CAN WE MAKE MEDICINE MORE PERMISSIONLESS?

MERCATUS CENTER
George Mason University

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INTERPROFESSIONAL CONTINUING EDUCATION

In support of improving patient care, this activity has been planned and implemented by Idaho State Board of Pharmacy and Idaho State University. Idaho State University is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC), to provide continuing education for the healthcare team.

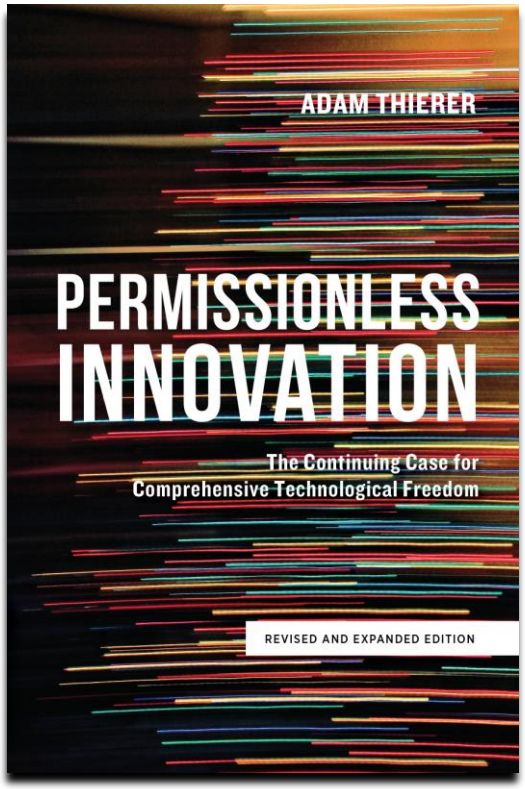
Conflict of Interest Disclosure

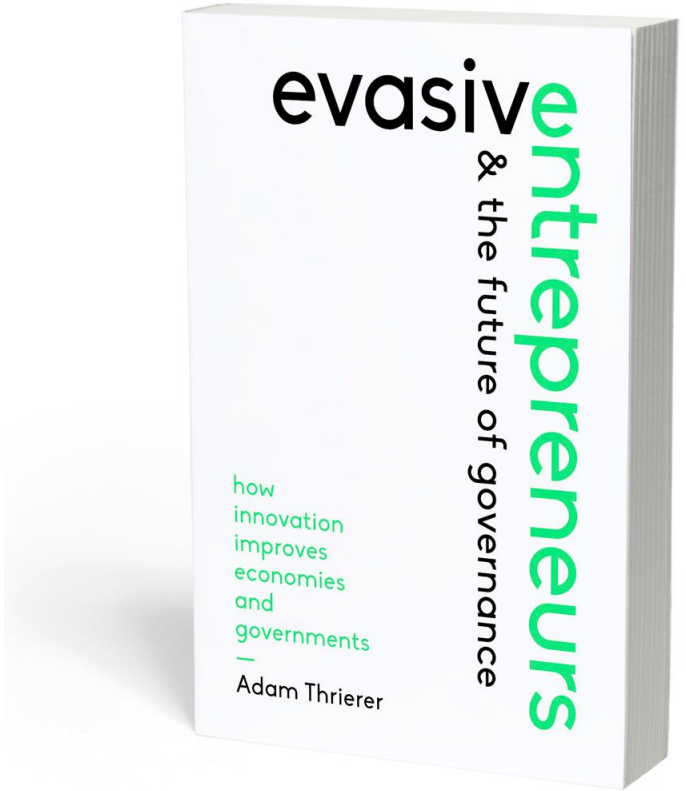
The planners and presenters of this presentation have no relevant financial relationships with a commercial interest pertaining to the content of this presentation.

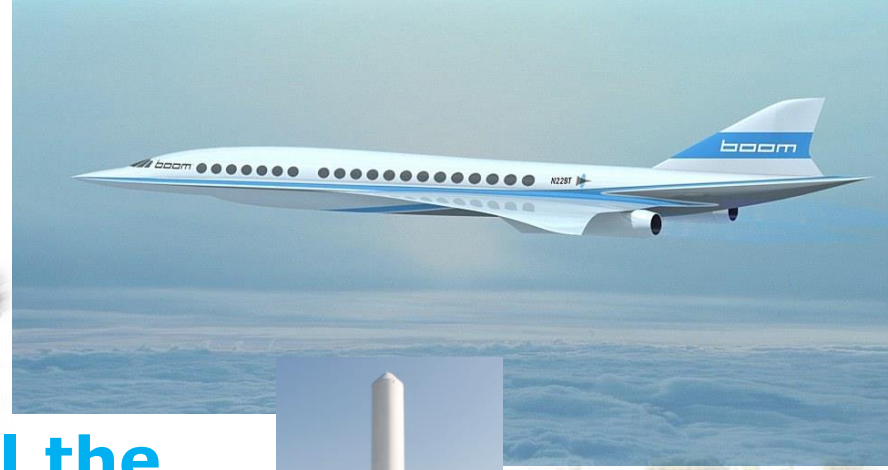
Learning Objectives

- Describe a method used to regulate the advancement of technology
- Define precautionary principle
- Discuss factors that allow pharmacy to safely advance under Permissionless Innovation

