Ph 2 test = risks of phase 2 drug
Evidence-based medicine and lab tests	Lab tests statistics & usage are much more complex than usually appreciated (e.g. Bayesian statistics; spectrum effects; Reigelman (2004); Feinstein (2001).)
Payor resistance	Few payors cover warfarin genetics as of 9/2008 Medicare opens coverage review on warfarin genetics, 8/2008 Innovative tests require high margin above marginal cost; margin drives overutilization in payors’ view
Turnaround time; marketing	Mundane factors like “detailing” the test, physician mindshare, and turnaround time delay utilization
Ethical and policy issues	More complicated than one might guess (Garrison 2007; Marx-Stolting, 2007).

Feinstein AR (2001) J Epi Comm Health 56:330-2. Garrison LP et al. (2008) Metab Review 40:377-401. Lee T (2008) TJOLS Jan/08. Marx-Stolting L (2007) Pharmacogen J 7:293-6. Riegelman RK (2004) Studying a study, testing a test. Lippincott. Schoonmaker MM (2007) DeviceLink.com IVDT Jan/07. Wang SJ (2007) Pharmaceut Stat 6:283-96.