Startup Engineering
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Regulation, Disruption, and the Technologies of 2013

Overview

Perhaps the most common critique of the technology industry today is that too much money, ability, and energy is focused on social games, photosharing, advertising, todo lists, and the like. Some critics harken to a past where the Valley invested in tangible breakthroughs in PCs, semiconductors, and networking, others can't find much positive to say about technology in general, and generally many people feel that the Valley is now suffering from a failure of imagination (1, 2, 3, 4, 5, 6). A related and overlapping critique is that an innovation slowdown has occurred. This thesis has been most prominently advanced by Tyler Cowen in *The Great Stagnation* and by Founders Fund. While Cowen points to the macroscopic plateau in Total Factor Productivity, FF makes the empirical case for technological slowdown via three concrete examples in *What Happened to the Future*:

1. The travel speed from NY to London has actually decreased, with the retiring of the Concorde.
2. The cost of approving a drug has soared precipitously to $3-4 billion.
3. The cost of electricity in cents-per-kilowatt-hour has actually increased.

Let's pull these observations together and see if we can advance a causal hypothesis. Is there some kind of force that is discouraging future entrepreneurs from working on substantive problems, especially in the physical world, despite their large market size? Or is it simply a question of a lack of ideas or bravery on the part of Silicon Valley?

Gaining Context

Before we answer in the abstract, let's begin with an assemblage of news clips to set the stage, a bit like Nicholson Baker's Human Smoke. There are quite a few of these, but by the end you will have some context and perhaps some hypotheses as to what's going on.

Transportation and Lodging

A four year NHTSA ban on self-driving cars (CS Monitor):

> The last few years have seen self-driving cars go from the stuff of science fiction to the scientific method. Real cars are really driving themselves on some roads, and many current or near-future cars offer some form of assisted driving already. But the National Highway Traffic Safety Administration (NHTSA) wants to ban them.

> Or, NHTSA wants each state to ban them, at least. In an announcement today outlining its policy on automated vehicles, NHTSA called for the ban of public use of self-driving cars. . . .
>
> It's not yet clear how long NHTSA wants the ban to be in place; according to today's announcement, it could be a long, long ban:
>
> "While the technology remains in early stages, NHTSA is conducting research on self-driving vehicles so that the agency has the tools to establish standards for these vehicles, should the vehicles become commercially available. The first phase of this research is expected to be completed within the next four years," the agency said in the statement.

James Fallows, Atlantic Editor, on Uber vs. Washington DC (The Atlantic):

> As a longtime resident of DC, I am accustomed to misadventures in governance in our "taxation without representation" existence here. But a fight over a new competitor to the District's (often horrible) taxi service offers something I haven't seen in a while. Not routine retail-level corruption, nor skillful top-level favor trading, but instead what appears to be a blatant attempt to legislate favors for one set of interests by hamstringing another. I know, I know, this happens all the time – but the seeming crudity of this one gets my attention. ..
>
> But it appears that the DC Council will vote today on a proposal to cripple Uber by ensuring that its minimum fare is five times higher than that for metered taxis, which also rules out a lower-cost hybrid option Uber has just introduced. C'mon!

Uber, Lyft, Sidecar and the CPUC (LA Times):

> California Public Utilities Commission Chairman Michael R. Peevey sent a not-so-subtle message to the Los Angeles City Council on Tuesday: Hands off Uber, Lyft and Sidecar.
>
> The commission had previously asserted jurisdiction over the companies and their ilk, which enable customers to use a smartphone app to summon rides from limousines (Uber) or private cars (Lyft, Sidecar, InstantCab). Peevey's proposed rule, which the full commission could consider in September, declares that such "transportation network companies" are "charter party passenger carriers," which are subject to the PUC's jurisdiction, and not taxis, which would be subject to local oversight.
>
> Some members of the Los Angeles City Council have taken the opposite view, proposing an ordinance to regulate Web-enabled transportation companies as taxis.

Elon Musk of Tesla and Car Dealers (Jalopnik):

> Another week, another victory for Tesla in their ongoing war with car dealerships. This time it's in North Carolina, whose legislature has backed off on a bill that would have blocked Tesla sales in that state.
>
> That bill, backed by the N.C. Automobile Dealers Association, would have made the direct-to-customer sales model used by Tesla illegal in North Carolina. Though

> it didn't mention Tesla by name, the bill was intended as a shot at the company, whose sales model threatens the traditional dealer-as-middleman concept that dominates how cars are sold.
>
> The North Carolina bill made it through their senate, but the Raleigh News & Observer reports that House members weren't too keen on it - in part because of Tesla's strong quarterly profits, and because they liked the Model S after taking it for a test drive along with Gov. Pat McCrory.

John Carmack, co-founder of iD Software, lead programmer on Quake and Doom, and founder of Armadillo Aerospace (link)

> A couple things slowly brought me around to paying more attention. A computer game company doesn't need to have much to do with the government, but a company that flies rocket ships is a different matter. Due to Armadillo Aerospace, in the last decade I have observed and interacted with a lot of different agencies, civil servants, and congressmen, and I have collected enough data points to form some opinions.
>
> My core thesis is that the federal government delivers very poor value for the resources it consumes, and that society as a whole would be better off with a government that was less ambitious. This is not to say that it doesn't provide many valuable and even critical services, but that the cost of having the government provide them is much higher than you would tolerate from a company or individual you chose to do business with. For almost every task, it is a poor tool.
>
> So much of the government just grinds up money, like shoveling cash into a wood chipper. It is ghastly to watch. Billions and billions of dollars. Imagine every stupid dot-com company that you ever heard of that suckered in millions of dollars of investor money before leaving a smoking crater in the ground with nothing to show for it. Add up all that waste, all that stupidity. All together, it is a rounding error versus the analogous program results in the government. Private enterprises can't go on squandering resources like that for long, but it is standard operating procedure for the government.
>
> Even if you could snap your fingers and get it, do you really want a razor sharp federal apparatus ready to efficiently carry out the mandates of whoever is the supreme central planner at the moment? The US government was explicitly designed to make that difficult, and I think that was wise.
>
> So, the federal government is essentially doomed to inefficiency, no matter who is in charge or what policies they want it to implement. I probably haven't lost too many people at this point - almost nobody thinks that the federal government is a paragon of efficiency, and it doesn't take too much of an open mind to entertain the possibility that it might be much worse than you thought (it is).

Peers.org and Collaborative Consumption (Politico):

> Founding partners include short-term apartment rental company Airbnb, car-sharing companies Getaround and Lyft, solar projects company Solar Mosaic and others. . . . PEERS "is a grass-roots organization that supports the sharing economy movement. We believe that by sharing what we already have - like cars,

homes, skills and time - everyone benefits in the process." The group will be led by former Obama campaign and Democratic National Committee Digital Director Natalie Foster. Milicent Johnson, who founded a similar sharing advocacy group in the Bay area, will serve as director of partnerships and community building. Obama campaign veteran Alex Lofton will serve as managing director, while James Slezak will be director of strategy.

Drone Startups and the FAA (Wired):

> Domestic-Drone Industry Prepares for Big Battle With Regulators . . .
>
> "I didn't change any guidelines," Williams interrupted. "I didn't say that any guidelines changed. I said that if a farmer as an individual wants to operate an unmanned aircraft according to the modeling rules, they can do that. The FAA rules are very clear about for-compensation and hire. If you're going to operate an aircraft for compensation or hire, there's a different set of rules that apply. So, you know, I'm not gonna split hairs over whether the farmer is making a profit or not, nor are we going to go look for him, but the bottom line is the rules are the rules and we have to enforce them until they're changed."
>
> "So unmanned aircraft companies can operate R&D as long as they're within the modeling guidelines?" Novara continued. Laughter and applause broke out among the hundreds of drone enthusiasts inside the Tyson's Corner Ritz-Carlton.
>
> "That's why we have experimental certificates, to allow manufacturers-"
>
> "The farmer doesn't need an experimental certificate," Novara pressed, "and everyone knows the experimental certificate process is available but not actually functional."
>
> Williams conceded that the current FAA rules "need to change," since they were written for manned aircraft, "and that's why we're working hard to get the small unmanned aircraft rule out that will help resolve these issues. Until such time, we have to enforce the rules that are in place."
>
> "Is everyone else clear on this?" Novara asked, to bales of laughter. Some in the crowd shouted "No!" . . .
>
> "If we were all smart guys, we'd be in consumer products, right?" Novara tells Danger Room. "It's what I like doing. There's just no money in it."

AirBnB and New York State (Guardian):

> What about the legal issues, in cities and countries where people aren't allowed to rent out their rooms or properties without being licensed to do so? New York, Amsterdam and Quebec are just three high-profile examples of places where Airbnb has faced regulatory scrutiny.
>
> Gebbia was bullish in his response. "When the car was introduced in 1908, people could experience a brand new way to travel that was more efficient than a horse and buggy," he said.
>
> "Can you believe that cities tried to outlaw cars in the United States? Can you imagine driving a car for a year then having to go back to a horse and buggy? The policy-makers adjusted to meet the demands of the people. We believe it's

time for our invention, and it appears the world agrees, given we're in 40k cities in 192 countries."

Payments and Finance

Bart Chilton of CPUMC on Bitcoin (Reuters):

> The top U.S. derivatives regulator is considering whether the Bitcoin virtual currency should be subject to its rules, a top official at the agency said.
>
> Bart Chilton, one of five commissioners at the Commodity Futures Trading Commission, said he had asked staff to explore whether consumers needed more protection from any mishaps with Bitcoin, whose value collapsed last month.
>
> "Here's what I know for sure: we could regulate it if we wanted. That is very clear," Chilton told Reuters in an interview on Monday. The Financial Times was first to report on Chilton's plans.

Bitcoin Foundation Response to Cease and Desist Letter (Ars Technica, Coindesk):

> According to the DFI's letter, which was sent on May 30, the Bitcoin Foundation requires licensure as a money transmitter under California law.
>
> "The California state DFI said this was an invitation to talk. I've received nicer invitations, but we took it then as an opportunity to engage in a discussion about what we think the issues are and how we think the law agrees," Patrick Murck of the Bitcoin Foundation told CoinDesk.
>
> The primary points raised in the response letter are that the foundation doesn't sell bitcoins nor operates in California, so it is not under the jurisdiction of the DFI.
>
> "Even if we did operate an exchange or sell bitcoins, we have never done it with anyone in California, so they have no jurisdictional basis for coming and looking at us in the first place," said Murck. ...
>
> Murck went on to say he thinks the response letter, which was drafted by legal firm Perkins Coie, will lead to more discussions with the DFI over the next few weeks, and will hopefully result in a letter of opinion.
>
> Murck said attorneys are starting to become very popular among those in bitcoin and advised people with any concerns to seek legal advice. "It was great to walk into the Bitcoin London conference yesterday and have a legal panel that people love and pay so much attention to, but it's also a shame. "The people who should be front and centre on the stage are the entrepreneurs building companies. Hopefully we can get back to that place," he concluded.

Paypal and the Patriot Act (CNN):

> EBay's PayPal accused of violating Patriot Act
>
> PALO ALTO, California (Reuters) – A federal prosecutor has alleged eBay Inc. unit PayPal violated a 2001 anti-terror law aimed at fighting money laundering when it provided payment services to online gambling companies, the Web auctioneer said in its annual report filed Monday.

