



Reforming Regulation to Drive International Competitiveness

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Regulatory reform focused on traded sector industries can substantially reduce costs and boost competitiveness while maintaining, or even increasing, social benefits.

Without faster economic growth, America will be unable to deliver on the implicit promise of high employment and increased living standards that underlies our social contract. Unfortunately, many economists are starting to worry whether the economy has entered a period of secular stagnation. One promising antidote to this problem is regulatory reform. Poor regulation is especially damaging when applied to industries that face international competition. Unlike firms in other industries that face little global competition, these companies are more likely to move their production to jurisdictions where the cost of regulation is lower. Failing that, they may find themselves losing global market share to less burdened rivals in other nations. In either case, the U.S. economy suffers.

INTRODUCTION

Regulatory reform focused on traded sector industries can substantially reduce the costs that agencies impose on these industries and boost their competitiveness while maintaining, or even increasing, the social benefits. This paper analyzes some of the general policy issues associated with regulatory reform. It first looks at the regulatory process to show why it is unreasonable to expect that regulation will always maximize social welfare. In fact, it is not unreasonable to expect that some regulations will become significantly out of date or that the regulatory process imposes significant costs. The paper then looks at case studies in three areas—medical devices, aircraft production, and export controls of high-tech productions—in which regulation affects the competitiveness of specific industries that face

global competition. But the paper could have easily looked at other industries as well, including information industries, semiconductors, and life sciences.

The paper then lists general principles that regulators should follow:

1. Anticipate innovation.
2. Embrace transparency.
3. Concentrate on metagoals.
4. Place more trust in the consumer.
5. Place more emphasis on reducing the cost of over-regulation.
6. Recognize the value of time to industry.
7. Adhere to cost/benefit analysis.
8. Take into account the competitiveness impacts of regulation.

The paper concludes by proposing specific institutional reforms to ensure agencies follow these principles, especially with regard to industries facing international competition:

1. Create interagency councils to take a comprehensive look at the competitive environment facing traded industries, including a look at the regulatory structure.
2. Create an Office of Innovation Policy Review.
3. Open up the regulatory review process even further.
4. Congress should be more active in updating legislation and overseeing the regulatory process.
5. Provide agencies with the resources they need to regulate effectively.

HOW LACKLUSTER COMPETITIVENESS STIFLES GROWTH

More than five years after the end of the Great Recession, the U.S. economy has still not returned to full health. Although unemployment has fallen a great deal, it is still not back to full employment levels and much of the decline is due to workers who have given up looking. While economic growth typically bounces around from quarter to quarter, annual growth has remained sluggish. More worrisome, the Congressional Budget Office has lowered its estimate of long-term potential GDP growth to between 2.0 percent and 2.3 percent per year. Many economists are arguing that the United States has entered a prolonged period of secular stagnation. According to this theory, the U.S. economy may perform well below its potential for an extended period of time, due largely to structural weaknesses and a lack of adequate demand.¹

While there are multiple causes for this, one appears to be lackluster U.S. international competitiveness. The United States has run a trade deficit every year since 1975. As ITIF has shown, we lost 5.7 million manufacturing jobs between 2000 and 2009, mainly due to declining U.S. competitiveness.² And while our relative position has deteriorated more slowly in recent years, it is still problematic. As ITIF has also shown, real U.S. manufacturing output at the end of 2013 was below 2007 levels.³

Other nations are not standing still. Indeed, in the last decade, many nations have lowered statutory corporate tax rates, expanded tax incentives for investment, increased public investment in the building blocks of competitiveness (e.g., research, skills, and

infrastructure), and, most relevant to this report, worked to reduce the regulatory burden on their industries, particularly ones facing global competition. They did this in order to boost the competitiveness of their traded industries and to attract foreign investment from other countries.

While regulatory reform is good for all industries, it is particularly important for traded-sector industries because companies in these industries often have the option of moving their productive activities abroad to countries that impose less costly requirements. Indeed, they may have little choice in doing so; otherwise they will face competition from foreign companies that benefit from the lower standards or a more efficient and timely regulatory system. There are many signs that the legal, business, and regulatory environment may act as a significant brake, however. Therefore, given the limited political and administrative capacity for regulatory reform, we should concentrate first on the traded sectors of the economy because reform there increases our international competitiveness in addition to delivering the productivity and innovation gains normally associated with regulatory reform.

Current Problems with the Regulatory Process

The current political debate on regulatory reform is stalemated. Many conservatives seem to question the value of regulation altogether without offering any clear alternative for protecting customers, preserving the environment, or ensuring fair competition. Many liberals, however, often seem oblivious to the failures of regulation or their impact on competitiveness and economic growth.

Intelligent rules are vital to all capitalist markets. Buyers and sellers must know the terms under which contracts will be enforced and property will be protected. Moreover, in the absence of regulation, many companies would engage in activities that make society worse off. Giving private parties a common understanding of how markets will work can save a lot of time and reduce uncertainty that can inhibit market transactions. Centralized legislation or rulemaking is often a much more efficient process than case-by-case common law for deciding on the common rules that will govern market behavior. And it is usually better to have this regulation at the federal level rather than force companies to face a patchwork of 50 different state regulatory regimes. However, the quality of federal rulemaking and implementation matters a great deal, and there are well-known problems with trying to regulate modern industries.

