

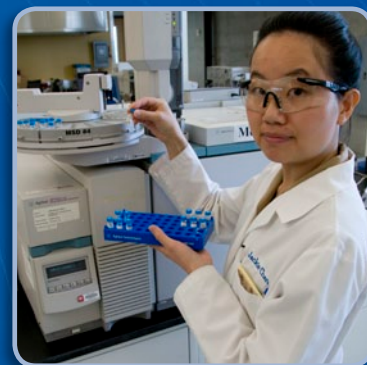
U.S. Food and Drug Administration

A Special Report



Revised July 7, 2011

Pathway to Global Product Safety and Quality



Pathway to Global Product Safety and Quality

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EXECUTIVE SUMMARY

We live in a nation that increasingly relies on other countries to produce the food, drugs, cosmetics, and devices we use in our daily lives. Between 10% and 15% of all food consumed by United States (U.S.) households is imported from abroad. According to the U.S. Government Accountability Office (GAO) nearly two-thirds of the fruits and vegetables—and 80% of seafood—eaten domestically come from outside the U.S. Half of all medical devices used in this country are imported, while 80% of the active pharmaceutical ingredients in medications sold here are manufactured elsewhere.

At the center of this global bazaar is the FDA. Today, nearly 25 cents of every dollar spent by Americans are on products regulated by the agency. FDA-regulated products account for about 10% of all imports into the U.S., arriving from more than 300,000 facilities in 150 different countries.

The growth in imports has been rapid—and promises to accelerate. Just a decade ago, 6 million shipments of FDA-regulated goods passed through the nation's 300 ports of entry. This year the number will quadruple to 24 million shipments. Each year over the last seven years, food imports have grown by an average of 10%, while imports of pharmaceutical products have increased at nearly 13% and devices have grown at over 10%. Between 2007 and 2015, it is estimated that imports of FDA-regulated products will triple, corresponding to a 15% growth rate.

In the decade ahead, the world economy will be shaped by several distinct forces: the rise of emerging markets, the scarcity of natural resources, and the increased flow of capital, information, and goods across borders. The cumulative effect of these trends means not only phenomenal growth in the import sector but increasing complexity for regulators, as the distinction between foreign and domestic products continues to blur.

The manufacturers and producers that FDA regulates face intense pressure to lower costs and improve productivity, fueling a cycle in which the quest for efficiency leads to increased production abroad and higher volumes of imported products to regulate. Goods entering the U.S. will come from new and different markets, flowing through long, multistep processes to convert globally-sourced materials into finished goods. The shift in global product flows will make it difficult to identify the “source” of a product and to ensure that all players along the supply chain meet their safety and quality responsibilities. And it is not just legal activity that poses challenges for the FDA. Increasingly, the agency must contend with ever more sophisticated threats of fraud, product adulteration, and even terrorism.

In short, globalization has fundamentally altered the economic and security landscape and demands a major change in the way FDA fulfills its mission to promote and protect the health of the American people. Just as public health leaders have long recognized that disease knows no borders, FDA in crafting its vision for the next decade knows that product safety and quality no longer begin or end at the border.

This rapidly changing environment, and a desire to move from a posture of intercepting harmful products to anticipating and preventing the arrival of such goods, has prompted FDA leadership to develop this “Pathway to Global Product Safety and Quality.”

Throughout history, FDA's primary tools for product safety and quality have been inspections at production facilities and ports of entry. Over time the agency has developed additional methods for

protecting the public, including laboratory sample analyses for select product categories (e.g., foods) and product safety reporting systems.

Yet the safety of America's food and medical products remains under serious threat. Imported vegetable protein contaminated with melamine has sickened and killed American pets, and milk tainted with melamine killed and injured children in China. Contaminated heparin, diverted and counterfeit glucose monitor test strips, glycerin contaminated with diethylene glycol (DEG), and low quality titanium destined for medical implants have all raised public health concerns. Peppers, eggs, peanut butter, pistachios, spinach, and cookie dough have all been associated with serious disease outbreaks in recent years. Many of the crises were due to, or exacerbated by, the regulatory challenges of globalization.

In response to increasing globalization, FDA has expanded its capabilities and regulatory authority. The PREDICT system, for instance, uses novel data analytics from the entire life cycle of a product to better identify and target high-risk products before they enter the country. Armed with better intelligence, FDA regulators can both speed admissibility of safe products and focus their investigative energies on the goods most likely to harm the public.

The agency has opened additional offices in key international locations and materially increased the number of certain types of foreign inspections. Inspections of overseas drug manufacturing plants, for example, increased from 333 in 2007 to 424 in 2009.

FDA has also collaborated with its counterparts in the U.S. and Australia on drug inspections, engaged in harmonization of drug regulation via the International Conference on Harmonization, and joined the Pharmaceutical Inspection Cooperation/Scheme (PIC/S) which is an informal organization of the drug manufacturing inspectorates from 39 countries. For devices, FDA and other global leaders are creating an expanded global regulators' forum for medical devices under the auspices of the Global Harmonization Task Force (GHTF).

In addition, under the FDA Food Safety Modernization Act (FSMA) enacted in 2011, FDA has been granted new authorities that allow the agency to better ensure the safety of food. Under the law, FDA has a new legislative mandate to require comprehensive, prevention-based controls across the food supply and new tools to hold players in the supply chain accountable. The law represents a paradigm shift in the area of imports. For the first time, importers will have explicit responsibility to verify that their foreign supplies have adequate preventive controls in place and that the food they ship to the U.S. is otherwise safe. The agency also has the power to establish a third-party program for certifying that foreign food facilities comply with U.S. food safety standards, to require certification as a condition of entry for certain high risk foods, and to reject entry of food if the foreign facility or country refuses an inspection by FDA or its designee. Significantly, FSMA also explicitly encourages arrangements with foreign governments to leverage resources, such as mutual recognition of inspection results, sharing electronic data, and training of foreign governments to build their regulatory capacity.

Despite such recent improvements, FDA does not—nor will it—have the resources to adequately keep pace with the pressures of globalization. In 2008 the GAO¹ recommended that FDA increase inspections of foreign drug establishments and improve information it receives to manage overseas inspections. But at current rates, it would take an estimated nine years for FDA to inspect every high-priority pharmaceutical facility just once.

The same holds for food products. FSMA directs the agency to inspect at least 600 foreign food facilities within the next year and double those inspections every year for the next five. While the goal may be attainable in the first year, it would be impossible for FDA to complete 19,200 foreign food inspections in year six without a substantial increase in resources or a complete overhaul in the way it operates.

For decades, FDA has been a recognized world leader in product safety standards. But as the agency looks to the future, it can no longer rely on the historical tools, activities, and strategies to regulate products. The reality facing FDA is that its mission will become ever more difficult to fulfill given the breadth and complexity of industries that it regulates during a time of constrained federal resources.

In order to cope with the magnitude of the fundamental shifts on the horizon, the agency is committed to substantially and fundamentally revising its approach to global product safety and quality. Over the next decade, FDA will transform itself from a domestic agency operating in a globalized world to a truly global agency fully prepared for a regulatory environment in which product safety and quality know no borders.

To achieve this transformation, FDA is developing an international operating model that relies on enhanced intelligence, information sharing, data-driven risk analytics, and the smart allocation of resources through partnerships. The new approach rests on four core building blocks:

- 1) FDA, in close partnership with its foreign counterparts, will assemble global coalitions of regulators dedicated to building and strengthening the product safety net around the world.
- 2) With these coalitions, FDA intends to develop a global data information system and network in which regulators worldwide can regularly and proactively share real-time information and resources across markets.
- 3) FDA will continue to expand its capabilities in intelligence gathering and use, with an increased focus on risk analytics and thoroughly modernized IT capabilities.
- 4) FDA will effectively allocate agency resources based on risk, leveraging the combined efforts of government, industry, and public- and private-sector third parties.