Eliot Spitzer and Paypal (Who Killed Paypal):

> But PayPal's regulatory troubles persisted. The banking industry had tried and failed several times to set up competitors to PayPal and Billpoint. As entrenched industries often do, it turned to government when its efforts in the marketplace failed. Oregon, California, Illinois, and Louisiana subsequently sent Billpoint notices that it had failed to get a money transfer license. A director from the American Banking Association told CNET that online payment services should be classified and regulated as commercial banks - a move that likely would have killed off all online payment services except those run by existing banks.
>
> More class actions followed. New York Attorney General Eliot Spitzer cited PayPal for posting a user agreement that "wasn't clear enough." He also subpoenaed all documents pertaining to PayPal's use in online gaming sites, suggesting the company was in violation of New York gambling laws. Spitzer's investigation was followed by a U.S. Justice Department determination that PayPal's use by gaming sites was a violation of the USA PATRIOT Act.
>
> The financial pressures of battling aggressive government officials and opportunistic class action lawyers, all while trying to stave off a better-funded competitor, soon became too much for the still-young company to bear. "It was clear," Jackson writes, "that PayPal now faced many challenges outside the marketplace. Entrepreneurial nimbleness may have helped us survive the company's post-merger internal turmoil and Billpoint's fierce competitive charge, but these new threats would require a different approach."
>
> In July 2002 PayPal executives sold the start-up firm to their longtime nemesis, eBay. Jackson notes that the sale had some obvious benefits. The company's new parent already had a formidable, well-funded legal team in place to deal with PayPal's litigation and regulation troubles. Also, eBay promised to do away with Billpoint, essentially securing PayPal's position as the premier online payment provider.

Online Poker and UIGEA (PDF):

> The business of online gambling spans the globe and touches every corner of the United States. Worldwide, online gambling is increasingly a legal and regulated activity that generates almost $30 billion of revenue a year. In the United States, public policy on the subject has been schizophrenic. Online gambling is presently being conducted domestically for pari-mutuel betting on horse races and for state lotteries, yet government policy has been hostile to otherforms of online gambling, and hasincluded criminal prosecutions of online gambling operators and their payment processing partners. Despite this government opposition, millions of Americans spend $4 billion every year to gamble online. Prosecutions against online gambling operators have driven the more responsible offshore operators out of the U.S. market, leaving Americans to conduct their online gambling through largely unregulated websites.
>
> In contrast, about 85 nations have chosen to legalize and regulate online gambling. Numerous Western nations - including the United Kingdom, France, Italy, and some provinces in Canada - have created structuresfor tight regulation of the online

gambling industry. This course provides consumer protections for individuals while also generating jobs, economic opportunity and government revenue.

SEC vs. Crowdfunding (Morrill, Crowdvalley):

> On March 26th The Funders Club received a no-action letter from the Securities and Exchange Commission stating that it will not recommend enforcement action against the year-old private equity investment platform, making it the first government sanctioned online VC.
>
> . . . AngelList, a competing service used by early stage companies to receive introductions to investors and take some online investment, received its own no-action letter just two days later on March 28th.

Goldman, Facebook, and the SEC (Wired):

> Goldman-Facebook Deal Draws SEC Scrutiny of Startup Investing (Updated)
>
> Goldman Sachs' $450 million investment in social networking juggernaut Facebook has prompted a federal inquiry into whether the deal is designed to avoid rules aimed at protecting investors, The Wall Street Journal reported, citing "people familiar with the situation."

Biotech

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a. There is No Right to Consume or Feed Children Any Particular Food. 25
b. There is No Generalized Right to Bodily and Physical Health. 26
c. There is No Fundamental Right to Freedom of Contract. 27
5. FDA's Regulations Rationally Advance The Agency's Public Health Mission. 27

Figure 1: *The FDA has officially taken the position that "There is No Right to Consume or Feed Children Any Particular Food", "There is No Generalized Right to Bodily and Physical Health", and "There is No Fundamental Right to Freedom of Contract" and that its regulations "Rationally Advance the Agency's Public Health Mission". (Source: FDA US District Court Brief, pages 25-27).*

FDA: "There is No Generalized Right to Bodily or Physical Health" (FDA Legal Filing):

> FDA: There is No Generalized Right to Bodily and Physical Health.
>
> Plaintiffs' assertion of a "fundamental right to their own bodily and physical health, which includes what foods they do and do not choose to consume for themselves and their families" is similarly unavailing because plaintiffs do not have a fundamental right to obtain any food they wish. In addition, courts have consistently refused to extrapolate a generalized right to "bodily and physical health" from the Supreme Court's narrow substantive due process precedents regarding abortion, intimate relations, and the refusal of lifesaving medical treatment.
>
> See Glucksberg, 521 U.S. at 721 (warning that the fact "[t]hat many of the rights and liberties protected by the Due Process Clause sound in personal autonomy does not warrant the sweeping conclusion that any and all important, intimate, and personal decisions are so protected"); see also Cowan v. United States, 5 F. Supp. 2d 1235, 1242 (N.D. Okla. 1998) (rejecting a claim that the plaintiff had the fundamental "right to take whatever treatment he wishes due to his terminal condition regardless of whether the FDA approves the treatment").

Reputation and Power, Chapter 1 (PDF)

> None of this import was lost on Genentech's executive at the time, G. Kirk Raab. Raab was hired specifically to smooth the company's journey through the regulatory process. Years later, Raab would describe regulatory approval for his products as the fundamental challenge facing his company. And he would depict the Administration in a particularly vivid metaphor.
>
> > *I've told a story hundreds of times to help people understand the FDA. When I was in Brazil I worked on the Amazon River for many months selling Terramycin for Pfizer. I hadn't seen my family for eight or nine months. They were flying in to Sao Paulo, and I was flying down from some little village on the Amazon to Manous and then to Sao Paulo. I was a young guy in his twenties. I couldn't wait to see the kids. One of them was a year-old baby, the other was three. I missed my wife.*
> >
> > *There was a quonset hut in front of just a little dirt strip with a single engine plane to fly me to Manous. I roll up and there is a Brazilian soldier standing there. The military revolution had happened literally the week before. So this soldier is standing there with this machine gun and he said to me: "You can't come in." I was speaking pretty good Portuguese by that time. I said: "My god, my plane, my family, I gotta come in!" He said again: "You can't come in." I said: "I gotta come in!" And he took his machine gun, took the safety off, and pointed it at me, and said: "You can't come in." And I said: "Oh, now I got it. I can't go in there."*
> >
> > *And that's the way I always describe the FDA. The FDA is standing there with a machine gun against the pharmaceutical industry, so you better be their friend rather than their enemy. They are the boss. If you're a pharmaceutical firm, they own you body and soul.*

> ... In practice, dealing with the fact of FDA power meant a fundamental change in corporate structure and culture. At Abbott and at Genentech, Raab's most central transformation was in creating a culture of acquiescence toward a government agency. As was done at other drug companies in the late twentieth century, Raab essentially fired officials at Abbott who were insuffi ciently compliant with the FDA.

Harvard's Daniel Carpenter (Princeton Press):

> The U.S. Food and Drug Administration is the most powerful regulatory agency in the world. How did the FDA become so influential? And how exactly does it wield its extraordinary power? Reputation and Power traces the history of FDA regulation of pharmaceuticals, revealing how the agency's organizational reputation has been the primary source of its power, yet also one of its ultimate constraints.
>
> Daniel Carpenter describes how the FDA cultivated a reputation for competence and vigilance throughout the last century, and how this organizational image has enabled the agency to regulate an industry as powerful as American pharmaceuticals while resisting efforts to curb its own authority.

Google fined $500 million by the FDA (NYT):

> The Justice Department's settlement of a criminal investigation of Google for allowing Canadian pharmacies to advertise drugs for distribution in the United States reflected an effort by prosecutors to extend the reach of federal drug laws. This may present future challenges to Internet search companies over their advertisements.

ONC and FDA clash over EHR Regulation (iHealthBeat):

> Under the direction of National Coordinator for Health IT David Blumenthal, ONC has pushed for greater adoption of EHRs by health care providers.
>
> FDA, charged with ensuring the safety and effectiveness of medical devices, has called for greater regulation of EHR systems. In February, Jeffrey Shuren – head of FDA's medical devices division – linked six deaths and more than 200 injuries to health IT problems, based primarily on voluntary reports to FDA.
>
> ONC has dismissed Shuren's findings as "anecdotal and fragmentary." EHR proponents contend that excessive regulation could stifle EHR innovation and inhibit EHR adoption. Proponents also state that, despite possible errors, EHRs are generally safer than paper records.

Drug Shortages and Regulation (Health Affairs):

> Output Controls. The Federal Food and Drug Administration (FDA) has been stepping up its quality enforcement efforts - levying fines and forcing manufacturers to retool their facilities both here and abroad. Not only has this more rigorous regulatory oversight slowed down production, the FDA's "zero tolerance" regime is forcing manufacturers to abide by rules that are rigid, inflexible and unforgiving.

> For example, a drug manufacturer must get approval for how much of a drug it plans to produce, as well as the timeframe. If a shortage develops (because, say, the FDA shuts down a competitor's plant), a drug manufacturer cannot increase its output of that drug without another round of approvals. Nor can it alter its timetable production (producing a shortage drug earlier than planned) without FDA approval.
>
> Even the Drug Enforcement Agency (DEA) has a role - because minute quantities of controlled substances are often used to make other drugs. This is the apparent reason for a nationwide shortage of ADHD drugs, for example, including the generic version of Ritalin. And like the FDA, DEA regulations are rigid and inflexible. For example, if a shortage develops and the manufacturers have reached their preauthorized production cap, a manufacturer cannot respond by increasing output without going back to the DEA for approval.
>
> The Centers for Medicare and Medicaid Services (CMS) also has a role levying large fines for "overcharging," forcing some companies to leave the generic market altogether.

Roche statement on LDTs, including "Specific Suggested Changes to the Draft Guidance by Line Number" (regulations.gov, pdf)

> Roche is becoming increasingly concerned about FDA's continued lack of oversight of LDTs. This lack of oversight, particularly when a cleared or approved IVD is available, has created a dichotomy in which manufacturers of diagnostic tests invest vast resources to research, develop, verify and validate innovative new tests that are subject to intense FDA scrutiny, while clinical laboratories develop and offer LDTs that are neither supported by clinical data nor subject to FDA's rigorous review . . . These differential standards, especially in companion diagnostics, generate unnecessary and unacceptable risks for physicians and patients who count on companion diagnostics to direct therapy, and create an uneven playing field for manufacturers of cleared or approved IVD companion diagnostics.
>
> Appendix: Specific Suggested Changes to the Draft Guidance by Line Number

Appendix

Specific Suggested Changes to the Draft Guidance by Line Number

Comment Number	Section	Line No	Proposed Change	Comment/Rationale
1	II	270-271	FDA should clarify requirements for IVD companion diagnostics for generics, specifically, that no separate IVD companion diagnostic submission would be needed for a generic form of the companion therapeutic.	The Draft Guidance document says that instructions for the use of an IVD companion diagnostic should be listed in the labeling of the therapeutics *and any generic equivalent* but no specifics are given. No separate submission should be required for generic equivalents.
2	II	280-286	FDA should clarify Footnote 4 to make clear when a companion diagnostic and its therapeutic constitute a Combination Product. The role of the Office of Combinations Products should be clarified.	We believe designation of companion diagnostics as combination products is generally inappropriate and unnecessary - in part because the Primary Mode of Action is already known; and thus there is no need for the Office of Combination Products to make that determination. An exception might be with any companion diagnostic that would be linked directly to a therapeutic intervention without physician intervention / interpretation prior to administration of the therapy. These should be considered combination products. An example would be a blood glucose monitoring insulin pump.