Agency rulemaking in the United States is generally governed by the Administrative Procedures Act (APA).⁴ The APA lays out a thoughtful process for trying to ensure that agency rules, which often have the force of law, are well thought out and based on accurate information about the problem the agency is trying to address. In most cases the APA requires an agency to publish a notice of proposed rulemaking telling the public that it is considering regulation in a certain area. It also requires the publication of preliminary rules. At each of these stages the public is given a chance to comment and submit information for the record. The record is open to everyone so that interested parties can see and comment on information submitted by others. The purpose is to make sure regulators have as much

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accurate information as possible before they draft final rules, and also to ensure that those rules are adequately supported by the public record.

The provisions of the APA have been supplemented by a series of executive orders by presidents seeking to gain greater control over the confusing and often unwieldy rulemaking process under them. The most recent of these is Executive Order 13563, signed by President Obama in 2011.⁵ It requires that the agencies reporting to him—which do not include independent agencies such as the Federal Communications Commission—ensure that the benefits of any new regulations exceed their costs and that agencies conduct a retrospective review of existing regulations to make sure they have not outlived their usefulness.

However, agencies do not always follow the spirit, or even the letter, of the APA. But even when they do, the APA often works better in theory than in practice. It is also incapable of dealing with some of the most serious problems with the modern regulatory process. Combined, these problems significantly limit the ability of regulators to implement rules that maximize the net benefit to society.

The first of these problems is the information disadvantage that regulators face. Modern markets are much more complex than they appear to the average citizen. They often involve hundreds of firms, thousands of products, complicated contractual agreements, complex technical specifications, and a great deal of uncertainty—much of it the inevitable consequence of systems that involve the independent decisions of thousands, if not millions, of people. No person or institution can ever know all of the information in the market. But companies almost always know many more of the details than do regulators. This is partly a consequence of companies having a stronger motivation to discover information. It also reflects the limited staff and budget of agencies. But without accurate information about market problems and the impact of various responses, regulators must often guess at what will work. Industry lobbying can play a large role in educating regulators, but the content of the information is often self-interested, giving the regulator only one of several possible views.

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A second limitation is the time it takes to issue new rules. In the best of circumstances the process of issuing a major rule on a complex subject can take years. The Obama Administration is still working on rules associated with its two most important achievements, the Affordable Care Act and the Dodd-Frank legislation, both passed in 2010. Political considerations and court challenges can often delay the process even further. As a result, regulations almost always address yesterday's problems rather than today's. They almost never address tomorrow's.

Third, regulators usually suffer from a scarcity of resources. This can lead to a number of problems, perhaps most importantly a delay in regulatory approvals or denials. Private companies can often raise almost unlimited sums as long as they can reasonably promise to deliver a competitive rate of return. Regulators, however, are bound by the political process, and both Congress and the president are often reluctant to devote extra resources to regulation and enforcement at a time when more popular government programs are being squeezed. Even when agencies have funded their operations with user fees, Congress

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has often succumbed to the temptation to use the resulting revenues for other purposes. As a result, agencies have a difficult time attracting and keeping the best people, or even simply retaining enough people to keep up with the workload. Indeed, working in an agency often becomes a stepping stone to a more lucrative job in the regulated industry, posing a threat to regulatory independence. This disadvantage may grow over the next decade as a large number of experienced federal agency baby boomers retire, taking their professional experience and institutional knowledge with them. Unless regulatory agencies are able to reform themselves in a way that attracts and retains some of the best young talent and increases their efficiency, their ability to keep up with industry developments will suffer.

Fourth, most agencies are not properly motivated to regulate efficiently and are even less motivated to be concerned with U.S. international competitiveness. Some observers deny that efficiency or competitiveness should even be a criterion for regulation, asserting that cost-benefit or competitiveness analysis inevitably undervalues important, but nonmonetary, political, social, and environmental benefits.⁶ Aside from this, the personnel in many agencies are often suspicious rather than supportive of the role that their industries play in the economy. Congress is not much help since it often starves agencies of needed funds and fails to conduct constructive oversight hearings to improve regulatory goals and methods. Although some agencies are able to pay more competitive salaries, few regulators are rewarded on objective metrics linked to either increasing the benefits of rules or reducing their cost on industry while still protecting the public.

Finally, the dominant regulatory approach continues to be technology-based, rather than performance-based. Instead of holding industry to sensible, long-term goals and then trusting technology and competition to deliver increasingly affordable ways of achieving these goals, most major regulatory systems continue to follow a dated process that largely relies on subjecting industry to complex rules whose applications to specific circumstances are not always clear.

Even when regulations are written properly, poor implementation can create enormous costs. If it takes an excessive amount of time to get the necessary approvals because the agency lacks either the resources or incentive to act in a timely manner, companies may be unable to pursue opportunities that are otherwise profitable. If implementation of the standards is inconsistent, firms may act too cautiously in order to avoid fines. And if the agency interprets the regulations in an arbitrary or partisan manner, it can transform a good regulatory scheme into a bad one.