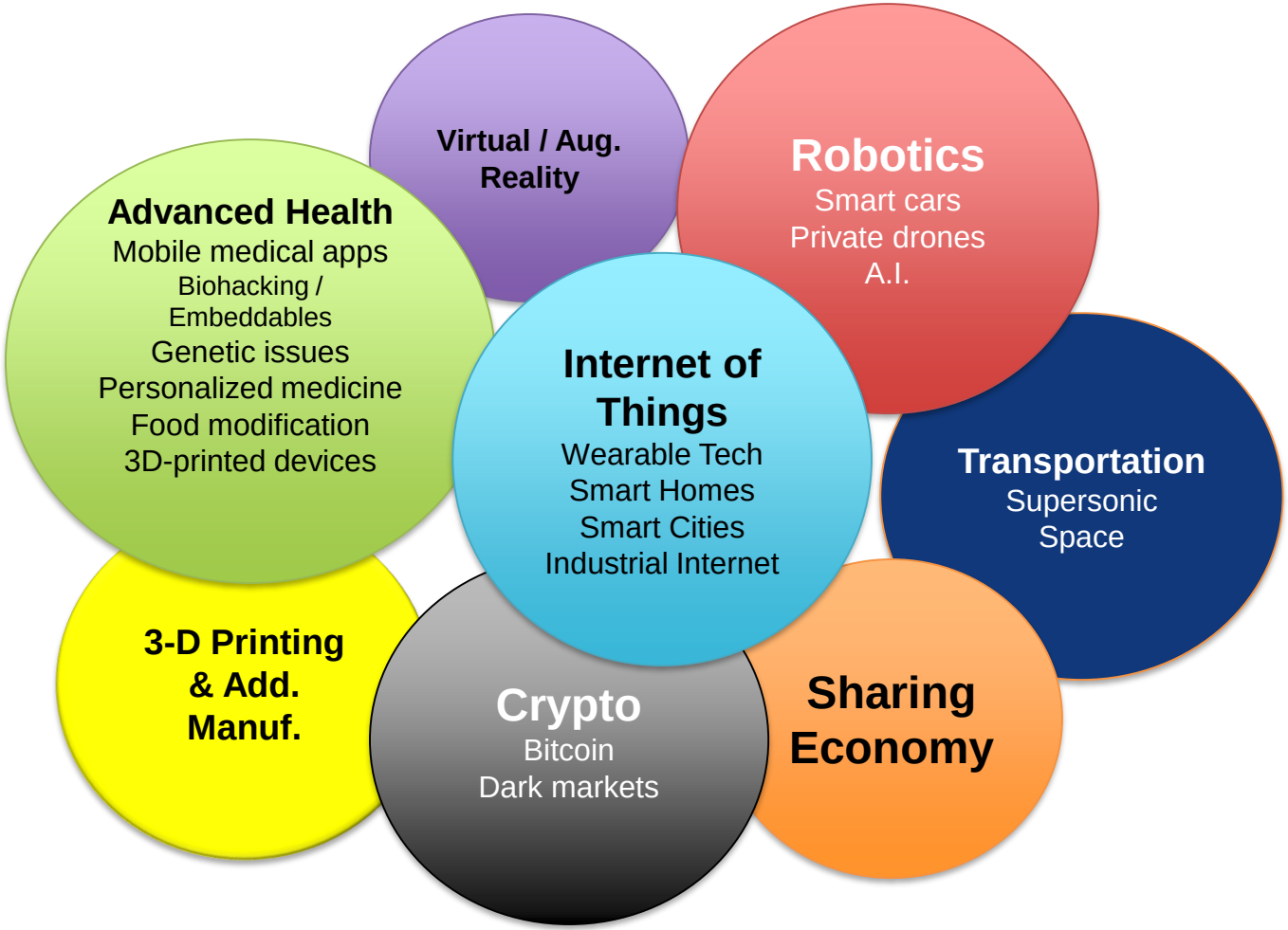
Presentation Based On…





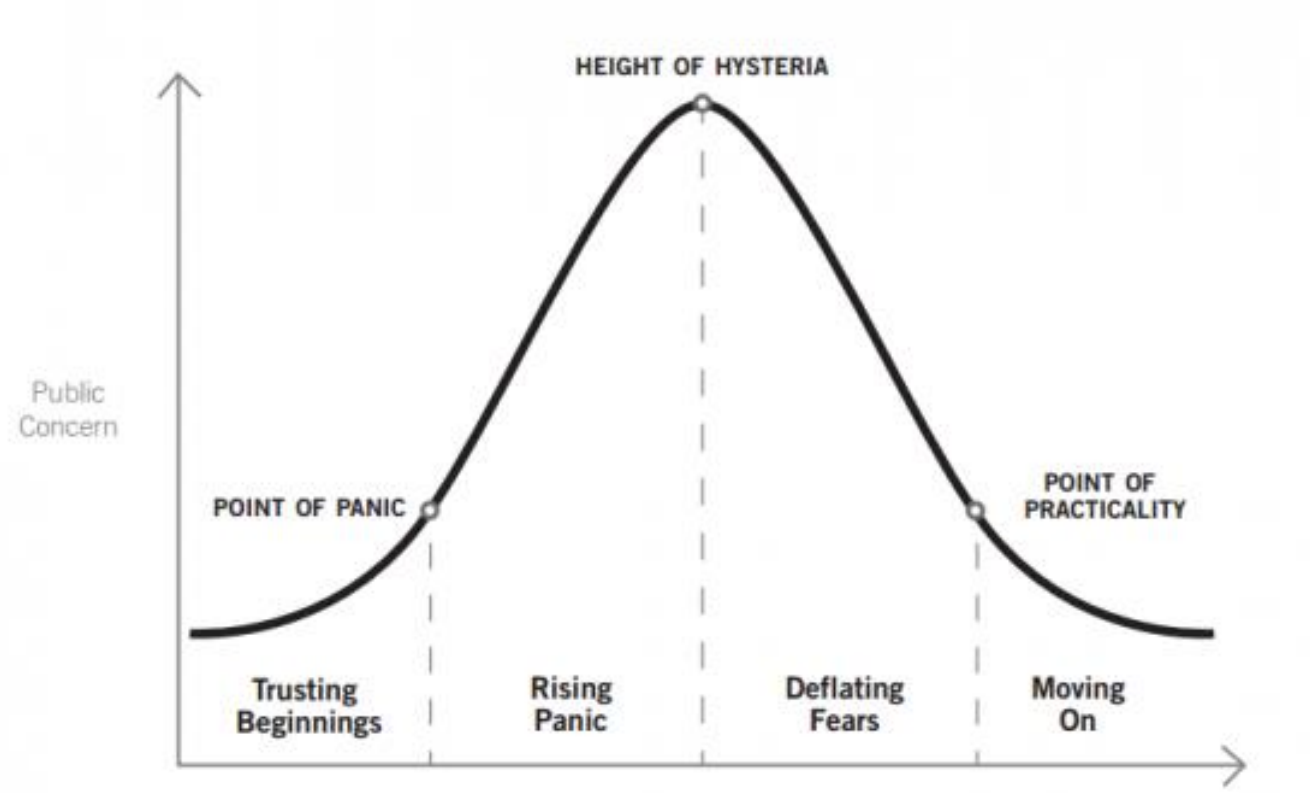


How Will the Future Be Governed?


Virtual / Aug. Reality
Robotics
Smart cars
Private drones
A.I.
Advanced Health
Mobile medical apps
Biohacking / Embeddables
Genetic issues
Personalized medicine
Food modification
3D-printed devices
Internet of Things
Wearable Tech
Smart Homes
Smart Cities
Industrial Internet
Transportation
Supersonic
Space
3-D Printing & Add. Manuf.
Crypto
Bitcoin
Dark markets
Sharing Economy

A “Technopanic” Mentality Dominates Policy Discussions

“Panic Cycles”



Source: Information Technology and Innovation Foundation

Technopanic dominates news headlines

There's Nothing Wrong with Being a Luddite

If the Robots Kill Us, It's Because It's Their Job

Don't kill us, guys.