The essence of this strategy marries creative international coalitions with cutting-edge investigative tools to continue to provide the consistently high level of safety and quality assurance the public expects—and deserves. FDA will continue to partner with other federal agencies, the states, and nations across the world. It will also look to Congress to modernize its antiquated authorities so that FDA's legal tools keep pace with globalization.

To meet these ambitious goals and achieve a true and lasting paradigm shift, FDA will engage all stakeholders in a process that will unfold over several years. Success will require boldness, creativity, and patience. It will not be easy, but it is imperative. Global supply chains, international trade, foreign sourcing, and terrorism remind us daily that the rest of the world will not stop and wait for regulators to catch up. It is incumbent upon FDA to engage its international counterparts, industry, and stakeholders worldwide to blaze the Pathway to Global Product Safety and Quality.

I. TEN YEARS FROM NOW, THE WORLD WILL BE VERY DIFFERENT THAN IT IS TODAY

There is a series of macro trends at work that are impacting global commerce as much as they are affecting daily life. The cumulative effect of these trends will ensure that 10 years in the future, the world will be very different than it is today, with a dramatic increase in the global flow of goods, including increases in imports to the U.S., governments playing an increasingly influential role in the healthcare of their citizens, and increased competition for global resources. Therefore, to understand the future of the food and medical products industries, it is imperative to first have a clear understanding and perspective on these trends.²

a. The great rebalancing.

The vibrancy of emerging-market growth will not be the only major disruption reshaping the global economy in the next decade, but it may prove to be the most profound. This decade marks the tipping point in a fundamental long term economic rebalancing that will likely leave traditional Western economies with a lower share of GDP in 2050 than they had in 1700.

Two cycles are at play. The first is declining dependency ratios, reflecting an increase in the overall proportion of a population that is working-age. Virtually all major emerging markets are undergoing demographic shifts well-proven to unleash an economic shift: simultaneous labor force growth and rapidly declining birth rates. The second is the largest urban migration in history. Nearly one-and-a-half-million people move to cities each week, almost all in developing markets. The resulting economic impact is a rapid increase in output per worker as people move off subsistence farms and into urban jobs. China and India are seeing labor productivity grow at more than five times the rate of most Western countries as traditionally agrarian economies become manufacturing and service powerhouses.

b. The productivity imperative.

Emerging markets are riding a virtuous growth cycle, propelled by larger and younger working populations. In the rich nations of the developed world, by contrast, low birth rates and graying workforces will make it enormously difficult to maintain what economist Adam Smith called “the natural progress of opulence.” These countries’ best hope for keeping the wealth creation engine stoked is improved productivity—producing more with fewer resources.

Paradoxically, doing that well across an economy is also the only way to generate lasting employment gains. The great tension here arises at the level of politics. Over time, the world’s rebalancing demands greater consumption and lower savings among the large developing countries, even as developed ones—the U.S. foremost among them—save, invest, and export more. Fostering policies that raise productivity, and avoiding or altering policies that impede it, will help ensure a smooth transition.

To eke out even modest GDP increases, Organization for Economic Co-operation and Development (OECD) nations must achieve large productivity gains. In the 1970s, the U.S. could rely on labor force growth to generate roughly 80 cents of every \$1 gain in GDP. During the next decade, this ratio will roughly invert. Accordingly, OECD nations are going to need to look for all sources of increased productivity. This will lead to greater levels of imports, changes to manufacturing processes, and increased pressure to reinvent the manufacturing process.

c. The global grid.

The last two decades have witnessed the rise of networks of unimaginable density and complexity. Money, goods, data, and people now cross borders in huge volumes and at unprecedented velocity. Since 1990, trade flows have grown 1.5 times faster than global GDP. Cross-border capital flows have expanded at three times the rate of GDP growth. Information flows have increased exponentially. The breakneck growth of these networks has resulted in a massive global communications and information grid that enables high volumes of rich and regular real-time interactions.

These days, a typical manufacturing company relies on more than 35 different contract manufacturers around the world. Auto and airplane manufacturers rely on tens of thousands. Trade in intermediate goods as a percentage of total trade has doubled. Meanwhile, dense links are being formed in a host of new directions. Trade flows between China and Africa, for example, have been growing by 30 percent annually, creating robust commercial networks that barely existed a few years ago. Similarly, Asia has supplanted North America and Europe as the Middle East's largest trading partner. Emerging-market-to-emerging-market transactions are on the rise.

d. Pricing the planet.

The tension between rapidly rising resource consumption and environmental sustainability is sure to prove one of the next decade's critical pressure points. Natural resources and commodities account for roughly 10 percent of global GDP and underpin every single sector in the economy. No one will sit on the sidelines in this debate. The interplay of three powerful forces—growing demand, constrained supply, and increased regulatory and social scrutiny—will determine what resources we use, how we use them, and what we pay for them.

Demand will grow – even the most conservative projections for global growth over the next decade suggest that the demand for oil, coal, iron ore, and other natural resources will rise by at least a third. Supply will be constrained and will come from harder-to-access, more costly and more politically unstable environments. We have already begun to see the impact from this as evidenced by rising commodity costs that have led to global food inflation.

Finally, there will be increased regulatory and political scrutiny. Around the world, political leaders, regulators, scientific experts, and consumers are gravitating to a new consensus based on fostering environmental sustainability. For businesses, this new sensibility will present itself in three ways: stricter environmental regulations, increasing demand from consumers, and employees that demand greater environmental responsibility by their employers. This increased scrutiny and regulation will force manufacturers and producers to adopt new processes and employ emerging technologies to meet the needs of their consumers and broader stakeholder groups.

e. Government and the marketplace.

While we expect the steady advance of market capitalism to continue, government is likely to play an ever-larger role over the next decade for three reasons. First, even before the financial crisis hit, governments everywhere found themselves increasingly called upon to mitigate the sometimes negative impact of globalization on individual citizens. Second, the crisis itself has prompted large-scale direct government intervention, both through fiscal stimulus and movement toward increased regulation. That tilt in the power balance has been reinforced in much of the world by the perceived

failings of the free-market model and the success so far of a Chinese model that, while market-oriented, assumes that the state will continue to play a leading role.

Third, the spread and dispersal of economic power around the world is making it harder to reach consensus on multilateral approaches to setting the rules of global interactions and fostering more bilateral and regional deal making. These more local arrangements remain largely market-based. Yet for business, the continuing shift away from a single set of rules will inevitably make seizing opportunities globally more challenging. It will also require companies to engage across many fronts with many critical regional and national government actions.

II. THE COMING CHANGES WILL MAKE FDA'S PRODUCT SAFETY AND QUALITY RESPONSIBILITIES FORMIDABLE AND MORE GLOBAL IN THE YEARS AHEAD

Because the changes shaping the world of the future will be so large and so fundamental, FDA must substantially evolve its product safety and quality model in order to keep ahead of the coming risks. Import growth will accelerate at the same time that highly-sensitive production processes are moving to new geographies. Increased access to the global marketplace will increase the specter of harm to consumers from economic or other intentional adulteration, fraud, and counterfeiting. FDA has already begun working diligently to build relationships with global and domestic partners, pushing for strong global safety standards. However, the magnitude of the challenge will require faster progress towards closer cooperation than has happened in the past.