THE COMPETITIVE IMPACT OF REGULATION

The development and implementation of poor regulation is especially damaging to industries that compete in international markets. If government imposes unwise regulatory burdens on non-tradable industries that must be produced and consumed in the United States, such as insurance brokers, dry cleaners, or home builders, it still reduces total welfare by limiting competition or unnecessarily increasing costs. But these businesses usually are able to pass on some or all of the cost to consumers or workers. Even if they cannot, they do not suffer any relative disadvantage against their main competitors since

everyone is in the same boat. And by definition, they cannot move their production overseas without also giving up their customers.

The situation is much different in markets for traded industries (industries that sell a not-insignificant share of their output outside the United States and where domestic consumption can be met through foreign production of goods or services), where high regulatory costs can harm U.S. producers and jobs without accomplishing any corresponding benefit relative to more efficient regulation. When business establishments in the United States face a competitive disadvantage due to regulation, they have only two choices: they can try to move production outside of the United States, or they can, all else being equal, lose market share to foreign competitors. In both cases they employ fewer American workers, and because traded sectors have a much larger multiplier effect on the economy than non-traded sectors, this loss will ripple through the economy, slowing growth and leading to a higher trade deficit.⁷ Although the United States can bar foreign goods and services that don't comply with our regulations, practical difficulties and trade agreements limit this ability when the rules deal with production methods rather than product quality. And in some cases that deal with products as opposed to process regulation, the advantage of other nations is not less stringent regulation, it is faster and more certain regulatory approval.

When business establishments in the United States face a competitive disadvantage due to regulation, they have only two choices: move production or lose market share.

Losing international competition in knowledge-based industries is especially dangerous because it means losing much more than just the firms and their output.⁸ A loss of competitiveness in these industries also means losing much of the value that would then be dispersed among unemployed workers and underutilized suppliers. Once leadership in technologically complex industries is lost it can be very difficult to regain because doing so would require reassembling a complex web of industry experts, suppliers, professional associations, and other knowledge-sharing organizations. With less domestic production, fewer students will acquire the knowledge needed to maintain that competitiveness and much of the tacit knowledge involved in competing in high-tech industries will disappear.

In reality, the regulatory environment is only one aspect of the environment that firms benefit from and compete in. Poor performance in one competitive aspect can be overcome by better performance in others. Thus, low-cost labor and access to a rapidly growing market in China has in the past outweighed the considerable political and legal risks for many firms. The United States still enjoys a number of strong advantages, including a stable legal environment, low trade barriers, a sophisticated, if aging, physical infrastructure, strong supply chain networks, and access to a top talent pool of managers and entrepreneurs. But in other areas, such as tax policy, public investment in key building blocks like research, and regulatory policy, we lag behind.⁹ U.S. regulatory policy imposes great costs on industry. In some cases these costs are direct, with industry having to pay more to comply. In other cases they are indirect, with industry paying the price in terms of delayed time to market, for example.

In some cases these costs are worth it because of the other benefits regulation generates. But in other cases they unnecessarily weaken our competitiveness. And in almost no cases are the costs of regulatory delay worth it. Because the costs are great and because the country

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has not focused on regulatory reform for a long time, sustained efforts to introduce best practices could have a noticeable positive effect on economic activity, including competitiveness. However, the complexity of the issues, scarce resources, and political opposition all serve to limit the capacity for legislative and regulatory reform. Given that, these efforts should initially concentrate on regulatory reform that most directly affects industries that have the largest impact on competitiveness: those that trade internationally.

The following case studies demonstrate some of the problems posed by regulation, even in industries that have been able to retain their competitiveness. Although the discussion is not detailed enough to suggest specific solutions, it highlights some of the current issues that regulators and firms face. Generally, agency inertia, lack of resources, and a lack of political agreement are greater barriers to reform than a lack of workable ideas.

THE MEDICAL DEVICE INDUSTRY

While the United States has lost its competitiveness in a number of industries, from consumer electronics to automobiles, it still largely retains it in medical devices.¹⁰ However, the lead is shrinking. One reason is that other regions are using faster approval processes as a competitive tool to attract innovative activity.

The Federal Food, Drug and Cosmetic Act generally requires a “reasonable assurance of safety and effectiveness” before a product can be sold.¹¹ But reasonable assurance does not imply certainty and over-regulation also has a cost, as does delay. First, besides keeping out dangerous or ineffective devices, the regulatory process also delays the introduction of beneficial devices, even as patients are suffering from a wide variety of illnesses, some of them life-threatening. Intelligent regulation needs to balance these two costs. Second, the relative efficiency of regulation affects the health of the U.S. medical device industry itself and the economic activity associated with it. Investors have a number of industries to choose from besides medical devices. And those who do invest in this area can increasingly conduct their research and development and production anywhere in the world, including in nations with streamlined regulatory approval processes.

The United States has an extensive regulatory system for medical devices, led by the Center for Devices and Radiological Health within the Food and Drug Administration (FDA). The general goal is to ensure that all medical devices are safe and effective. The system tries to vary regulatory scrutiny according to the potential harm posed by different devices, as well as to their similarity to devices that have already received regulatory approval.