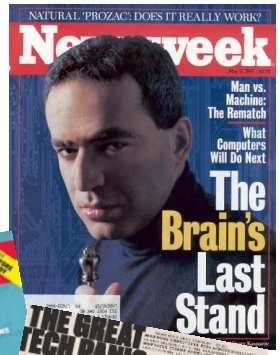
It's OK to Be a Luddite

As Robotics Advances, Worries of Killer Robots Rise

5 Ways Skynet Is More Real Than You Think

Robots may shatter the global economic order within a decade

A World Without Work



THE IDEAS ISSUE
Atlantic

Is Google Making Us Stoopid?

WHAT THE INTERNET IS DOING TO OUR BRAINS

Technology Might Be Killing Us, But It Doesn't Have to Be That Way

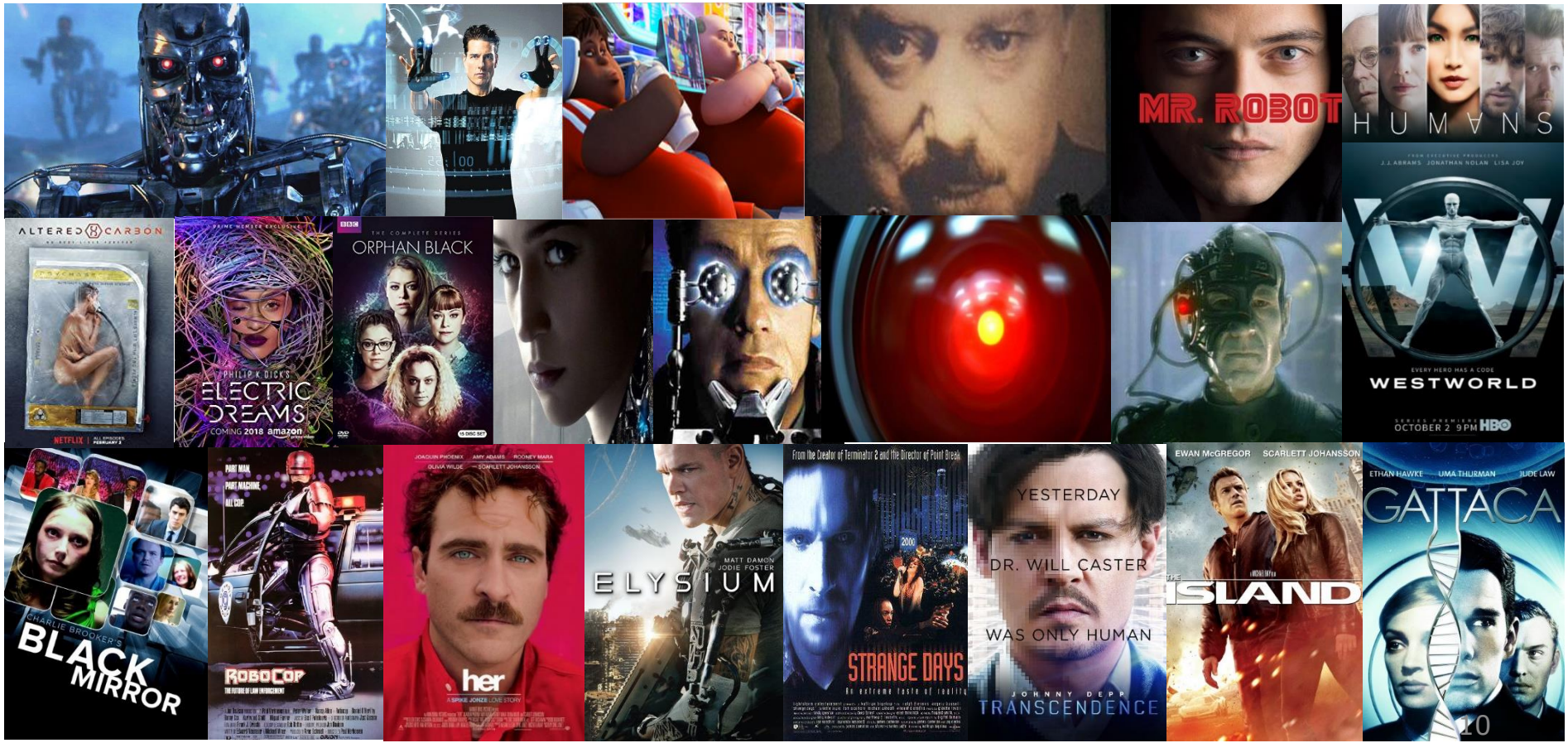
Have Smartphones Destroyed a Generation?

The Threat of Big Tech Is Real

Curse of the Frankenfoods

Technopanic dominates academic writing

Technopanic dominates pop culture



The Clash of Policy Paradigms

Permissionless Innovation
vs.
the Precautionary Principle

Tech Policy Paradigms / Governance “Visions”

Permissionless Innovation = The general freedom to experiment & learn through trial-and-error. A general openness to change, disruption, risk-taking & the possibility of failure.

Precautionary Principle = Crafting public policies to control or limit new innovations until their creators can prove that they won’t cause any harms.

“Hopper’s Law”

“***It’s easier to ask forgiveness than it is to get permission***.”

- Former Navy Rear Admiral Grace Hopper explaining how she got things done as a computer programmer in the US Navy.

The Conflict of Visions over Innovation Policy

	Precautionary Principle	Permissionless Innovation
Innovation	must be carefully guided	should be free-wheeling
Priority	Stability / equilibrium	Spontaneity / experimentation
Risk	risk *anticipation* is preferred	risk *adaptation* is preferred
Solutions	Preemptive (*ex ante*) top-down controls/solutions	Reactive *(ex post)* bottom-up remedies
Presumption	Innovators must ask, "Mother, May I?"	Innovators are "innocent until proven guilty"
Ethos	"Better to be safe than sorry"	"Nothing ventured, nothing gained"

Why Permissionless Innovation Should Generally be the Default

If we spend all our time living in constant fear of worst-case scenarios—and premising public policy upon such fears—it means that *best-case* scenarios will never come about.