Global changes will have significant implications for the manufacturers and products that FDA regulates

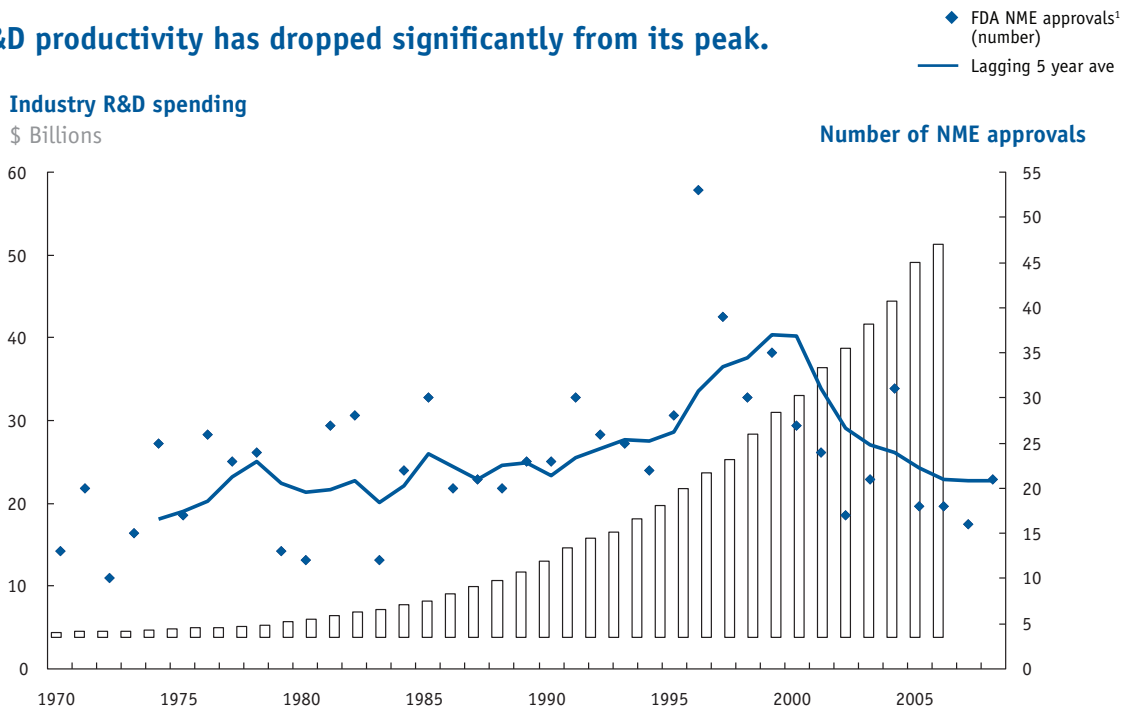
The global trends in the coming decade will have major implications for FDA. The manufacturers and producers that FDA regulates will face intense pressure to lower costs and increase worker productivity. Government agencies, meanwhile, will become even more active and influential stakeholders in the global market. These pressures will continue to drive more, as well as more complex, production abroad, dramatically increasing the already high volume of FDA-regulated products that are imported into the U.S. Products entering the U.S. will come from new and different markets and will flow through long, multi-step processes to convert globally sourced materials into finished goods. As global product flows change, many individuals will encounter the growing dangers of fraud and economic or other intentional adulteration of both foods and medical products. In order to cope with the magnitude of the fundamental global shifts on the horizon, FDA must substantially revise its approach to global product safety and quality.

a. Increasing pressure to reduce costs and increase productivity.

The push to drive down production costs will be a pervasive influence on many countries across a range of industries, particularly those regulated by FDA. Growth in the prescription drug market has flattened in recent years and the rate of return on biopharmaceutical investments has dropped to just above the cost of capital.³ Exhibit 1 shows a steady and significant increase in spending on R&D in the pharmaceutical industry, even as the number of NME approvals has dropped dramatically in the last 10 years.

Exhibit 1 - R&D productivity declining

R&D productivity has dropped significantly from its peak.



1 Lagging 5 year average, includes NCEs and BLAs. BLAs included 1986 onward; biologics approvals in prior years assumed negligible.

Source: NME data for 1966 - 1971 from Peltzman, S. (1973) J. of Political Economy 81, no. 5: 1049-91. NME data for 1972-1979 as reported in Hutt, P.B. (1982) Health Affairs 1(2) 624. NME Data for 1980-2007 from Parexel's Pharma R&D Statistical Sourcebook 2009/2010, FDA, and PhRMA. Industry R&D spend data from PhRMA Annual Membership Survey, 2008 and Parexel 2009/2010.

On the demand side, cost-conscious patients and payors will continue to insist on access to lower-cost medical products and services. Together with the low sales growth shown in Exhibit 2, this has placed a heavy strain on profit margins for pharmaceutical companies.

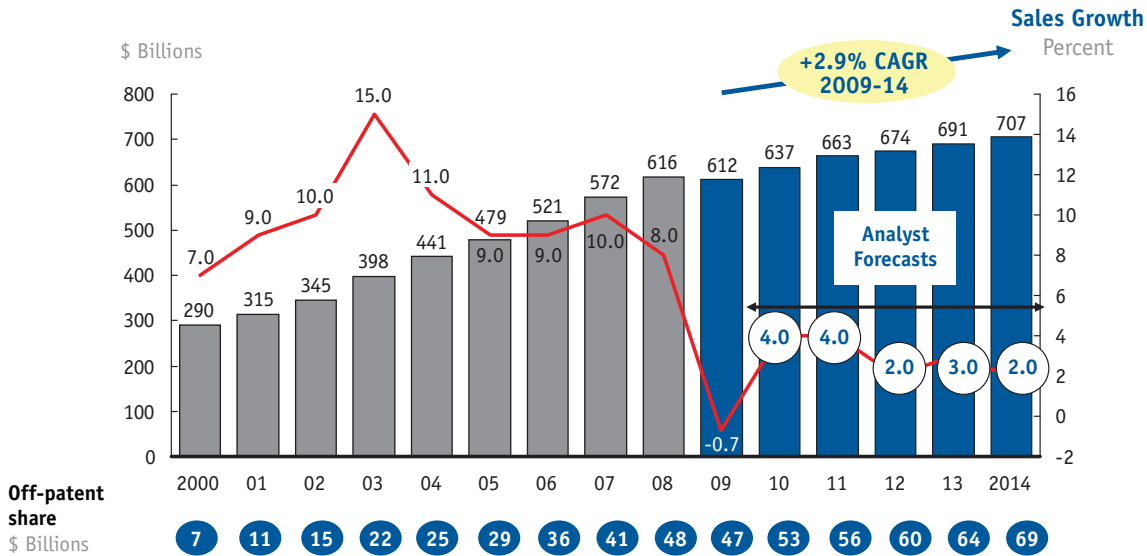
The pressure for cost savings will be similarly intense for food and consumer goods companies. Consolidation among retailers has already given a few powerful, global players tremendous leverage to negotiate down prices as they compete for cost-conscious shoppers. Upstream, four players control nearly 50% of the global seed market.⁴ This, coupled with increased scarcity in a number of source materials, means producers will be paying more to their suppliers at the same time they are bringing in less revenue from retailers. Adding to the struggle for name-brand consumer goods manufacturers, price-sensitive consumers are turning to private label goods, increasing the market share of those products (food and personal care products) to an estimated 24% by 2016. Retailers have tried to reinforce this trend by using more sophisticated branding as a source of differentiation from other retailers.⁵

Coping with these increased cost pressures, the healthcare industry in particular will have to find ways to increase labor productivity. Over the past 15 years, employment in this sector has grown approximately 3% with little substantial increase in employee productivity.⁶ This workforce will need to find ways to become more efficient and productive in the years ahead to meet growing demands without adding to already stretched costs. As a result of these influences, managers will look to identify cost savings opportunities at every stage of production and will continue to challenge requirements that add expense to the manufacturing process.