Figure 2: *Roche's specific line-item edits to proposed FDA regulation, by line number (Source: Roche regulations.gov filing)*

FDA and DNA Dilemma Interview (Newsweek):

> Newsweek: What exactly would constitute a "medical claim?" Would pointing people to medical research papers [qualify]?
>
> FDA: It depends. There are rules as to how one can do that - Those rules are actually worked out pretty well, and they just would need to make sure they're staying within the rules.
>
> Newsweek: Are those rules on the Web?
>
> FDA: I don't know where the policy is. I would have to get it for you. It's an agencywide policy. I would have to find it for you. And it won't be that easy for people to follow it...

FDA on information security (Washington Post):

> The agency has urged hospitals to allow vendors to guide them on security of sophisticated devices. But the vendors sometimes tell hospitals that they cannot update FDA- approved systems, leaving those systems open to potential attacks. In fact, the agency encourages such updates.
>
> "A lot of people are very confused about FDA's position on this," said John Murray Jr., a software compliance expert at the agency.

The Park Doctrine (Merola):

> In United States v. Park, the Supreme Court held that a responsible corporate official can be convicted of a misdemeanor based on his or her position of responsibility and authority to prevent and correct violations of the Food Drug and Cosmetic Act (FDCA). Thus, evidence that an individual participated in the alleged violations or even had knowledge of them is not necessary.

FDA issued one Form 483 every 50 minutes in 2011 (FDAZilla):

> Based on new data obtained by FDAzilla, the FDA should surpass 10,000 483s in 2011 for the second time in its history, breaking its all-time record for the third consecutive year. In 2010, the FDA issued 10,437 483s, breaking the previous high-water mark of 9,666 in 2009. Through November 2, 2011, the FDA has issued 9,052 483s, approximately 215 more 483s than the same time period in 2010, roughly a 2.4% increase. Extrapolating for the rest of the year, we expect the FDA to issue roughly 10,690 483s for 2011. That's one 483 every 50 minutes.

UltraRad's UltraPACS device labeled "adulterated", in part for insufficient revision history of Microsoft Sharepoint (fda.gov):

> This inspection revealed that this device is adulterated within the meaning of section 501(h) of the Act...
>
> Off-the-shelf software (Microsoft SharePoint) is being used by your firm to manage your quality system documents for document control and approval. However, your firm has failed to adequately validate this software to ensure that it meets your

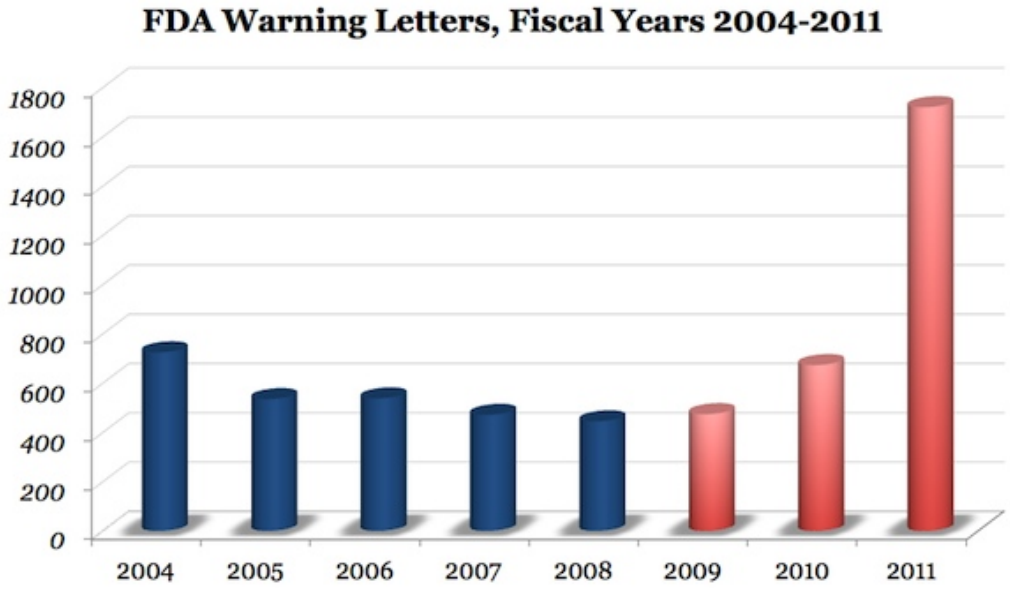

Figure 3: *Historical trend in FDA Warning Letters.*

needs and intended uses. Specifically. at the time of this inspection there were two different versions of your CAPA & Customer Complaint procedure, SOP-200-104; however, no revision history was provided on the SharePoint document history. Your firm has failed to validate the SharePoint software to meet your needs for maintaining document control and versioning. ...

You should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties.

Drug Approvals Cost $4B on Average (Matthew Herper):

The Truly Staggering Cost Of Inventing New Drugs

During the Super Bowl, a representative of the pharmaceutical company Eli Lilly posted the on the company's corporate blog that the average cost of bringing a new drug to market is $1.3 billion, a price that would buy 371 Super Bowl ads, 16 million official NFL footballs, two pro football stadiums, pay of almost all NFL football players, and every seat in every NFL stadium for six weeks in a row. This is, of course, ludicrous.

The average drug developed by a major pharmaceutical company costs at least $4 billion, and it can be as much as $11 billion.

Mobile Health and the FDA (Entrepreneur):

When the U.S. Food & Drug Administration sent a warning letter to an Indian app developer in late May, tech entrepreneurs in this country took notice. The FDA warned Biosense Technologies Private Ltd. that its app - which is designed

to work with a urine-testing kit - is actually a medical device, and therefore it must be cleared by the agency.

The large and growing community of app developers doesn't expect this to be the last time the FDA weighs in on mobile apps marketed for health-related uses. "There are millions of medical apps out there. The industry is concerned," says Gabriel Vorobiof, a Los Angeles cardiologist and co-founder of PadInMotion, a New York company developing mobile tools for hospital use. "It's just not clear how far [the FDA] will go."

The Lauren Stevens Case (MJ, IC, pdf):

MJ: No matter what they say, or don't say, there must be people in the Justice Department who wish they had never heard of Lauren Stevens, the former GlaxoSmithKline vice president and counsel who was acquitted on Tuesday of lying to the federal government about GSK's marketing of a drug.

Prosecutors made tactical mistakes, to be sure. But far worse than that, they aggressively pushed a case that never should have been brought in the first case, a federal judge concluded as he took the unusual step of acquitting Stevens before the jurors could even start deliberating.

It would be a miscarriage of justice to permit this case to go to the jury; U.S. Judge Roger Titus of the District of Maryland ruled in tossing out the six charges: one count of obstructing an official proceeding, one of concealing and falsifying documents and four of lying to the Food and Drug Administration. "I conclude on the basis of the record before me that only with a jaundiced eye and with an inference of guilt that's inconsistent with the presumption of innocence could a reasonable jury ever convict this defendant" Titus declared.

IC: It's not often that we in-house lawyers get a scare like United States v. Lauren Stevens. Since the trial ended on May 10 when the judge granted a motion for acquittal, and the jury reportedly stood up and applauded, law firm advisories, blogs and seminars on how in-house lawyers can avoid going to jail for making statements to the government have been pouring forth.

Mobile MIM and the FDA (link):

Two of our lead engineers, Jerimy Brockway and Dave Watson, downloaded XCode, learned Objective C, and built a prototype, all on their off hours, and in only one week. It was remarkable. We saw the CT scan on the iPhone, scrolled through slices, and realized that everything had just changed. ...

We were one of eleven developers that presented during the [Apple WWDC] keynote. That week we won an Apple Design Award for Best iPhone Healthcare & Fitness Application.

Within only a few weeks of submitting, we were contacted by the FDA and told that our app could not be on the app store (despite the fact that it was both free and labeled as "not intended for diagnostic use") because it served as marketing for a device that was not cleared for marketing. We promptly removed it. ...

> Then, over the next few months, we discovered that our proposed device raised more questions than we had anticipated. In order to make their determination, the FDA wanted more information than we had provided. The process stalled out as we reviewed what we would have to do next. This 510(k) was declared not substantially equivalent (NSE) because of insufficient data. . . .
>
> To be honest, this dramatically new direction for our company, and the speed at which it occurred, left us ill-prepared for the scope of the regulatory process that would unfold.

The "It Has Come to our Attention" Letter (Eye on FDA):

> There are Warning Letters, Untitled Letters, otherwise known as Notice of Violation Letters, and now there is the "It Has Come to Our Attention Letter". I have to admit, I had not heard of this particular kind of letter before, but one was sent this month the maker of a medical app that performed the task of urine analysis. I did end up finding a few other examples, however, this was the only one I found that was actually had that as a title at the top - "It Has Come to Our Attention Letter".
>
> In any case, this "It Has Come to Our Attention Letter" - hereafter IHCOAL - raised the fact that FDA became aware of the existence of an app that served as a device allowing one to perform one's own urine analysis with the assistance of a smart phone. . . . In that case, then FDA said there needs to be clearance for the whole new system of analysis - the app used in conjunction with the strips.

"Bold move to make themselves noticed. . . brought them to our attention" (GenomeWeb):

> Lastly, ignore FDA's sudden and questionable interest in a private company's marketing budget. As OIVD Director Alberto Gutierrez described it this week to my colleague Turna Ray, "[t]he fact is that Pathway's bold move to make themselves noticed achieved its end and brought them to our attention."

Labcorp, FDA, and Ovasure (MDT):

> In an Oct. 20 letter to FDA, LabCorp defends its decision to launch OvaSure out of its nationwide lab network in June without FDA clearance or approval, but also announced plans to discontinue the product as of Oct. 24 to maintain "positive and responsible relationships with regulatory agencies." LabCorp is requesting a meeting with FDA's Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD). . . .
>
> The enforcement action is unusual since FDA typically does not exert authority over "home brew" tests used as a lab service. Instead, CMS regulates lab processes and protocols under the Clinical Laboratory Improvement Amendments.

Antitrust and Acquisitions

Instagram Antitrust Scrutiny in the US and UK (ZDNet):

> You'd think it would be simple: Facebook wants to buy Instagram, the parties agree on a price, Facebook writes a big fat check, Facebook owns Instagram, now you can follow Justin Beiber and apply special effects to photos of your cat, using both services, seamlessly, whether you're at your desk or on your phone.
>
> Nothing is simple, however, when the antitrust regulators get involved.
>
> Under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (HSR), any purchase over $68.2 million requires a detailed filing with the Federal Trade Commission (FTC) and Department of Justice (DOJ). This number gets adjusted each year relative to GDP.
>
> In the case of Facebook's acquisition of Instagram, a $1 billion transaction, the FTC has now served Facebook with a "second request," in other words Facebook must now produce a mountain of documents that an army of government lawyers will review to make sure the purchase of Instagram didn't violate any antitrust laws.