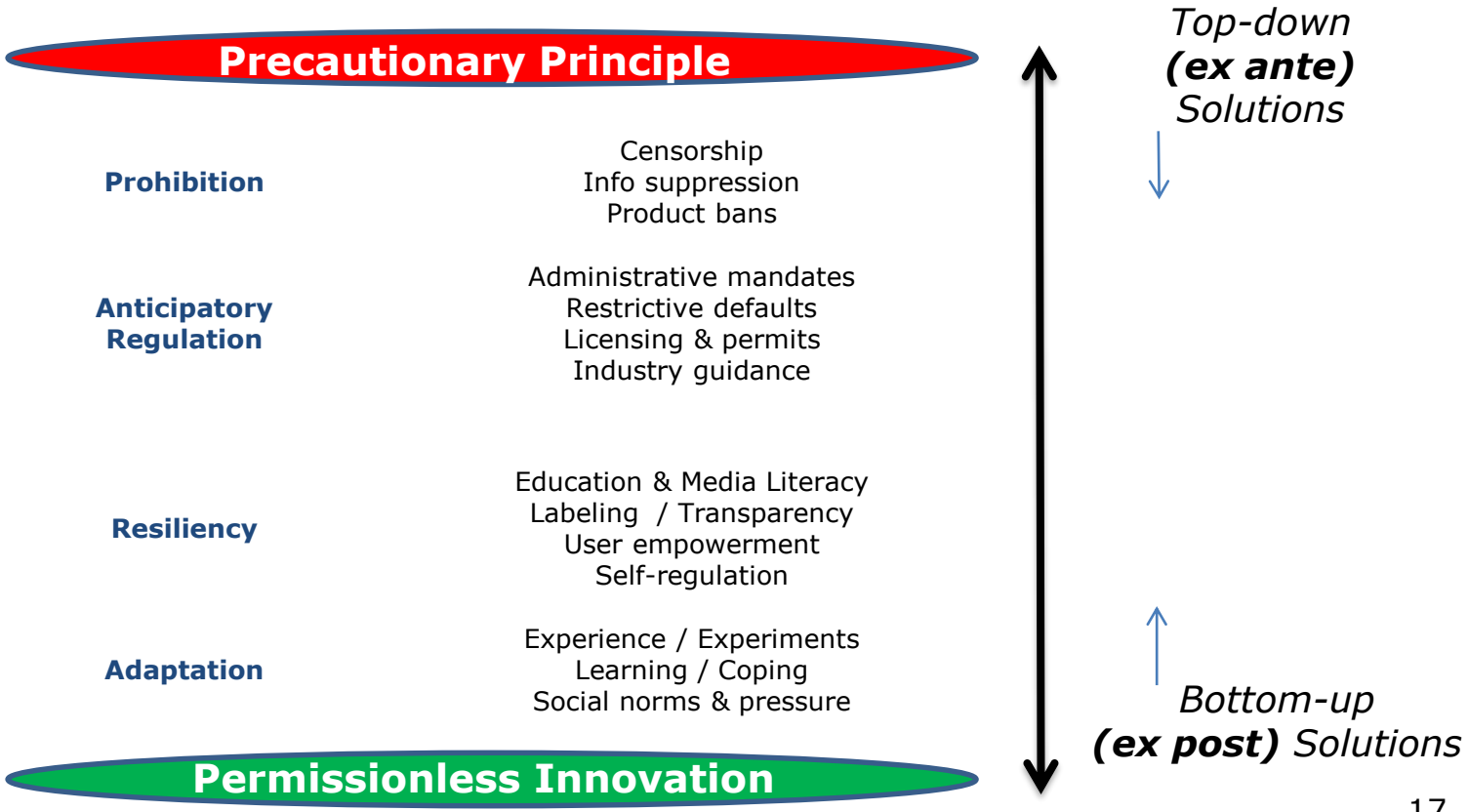
Wisdom and progress are born from experience, including experiences that involve risk and the possibility of occasional mistakes and failures.

“The Risk of Avoiding All Risks”

There can be no reward without some risk.

The Precautionary Principle vs. Permissionless Innovation

A Range of Responses to Technological Risk



What Happens When Worlds Collide?

… when digital tech invades health & medical arena?
… when old & new policy paradigms conflict?

A Conflict of Visions for Medicine

Traditional Medicine

- Paternalistic
- Permission-based
- Risk is feared
- Prior restraints (*ex ante* controls)
- "Mother, May I?"
- "Fortress" mentality

Internet Model

- Freedom-oriented
- Permissionless
- Risk is embraced
- No prior restraint (*ex post* remedies)
- "Innocent till proven guilty"
- "Frontier" mentality

Problem: These worlds are colliding.

Technologies That are "Born Free" Will Have an Easier Time than Those "Born in Regulatory Captivity"

"<u>Born Free</u>"

(less law / few agencies)

- online services / social media
- Smartphone apps
- 3D Printing
- Virtual Reality / AR
- robotics
- Artificial intelligence

"<u>Born Captive</u>"

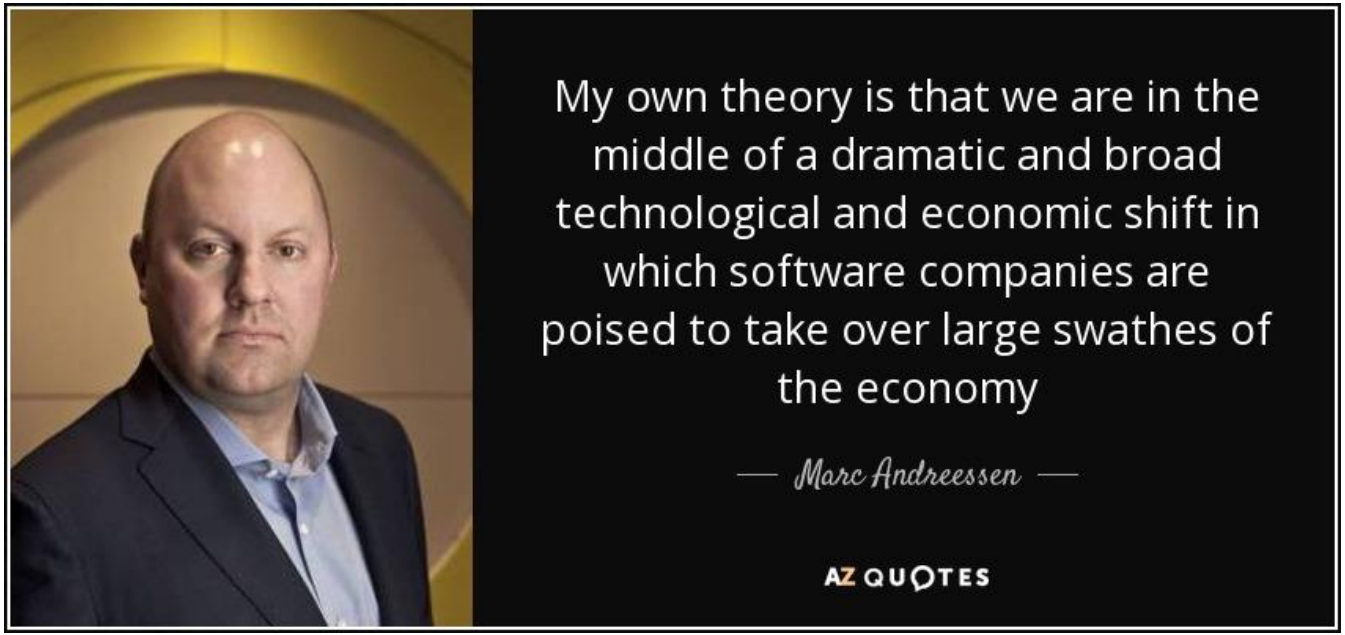
(lots of law / existing agencies)