Exhibit 2 – Cost pressures facing pharmaceutical companies

Pharmaceutical company revenues are under pressure and unlikely to regain historical levels of growth.

Worldwide total prescription drug sales 2000-14



- 1 EvaluatePharma focuses on manufacturer's selling price for Top 500 pharma and biotech companies (IMS traditionally higher since it includes all retail/wholesale invoices and excludes rebates).
- 2 Majority of industry estimates more conservative in early 2009; IMS revised in late 2009 to project 4-7% CAGR growth through 2013.

Source: EvaluatePharma April 2009; team analysis

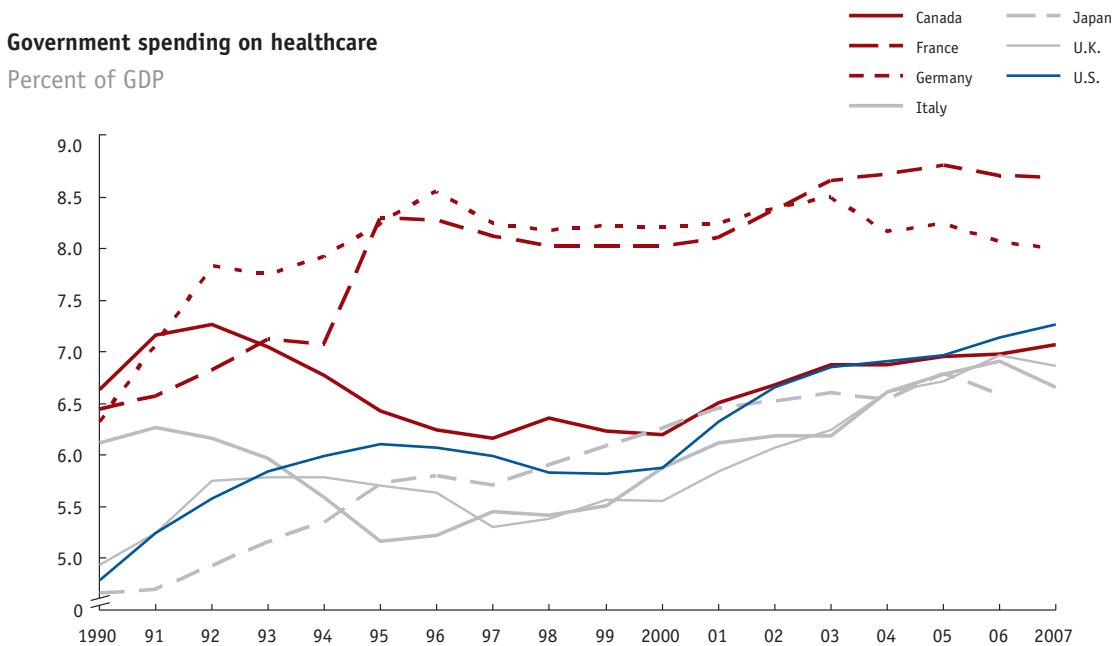
b. Greater government influence in healthcare markets.

Officials managing the skyrocketing costs of growing public health programs in all parts of the world are becoming more proactive in seeking to control costs and improve quality. Government spending on healthcare has been on the rise since at least 1990 in the G7 economies, as seen in Exhibit 3.⁷ In the U.S., Medicare expenditures are projected to reach nearly \$900 billion by 2018.⁸ Between 2000 and 2025, experts predict that the Medicare population will grow at four times the rate of the “employed” population between ages 18 and 64.⁹ The sum of all non-private hospital expenditures is likely to reach over \$1 trillion by 2015.¹⁰ To cope with the growing public burden, countries like the U.K. and Australia are becoming more proactive in managing the costs of healthcare products and services, including deeper engagement with providers and more strategic contracting. The Center for Medicare and Medicaid Services already requires that hospitals report quality information in order to receive full reimbursements,¹¹ and a wave of new regulations in connection with the 2010 Affordable Care Act carry significant implications for all players in the healthcare sector.

Like the consumer demand for low cost and high quality, governments will play an increasingly active role in shaping the dynamics of the healthcare market. Successful manufacturers will account not only for the preferences and habits of individual customers and providers, but also the needs of an increasingly strained public healthcare system. Like the private manufacturers, FDA will find other U.S. government agencies to be significantly more important and potentially more influential stakeholders in their work than ever before.

Exhibit 3 – Increase in government healthcare spending

Most countries are seeing increases in healthcare spending.



Source: OECD Health Data 2009

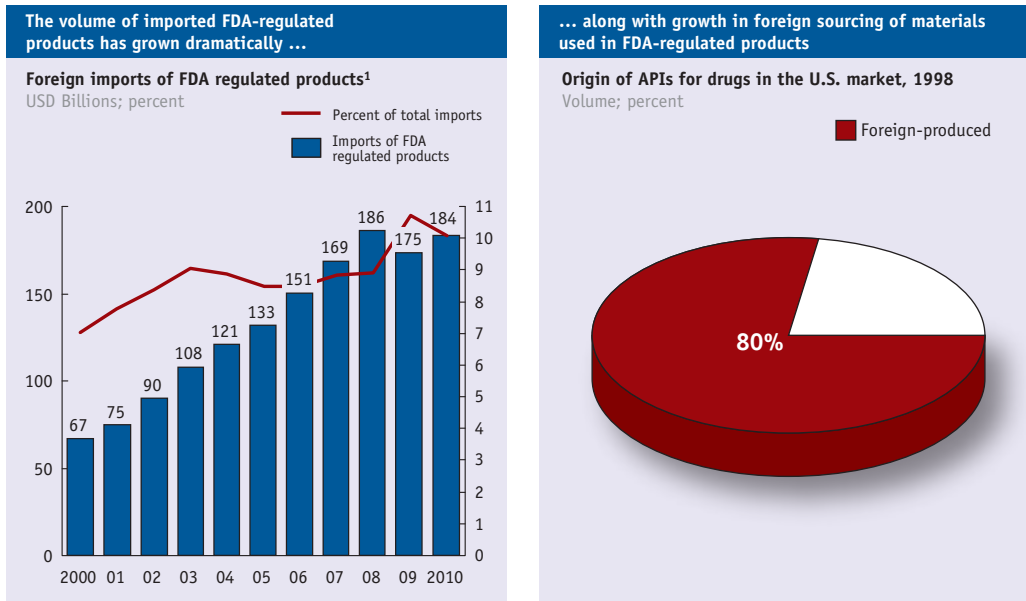
c. Growing globalization of production of FDA-regulated products leading to growth in imports.

One of the most important consequences of the pressure to reduce costs and increase productivity will be that companies continue to move manufacturing activities to new and different locations, looking to global supply chains to reduce production costs. Some estimates predict that by the end of 2010, more than 40% of the final assembly in the consumer goods and life sciences industries will be performed outside of the producer's home country, due largely to the lower cost of production.¹² In pharmaceutical production in particular, the cost of formulation of an Active Pharmaceutical Ingredient (API) can range from 15% to 40% less to produce in India as compared with the U.S.¹³ Just as cost pressures will only become more severe over time, companies will continue the movement of manufacturing and production activities to low cost countries for the foreseeable future.

