



Aligning Incentives between Saving Lives and Making Money

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Trust

- Good decisions
- Open, credible process
- Accountability for process and reasoning (cf. Norman Daniels)

Trust: reduces transaction costs and speeds good decisions

Trustworthiness: whether an institution deserves trust

Hysteresis: very expensive and slow to restore trust once lost

Kenneth Arrow on Trust in Medicine

"Trust has a very important pragmatic value, if nothing else. Trust is an important lubricant of a social system. It is extremely efficient; it saves a lot of trouble to have a fair degree of reliance on other people's word. Unfortunately this is not a commodity which can be bought very easily."

Kenneth J. Arrow, 1974, *Limits of Organization*

"Delegation and trust are the social institutions designed to obviate the problem of informational inequality"

Kenneth J. Arrow, 1963. Uncertainty and the Welfare Economics of Medical Care. *American Economic Review* 53: 941-73

"the high level of trust that is needed in order to cope with the intense anxiety that results from uncertainty in the face of illness."

Mark A. Hall, *J Health Politics, Policy & Law* 26: 1131-44, 2001, commenting on the article above

System features: Industry

- Highly lucrative 1980s through 1990s
- Do well by doing good
- Highly intricate mutualism with both new biology and clinical medicine

Remedies: Goal = Trustworthiness

- **Policy remedy = disclosure**
 - But disclosure crude
 - Necessary but insufficient
 - Can induce perverse behaviors
- **Transparency**
- **Accountability for reasonableness**

Industry

- Commission sales (detailers)
- Rapid launch
- Indication creep
- Control of what information becomes public
- Pay for health outcomes
- Arms-length from academe
- Independence of R&D evidence base for coverage/reimbursement

Patents necessary?

- **No**
 - pBR322, DNA sequencing, Southern blot
- **Yes**
 - Instruments, therapeutics
- **Equivocal**
 - Diagnostics, research tools

Inherited susceptibility to *breast and ovarian* compared to *colon* cancers

A natural case study comparison

- Serious, high-prevalence cancers
- Similar fraction of cases from inherited risk
- Positive test used to decide about surgery
- Discoveries made in similar periods (mid-1990s)
- One patent-holder (BRCA) versus many (colon)

Inherited susceptibility to *breast and ovarian* compared to *colon* cancers

- Myriad has aggregated patents
- Sole provider in US (not elsewhere)
- \$3120 for BRCA1 & 2
- Unit cost lower for BRCA than colon tests
- DTC advertisements
- >90% of patients covered
- >90% of costs covered
- Powerful, organized constituencies
- Multiple patents, nonexclusively licensed
- Multiple laboratories
- \$1200-\$4760
- Myriad in middle for price
- No DTC advertising
- ? Coverage and out-of-pocket
- Less organized constituencies

Other cases

- Alzheimer's disease
- Cystic fibrosis
- Tay-Sachs v Canavans
- Hearing loss
- Hereditary hemochromatosis
- Spinocerebellar ataxias
- Long-QT syndrome

Role of academic institutions

- 75% of patents exclusively licensed to Athena university-based
- High fraction of DNA patents (10X higher than patents in general)
- Licensing practices of universities therefore matter more than in most areas
- University labs are among those 'shut down' by patent enforcement
- Academic clinical research chilled by threat of enforcement?

Policy levers

- What can be patented?
 - DNA sequences?
 - Biomarkers with credible prospect of clinical utility?
 - Clinically validated Dx and Prognostics?
- How patents are licensed
 - Especially for inventions arising from federally funded R&D
- Coverage and reimbursement policy (monopsony power with innovation incentives)
- Data exclusivity for market approval or coverage/reimbursement
- Research exemptions for basic research, clinical research, and producing data for introducing improved products/services
- Compulsory licensing
- Clinical standards and market commitments