- Driverless cars (DOT)
- Medical technology (FDA)
- Food tech (FDA, USDA)
- Commercial drones (FAA)
- Supersonic & Space (FAA)
- Financial services

Problem: Again, these worlds are colliding!

“Software Is Eating the World”

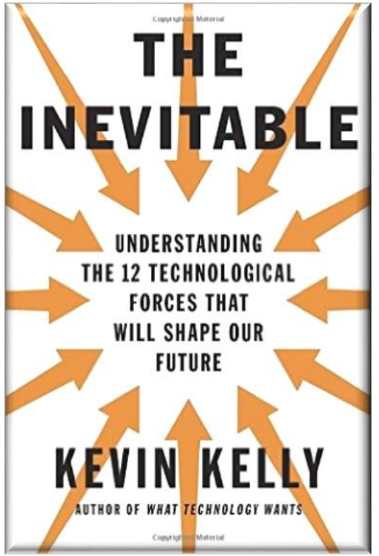
- Marc Andreessen



“Health care and education, in my view, are next up for fundamental software-based transformation.”

Drivers of Modern Tech Disruption are Spreading

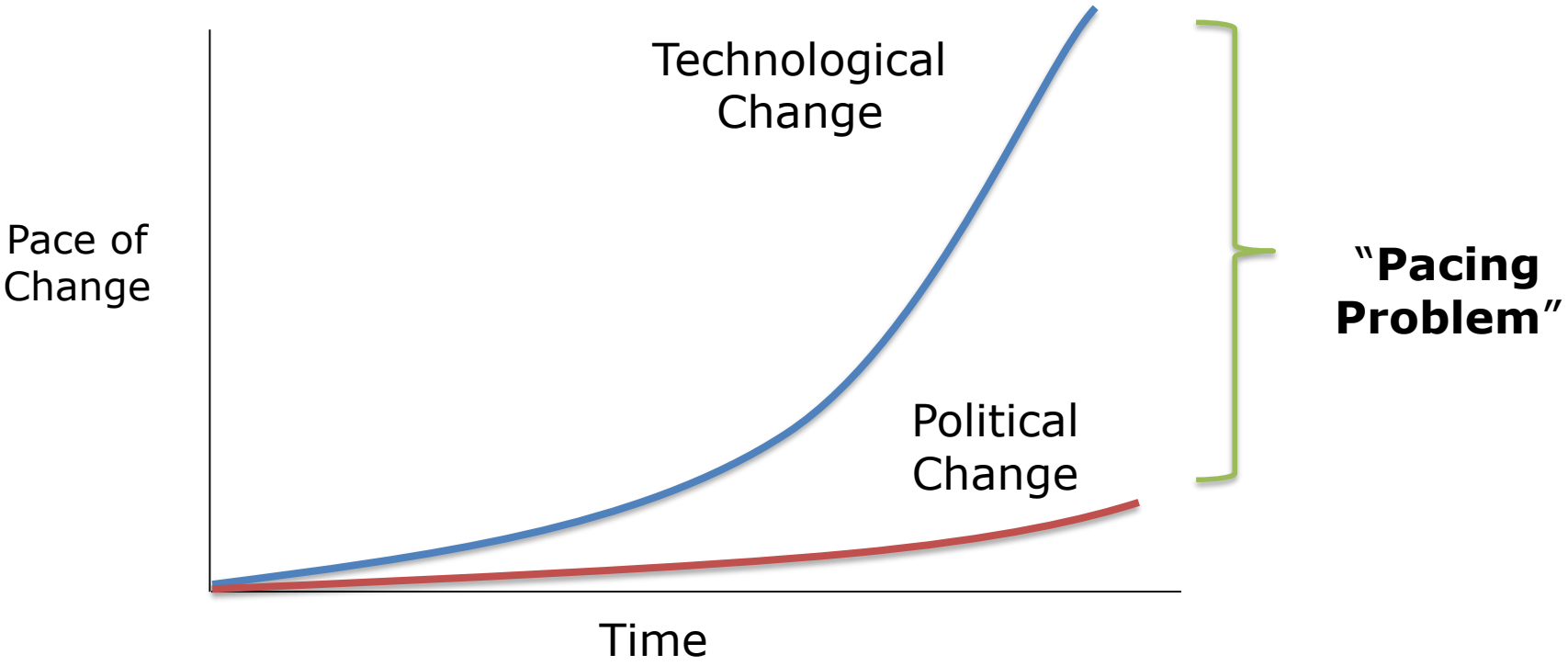
- ✓ the **digitization** of all data
- ✓ massive increases in **processing power**
- ✓ exploding **storage capacity**
- ✓ ubiquitous **networking capabilities**
- ✓ steady **miniaturization** of everything
- ✓ increasing **sensorization** of the world
- ✓ falling **cost** of almost everything



These factors are now putting pressure on the medical profession and its regulation.

“Pacing Problem” is Intensifying

Technology changes *exponentially*; Political systems change *incrementally*.