A manufacturer can take its device to market in either of two ways. The first is to apply for premarket approval (PMA) and conduct clinical trials to show that the device is safe and effective. The second is to submit a 501(k) notification showing that the device is substantially equivalent to one already on the market (a predicate device) that does not require a PMA.¹² The PMA process usually applies to new and high-risk devices and is typically lengthy and expensive. Once approved, manufacturers must still comply with regulations on manufacturing, labeling, product tracking, and adverse event reporting.¹³

A 2011 report by the Institutes of Medicine concluded that the 501(k) process was not and could not be a reliable screen for the safety and effectiveness of moderate-risk devices. It

recommended the development of an integrated pre- and post-market review framework but found that there was insufficient information to design a replacement to the current system.¹⁴ The report's summary of FDA's relationship to innovation can generally be applied to all regulatory agencies:

FDA's role in facilitating innovation ... should be to create a regulatory framework that sets appropriate thresholds for bringing products to the market. Those thresholds should be stringent enough to satisfy the agency's objective of ensuring that marketed medical devices will be safe and effective throughout their life cycles but realistic enough to permit timely entry of new devices that may offer improvements over already marketed devices. Rather than be charged with *promoting* innovation, the committee believes that the FDA should seek to *facilitate* it.¹⁵

Even if it were perfectly organized and managed, FDA would face significant challenges in applying the optimal amount of regulation to medical products. The rapid pace of technology is likely to result in a significant increase in product applications, many of which use new, cutting-edge technology requiring specialized knowledge to evaluate.¹⁶ Future budget deficits due to growing entitlement programs will continue to place increased pressure on FDA budgets, even though users already fund much of the agency. Moreover, a growing wave of retirements will lead to a loss of institutional knowledge. Finally, to the extent that it remains healthy, the medical device industry itself will likely continue to lure away some of FDA's best personnel with the promise of higher salaries.

But in addition to these challenges, the current regulatory process creates unnecessary delay and cost. The oversight of medical devices has appeared on the Government Accountability Office (GAO) list of high-risk government programs since 2009. GAO's latest report found that, despite progress, several challenges remain, including implementation of the Safe Medical Devices Act of 1990, dealing with the growing number of devices manufactured overseas and complex supply chains, and conducting application reviews in a timely manner.¹⁷

In theory, it might be best if the cost of regulation was paid for by the industry itself. But in many cases, such as with drug discoveries and medical devices, innovations have large externalities because the producer is not able to capture the full social benefit. Thus, some public subsidization is appropriate. Moreover, users are likely to oppose higher fees unless they are linked to greater oversight or faster approvals. It is also unwise to give regulators more resources without ensuring that the additional funds are spent wisely. Yet Congress—rather than the industry—is probably better placed to conduct oversight in the public interest.

In 2002, Congress initiated a user fee program to partially pay for the cost of approving medical devices. The fees are intended to reduce the time it takes FDA to review and make decisions on applications. FDA negotiates these fees with industry in conjunction with a set of performance goals for premarket review.¹⁸ However, GAO found that FDA has not met many of the goals for reviewing product applications in a timely manner. Manufacturers point out that even meeting the goals does not preclude long delays because they only

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apply to the time that an application is in FDA's hands. Delays caused by an inability to meet with FDA officials prior to filing an application and FDA requests for additional information are not counted, even though they are just as costly to the company. Other common complaints include: an inconsistency in standards between reviewers, which makes it difficult for companies to know what they need to include in an application; frequent turnover of FDA staff, which often forces the company to start over in order to bring the new examiner up to speed; and delays in meeting with key FDA officials.¹⁹

Other countries are often faster to grant regulatory approval. This gives companies a strong incentive to introduce their products overseas rather than in the United States, and allows a product to start generating revenue years ahead of when it might otherwise. It also preserves the company's market position against competitors that might try to gain a foothold in foreign markets. To the extent that the decision to move initial marketing activity overseas also draws research and development and manufacturing activity abroad, America's competitive position might be severely eroded. American companies that get fast approval in other countries will have little incentive to do much research or manufacturing here, especially since repatriating profits from overseas sales often incurs a large tax bill. Meanwhile, they do not earn any domestic revenue while their products await FDA approval.

There are signs that this is already happening. An industry submission to Congress argues that for complex products, the "new normal" is to conduct clinical trials and product introductions outside the United States.²⁰ The paper attributes this to the high cost of conducting trials here and delays and inconsistencies in FDA approval. The Boston Consulting Group found that in FY 2010, Europe granted premarket approvals almost four years faster than the United States, up from just over a year in 2004. U.S. performance was relatively on par with Europe when it came to 510(k) applications. Average review times for 510(k) applications increased by 43 percent between 2003 and 2007, and for complex PMAs average time to review jumped by 75 percent.²¹ These delays affect sales not just here, but also in countries that require approval in the country of origin, such as China and other countries in Latin America and Asia.