As a result of the increase in the globalization of production, more food and medical products are entering the U.S. than ever before, and the growth in imports will only accelerate in the future. Since 2002, imports of FDA-regulated products have grown almost three-fold from 7.9 million import lines per year to 18.5 million lines per year in 2009, shown in Exhibit 5.¹⁴ This amounts to a 13% annual growth rate across FDA-regulated products, with imports of medical devices and radiation-emitting consumer products quadrupling during the period 2002-2010. In fact, FDA-regulated products now account for approximately 10% of all imports to the U.S. and already an estimated 16% of U.S. consumer spending on these items is spent on imported goods.¹⁵ While foods and medical devices have seen the largest volume of imports, all of FDA's product groups have seen substantial import growth and will likely experience more.

Exhibit 4 – Growth in FDA imports

Increases in global trade are increasing the exposure of U.S. consumers to foreign products and source materials.



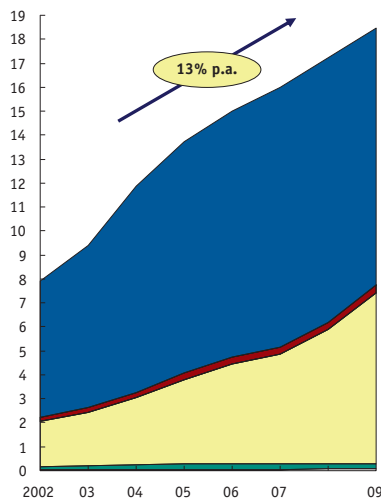
¹ IHS Global Insight industry categories were used to compute these figures; categories do not exactly match FDA-regulated products.
Source: IHS Global Insight, Frost & Sullivan, GAO: Improvements Needed in the Foreign Drug Inspection Program

Exhibit 5 – Import lines of FDA-regulated products

Import shipments of FDA-regulated products have been growing at 13 percent per year.

Imported lines¹(millions)

Total = 7.9 MM in 2002; total = 18.5 MM in 2009



CAGR 2002-09 Explanation of center's products

Category	CAGR	Explanation of center's products
Foods	9.5%	<ul style="list-style-type: none"> Food products for human, animal, pet use, except meat and poultry Articles for cleansing, beautifying, promoting attractiveness of body
Drugs	12.9%	<ul style="list-style-type: none"> Prescription and OTC drugs for human
Devices	20.8%	<ul style="list-style-type: none"> Medical devices for human use Products that emit radiation (e.g., microwaves, lasers, x-ray machines)
Veterinary products	6.7%	<ul style="list-style-type: none"> Drugs, devices, and food additives for animals and pets
Biologics	15.8%	<ul style="list-style-type: none"> Blood products, vaccines, and tissues for transplantation

¹ An import line represents the portion of a shipment listed as a separate item on an entry document. The number of units can vary.
Source: FDA

Food products, representing the largest share by volume of import lines,¹⁶ have grown by an average of nearly 10% each year for at least seven years.¹⁷ This growth led to an increase in the volume of food import lines from 5.6 million in 2002 to 10.7 million by 2009, with seafood and spices among the most imported food items.¹⁸ Currently, between 10% and 15% of all food consumed each year by U.S. households is imported from abroad.¹⁹ Factoring in the use of foreign-produced spices, the proportion of American diets impacted by imports is even higher. In some food categories, more food is imported than produced domestically. For example, according to the GAO 60% of fruits and vegetables and 80% of seafood are produced outside the U.S.²⁰

Imports of pharmaceutical products have also grown rapidly, at approximately 13% per year, over the past seven years and accounted for more than 350,000 import lines in 2009.²¹ This volume accounted for approximately 30% by value of pharmaceutical products used annually.²² The rise in imports has contributed to a growing trade deficit in pharmaceutical products. In 2000, the U.S. imported \$1.7 billion more in pharmaceutical products than it exported.²³ By 2008, that discrepancy had grown ten-fold to \$18 billion. Even more than finished medications, the U.S. is increasingly relying on foreign producers for key components. For example, approximately 80% of active ingredients found in pharmaceutical products on U.S. store shelves come from overseas,²⁴ growing from \$2.8 billion in 2000 to nearly \$4.6 billion just seven years later.²⁵

As with foods and drugs, medical device imports have been growing steadily. The number of medical device import lines has risen an average of 10% per year between 1998 and 2008,²⁶ and now stands at 7.1 million lines per year. Importation of medical devices is broad-based, spanning all major device types. Today, imports represent more than 35% of the U.S. medical equipment market.²⁷

Table 1 – Proportion of FDA-regulated products that are imported²⁸

	Number of import lines in (2009)	Proportion of total spend met through imports (2010)
Food	10.7 million	10-15
Medical Devices	7.1 million	52
Drugs	0.35 million	28

Source: FDA Import Data, IHS Global Insights

With the expected growth in foreign manufacturing in the coming years, the U.S. will likely continue to increase the volume of FDA-regulated products that it imports, though estimates of the growth rate of imported products vary. On the low end, some expect a 5-8% projected growth rate, slightly lower than the 10% growth rate of the past decade. On the high end, there have been estimates that imports of FDA-regulated products will triple between 2007 and 2015, corresponding to a 15% growth rate.²⁹ In either scenario, the growth in imported products is expected to outpace the growth of domestic products, leading to an even higher proportion of food and medical products coming from overseas.

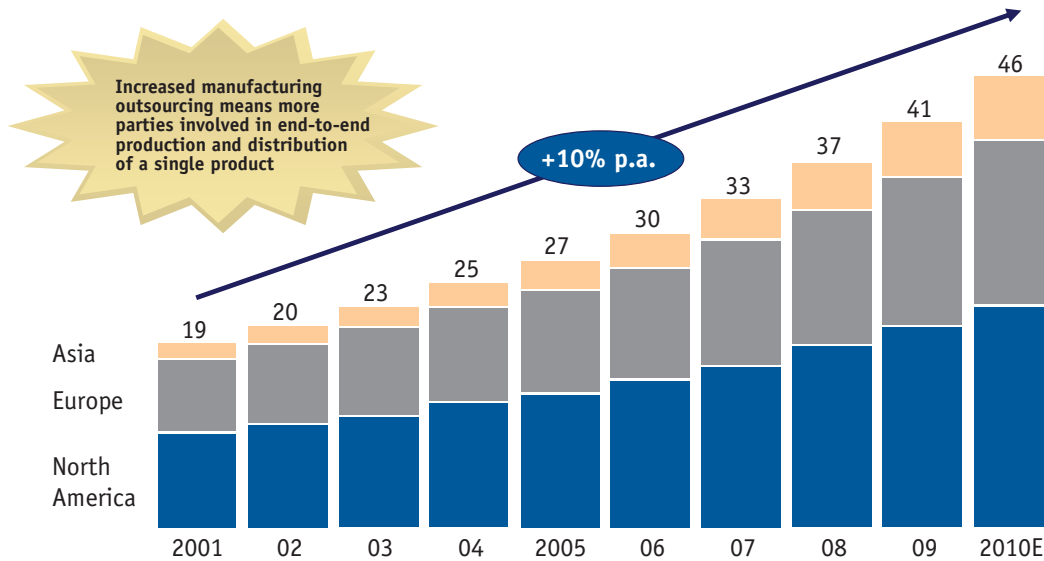
d. Changing nature of risk in global supply chains.