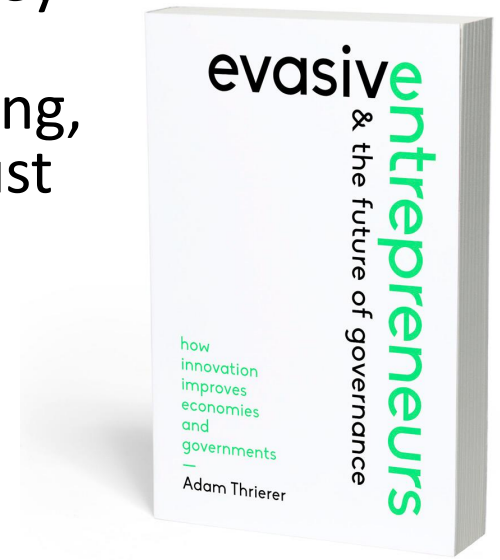


The “Collingridge Dilemma“

- It’s hard to put the proverbial genie back in the bottle once a given technology has reached a certain inflection point.
  - “The social consequences of a technology cannot be predicted early in the life of the technology. By the time undesirable consequences are discovered, however, the technology is often so much part of the whole economics and social fabric that its control is extremely difficult.” - David Collingridge, *The Social Control of Technology* (1980)
  - In other words, once people have it, they won’t give it up easily.
- Collingridge referred to this as the “dilemma of control.”
  - “When change is easy, the need for it cannot be foreseen; when the need for change is apparent, change has become expensive, difficult and time-consuming.”

Technological Civil Disobedience or Evasive Entrepreneurialism

- The refusal of innovators (individuals, groups, or even corporations) or consumers to obey technology-specific laws or regulations because they find them offensive, confusing, time-consuming, expensive, or perhaps just annoying and irrelevant.
- Examples:
  - Uber, AirBnB
  - 3D printing of medical devices
  - Smartphone fitness & diet applications



“Innovation Arbitrage” increasing

- Getting easier for innovators to relocate to jurisdictions that provide legal and regulatory environment more hospitable to entrepreneurial activity.
- What happened with capital flows now happening with innovative activities.
- Happening at both global and domestic scale.
- Ex: genetic testing & modification; medical tourism

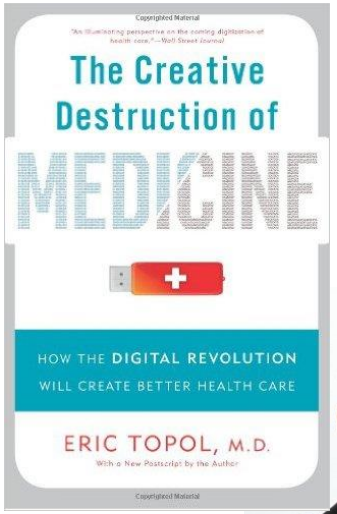
Congress is Less Engaged in Tech Policy

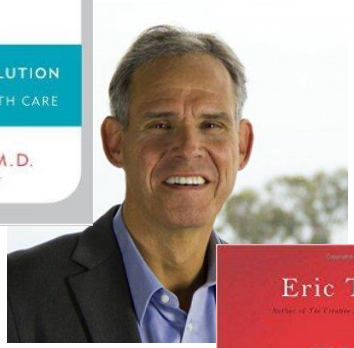
- legislative and executive efforts to craft policy undermined by chronic "demosclerosis"
  = **growing government dysfunctionalism brought on by the inability of public institutions to adapt to changes**
  - Causes: regulatory accumulation, bureaucratic bloat, special interest rent-seeking, lack of expertise, etc.
- we shouldn't expect federal lawmakers to play as much of a role in technological governance as they did in past decades

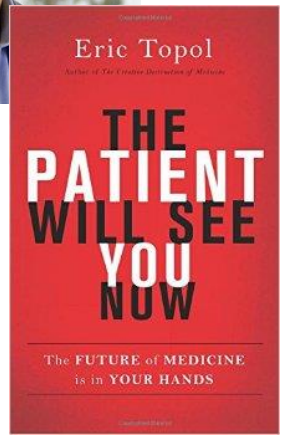
The Combined Effect of All These Trends

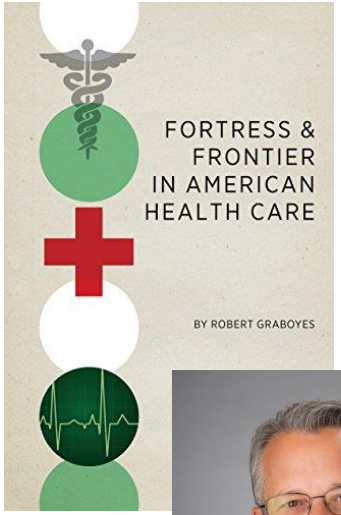
- Combination of pacing problem + evasive entrepreneurialism + global innovation arbitrage + unlevel playing fields + demosclerosis = **gradual decline of "hard law"**
- Corresponding rise of "spontaneous private deregulation"
  - the *de facto* rather than the *de jure* elimination of traditional laws and regulations
  - no laws have been altered; no formal deregulation has occurred and yet liberalization has occurred

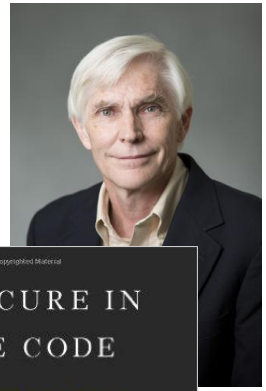
What Does This Mean for Medicine?

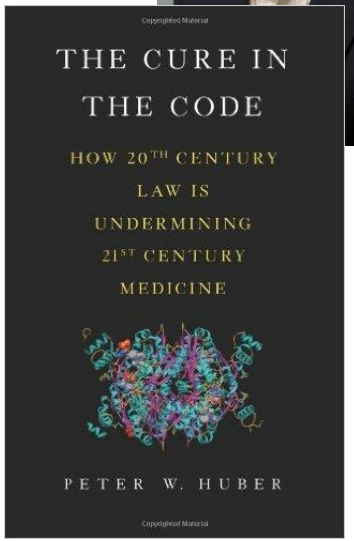












5 Specific Future Fault Lines

1. Smartphones, health apps, IoT & wearables
2. 3D Printing of medical devices
3. Big Data, artificial intelligence & “precision medicine” or “personalized medicine”
4. Genetic testing & editing
5. Biohacking & open source science / citizen science

Wearables, Mobile Health & the "Quantified Self"

Nathan Cortez's "Typology of Mobile Health Technologies"

- ***Connectors***: applications that connect smartphones and tablets to FDA-regulated devices, thus amplifying the devices' functionalities.
- ***Replicators***: applications that turn a smartphone or tablet itself into a medical device by replicating the functionality of an FDA-regulated device.
- ***Automators & Customizers***: apps which use questionnaires, algorithms, formulae, medical calculators, or other software parameters to aid clinical decisions.
- ***Informers & Educators***: medical reference texts and educational apps that primarily aim to inform and educate.
- ***Administrators***: apps that automate office functions, like identifying appropriate insurance billing codes or scheduling patient appointments.
- ***Loggers & Trackers***: apps that allows users to log, record, and make decisions about their general health and wellness.