A 2011 study by PriceWaterhouseCoopers showed that although the United States still led on each of the five pillars of innovation in medical devices, its lead was slipping.²² This is showing up in investment trends. A survey of U.S. venture capitalists found decreased investment in biotechnology and medical devices start-ups and a shift in focus toward Europe and Asia.²³ FDA regulatory challenges were cited by 61 percent of the respondents as having the highest impact on venture capital investment.²⁴ This was confirmed by the fact that expected investment in specific health care sectors varied depending on the amount of FDA regulation applied to that sector.²⁵ Although only 13 percent of respondents thought they would increase health care investments in the United States (whereas 32 percent anticipated decreasing it), 44 percent intended to increase investment in Asia and 36 percent said the same about Europe. Three of the top concerns expressed by the venture capitalists dealt with how FDA makes decisions rather than the substance of those decisions. The top factor was increased predictability of decisions. Increased efficiency and improved transparency of communication were also cited.²⁶

A GAO report concluded that the elapsed time from submission to final decision had increased substantially in recent years and that FDA was generally inconsistent in meeting its own performance goals for reviewing PMA submissions.²⁷ FDA was meeting its goals on 510(k) applications, although these goals did not take into account delays caused by requests for more information. GAO interviews with industry and consumer advocacy groups highlighted the following issues:

- Insufficient communication between FDA and stakeholders.
- A lack of predictability and consistency in reviews.
- An increase in time to final decision.
- Inadequate assurance of the safety and effectiveness of approved or cleared devices.

In summary, FDA could do a significantly better job of approving medical devices and that improvement would likely have a beneficial impact on U.S. competitiveness in the industry.

AIRCRAFT PRODUCTION INDUSTRY

The aircraft production industry is already heavily globalized. The production of large passenger airplanes is largely composed of Boeing in the United States and Airbus in Europe. However, each of these companies has hundreds of suppliers spread across the world. Production of smaller planes is more diversified. Major companies include Bombardier in Canada, Embraer in Brazil, and Cessna in the United States. Because of the high upfront and fixed costs associated with airline production, each company must aggressively seek sales across the globe in order to remain cost-competitive. And for Boeing, this process is getting harder, in part because of large government subsidies for its competitors. For example, the Chinese government has mounted a major effort to not only subsidize its way to a jet airplane industry, but to coerce technology transfer in exchange for aircraft sales in China.²⁸

Given the multinational nature of air travel, a significant part of airline regulation is already international. The International Civil Aviation Organization (ICAO) supervises a multi-level certification process for ensuring the safe production and operation of passenger airplanes. ICAO establishes high-level standards for airplane design and construction that national regulators then implement. Partly for this reason, airplane designs tend to be similar around the world.

Manufacturers must generally pass three levels of certification. The type certificate, initially issued by the manufacturer's home country (the state of design), ensures that the plane's design meets all safety requirements. The production certificate ensures that each facility involved in the manufacture and assembly of planes meets high standards for quality control. Finally, the airworthiness certificate approves individual planes. For the last two levels, bilateral agreements usually ensure that certifications by the home regulator are accepted by other national agencies.

The design process generally tries to ensure that all parts and components of the plane are properly designed to meet high safety standards. Other countries may also require the design to be approved by their regulators, but agencies try to promote harmonization and

many smaller countries simply rely on approval by the U.S. Federal Aviation Administration (FAA) or other bodies. However, regulators could promote efficiency by going further in agreeing on globally accepted design standards.

Although standards tend to be the same no matter where the design is approved, the process for verifying adherence to the standard differs. FAA tends to impose more specific regulations on designs whereas the European Aviation Safety Agency (EASA) relies on more general standards regarding design and safety, giving manufacturers greater flexibility in demonstrating compliance. U.S. industry officials have testified that product certification delays are a main impediment to their manufacturers' global competitiveness.²⁹

Like most regulatory agencies, FAA faces serious resource constraints. The domestic industry is growing as airlines purchase more planes and manufacturers begin the process of “refreshing” existing models, sometimes with significantly new designs, as with the new 777 composite wing design. Boeing estimates that, over the next 20 years, the world's fleet of aircraft will double, with 80 percent of these aircraft being purchased abroad.³⁰ Yet, without a bipartisan agreement on taxes and entitlements, discretionary spending of the type that funds FAA will continue to get squeezed, forcing the agency to do more with less. As such there is a danger that FAA will become a significant roadblock to progress in the U.S. aeronautics industry. Also, like other agencies, FAA is beginning to experience increased retirement among its most senior people. According to industry testimony, the average age of FAA's inspector workforce is 52 years and almost 30 percent are currently eligible to retire.³¹ Decades of political stalemate and sparse budgets have reduced the number of middle-level workers available to replace these workers.

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Although FAA is focused on familiar issues, not all of these are critical to airline safety. The industry has been pressing FAA to step back from the details of regulation in order to concentrate on broader standards. There are several ways that the agency could do this. One is to spend less time on routine design issues and focus more on the interactions within airplane systems. Another is to train people to move from design tasks to setting robust standards that the airlines can design to. FAA should also work more closely with other countries so that the latter feel comfortable relying on FAA certification. But of course, that is difficult to do without greater resources.

The competitive threat is limited somewhat by concerns about whether EASA could expand enough to handle the design stage if Boeing moved to Europe. Even the movement of major manufacturing activity would challenge the agency at least in the short term until the ramp up in personnel. In any case, Boeing would still have to get FAA certification for its planes to fly in the United States. However, inefficiencies in regulation add costs, and Boeing and other U.S. manufacturers compete fiercely on price with foreign brands.

Sections 312 and 313 of the FAA Modernization and Reform Act of 2012 required the agency, in consultation with industry, to conduct studies of the aircraft certification and approval process and the consistency of regulatory interpretation, respectively.³² Although both of these reports contained good recommendations, FAA implementation has been slow.