Companies will not only be producing more FDA-regulated products abroad, but the products will follow complex paths through multi-step supply chains to reach the U.S. One example of this complexity is an increased number of processing steps and number of entities touching a given product. The market for contract manufacturing outsourcing in pharmaceutical production is evidence of this trend, growing to an estimated \$46 billion in 2010, more than double the size of the market nine years ago, as seen in Exhibit 6.³⁰

Exhibit 6 – Market for Contract Manufacturing Outsourcing

Increased fragmentation of regulated producers adds a new challenge to the FDA’s safety assurance efforts both domestically and abroad.

Pharmaceutical contract manufacturing outsourcing market
USD Billions



Source: Frost & Sullivan

One stark illustration is the multi-stage path that a single commodity, canned tuna, takes from the time the fish is caught in East Asia to the time the finished product reaches store shelves in the U.S., shown in Exhibit 7.

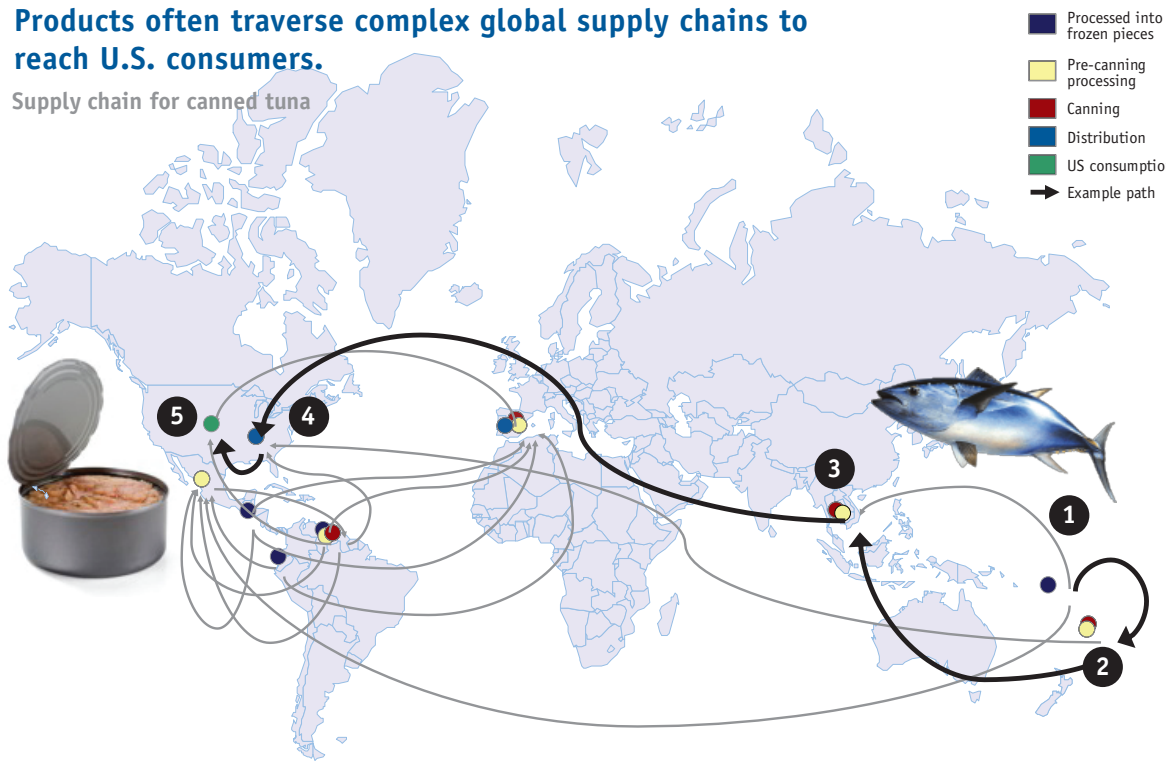
A growing number of the products regulated by FDA will follow similarly complex paths before they reach American consumers. With so much movement across such large distances, businesses and regulators face a difficult challenge maintaining visibility into the end-to-end process. It will also become increasingly difficult to prevent and detect the intentional efforts by some importers to manipulate the system and avoid scrutiny.³¹

As supply chains become more global and complex, they will also carry an increasing number of complicated, high-risk products to the U.S. from abroad. Between 2000 and 2007, the U.S. quadrupled its importation of “high risk” medical products, such as vaccines.³² For foods, between 70% and 85% of the import refusals of produce and seafood,³³ the two largest categories of food imports, were

Exhibit 7 – Illustrative supply chain for canned tuna

Products often traverse complex global supply chains to reach U.S. consumers.

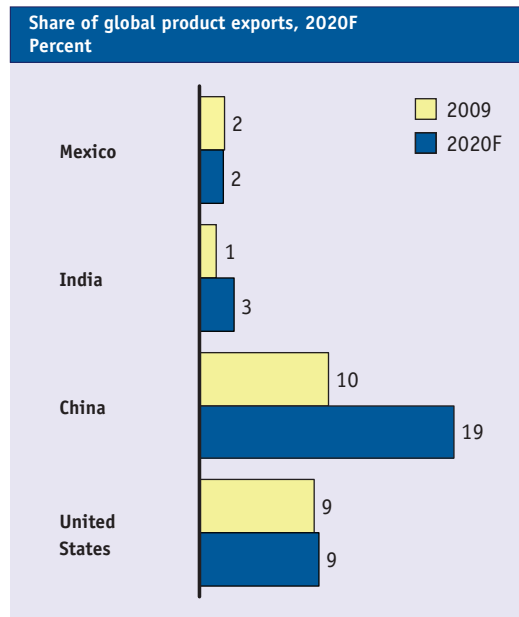
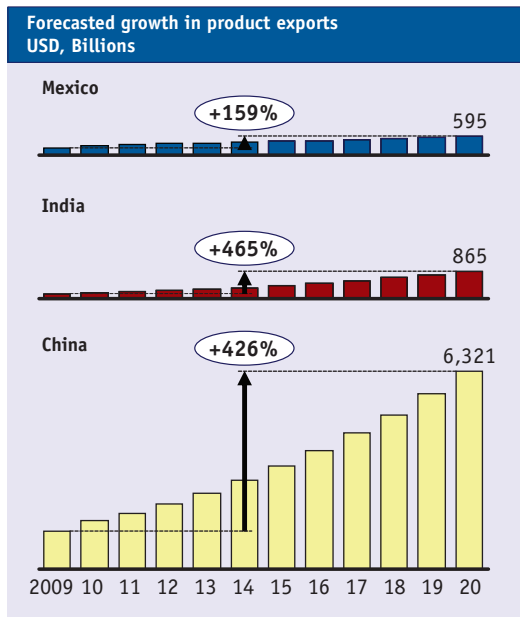
Supply chain for canned tuna



Source: <http://www.ilo.org/public/english/dialogue/sector/techmeet/tmfce07/tmfce-r.pdf>

Exhibit 8 – Increase in total foreign exports from developing countries

A significant portion of the increase in foreign products will come from developing countries.



Source: McKinsey Global Insights

for potentially dangerous violations including the presence of pathogens, chemical contamination, and “other sanitary violations.”³⁴ For medical devices, complex products, which were once primarily manufactured domestically, are increasingly being manufactured overseas and imported.³⁵ As a consequence, it will become more difficult to distinguish the risk and complexity of a product based on where it is produced.