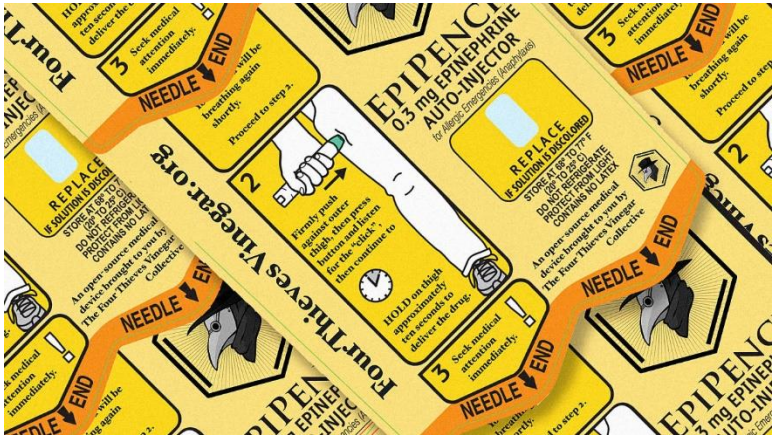
The “Sci-Fi” Future of IoT & Wearables Will Arrive Shortly

- “**Implantables**” = IoT implanted under skin
- “**Ingestibles**” = IoT tech that is swallowed

- “**Biohacking**”= Body modification to enhance or repair human abilities
  - *see:* http://forum.biohack.me

Citizen Scientists & Community Open Science Labs

Should DIY citizen scientists & community labs be allowed to make free life-saving drugs and devices?



3D-printed prosthetic limbs

"e-NABLE" volunteers use open-source blueprints & 3D printers to give kids free prosthetic limbs. FDA violation?

Families custom-made insulin pumps & orthosis

Parents using 3D printers & open source code to help their children with diabetes or cerebral palsy. Do we regulate parents?

NIGHTSCOUT
#WeAreNotWaiting

3D-Printed orthodontics

23-year old Amos Dudley used a 3D printer to make his own braces. Did this kid violate FDA regs? What if he would have taught others how to do it themselves? Or sold them?

Will We Get the "Right to Try" to Medical Tech Without Ever Passing Any Laws?

- In this new world, traditional "command and control" regulation will start breaking down
- Citizens will gain "right to try" many new technologies without getting anyone's permission
- What are we to do about "technologically-enabled civil disobedience"??

A New World Demands New Solutions

3-Part Plan

1. **Old barriers need to be reformed quickly**
   - *Federal*: food & drug law reform / FDA reforms
   - *State*: relax licensing laws / barriers to entry
2. **"Soft law" becomes essential**
   - Agency "guidance" & best practices become new norm
3. **Need for stepped-up risk education**

Remove Barriers to Innovation

“Right to Earn a Living” / Occupational licensing reform:

(1) “All occupational regulations shall be limited to those demonstrably necessary and carefully tailored to fulfill legitimate public health, safety, or welfare objectives.”
(2) “Within one year following enactment, every agency shall conduct a comprehensive review of all occupational regulations and occupational licenses within their jurisdictions.”

“Right to Try” / “Right to Tinker”

The Innovator’s Presumption: *Any person or party (including a regulatory authority) who opposes a new technology or service shall have the burden to demonstrate that such proposal is inconsistent with the public interest.*

The Sunsetting Imperative: *Any existing or newly imposed technology regulation should include a provision sunsetting the law or regulation within two years.*

The Parity Provision: *Any operator offering a similarly situated product or service should be regulated no more stringently than its least regulated competitor.*

Soft Law: Hard to Define, But Dominant

- "**Instruments or arrangements that create substantive expectations that are not directly enforceable**, unlike 'hard law' requirements such as treaties and statutes." (Marchant and Allenby)
- *Informal, collaborative,* and *constantly evolving* governance mechanisms
- Soft law already the dominant governance model for today for technology such as: driverless cars, mobile medical applications, the Internet of Things, biometrics, nanotech, biotech, 3D printing, bitcoin, online advertising, and more

Soft Law Mechanisms for Emerging Tech

- Guidance documents
- “Sandboxes” (informal consultations) & soft nudges
- Multistakeholder processes
- Agency workshops & reports
- Best practices & codes of conduct
- Industry self-regulation, co-regulation & other collaborative efforts

Soft law has become the dominant *modus operandi* for modern technological governance, at least in the United States

Examples of Modern Soft Law

- NHTSA
  - **Policy guidance** on autonomous vehicles
  - **Proactive principles** for vehicular cybersecurity
- NTIA
  - **Best practices** for commercial facial recognition technology
  - **Privacy best practices** and **multistakeholder process** for commercial unmanned aircraft systems
  - **Voluntary frameworks** and **multistakeholder process** on IoT security upgradability
- OSTP
  - **White papers** and **reports** on AI and big data
- FDA
  - **Guidance for industry** on clinical trial best practices, "medical" smart phone apps, and 3D-printed medical devices
- FTC
  - **Staff reports** and **guidance documents** on the IoT
- FAA
  - **Advisory circulars** on small unmanned aircraft systems

FDA Stepping Up Use of Soft Law

- FDA has been using guidance documents since it was the Bureau of Chemistry
- FDA is the most prolific agency promulgator of soft law releasing over 100 guidances every year
  - Reliance is so significant “that a Government Accountability Office report from 2015 noted that, ‘certain provisions of the OMB Bulletin [on “Good Guidance Practices”] were informed by written FDA practices for the initiation, development, issuance, and use of their guidance documents.”