Antitrust, Blockbuster, Hollywood Video, and Netflix (Motley Fool):

> Little more than a year ago, a combination between the largest movie rental company, Blockbuster (NYSE: BBI), and the second-largest, Hollywood Entertainment (Nasdaq: HLYW), would have certainly raised antitrust questions. Blockbuster has more than 9,000 retail locations worldwide and would combine with Hollywood Video's nearly 2,000 locations to simply dominate the industry.
>
> But things still change quickly in Internet time, which is why antitrust considerations on Blockbuster's $700 million offer for Hollywood Entertainment, should they come up at all, would be seriously wrongheaded. The retail movie rental business has been thrown into turmoil by the emergence of Netflix (Nasdaq: NFLX), the online mail-order DVD rental company.
>
> When I say "would have raised antitrust questions," I'm not guessing. More than five years ago, the Federal Trade Commission scotched a planned merger between the companies on the basis that it concentrated too much of the industry's volume in one company.

Complete Genomics and Antitrust (NYT):

> The Chinese firm, BGI-Shenzhen, said in a statement this weekend that its acquisition of Complete Genomics, based in Mountain View, Calif., had been cleared by the federal Committee on Foreign Investment in the United States, which reviews the national security implications of foreign takeovers of American companies. The deal still requires antitrust clearance by the Federal Trade Commission. ...
>
> Much of the alarm about the deal has been raised by Illumina, a San Diego company that is the market leader in sequencing machines. It has potentially the most to lose from the deal because BGI might buy fewer Illumina products and even become a competitor. Weeks after the BGI deal was announced, Illumina made its own belated bid for Complete Genomics, offering 15 cents a share more than BGI's bid of $3.15. But Complete Genomics rebuffed Illumina, saying such a merger would never clear antitrust review. ...

BGI and Complete Genomics point out that Illumina has long sold its sequencing machines - including a record-setting order of 128 high-end machines - to BGI without raising any security concerns. Sequencing machines have not been subject to export controls like aerospace equipment, lasers, sensors and other gear that can have clear military uses.

Government

GovExec.com About page (govexec.com):

> Government Executive's essential editorial mission is to cover the business of the federal government and its huge departments and agencies - dozens of which dwarf the largest institutions in the private sector. We aspire to serve the people who manage these huge agencies and programs in much the way that Fortune, Forbes, and Business Week serve private-sector managers.

China and the USG (Washington Post):

> The information compromised by such intrusions, security experts say, would be enough to map how power is exercised in Washington to a remarkably nuanced degree. The only question, they say, is whether the Chinese have the analytical resources to sort through the massive troves of data . . .
>
> "They're trying to make connections between prominent people who work at think tanks, prominent donors that they've heard of and how the government makes decisions," said Dan Blumenthal, director of Asian studies at the American Enterprise Institute, which also has been hacked. "It's a sophisticated intelligence-gathering effort at trying to make human-network linkages of people in power, whether they be in Congress or the executive branch."

Matthew Yglesias on Food Trucks (Slate):

> An existing provision of the San Francisco municipal code, for example, states that any business may comment on an application for a new vending license and directs the city to "consider" whether the proposed operation is located within 300 feet of a business that sells the same type of food or merchandise. It would be as if Slate were allowed to complain that it should be illegal to launch a new website to compete with our offerings, and that government should take our complaint seriously. . . .
>
> It's difficult to know precisely where the line should be drawn. The food service industry is generally heavily regulated for safety purposes, and trucks should be no exception to that. And food sales are intimately related to parking, a fraught and much-regulated activity all its own. But a basic rule of thumb seems to suggest itself: The fact that business owners would prefer not to face competition is not a valid regulatory purpose. A food truck is a kitchen and a vehicle and should need to follow the rules that generally apply to both thing.
>
> Most of all, the fact that an existing business owner objects to the practices of a new business is a terrible reason to block a truck from operating. Space is scarce and rents are high in the centers of major American cities. If new competition can bring prices down, we'll all be better off in the long run.

Matthew Yglesias on Small Business (Slate):

> And thus I became a small-business man. Or, rather, I'm becoming one. Entrepreneurship - even on the smallest and most banal scale - turns out to be a time-consuming pain in the you-know-what. My personal inconveniences aren't a big deal, but in the aggregate, the difficulty of launching a business is a problem and it may be a more important one as time goes on.
>
> In the District of Columbia, I need to get a simple Basic Business License to rent out a single dwelling. After puzzling over the Department of Consumer and Regulatory Affairs website for a bit, it became clear that step No. 1 was actually to file form FR-500 with the Office of Tax and Revenue, which you can do online. Then it was time to hustle down to the DCRA (which closes at 4:30 p.m.) to file the paperwork. Once there, I learned that filing the FR-500 online wasn't good enough - I needed a hard copy. Fortunately, the Office and Tax and Revenue was right across the street, so I went there and refiled. Then it was back to the DCRA to stand in line to get a number, wait for the number to be called, do some more paperwork, wait in another line for the cashier, fork over $100 in fees, then get a slip from the cashier to finalize the paperwork.
>
> But then it turned out I needed to go to a third office, the Rental Accommodations Division of the Department of Housing and Community Development. It closes at 3:30 in the afternoon and required a 15-minute walk through a sketchy neighborhood. So the next morning I went down to that Rental Accommodations office to file a paper claiming exemption from D.C.'s rent control law.
>
> The striking thing about all this isn't so much that it was annoying - which it was - but that it had basically nothing to do with what the main purpose of landlord regulation should be - making sure I'm not luring tenants into some kind of unsafe situation.

Microsoft and K-Street (Tim Carney):

> But it grated on Hatch and other senators that Gates didn't want to want to play the Washington game. Former Microsoft employee Michael Kinsley, a liberal, wrote of Gates: "He didn't want anything special from the government, except the freedom to build and sell software. If the government would leave him alone, he would leave the government alone."
>
> This was a mistake. One lobbyist fumed about Gates to author Gary Rivlin: "You look at a guy like Gates, who's been arrogant and cheap and incredibly naive about politics. He genuinely believed that because he was creating jobs or whatever, that'd be enough."
>
> Gates was "cheap" because Microsoft spent only $2 million on lobbying in 1997, and its PAC contributed less than $50,000 during the 1996 election cycle.
>
> "You can't say, 'We're better than that,' " a Microsoft lobbyist told me on Friday. "At some point, you get too big, and you can't just ignore Washington."
>
> "You can sit there and say, 'We despise Washington and we don't want to have anything to do with them,' " the lobbyist said. "But guess what? We're going to have hearings about the [stuff] you do." ...

> Microsoft now plays ball in Washington, and Orrin Hatch's public flogging of Gates was a major reason. "It's been a year since I was in D.C.," Gates wrote the night before his Hatch hearing. "I think I'm going to be making this trip a lot more frequently from now on."

Eric Schmidt, Google Chairman and former CEO (Washington Post):

> And one of the consequences of regulation is regulation prohibits real innovation, because the regulation essentially defines a path to follow - which by definition has a bias to the current outcome, because it's a path for the current outcome. . . .
>
> So what happened was that there was something called the Clipper chip, which was the attempt by the government to enforce encryption on a particular communications aspect. And this was 1994. And it was the first time I know of that the Valley organized around a stupid technological thing that was going to be forced on us. . . . All of us spent a lot of time and we eventually defeated it, but I think for many people that was sort of a wake-up call that the government could actually pass a law that was stupid, that would actually do something wrong and wouldn't work. . . .
>
> And then we had the bubble, so all of a sudden the politicians showed up. We thought the politicians showed up because they loved us. It's fair to say they loved us for our money. And this was before caps were in place, so there's this huge fundraising cycle in the late 90s. Republican and Democrat by the way. Everyone fed at the trough of money.
>
> But at the time, we took the position of 'hands off the Internet.' You know, leave us alone. And that's probably still the general view here. The government can make regulatory mistakes that can slow this whole thing down, and we see that and we worry about it.

Steve Jobs on US Factories (NYT, Politico):

> But as Steven P. Jobs of Apple spoke, President Obama interrupted with an inquiry of his own: what would it take to make iPhones in the United States?
>
> Not long ago, Apple boasted that its products were made in America. Today, few are. Almost all of the 70 million iPhones, 30 million iPads and 59 million other products Apple sold last year were manufactured overseas.
>
> Why can't that work come home? Mr. Obama asked. Mr. Jobs's reply was unambiguous. 'Those jobs aren't coming back,' he said, according to another dinner guest.
>
> . . . According to Walter Isaacson's biography of Jobs, he expressed admiration for Chinese business practices and decried U.S. regulations and labor rules.

Peter Thiel and Eric Schmidt (CNN, MR):

> PETER THIEL: But, if we're living in an accelerating technological world, and you have zero percent interest rates in the background, you should be able to invest all of your money in things that will return it many times over, and the

> fact that you're out of ideas, maybe it's a political problem, the government has outlawed things. But, it still is a problem. ...
>
> ERIC SCHMIDT: What you discover in running these companies is that there are limits that are not cash. There are limits of recruiting, limits of real estate, regulatory limits as Peter points out. There are many, many such limits. And anything that we can do to reduce those limits is a good idea.

Chris Dixon of A16Z (Blog):

> A common way to think of business regulations is by analogy to sports: the rules are specified up front, and the players follow the rules. But real regulations don't work that way. Regulations follow business as much as business follows regulations.
>
> Sometimes the businesses that change regulations are startups. Startups don't have the resources to change regulations through lobbying. Instead, they need to start with regulatory hacks: "back door" experiments that demonstrate the benefits of their ideas. With luck, regulators are forced to follow. ...
>
> Nextel was one of the all-time great regulatory hacks. In the late 80s and early 90s, the FCC's rules banned more than two cellular operators per city. As Nextel's cofounder said, "the FCC thought a wireless duopoly was the perfect market structure". Nextel (called Fleet Call at the time) circumvented these rules by acquiring local (e.g. taxi, pizza truck) dispatch radio companies, which they then connected to create a nationwide (non-dispatch) cell phone service.
>
> Predictably, the cellular incumbents tried to regulate Nextel out of existence. ... The incumbents argued that Nextel's service would interfere with public safety frequencies and therefore endanger the public. They also argued that Nextel's service would be too expensive ... And their call quality would be inferior ... The FCC eventually decided not to block Nextel. Nextel grew to become a top five US cellular operators before it was acquired by Sprint in 2004 for $35B. Their service turned out to be cost-competitive, high quality, and safe. The only thing endangered were the incumbents' profits.
>
> Of course regulations that truly protect the public interest are necessary. But many regulations are created by incumbents to protect their market position. To try new things, entrepreneurs need to find a back door. And when they succeed, it will all look obvious in retrospect. Today's regulatory hack is tomorrow's mainstream industry.