The challenge extends to new aerial technologies. Unmanned airborne vehicles (UAVs) are likely to join driverless cars as one of the subjects of rapid innovation over the next two decades. The proper regulation of this technology involves complex problems regarding software, logistics, and safety. Practices that are perfectly safe in the middle of an Iowa cornfield could be deadly near an airport or sports stadium. Similarly, the high degree of caution justified in the latter two settings should not preclude UAV use in remote areas. In addition, the industry will continue to rapidly evolve, becoming safer as it does so. Yet FAA, in contrast to regulators in Canada, has frozen virtually all commercial uses. In 2012, Congress passed legislation requiring FAA to allow commercial uses. Yet the agency has only recently prepared a draft rule and a final rule may take another two years. Recently the agency has issued case-by-case approvals on a limited basis.³³ The likely result is that both manufacturers and users will conduct their innovation elsewhere. Eventually even FAA will see that its position makes little sense, but by then the locus of production and innovation may have moved offshore for good.

EXPORT CONTROLS

The United States, usually in coordination with other allies, tries to control the export of technology that could be used by our adversaries for military purposes. In both theory and practice, export controls protect the nation's security and help it accomplish important diplomatic goals. However, the implementation of these controls is often confused and ineffective. Some tension in the implementation of these rules is inevitable. A study by the Congressional Research Service noted that "the balance between national security and export competitiveness has made the subject of export controls controversial for decades."³⁴

But the problems with the program go well beyond this, unnecessarily increasing cost and reducing exports. Rather than narrowly targeting a limited set of technologies with the highest military significance, export controls involve an often confusing set of technologies, international agreements, and domestic agencies in an effort that often exposes American companies to great risk and uncertainty while denying them the ability to export products that targeted nations can readily get from other countries.

The restricted technology covers several categories:

- Highly sensitive military technology that the United States keeps only for itself or its closest allies.
- Less sensitive military technology that is denied to nations that are not allies.
- Dual-purpose technology that has both civilian and military uses.
- Virtually all technology in the case of broad export controls to nations like Cuba, North Korea, and Iran.

In addition to unilateral controls, U.S. policy is governed by a number of international agreements, each involving different countries and covering different technologies:

- Australia Group
- Missile Technology Control Regime
- Nuclear Suppliers Group
- Wassenaar Arrangement

Finally, within the United States, a number of agencies share authority over different parts of the law. A partial list includes:

- Department of Defense
- Department of Commerce
- Department of Homeland Security
- Nuclear Regulatory Commission
- Department of Justice
- Federal Bureau of Investigation

GAO put the nation's export control regime on its High-Risk Series in 2007, concluding that "each program has had its own set of challenges, which are largely attributable to poor coordination within complex interagency processes, inefficiencies in program operations, and a lack of systematic evaluations of program effectiveness."³⁵ The 2007 report cited poor coordination among agencies, disagreements over jurisdiction between the Departments of State and Commerce, unnecessary problems in obtaining export licenses, and a lack of mechanisms to evaluate the effectiveness of export controls.³⁶ It concluded that: "[g]overnment programs established decades ago to protect critical technologies are ill-equipped to weigh competing U.S. interests as these forces continue to evolve in the 21st century."³⁷ As one example of failure, GAO noted that the Department of Defense had stopped maintaining the Military Critical Technologies List in 2011 because of a lack of funds.³⁸

To make matters worse, the Export Administration Act, which partially governs export control laws, has expired. As a result, dual-use controls are being enforced through the president's residual powers under the International Emergency Economic Powers Act.

Administrators of the export control act face a dilemma. High-technology goods and services are likely to be more sensitive from a security perspective. But these exports are also likely to earn U.S. companies the highest margins and be the most important to maintaining U.S. international competitiveness. Moreover, in many cases, if U.S. companies do not make the sale their direct competitors will, strengthening their competitiveness position while ours is weakened.

The Obama Administration has been working to improve the program. For example, it has been trying to reduce times for processing commodity jurisdiction cases by consolidating both the decision-making and the information systems, but has made only partial progress.³⁹

EIGHT REGULATORY PRINCIPLES FOR THE INNOVATION ECONOMY

The complexity and rapid evolution of today's economy increasingly challenges regulators' abilities to shape the institutional constraints within which all markets must function. The problem is especially difficult in markets where the pace of innovation is swift or where there is strong international competition. The question is not whether regulation will be needed in the new global economy—it will be. The question is whether regulators can promulgate timely rules that effectively accomplish important goals at a minimal cost and then expeditiously process requests for industry approvals.