More Risk Education Needed

- aim to better inform citizens about relative risk trade-offs they face with new technological capabilities.
- risk education should focus on both the general public and the innovators
- essential in a world of highly personalized medicine, where citizens are more empowered to make their own wellness decisions
- Already part of the FDA's mission, but secondary
  - *Strategic Plan for Risk Communication* (2009)
  - *Communicating Risks and Benefits: An Evidence-Based User's Guide* (2011)

New Policy Approach

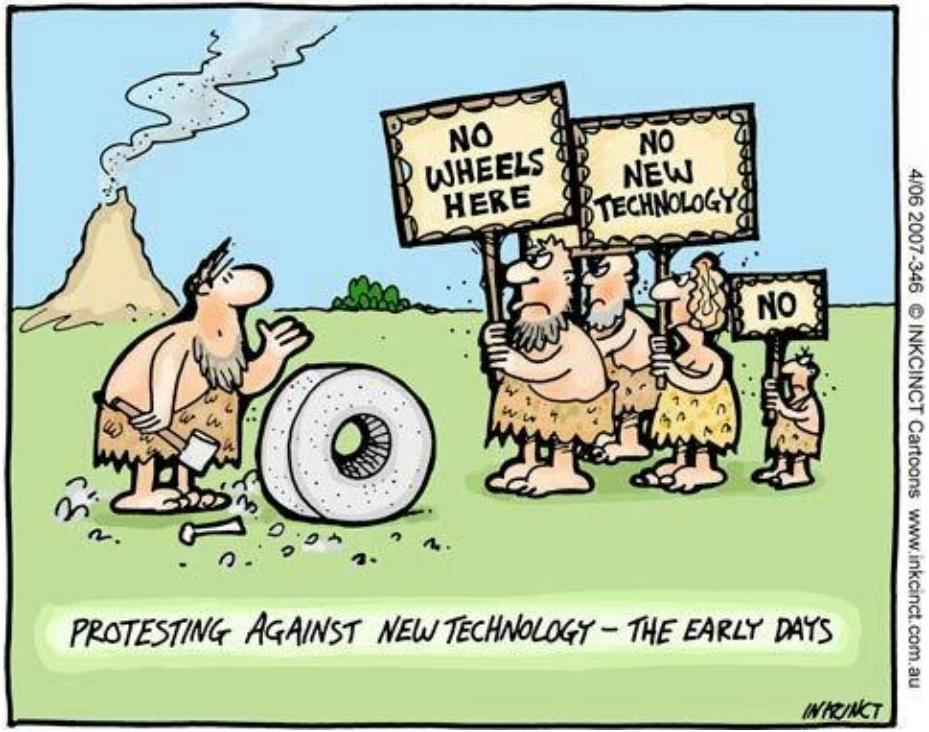
- Move toward permissionless innovation where possible
  - innovators are innocent until proven guilty
  - opt for “educate & empower” before “legislate & regulate”
- Science before politics
  - Cost-benefit analysis; sensible definition of “harms”
- Touchstones of good governance…
  - adaptability, flexibly, openness to change
  - humility, patience, forbearance
  - lots of room for experimentation & reevaluation
  - “simple rules for a complex world”

Borrow from Clinton's Internet Vision

Framework for Global Electronic Commerce (1997):

1. "the private sector should lead. The Internet should develop as a **market driven arena** not a regulated industry."
2. "**governments should avoid undue restrictions** on electronic commerce" & "parties should be able to enter into legitimate agreements to buy and sell products and services across the Internet with minimal government involvement or intervention."
3. "where governmental involvement is needed," the Framework continued, "its aim should be to support and enforce a **predictable, minimalist, consistent and simple legal environment** for commerce."

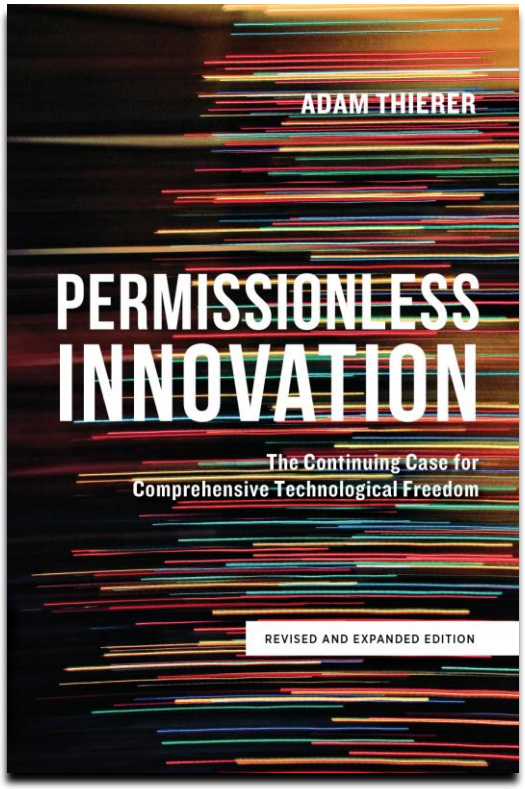
Let's Keep the Wheels of Progress Moving!

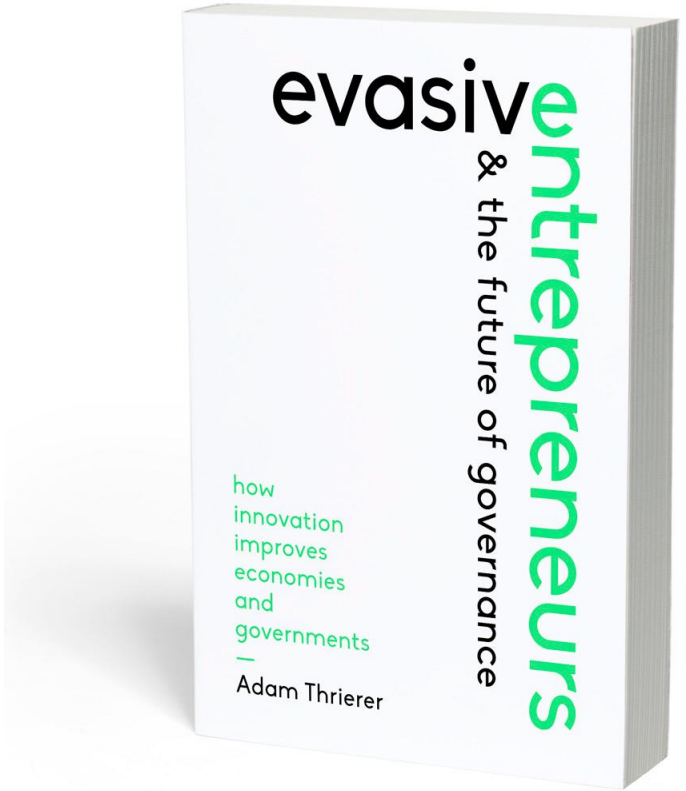


"The biggest risk that society faces by adopting approaches that suppress innovation is that they amplify the activities of those who want to preserve the status quo by silencing those arguing for a more open future."

- Calestous Juma

For more information…





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