Alex MacCaw, Stripe/Twitter Engineer and O'Reilly Author (Blog):

> Paradoxically, regulation can sometimes result in innovation. Within highly regulated industries, you often get entrenched businesses and monopolies ripe for disruption. While regulation and red tape may strangle fledgling startups, if they can struggle through and overcome it they have a distinct advantage - less competition.
>
> What's more, regulation is often 'hackable'. Look hard, and you'll see lots of startups out there flirting with grey areas and testing the boundaries. Often it requires

> a startup environment to think outside the box when it comes to interpreting and applying regulations. Most don't like to talk about it for obvious reasons.
>
> The are three industries that are great examples of this phenomena at work: drones, bio-tech and payments. ...

A Summary

All right. That's a fair bit of material, but the reason we chose so many articles is to illustrate that the phenomenon we are about to discuss is:

- *Not limited to low-quality companies*. Note the seniority and technological accomplishments of many of the individuals involved: Schmidt, Thiel, Jobs, Carmack, Musk, and so on.
- *Not limited to particular industries*. The articles cover food, planes, cars, drugs, devices, sequencing, medical records, hotels, space travel, payments, investment, and even online poker and photosharing.
- *Not limited to a particular political orientation*. Natalie Foster and Matthew Yglesias are Democrats; Orrin Hatch and the North Carolina and Texas Senate are Republican.

With those points made up front, let's see if we can summarize a few points for the prospective entrepreneur:

1. *Understand regulation.* Any business in the US that involves the physical world (1, 2, 3), and many businesses in the digital world (1, 2, 3), will mean concerning yourself with regulation at the local, state, and federal levels.
2. *Non-US businesses may have more latitude.* If you are outside the US, you may have much more latitude (1, 2). However, you may still be directly subject to US regulations if you serve US customers, or else indirectly subject if your local regulatory agency has "harmonized" its regulatory structure with its US counterpart.
3. *DC is not civics 101.* Washington does not necessarily work like civics 101, where the only players are the executive, legislative, and judiciary. Academia, the press, nonprofits, and regulatory agencies all play crucial roles in "how the government makes decisions" (1, 2).
4. *Agencies are active, not passive.* Regulatory agencies are active entities and experience turf conflicts between themselves (1, 2, 3, 4).
5. *Agency interpretations may be found illegal.* Regulatory agencies have interpretations of the law and their authorities under the law that do not always hold up in court (1, 2, 3).
6. *News attracts regulation.* The attention of a regulator is often a function of a company's prominence in the news media (1, 2, 3)
7. *Legacy businesses often use regulations in their favor.* From restaurants and taxis to car dealers and MNC pharmas, legacy businesses use regulation to erect barriers to entry (1, 2, 3, 4)

8. *Regulators are police agencies.* Regulatory agencies have the power to impose fines and mount raids (1, 2, 3), and have budgets that are comparable to huge Fortune 500 companies (1, 2)

9. *Travel or technology can change jurisdiction.* Overseas travel (1, 2) or modern technology can often obviate an existing regulation or render its applicability in doubt, pending a court case.

10. *Understand what regulation means for you.* Finally, as an entrepreneur in a regulated industry, you may face civil and criminal penalties if the regulator's interpretation of the law holds up, even if you had no awareness or involvement in the issue at hand (1, 2)

Collectively, this may give some insight into why many entrepreneurs have in the past pursued social gaming and photosharing rather than enterprises in regulated industries. Given the totality of evidence, let's postulate that while a lack of imagination may play a role, at least some of the reticence towards doing businesses with big ideas is indeed regulation.

What about the Good Aspects of Regulation?

We are expressly *not* making any policy recommendations in this document; our purpose is to provide a set of facts and articles for the entrepreneur or early engineer to understand many of the details of starting a company in a regulated industry. Because the practical aspects of operating amidst regulation are not covered in most engineering or business school curricula, in order to discuss them we will necessarily present facts that are not commonly circulated, and may thus be at variance with the popular understanding of how regulation is "supposed" to work.

But to engage the point briefly, are there regulations written with good intentions, regulations to manage externalities, regulations to prevent terrorism? Surely there are. And in theory, it may even be the case that the current set of regulations optimally balances Type I and Type II error rates in all circumstances, e.g. that the number of excess deaths due to delayed pharmaceuticals is exactly equal to the number of excess deaths from defective pharmaceuticals. However, in practice this is an empirical question, and one that can be personally adjudicated after you become directly familiar with the details of navigating regulations, preferably after starting a company. Most non-founders are insulated from such questions and lack direct experience with the issues. As a useful analogy, consider the following statements about the Transportation Security Administration (TSA):

1. Millions of people go through TSA checkpoints every day.

2. The regulations are nontechnical and characterized by many as impotent; two permitted three-ounce bottles, for example, may be combined into a banned six-ounce putative weapon-of-mass-destruction through the advanced terrorist technology known as "mixing".

3. The economic stakes associated with missing a flight and/or a meeting at the destination are in the hundreds to thousands of dollars, so people generally nevertheless comply with arguably irrational rules and refrain from making jokes.

4. A traveller is only under the jurisdiction of the TSA for a time-limited interval of a few hours.

5. In theory, then, it should be feasible for travellers to challenge the TSA. In practice, the TSA's budget has increased from $1.3B in 2002 to $8.1B in 2011, and it has been ramping up the Visible Intermodal Prevention and Response (VIPR) program in its plan to expand beyond airports to search travellers at train stations, bus stops, subways, and more.

These statements about the TSA should not prove too controversial to anyone who has traveled on a commercial airliner within the US. However, now imagine that the only information you had about the TSA came from its blog and numerous social media accounts. In the absence of direct experience with a TSA checkpoint, you might then be more likely to believe that what Bruce Schneier has called security theater has indeed made people safer. Now let's consider founding a company that deals with another regulatory agency, like the SEC.

1. At most a few thousand entrepreneurs contend with the agency each year.

2. The regulations are highly technical and often phrased in a forbidding way; for example, dihydrogen monoxide may cause severe burns and is fatal if inhaled.

3. The economic stakes associated with being penalized by regulators can range into the hundreds of millions or billions of dollars, costing you years of work and your very freedom.

4. You are under the jurisdiction of the regulator for the lifetime of your company, whether you know this at the outset or not.

5. The budget of your regulator is likely to increase over time (historical data, see page 91).

So: there are far fewer people passing through the regulatory aperture, the stakes are in the millions of dollars, the timeframe is years rather than hours, and the penalties for speaking up are significantly greater than making a joke in a TSA line. We are now no longer talking about the possibility of a retaliatory wait time that makes you miss your flight, but rather the possibility of a retaliatory denial that ends your company as a going concern. Now, it might nevertheless be the case that your particular regulatory agency is in fact benevolent; we are by no means gainsaying that as a possibility. However, as an entrepreneur, the moment you start a company and walk through the metaphorical metal detectors into a regulated industry, you will be able to judge for yourself whether your regulator generally achieves its stated objectives or whether its activities are best compared to safety theater.

Anticipate the Argument

Whatever the justness of regulation in the abstract you should plan for your specific business, once successful, to become characterized as a threat to health or safety or both. If in doubt, think deeply about how your business could become a tool for terrorism and/or used against the children. For example:

- Uber carries terrorists (Link: *Later, another witness warned that Uber's cars are the perfect weapon for terrorists.*)

- Myspace allows predators to stalk children (Link: *MySpace: Your Kids' Danger?*)
- Paypal can be used to funnel money to terrorists (Link: *[T]he company now has six months. ... to protect its online payment system from being used by money launderers and financers of terrorists.*)
- Google allows children to access inappropriate sites (Link: *Google SafeSearch 'Moderate' Setting Fails to Filter 'Playboy'*)
- Bitcoin is used for money-laundering and terrorism (Link: *Bitcoin might logically attract money launderers, human traffickers, terrorists*)
- Facebook is unsafe for children (Link: *EU: Children unsafe on Facebook*)

If you can't think of something involving terrorists or children, become more creative:

- A personal genomic test can make someone jump off a bridge (Link: *There's been an apocryphal amount of fear in the field that patients may not be ready for this information, that they'll jump off a bridge or whatever if they have a certain gene*)
- Cell phone competition endangers public safety (Link: *Nextel Communications Inc. agreed to spend $2.8 billion and give up airwaves worth $2.06 billion in exchange for new spectrum under a U.S. government plan to lessen interference of public safety radios.*)

There will always be some sense in which your product is a threat to health and safety. Everything from Buckyballs to spinach can and will be banned/regulated if there is incidence of a health hazard; the actual frequencies of said hazards are less material than the associated press coverage. In general, if you can anticipate the likely line of attack, you may disable it pre-emptively by talking about your various anti-terrorist and/or pro-children features.

The A/B/C/D Theory of Regulation

Let's now step back for a second and see if we can enumerate some general patterns. The fundamental concept behind a *regulation* is as follows: A and B wish to engage in an exchange, but a politically powerful party C finds some aspect of this exchange distasteful and gets party D (the government) to ban it (Figure 4). For example, a store (A) may wish to sell to customers (B) for 24 hours per day. However, the neighbors of this store (C) complain about the late night noise to the local govt (D), who can then choose to imposes zoning restrictions that ban commercial transactions between certain hours (example). As another example, a working individual (A) may wish to invest in a company (B), but enough other investors have lost their money (C) that the SEC (D) can choose to ban transactions between A and B. As a third example, an individual (A) wishes to try an experimental drug from a pharma co (B), but others (C) feel that he might hurt himself, and so get the FDA (D) to block this transaction.

Note the term *choose*. Regulatory agencies and local governments are run by humans with their own incentive structures, and they have discretion in choosing whether or not to enforce a law (or issue a new draft guidance, guidance, rule, regulation, or NPRM filing). For example, shift workers might complain to the local government about their inability to obtain supplies during off hours due to the ban on late-night commerce. Or people below the SEC's accredited investor threshold might reasonably demand the freedom to invest in their friend's