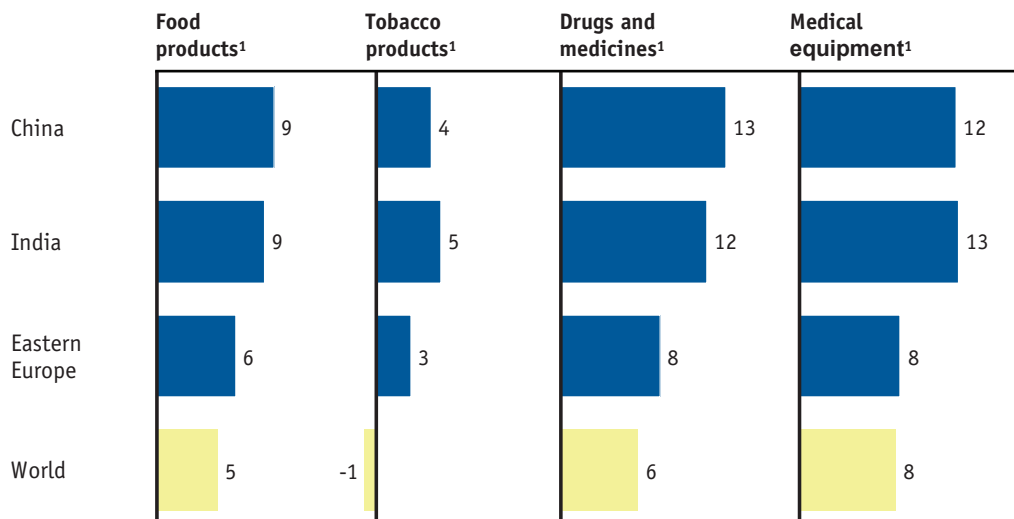
Compounding the difficulty of evaluating such risks, FDA needs to fully understand the dynamics of a new set of foreign trading partners that will be important sources of FDA-regulated products. While a large portion of U.S. medical product imports have historically come from Western Europe, there are indications of a shift. Import lines from emerging markets, including Mexico, India, China, and Thailand, increased faster between 2002 and 2009 than lines from developed markets, and this disparity is likely to continue. China and India are each expected to see a more than 400% increase in their product exports between now and 2020, with China accounting for nearly 20% of all global product exports by that time.³⁶

This export growth will have a direct impact on FDA’s product safety efforts, as seen in Exhibit 9. The value of local pharmaceutical production in 2012 in India and China will likely be 2.5 times what it was in 2006. China already has the largest number of foreign, FDA-registered drug manufacturing establishments, followed by India.³⁷ The picture is similar for foods and medical devices as well. China and India are each expected to see 9% annual growth in food exports between 2010 and 2020,³⁸ and China has the fourth highest volume of imports to the U.S. of medical equipment and is the leading supplier of sutures, sterile, surgical, and dental goods as well as mechano-therapy apparatus.³⁹ In fact, China has the highest number of FDA-registered class II or class III medical device manufacturing establishments of any country in the world outside the U.S.⁴⁰

Exhibit 9 – Growing exports of FDA-regulated products from emerging economies

Emerging economies are expected to grow their exports of FDA regulated products faster than the worldwide growth in exports.

Forecast growth in worldwide exports and exports from China, India, Eastern Europe, 2010-20 Percent; CAGR



¹ Categories based on IHS Global Insight do not perfectly mirror FDA regulated products and centers.

Source: IHS Global Insight

The expected cost pressure confronting global businesses may be the most influential factor driving a higher volume of production to developing markets. Both India and China offer a number of cost advantages, most notably the cost of skilled labor. India in particular trains six times the number of chemists annually than the U.S. produces and companies can access this talent for 10% of the cost of the same talent in America.⁴¹ In total, estimates indicate that bulk manufacturing in India can reduce costs for U.S. and European companies by 30% to 40%.⁴²

The cost advantage of skilled labor in India and China has also increased the number of drugs developed in Asia. Together, India and China have more than 30% of the world's drug master files (DMF), and the number has been growing due in part to the abundant supply of trained scientists and a significant cost differential for product development. The cost of developing a DMF in India is one-quarter the cost in the U.S.⁴³ At the same time, China has tripled its annual R&D investment over the past 15 years and will likely have the largest R&D workforce in the world by 2015.⁴⁴

In addition to new geographies, imports of FDA-regulated products are coming from a wide and diverse range of producers. Almost half of all imports to the U.S. are the only shipment that the exporter sends in a given year.⁴⁵ Fully 80% of imports come from companies that send 11 or fewer total export shipments each year.⁴⁶ This means that public safety will require effective supervision of a high number of small producers and importers.

The anticipated shift in global production will mean new and different challenges for FDA. A recent survey of retailers in Asia revealed their greatest sources of safety concern to be residual chemicals, contamination and spoilage, veterinary and plant diseases, and intentional poisoning.⁴⁷ Mexico and China already account for a high percentage of food imports and a higher percentage of import refusals, while India accounts for 2% of food imports and more than 10% of import refusals. As these countries account for an increasing proportion of U.S. food and drug imports, FDA must first study past non-compliance issues and then take an integrated global view of product safety risk and align its resources with the greatest sources of future risk.

e. Increased risk of counterfeiting and other fraud.

Perhaps the most serious challenge on the horizon for FDA is that growing access to the global marketplace will also expose Americans to a set of economically-motivated harms including counterfeiting, fraud, and other intentional adulterations. Recent, highly-public incidents involving adulterated heparin and melamine-tainted baby formula underscore how serious the potential danger can be and the daily collection of unsolicited email that the average American receives regarding pharmaceutical products sold via the Internet is a stark reminder of the prevalence. They also serve as a reminder that there are manufacturers around the world for whom the temptation of economic gain is greater than any concern for risk to human and animal health. Asian retailers already rate intentional poisoning as one of their top concerns.⁴⁸ The profits to be earned through fraud or adulteration will only increase as pure source materials become scarcer and more expensive.

The U.S. has seen a steady increase in the number of counterfeiting incidents. The World Health Organization estimated that between 5% and 8% of all of pharmaceuticals worldwide were counterfeit in 2003.⁴⁹ Americans' increased willingness to purchase pharmaceuticals online to be shipped directly to their homes from around the country and world makes them even more vulnerable. Even substances that are not by themselves harmful can be life-threatening if fraudulently substituted for critical treatments. As criminals find new incentives and new opportunities to manipulate the

contents of FDA-regulated products and easy access to distribution channels via the Internet, the agency must remain vigilant and proactive.

III. FDA MUST SUBSTANTIALLY CHANGE ITS OPERATING MODEL TO ADDRESS THE CHALLENGES OF THE FUTURE

FDA is one of the world's oldest food and drug regulators with a reputation and proven track record for being a leader in product safety and quality. As it looks to the future, the agency can no longer rely solely on its historical tools and activities to regulate products. A part of this transition will include realignment and refocusing of existing global safety resources as well as a more strategic engagement with foreign counterparts to emphasize tangible steps to improve product safety and quality. The reality facing FDA is that its mission will become ever more difficult to fulfill given the breadth of industries that it regulates combined with available resources. It is imperative, therefore, that FDA finds the most effective way to revise the approaches and tools at its disposal and leverage relationships beyond the agency to other federal departments, the states, foreign governments, and industry.

a. There has been little change to the fundamental operating model for regulators over the past several decades.

When Congress passed the Pure Food and Drug Act of 1906, the precursor to the legislation creating FDA, the industry that FDA regulated was predominately local, the volume of imported products was low, and even the movement of goods across country was minimal. Public concern about a lack of oversight of U.S.-produced goods for domestic consumption and for export was the driving force behind the legislation. Therefore, the authority granted under this legislation was sufficient to ensure the safety and quality of products at that time. This authority allowed FDA to visually inspect regulated products presented at the border for import and to refuse entry to goods that appeared not to conform to the relevant safety requirements.⁵⁰

Since then, innovations in refrigeration, transportation, and communication have enabled consolidation and globalization, particularly in food production, contributing to the rise in food imports. Likewise, the transport of drugs, medical devices, and biologics over long distances while maintaining stability and product integrity has become commonplace, leading to increased levels of importation. While high-profile domestic incidents have provided stark reminders of the important role that FDA plays in regulating U.S. companies, the trend toward globalization has increased public awareness about the safety risks of foreign imports. These public health concerns represent a marked shift from the oversight issues that had been the focus in the past.