Because the U.S. faces the stiffest international competition of its 226-year history, regulators need to acquire a greater appreciation of the economic impact of their actions, especially as they relate to globally traded industries.⁴⁰ They are likely to have more success if their approach is guided by eight basic principles:

- *Anticipate innovation.* In advanced technology industries especially, companies must continually adapt in order to remain competitive. This means that the rules governing their markets must also adapt, often far faster than the normal regulatory process allows. Regulators need to anticipate that the production processes and product mixes of today might be radically different in five years. Unless regulations anticipate this need for change, they will quickly become obsolete or counterproductive.
- *Embrace transparency.* Regulators will always suffer from an information deficit. With limited budgets and career personnel, they can never know as much as industry experts about the markets they regulate. Moreover, much of the information submitted to them by all sides is self-serving. Rather than trying to cloak their lack of information in secrecy, agencies need to adopt as much transparency as possible. This minimizes the chances that they will make major missteps and gives all parties the ability to correct or place in context any information provided by other parties by commenting on all of the documents in the regulatory record.
- *Concentrate on metagoals.* Because micromanagement will increasingly impose too high a cost in terms of unintended consequences or a lack of competitiveness, agencies will increasingly have to decide what is really important to them and then communicate those metagoals to interested parties. The agency will find that at least sometimes industries share goals like worker safety, product assurance, and environmental quality. Public conversations about how to achieve measurable progress toward these goals within a five- to ten-year time frame can often accomplish more than mandatory approaches that try to impose a single solution immediately.
- *Trust the consumer.* Regulators often see themselves as protecting the public against bad corporate behavior. But consumers and voters are often much more intelligent than agencies assume, especially if they are empowered with collaborative rating tools. They are likely to be the best judge of what constitutes good behavior. Customers are very effective at demanding constant improvements in performance and price from companies. They are also increasingly willing to take corporate social behavior into account when making their purchasing decisions. As a result, companies increasingly pay attention to reputational questions. Making sure that the public has accurate information about both the costs and benefits of different products and about how companies operate will usually put more pressure on companies than will agency regulations. In today's age of social media, consumers have more access to this type of information through sites like Angie's List and Zocdoc than ever before.

- *Place more emphasis on reducing the cost of over-regulation.* Agencies are usually focused on minimizing Type II errors, or cases in which they fail to prevent a public harm by regulating. An example of successfully avoiding a Type II error is the FDA's refusal to license thalidomide, a drug that was later found to cause serious birth defects in pregnant women. When markets change slowly and international competition is minimal, the cost of Type I errors—over-regulating in a way that inhibits beneficial innovations—is low. But when innovation increases and companies must compete against international rivals, the cost of unwise regulation rapidly increases. Given the rapid progress in genetic medicine, FDA's slow and costly process of double-blind trials is likely to delay the introduction of important new drugs. In fact, FDA eventually bent these rules in order to approve thalidomide so that it could be used off-label to treat AIDS patients.
- *Adhere to cost-benefit analysis.* Regulation always brings both costs and benefits. The regulator's job is not to eliminate all risk or bad behavior. Doing so would be prohibitively expensive in many spheres of life. Their job is to improve public welfare through market rules that accomplish important public goals at a reasonable cost and that reward innovations that increase consumer value and public welfare. Some costs and benefits are difficult to quantify. However, cost-benefit analysis promotes social welfare by forcing agencies to explicitly state their assumptions and reasoning in a way that other parties can respond to. It helps ensure that public decision making will be fact-based and open and that any final action will improve society. Bad regulation usually occurs when agencies are allowed to keep their deliberations and reasoning hidden from the public.
- *Recognize the value of time.* Actual compliance with regulations is not always the largest cost to business; often the delays associated with waiting for regulatory approval impose even greater costs. An excellent example is the proposed Keystone pipeline to carry Canadian oil through the United States for export. Although it has all of the necessary information, the Obama Administration has delayed a decision for years because of the political consequences. Giving the pipeline's sponsors a quick yes or no would have saved them enormous sums of money and allowed them to plan their next steps, whatever the decision was.
- *Take into account the competitiveness impacts of regulation.* Regulators are not usually attuned to the impact of their actions on the profitability of the companies they regulate. They are even less attuned to the competitive effects of their actions. Yet regulation can have a large effect on where businesses decide to locate and on the ability of U.S. firms to hold their own against foreign competition.

CONCENTRATING ON COMPETITIVENESS

Adherence to the general principles listed above would go a long way toward increasing the competitive environment in which U.S. companies operate. But these principles have been commonplace for a long time, yet little regulatory reform has occurred. In the case of cost-benefit analysis, several presidents have issued executive orders trying to compel agencies

that report to them to comply with the basic proposition that the benefit of rules should outweigh their cost. Yet, agencies still routinely disregard this requirement. As a result, we also need specific institutional reforms that either reduce the cost to agencies of taking competitiveness concerns into account or increase the cost of not doing so. Toward that end, we propose five recommendations for Congress and/or the administration to adopt:

Create interagency councils to take a comprehensive look at the competitive environment facing traded industries, including a look at the regulatory structure.

Another beneficial reform would be for administrations to institute an ongoing process where they take a comprehensive look at specific industries facing strong international competition to see what changes could improve the environment in which they operate. Such an effort would definitely have to include a review of existing regulation to see whether any can be streamlined or eliminated.