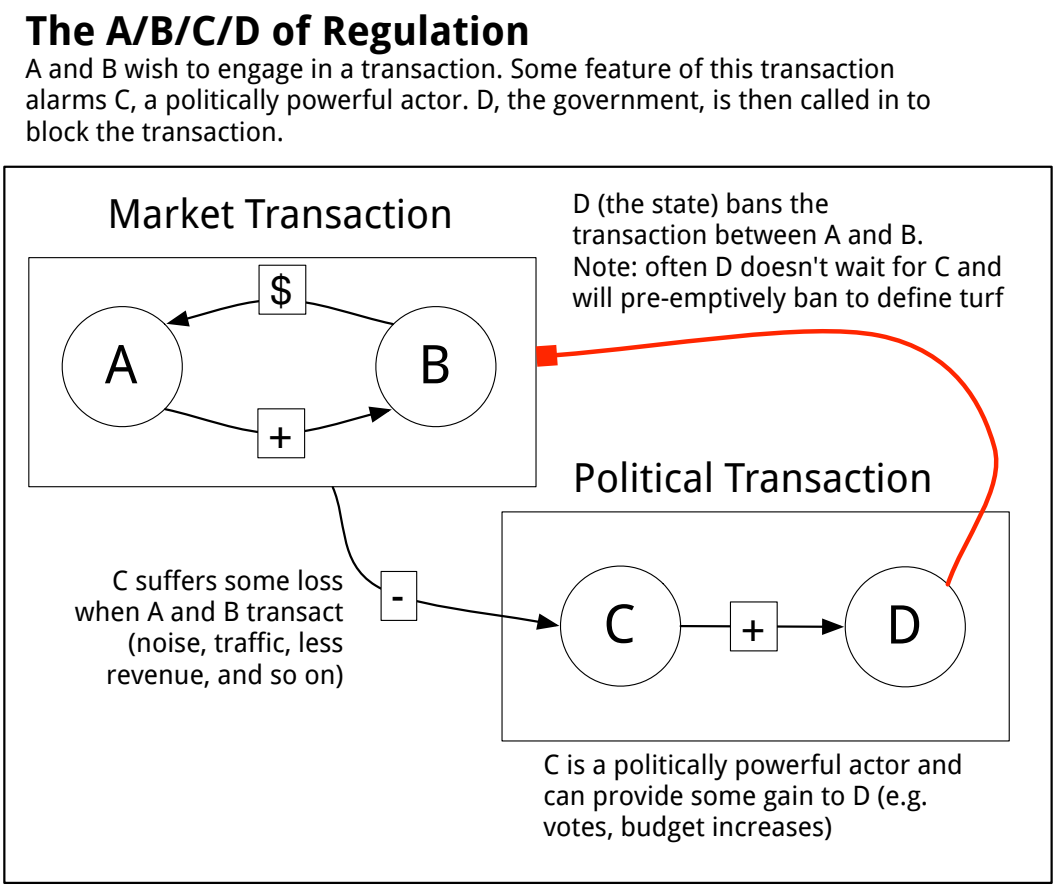

Figure 4: *The A/B/C/D Theory of Regulation.*

new startup. Which voices then are heard? According to public choice theory, the decision as to which citizen voices are amplified and which are damped often reduces to the question of which voices provide grounds for agency budget/power increases. The reason is simple: like a corporation, those agencies over time that do not grow are absorbed or sidelined by those that do.

Technological Legalization

Importantly, with new technology it is now often feasible to revisit this A/B/C/D relationship and restructure it in some way such that it is legalized. For example, you can set it up such that:

- The A/B transaction is placed into a legal gray area by new technology, and then grows at internet speed such that it becomes "unbannable" (C's objections are overwhelmed and D lacks the political capital to ban it)
- A or B are organized via the internet to put pressure on D, balancing C's pressure
- C is no longer vexed by the A/B transaction externality
- C now receives some benefit when A and B transact

- D (the government) receives enough benefit that C's entreaties suddenly fall on deaf ears
- D+ (a superior government agency) receives enough benefit to veto D
- E (a foreign government) receives a large enough benefit that D's disapproval no longer matters and E legalizes the transaction on its terrain.

Many successful companies use one or more of these techniques. Let's go through several case studies in Figure 5.

A (Seller)	B (Buyer)	Transaction	Objection	C (Blocker)	D (Govt)	Startup/Tech Restructuring	Concept
Small business	Customer	24 hour sales	Late night noise	Neighbor	Local gov	Amazon.com open 24 hours	C objection obviated
Payment company	Vendor	Direct sales	Unlicensed money transmitter	Banks and competitors	State gov	Square fundraising for politicians	D+ rev share
Car maker	Car buyer	Direct sales	Unlicensed dealer	Car dealers	State gov	Tesla direct showrooms	D+ support
Private company	Investor	Buy shares	Non-public sale	Bank competitors	SEC	FB/Goldman SIV: non-US	D denied jurisdiction
Citizen driver	Traveller	Hail a cab	Unlicensed taxicab	Taxi unions	Local/State gov	Uber internet petition	A/B org via web vs. D
Startup	Investor	Buy shares	Investor may lose money	Legacy banks	SEC	Angel List online petition	A/B petition of D+
Citizen host	Traveller	Sublet a room	Illegal hotels	Legacy hotels	State gov	Airbnb online booking	D+ support
Car maker	Customer	Install video dashboard	Distracted driving	Other drivers	NTSB	Google self-driving cars	C objection obviated
Plane inventor	Test pilot	Test new plane	Possible harm to pilot	Concerned citizens; FAA	FAA	Unmanned drones	C objection obviated

Figure 5: *A regulated transaction in which A is banned from selling to B can be restructured through technology, startup chutzpah, or both such that it becomes legal. See text for more.*

Amazon.com: invalidate zoning via web ordering, anesthetizing C

An underappreciated aspect of Amazon.com and all e-commerce sites is that physical zoning restrictions do not apply; aside from the IRS' EIN site, it is rare to find a website that operates only during business hours. Thus, they can use technology to remain open 24 hours per day, placing a storefront on every desk, phone, and lap. One can order grand pianos without making a sound, thereby obviating C's objection of late night noise.

Square: cut in D on the deal via fundraising

As another example, consider the Square dongle. From the financial industry's perspective, this is as disruptive as it gets. All kinds of small merchants can now accept physical credit card payments without paying[1] large banks. And no doubt this is illegal under some statute, or can be deemed so, especially if there is enough pressure from existing financial institutions. But Square has canny executives, and they spent quite a lot of effort on the Square fundraising app (1, 2, 3). One can now envision the situation in which a lobbyist for BigBank is talking to a politician about banning Square, clearly a crime against humanity, decency, and the American way. An aide whispers in said politician's ear ("Sir, we raised $100,000 over the last three months using Square") and now the bank's entreaty falls on deaf ears. In this manner one can co-opt D before C does.

Tesla: cut in D+ on the deal to overcome local car dealers

Tesla received a large $465M loan from the Department of Energy. While many of the other companies in that program (A123, Solyndra, etc.) have ended up failing or going bankrupt, Tesla is developing into a success. As such the federal government (D+) has a strong incentive to remove unnecessary roadblocks from Tesla's path. In particular, now that local car dealers have started objecting that direct sales violated state law, Tesla has the political connections to bring in federal favors to overwhelm the state governments ("Tesla may take dealer fight to feds"), should that be necessary.

Facebook/Goldman: Market to non-US individuals, denying D jurisdiction

In 2011, the New York Times ran a negative article on an upcoming investment in Facebook by various private investors, with the round managed by Goldman Sachs. The SEC reprioritized based on the front page NYT article and began sending letters to Facebook and Goldman, indicating that to continue with the transaction would be illegal unless they filed for an IPO. Since becoming a public company is an extraordinarily complex and lengthy process, this would have put the kibosh on the investment. Had the capital been needed for servers and salaries and the like, it might even have put the kibosh on Facebook itself. So Facebook's solution was simply to offer the transaction to non-US investors, thereby obviating the SEC's claim of jurisdiction. This option of *jurisdictional arbitrage* is a relatively new phenomenon that has been made feasible by the economic rise of the BRICs and the Asian Tigers relative to the West.

Uber: Use the internet to organize A/B against C/D

Uber is one of the companies that is in the thick of it with respect to regulation (Figure 6). Their initial smartphone app for internet booking took a loophole in the law and drove a truck (or a black car) through it. This allowed them to grow rapidly in the early days before the

[1]Square is a another example of a good idea where there is knowledge of a term that people outside the industry don't know. At first one might think Square was a bad idea, as you'd think people could just type in their card details into a mobile phone or tablet, rather than going to the trouble of actually building and installing a physical hardware device. At least one of the underlying reasons is the distinction between CP (card present) vs. CNP (card not present). A transaction that includes a physical card swipe is labeled CP: because the card is present, there is fundamentally lower risk of fraud and hence higher profit margins for Square.

law caught up to them. Crucially, once the cease and desist letters started flying, Uber only faced state/local regulation rather than federal regulation. As such they could monetize in one city while fighting regulations in another city. This is very different[2] from dealing with a federal regulator like the SEC; to avoid a federal regulator requires going outside the country (as in the case of Facebook and Goldman).

[2]Moreover, travellers like James Fallows could use Uber in one city while on the road and then be dismayed when it was banned in their home city. To do this with a federally regulated product would require travelling outside the country, which is less common.

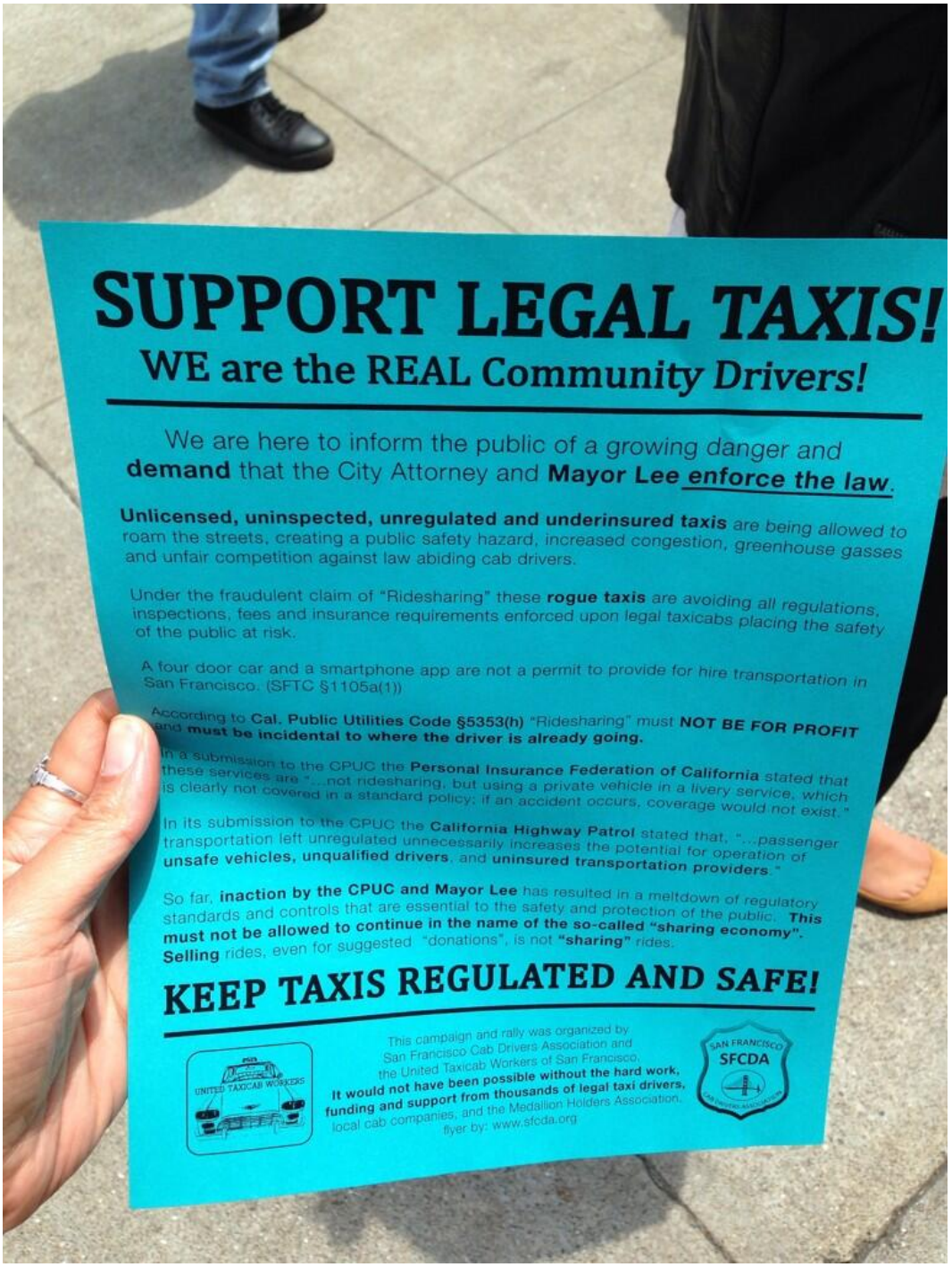

Figure 6: *A flyer calling for Uber to be banned due to "unfair competition". Source.*

And this led to a second Uber tactic for dealing with regulation: use the internet's capacity for direct democracy to organize A and B against C (competing cab drivers) and D (local government). Local politicians like Mary Cheh who'd enjoyed cozy relationships with the local taxicab industry suddenly found that they had misestimated the balance of forces:

> In many of those battles, Uber's secret weapon has been its customers: The kind of well-heeled, tech-savvy urbanites willing to pay a hefty markup to avoid the annoyance of hailing a cab. They may never before have shown an interest in any other aspect of local governance. But when some taxi commissioner or city councilor tries to take away their newfound convenience, they'll rally to its defense with calls, e-mails, and indignant tweets. ... "We are building a playbook for how to do this," [Uber CEO Kalanick] told a Washington, D.C., audience of policy wonks in January. "Other companies are going to follow suit in all kinds of industries that each is affecting. And I think folks in D.C. and cities across the country, you're going to be in the middle of it."

Perhaps the most important quality that Uber has is the psychological unwillingness to submit, the defiance to actually fight. Because with venture capital and superior technology, it is for the first time in recent memory possible to fight city hall, and win.

Angel List: Use A/B to petition D+ and change D's jurisdiction

In the middle of 2012 something unusual happened. The JOBS Act included a provision that actually legalized equity-based crowdfunding, unbanning certain kinds of transactions. As Ben Horowitz of A16Z said:

> When Ben Horowitz stopped by PandoMonthly last June, he celebrated the work done by AngelList's Naval Ravikant to help push the Jumpstart Our Business Startups (JOBS) Act through Congress. Horowitz said, "He went to Washington and he changed the law! That blew me away."
>
> ... Ravikant set out to convince lawmakers that the JOBS Act, which eases securities laws, would encourage more small business investment. Any one who's seen a debate or political speech over the past four years knows that "building small businesses" is golden rhetoric for politicians on both sides of the aisle. But even amid this climate, it wasn't easy. "People told us that it was impossible - and it actually basically is impossible," Ravikant said. "We just pulled out all the stops."

This provision did not come without quite a fight. As context, Angel List, Funders Club, and several other crowdfunding platforms were living for many years with the Sword of Damocles over their heads. At any time, the SEC's David Blass could decide that they were in violation of the law and choose to press charges against them (they eventually chose not to). This is known as enforcement discretion. In the DOJ, for example, US Attorneys like Carmen Ortiz have plenary authority in their territory and the ability to press charges or not as is their wont (see also Three Felonies a Day). Any civilian will be familiar with this in the context of the highway patrol: a policeman has the power to pull you over, and need not justify his decision to *not* pull all the *other* speeding motorists over.

What Angel List did was phenomenal: even with this Sword of Damocles hanging over them, they coordinated a campaign of signatures in favor of the new provisions in the JOBS Act. The entrepreneurs (A) and investors (B) who benefited from Angel List were able to organize through the internet to outweigh the interest groups (C) and regulators (D).

And More...

At this point you may begin to get the idea of how one can legalize previously banned transactions through a combination of technology and business strategy. Airbnb used their online booking system to host people during Hurricane Sandy and put out a joint press release with Michael Bloomberg at nyc.gov; this support from D+ (the Mayor) may help in their new battle with the city itself. The Department of Transportation imposed many restrictions on the kinds of devices that can be included in cars, with the idea being to avoid driver distraction; but if self-driving cars are legalized this issue will be obviated (though this itself is in doubt). And, as a third example, there are stringent rules on test pilots that must be followed for new aircraft, but with unmanned aerial vehicles (i.e. drones) one can in theory fail many more times with more aggressive designs before including the first human pilot. In short, there is often a way to use technology to restructure a banned transaction such that it is over the threshold of acceptability.

Disruption and the Technologies of 2013

Let's talk now for a bit about what it means for software to eat the world, in the context of some of the most important[3] technologies of 2013. We begin with six technologies and premises about what the coming decades will be like.

1. Management is Automation (Industrial Robotics)
2. Regulation is DRM (3D Printing)
3. Immigration Policy is a Firewall (Telepresence)
4. Medicine is Mobile (Quantified Self, Telemedicine)
5. Capital Controls are Packet Filtering (Bitcoin)
6. Warfare is Software (Autonomous Drones)

Let's elaborate on these statements.

Industrial Robotics: Management is Automation

Perhaps the defining industrial innovation of the 20th century was the assembly line. For the 21st, it may be industrial robotics. While factories have had robots of some form for quite a while, recent advances in robotics have made it possible to write code to automate whole facilities (1, 2, 3, 4). Even tasks that require extreme manual dexterity will soon be done by robot hands.

[3] We intentionally exclude photosharing and social gaming for now, as well as most ecommerce and enterprise app plays, as most of the difficulty in these companies is in the execution rather than the technology itself. There's nothing wrong with that, it's just not as interesting from a technology perspective.

This will have significant consequences. Among other things, by turning management into code, management now becomes tangible. As context, the stereotypical image of the manager in the early 20th century was a fatcat boss with his feet up on a desk smoking a cigar, while workers slaved away below on the assembly line. From today's vantage point, however, we can start to assign some value to the employee training manuals, assembly line layouts, and even internal memos that those 20th century managers used to organize their factories. This is because the 21st century manager of an assembly line can replace employee training with scriptable machine images, can substitute architectural diagrams for assembly line configurations, and can think in terms of message passing protocols rather than internal memos. In other words, the previous intangible informational tasks done by the manager now become tangibly recorded in git logs and database entries. In this world the manager blends into the worker, and the assembly line morphs into a robotic factory scripted by said manager/worker.

Not only does this mean far fewer workers, it means far fewer constraints. For better or for worse, no employment law provisions apply to robots. There are no hourly restrictions, minimum wage laws, collective bargaining agreements, or decommissioning restrictions (WARN act) when it comes to robots. OSHA's power over the workplace also plummets when there are no workers. In many ways this scenario is alarming to not just the already embattled US factory worker, but to workers at Chinese companies like Foxconn that may be replaced by robots. The flipside, though, is that as this technological trend begins to accelerate, the capital requirements to mass produce a good will decline precipitously. To run a small robotic factory will be like running one's own datacenter, well within reach of the individual entrepreneur.

3D Printing: Regulation Becomes DRM

3D printing (1, 2, 3) has been hailed as the replacement for the assembly line, as a tool that will allow at-home manufacturing. However, it's hard to see how the first generation of 3D printers can produce plastic goods that have the quality and robustness of highly-optimized, mass produced metal items. One could make the argument that 3D printing can enable just-in-time manufacturing and reduce supply chain lag times and inventory volumes, and that likely will be true as the field progresses, but that's not likely to be the most immediate application if the plastic goods produced are significantly below the quality of mass-produced goodsa.

An alternative view is that the most important consequence of 3D printing will be to make it impossible to ban goods. Already we have working versions of 3D printed guns (1, 2, 3, 4, 5, 6), drones, cars, and medical devices. And in the UK Professor Lee Cronin is working on a way to 3D print pharmaceuticals and other chemicals (1, 2, 3). People have not yet begun to process the consequences of this. A whole alphabet soup of agencies, from the ATF to the DHS to the FAA to the FDA to the NHTSB derive their raison d'etre from banning or limiting access to these controlled goods. But now, because information can be freely transmitted across the internet and then reconstituted into a physical object via a 3D printer it will be impossible to ban these goods. As Homeland Security itself notes:

> "Significant advances in three-dimensional (3D) printing capabilities, availability of free digital 3D printer files for firearms components, and difficulty regulating file sharing may present public safety risks from unqualified gun seekers who obtain or manufacture 3D printed guns," reads a May 21 bulletin ... "Limiting access may be impossible."

> Still, they exist on the same peer-to-peer file sharing services that distribute pirated entertainment (and legal software). "Even if the practice is prohibited by new legislation, online distribution of these digital files will be as difficult to control as any other illegally traded music, movie or software files."

And consider in particular these four points:

1. There are now one billion internet-connected, unlockable Android devices built on a Linux kernel
2. VPNs can be used to defeat deep packet inspection
3. Steganography can be used to hide substantive payloads in the photos and videos sent over social networks
4. It has generally proven infeasible to ban encryption or even 3D printing due to their substantial non-infringing uses

Taken together and projected out a few years, this means it is now possible to envision a world aflood with tiny $35 Raspberry Pi servers chock full of banned goods. If history is any indicator, the alphabet soup will not completely give up without a fight. It will seek to push the hardware manufacturers to install DRM on their printers to disallow the printing of particular form factors (and this has already begun). This will be similar to the efforts to disable Photoshop from editing dollar bills, or the various efforts of Hollywood to put digital rights management into media players. In other words, the ability of regulators to control access to prohibited devices will reduce to the strength of their DRM.

But because we are dealing with continuous objects rather than discrete ones, the ability of DRM to actually block the printing of certain forms is likely to be a cat and mouse game. For example, consider the evolution in just two months time from a single shot 3D printed gun to a multishot gun to a full 3D printed rifle capable of firing fourteen rounds. Even without fully disabling DRM, one would only need to continuously deform an object enough to 3D print it.

Telepresence: Immigration Policy is a Firewall

Another interesting technological trend is the rapid improvement in telepresence. Beginning with Trevor Blackwell's Anybots, a host of new companies like Double Robotics have arisen that provide a video-game like interface to a remote machine. Rather than using the W/A/S/D keys to navigate through the mazes of Doom, you now use them to remotely attend a happy hour in San Francisco while you are in Bangalore. This is telepresence: not simply video chat, but video chat on wheels.

The technology is just getting started, but project it out a few years. Combine Oculus Rift, Myo, 3D Treadmill as input and Double Robotics, Petman, and Google Glass as the remote machine. You now have a device similar to that from the movie Surrogates. You would be using the three input devices to remote control a humanoid robot in another country or jurisdiction. Said robot would be able to record and stream its environment back to you. Though the system integration will be nontrivial, all six of these technologies exist today and are individually functional.

The whole will be greater than the sum of its parts, however. Telepresence of this kind will become an imperfect but extremely cheap substitute for a tourism junket or work visa.

And because physical presence is no longer necessary, nation states will find that the only way to restrict access to certain immigrants will be to set up a firewall that restricts particular kinds of international telepresence connections. In this manner, a nation's immigration policy will be as good as its firewall.

Quantified Self: Medicine is Mobile

We spoke about the quantified self trend the last time, but it's worth thinking about this a bit more. The combination of telemedicine, mobile appointment booking, quantified self, 3D printed devices and drugs, and medical tourism will make it much more difficult to limit access to new biomedical technologies. Put these together and you will find people routinely self-diagnosing via quantified self, doing a video chat with a physician in another state or country, traveling to meet that physician for surgery, or even 3D printing their own medical devices or drugs.