Other nations have begun these kinds of efforts. For instance, in October 2013, France began an effort to develop roadmaps for 34 specific sector technologies in an attempt to increase the country's competitive position in each.⁴¹

The United Kingdom has also experimented with industry-government councils. The Automotive Council, for example, was set up in 2009 and involves top officials in government and industry in a collaborative effort to improve the country's competitiveness as a place to produce cars. The Council has focused on a few key tasks, including the development of a technological roadmap for the domestic industry, attempts to boost the presence of U.K. companies in the domestic supply chain, and general efforts to improve the business environment and skills of the workforce.⁴² The last task includes joint efforts on regulatory issues. Britain also provides businesses with a direct means of submitting proposals to its Better Regulation Executive for how specific rules can be improved.⁴³

The United States should launch a similar effort to develop specific policies to improve the viability of U.S.-based companies facing strong international competition. This effort should be led by the White House National Economic Council, with much of the actual work done by the Department of Commerce, and should include a comprehensive regulatory review looking at the complexity of rules, their cost-benefit ratio, and consistency of interpretation, as well as the ease of getting permits and approvals for individual industries. This would entail the White House, Commerce, and the relevant agencies meeting to analyze the impact of regulations on industry competitiveness and to come up with recommendations. Not all industries could be reviewed at once, but the goal should be to review two or three industries at a time, and then move on to the next group of several industries.

Create an Office of Innovation Policy Review.

In a previous ITIF paper, Duke law professors Stuart Benjamin and Arti Rai advocated the creation of an Office of Innovation Policy (OIP), which would opine on regulatory issues having a major effect on the competitiveness of U.S. companies.⁴⁴ In the absence of action from Congress, they called on President Obama to establish the Office by executive order. The Office would have the power to comment on the competitiveness effects of major regulatory actions. It could also study the need for a revision of existing regulations,

something that agencies are normally reluctant to do given their strained budgets and intense focus on current issues. Agencies would not have to incorporate the OIP changes and OIP would lack the power to veto regulatory action. But the mere fact that one part of the government had expertise in competitiveness issues and was able to raise public concerns about agency action would hopefully make it easier for agencies to incorporate these concerns before they issued new rules and would concentrate their attention on competitiveness issues in a way that they currently are not.

Open up the regulatory review process even further.

As a general rule the government would benefit from opening the regulatory process up to more voices. Right now agencies are not required to respond to suggestions that existing regulations are obsolete or even harmful. ITIF has even suggested that regulators should experiment with “crowd sourcing” regulatory review to get a better view of how regulations are working in practice.⁴⁵

Congress should be more active in updating legislation and overseeing the regulatory process.

A fourth institutional reform involves Congress. Congress needs to become more involved in overseeing the regulatory process. After all, agencies only have the powers that Congress delegates to them through legislation. Many of the statutes that govern industries like pharmaceuticals, communications, and education are decades old. Congress needs to update them to reflect modern reality. Michael Mandel and Diana Carew have suggested that Congress could also create a special body to deal with the steady accumulation regulation by rationalizing existing rules.⁴⁶ The committees of jurisdiction also need to conduct more focused oversight of the current regulatory process, especially with regard to how it affects the ability of industry to compete in foreign markets. Congress should engage in an active dialogue with administrators about how they are going to approach existing challenges and the costs and benefits of different approaches.

Provide agencies with the resources they need to regulate effectively.

Finally, Congress must make sure that agencies have the resources needed to regulate intelligently. Because financial and human resources are likely to remain constrained for the indefinite future, additional resources need to be concentrated where they will have the greatest effect on the nation’s welfare, including especially those areas where better regulation would enhance competitiveness. In some cases, user fees may need to be increased. However, these fees should supplement rather than replace appropriated funds. It is also important that the fees be part of a negotiated deal between industry, Congress, and the agency, in which the latter commits to use the additional resources to meet specific performance goals.

CONCLUSION

Americans still have trouble accepting the fact that the post-War era was an exceptional period, not the rule. Not only are the conditions of the 1950s and 1960s unlikely to be repeated, but living standards and economic conditions were not as good as many remember them to be.

The present and the future hold much more promise for us. But they are also much more challenging. Companies in the United States will be facing even more intense global competition, some of it fair (such as more competitive tax rates and better regulatory regimes), and some of it unfair (such as theft of U.S. intellectual property and government subsidies). Their ability to do so will affect job creation, wage growth, and living standards.

A key component of competitiveness will be the ability and need to innovate. We all benefit if China or the United Kingdom invents a new cure for cancer. But we benefit more if the discovery and production occurs here. Competitiveness depends on many things; one of the most important is the environment within which companies operate. While the United States still enjoys advantages in the overall competitiveness of its economy, other countries have been focusing on improving their competitive environments as well. America can no longer take either its strengths or the weaknesses of others for granted. Indeed, our lead is slipping and we have been suffering the economic costs of that decline.

Regulatory reform is one area where significant improvements in competitiveness can be made at little cost. It is also one where bad or obsolete regulations can impose a large economic cost by harming companies that must compete on an international field. The challenge of regulation is likely to become more difficult as global competition heats up even more and rapid technological advances continue. Unless federal regulatory agencies adopt a strong focus on competitive issues, an increasing amount of economic activity will be attracted to nations that do.

ENDNOTES

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The Information Technology and Innovation Foundation (ITIF) is a Washington, D.C.-based think tank at the cutting edge of designing innovation strategies and technology policies to create economic opportunities and improve quality of life in the United States and around the world. Founded in 2006, ITIF is a 501(c) 3 nonprofit, non-partisan organization that documents the beneficial role technology plays in our lives and provides pragmatic ideas for improving technology-driven productivity, boosting competitiveness, and meeting today's global challenges through innovation.

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