The last step might seem particularly radical, but keep two points in mind. First, the nature of open source software platforms is that over time even this process of drug printing or device printing will be turned into a one-click operation. It's very hard to write a video codec or to produce a feature film, but it's not that hard to download a torrent and watch it on VLC. In the same way, the open source community will quickly refine device and drug plans and circulate them for use by early (and then not-so-early) adopters. And some of these open source contributors will even be skilled physicians.

Second, if a patent or a paper on a drug is publicly available and yet someone can't get access to it for monetary or regulatory reasons, they may choose to try a radical step rather than simply surrender to their illness. In Cowan vs. US, for example, a terminal patient sued to get access to a drug that was being kept from him by federal regulations.

> Plaintiff and Plaintiff's doctor testified that Plaintiff is terminally ill. . . .
>
> The Court is sympathetic to Plaintiff's situation. However, the law is very clear, and under the current statutes and regulations, Plaintiff's physician may not administer the goat neutralizing antibody drug absent prior approval of the FDA. In Court, Plaintiff argued that he should have the right to take whatever treatment he wishes due to his terminal condition regardless of whether the FDA approves the treatment as effective or safe, and that to prohibit him from taking the treatment he wishes violates his rights under the United States Constitution.
>
> . . .
>
> This Court is in no way criticizing the intentions of Plaintiff and his physician or the potential effectiveness of the proposed treatment. Plaintiff's physician should pursue approval of his Investigational New Drug application as quickly as possible. Plaintiff's doctor must obtain appropriate approval through the proper regulatory authorities. As much as this Court may empathize with Plaintiff, the authority to provide some type of exemptions for individuals such as Plaintiff rests with Congress and not with this Court.

It's difficult to read about what happened to Mr. Cowan; he's probably passed on now. Someone in a similar situation in 2018 or 2023 might simply (a) 3D print their drug or (b) find a prescribing physician via telemedicine, travel overseas, and take his drug in another country. In this manner medicine may become mobile.

Bitcoin: Capital Controls are Packet Filtering

Bitcoin is a new kind of digital currency, native to the Internet, that can be variously thought of as an open-source project (like Linux), a protocol (like HTTP), or a commodity (like gold); see this short introduction for more. The fundamental innovation behind Bitcoin is a breakthrough in distributed systems; the underlying Bitcoin protocol can now be used to distribute many kinds of algorithms that were thought to involve a central server, including transaction processing. Specifically, rather than increment or decrement an account's balance on a central bank server, Bitcoin has a clever way of recording it on a distributed network of computers and updating it as you send and receive payments.

Though the distributed Bitcoin network began processing transactions all the way back in January 2009, the Cyprus bank account seizures of March 2013 were by many accounts a major shot in the arm for Bitcoin adoption. Bitcoin prices spiked all the way up to $266 USD/BTC before falling back down to a relatively stable $100 USD/BTC. Cypriot bank accounts were frozen and funds were seized, with the final toll being at least 47.5% of assets on all accounts with at least $132,000 in savings:

> Depositors at bailed-out Cyprus' largest bank will lose 47.5% of their savings exceeding 100,000 euros ($132,000), the government said Monday.
>
> The figure comes four months after Cyprus agreed on a 23 billion-euro ($30.5 billion) rescue package with its euro partners and the International Monetary Fund. In exchange for a 10 billion euro loan, deposits worth more than the insured limit of 100,000 euros at the Bank of Cyprus and smaller lender Laiki were raided in a so-called bail-in to prop up the country's teetering banking sector.
>
> The savings raid prompted Cypriot authorities to impose restrictions on money withdrawals and transfers for all banks to head off a run. Christopher Pissarides, the Nobel laureate who heads the government's economic advisory body, forecast Monday that the bank controls could be in place for another two years.

More bailouts and haircuts for Cypriots may follow:

> The Cyprus government is looking to the European Central Bank to provide a restructured Bank of Cyprus with as much liquidity as it needs to help turn the country's tanking economy around by lending to cash-starved businesses. Anastasiades last month warned ECB chief Mario Draghi that Bank of Cyprus' cash reserves were running dangerously low.

And for the last several months, stringent capital controls have been imposed on Cyprus, limiting the amount of money that can be taken out of the country. Finally, well before the Cyprus haircuts occurred BCG published a document that calculated the size of haircuts required in 10 countries with high debt to GDP ratios (Figure 7).

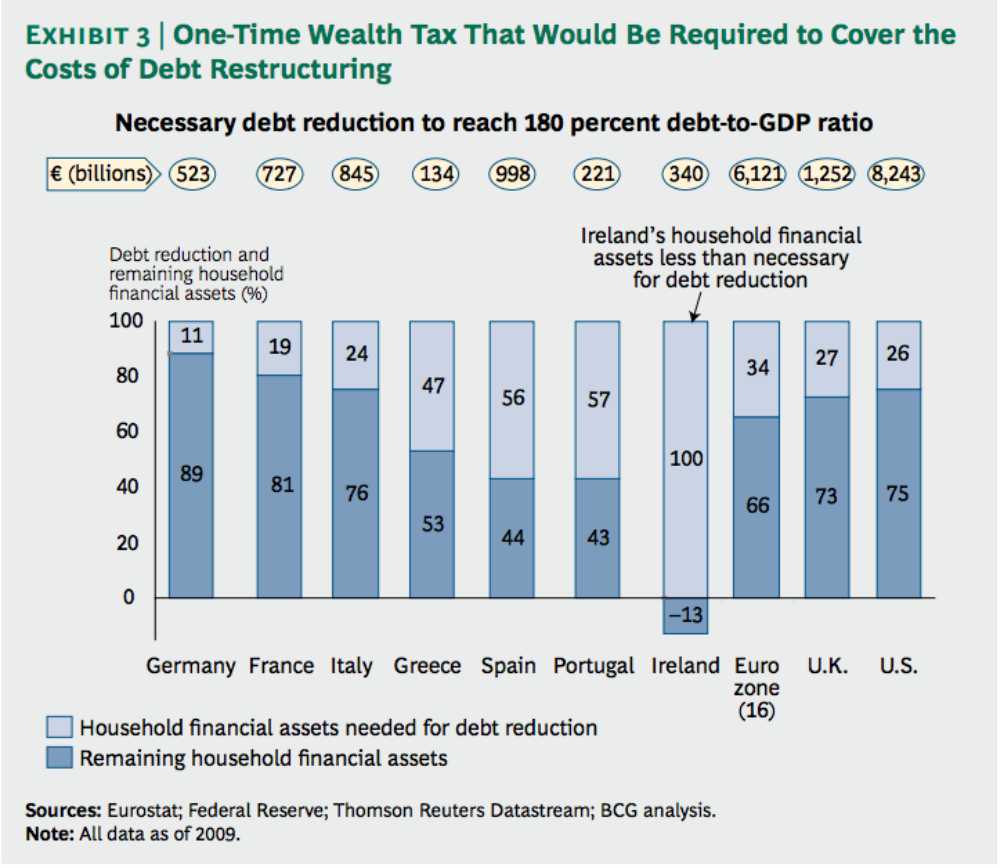

Figure 7: *BCG's estimated wealth tax in ten industrialized nations, as of 2011. (Source)*

While it certainly will not happen overnight, if Bitcoin grows in adoption it will make wealth seizures and capital controls much less feasible. Wealth seizures become much more difficult because Bitcoin private keys can be held on local laptops, stored on USB keys, or printed on paper wallets. Unlike bank accounts held on the servers of private banks, these air-gapped Bitcoin storage systems are not detectable or automatically debitable by central systems.

More interestingly, capital controls also become less feasible. Traditionally one has to declare at customs if one is carrying large amounts of physical cash (1, 2, 3). But Bitcoin defeats this paradigm of capital controls. Not only can Bitcoin be transferred through the internet, the private keys to a Bitcoin address can be put into a cloud folder. One could then imagine a traveller who steps through an airport and truthfully declares that s/he has no cash on their person. Then, once on the other side, said traveller simply downloads their private keys from their Dropbox or Google Docs folder, or their own personal server which is still physically present in Peoria, Kansas. And truth be told, such a trip is not even genuinely necessary. So long as an encrypted connection can be established between two parties, Bitcoin can be sent between those parties. And if Zerocoin and the like continue to improve, the ability to trace that transaction through the Bitcoin Blockchain will also grow cold. In other words, we may be approaching a future where the ability to control the entrance and exit of capital from a jurisdiction reduces to the ability to perform deep packet inspection and packet filtering, searching for signatures of Bitcoin transactions.

Autonomous Drones: Warfare is Software

Finally, let's talk about drones. Self-driving cars, walking robots, and unmanned aerial vehicles are about allied technologies: the ability for a machine to navigate from point A to point B without constant human intervention and correction. Until you've actually flown a drone like the consumer Parrot AR machines, it's easy to forget the fundamental difference between drones and RC planes: unlike RC planes, drones can fly outside the line of sight without constant ground control.

This is somewhat magical. It means that you can, in theory, set waypoints for a drone and then sit back and have it deliver you a taco, steering past obstacles and landing with aplomb. But the applications move beyond tacos. Right now it requires five soldiers to control a single Predator drone. But over time the number of drones controller per individual operator (the fan out) will rise from 1:5 to 5:1 and beyond. And those drones will be not just aircraft but humanoid drones.

As that number rises, military strategy starts to resemble a real-life game of Starcraft. Everything becomes about controlling your drones. And then everything becomes about finding zero-day vulnerabilities in the drones and/or drone control systems of your opponent. By taking control of their drones you can turn them against the enemy or set them to self-destruct. Ultimately what this means is that warfare becomes more than ever about quality, not quantity. The number of soldiers won't matter; to win a war, you will need better software.

Coda

When we put these technological trends together we can see a future of radical, disruptive legalization through technology. Everything of significance is reduced to whether or not individuals can securely transmit packets to each other, via VPN or steganography or other means. If that right is preserved, it will be impossible to block these technologies. And with

close to 1 billion mobile internet connected devices released in the world, it can be argued that the cat is already out of the bag. Unlocking those mobile devices and using them to send/receive encrypted packets over the internet is likely to be the means by which this future is achieved.

There is, however, one remaining potential roadblock: the actual physical internet backbone itself. International transmission of information still travels over a huge worldwide network of underseas cables, and in the event of serious exigency these cables are still under the control[4] of traditional nation states. Google's Project Loon is perhaps the most interesting way to address this, with a network of high-flying balloons providing internet connectivity.

Whether Loon will provide an unblockable internet or not remains to be seen, but if everything else becomes virtual and if these technologies continue to advance we can expect the physicality of the internet backbone to move from the background to a battleground. If that does in fact happen - if interference with the physical backbone becomes the only way for nation states to stop disruptive technological legalization, to reassert their jurisdiction via packet filtering, firewalls, and DRM - at least one thing is certain. No one will contend any more that Silicon Valley's imagination is limited to social gaming and photosharing.

[4]When Syria stopped all internet traffic leading into the country for a period of 48 hours, the initial speculation was that the government had actually cut the cables, but eventually it looked like they had just gone after the routing tables. See Cloudflare (1, 2, 3) for more details.