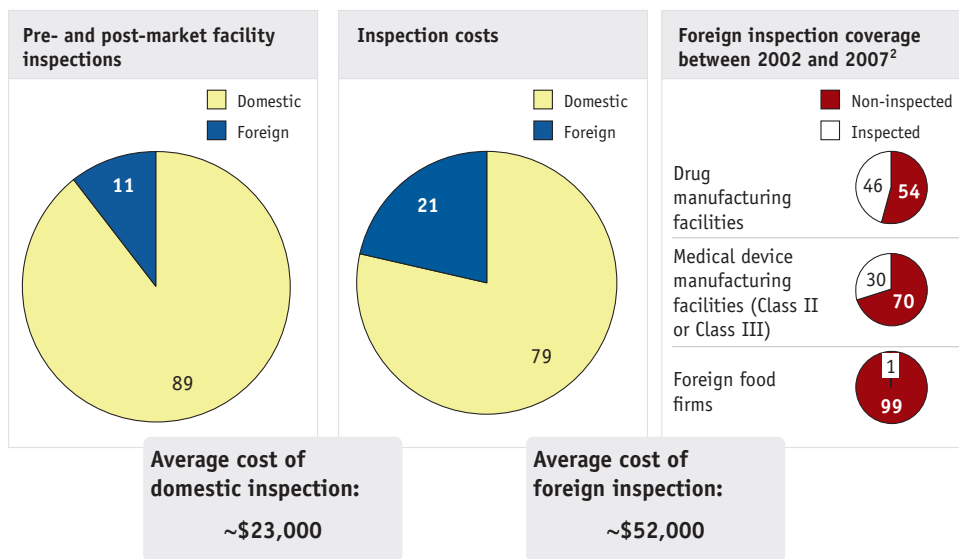
Recognizing these trends, FDA has made changes to its approach. For example, the agency has, in the last several years, started moving toward an approach which takes into account the risks across the product's life cycle, from production abroad to consumption in the U.S. FDA has developed the PREDICT system, which uses risk based data and analytics from the entire life cycle of the product to make entry admissibility decisions, rather than just relying on border inspections. FDA has also taken many other steps such as increasing its collaboration and information-exchange with its foreign counterparts, employing sophisticated risk models, developing advanced handheld testing for use at the border, and educating industry about how to minimize risks to products and supply chains.

Despite these incremental improvements, FDA's underlying approach to import safety has remained relatively unchanged. Throughout its existence, the agency's primary tools for global product safety and quality have been facilities inspections and border inspections and remain so today. This has been supplemented over time with additional tools such as laboratory sample analyses for select product categories (e.g., foods) and product safety reporting systems.

One might suppose that, given that FDA's operating model has served it well over the years, one option to meet the challenge of assuring product safety and quality in a globalized world is to scale the current model. However, achieving a comparable average inspection frequency of foreign facilities would require a significant increase in resource levels as shown in Exhibit 10 below. An alternative approach that relies on enhanced intelligence and data-driven risk analytics and allocation of resources achieved through partnerships has the potential to achieve greater levels of assurance of product safety and quality and do so with fewer resources.

Exhibit 10 – Cost and coverage of foreign inspections

The average cost of foreign inspections is two times the cost of a domestic inspection but there is a significant gap in foreign inspection coverage.



1 FDA entry reviewers conduct document reviews on nearly all import lines. A subset of those lines that are reviewed are also sampled.
 2 Food inspections calculated from 2001 through 2007.

Source: FDA Enforcement Story; FY 2011 Congressional Budget, GAO 08-909T, GAO 10-699T, GAO 08-428T, GAO 08-701T

Traditionally, and with very few exceptions, FDA has used its own employees to perform all oversight activities. Alternative approaches including third-party inspection programs and international cooperation have not been the primary focus. Given the significant change that will be required to cope with future trends in global product safety, FDA will need to continue to identify ways to innovate in its oversight efforts and work with its federal partners to develop the necessary tools and authorities.

For food products in particular, the recent passage of the FDA Food Safety Modernization Act (FSMA) offers many opportunities to move toward a system that focuses on ensuring the safety of products

prior to arrival at the border. FSMA, signed into law by President Obama on January 4, 2011, gave FDA important new tools to hold imported foods to the same standards as domestic foods and directs FDA to build an integrated national food safety system in partnership with others. Under the new law, FDA will have several new mandates with respect to food produced outside the U.S. For the first time, importers will have explicit responsibility to verify that their foreign supplies have adequate preventive controls in place and that the food they ship to the U.S. is otherwise safe. The agency also has the power to establish a third-party program for certifying that foreign food facilities comply with U.S. food safety standards, to require certification as a condition of entry for certain high risk foods, and to reject entry of food if the foreign facility or country refuses an inspection by FDA or its designee. Significantly, FSMA also explicitly encourages arrangements with foreign governments to leverage resources, such as mutual recognition of inspection results, sharing electronic data, and training of foreign governments to build their regulatory capacity.

b. Current international efforts at addressing these challenges are not sufficient.

Despite significant effort and investment of resources, FDA's successes in engaging foreign partners have not helped the agency substantially increase the coverage of its safety and quality assurance activities. To date, FDA has taken a range of different approaches to international collaboration ranging from training and capability building, to harmonization of highly technical safety standards, to its recent admission into the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S system) of information sharing regarding pharmaceutical facility inspections. These interactions have been immensely helpful in building positive relationships with counterparts and enhancing skills in a number of different countries and have given FDA valuable insight into the challenges that others have been facing.

However, the more complex, globalized environment anticipated in the near future requires FDA to make faster progress toward meaningful collaboration and impactful output than some of the current programs are on pace to produce. Some programs have begun to move the world toward strong, common safety standards, but FDA has only used these as an acceptable alternative to its own standards in limited circumstances. For example, at the current rate of progress and through the current mechanisms, it would take decades to reach a comprehensive set of common standards that could form the basis for FDA to leverage the work of public and private third parties both domestically and abroad. This is due to extensive negotiations and careful consideration that is exerted by participants, including FDA, in these international programs. Yet serious global safety risks loom on the horizon and warrant near-term, tangible activities that cannot wait for existing programs alone to run their course.

c. Several of FDA's foreign counterparts have begun to implement innovative solutions to address the global safety challenges facing FDA.

Like FDA, food and medical product regulators around the world have begun efforts to become more effective and efficient at global product safety and quality oversight. Some regulators in Asia have made the strategic decision to rely on the determinations of certain trusted foreign counterparts, directing their own resources instead to facilities and jurisdictions that are not already covered by these trusted parties to help expand capacity by reducing duplicity of effort. Similarly, Mexico recently announced that it would treat device reviews conducted by FDA as equivalent to reviews conducted by Mexican regulators and Costa Rica has announced its intention to do the same. In Europe, each drug manufacturer is constantly supervised by a qualified person employed by that manufacturer

but responsible to the government for ensuring the safety and quality of all batches of the approved product, regardless of where it was produced. More recently, a sub-set of the PIC/S participating countries have established a work-sharing program founded on the standardized inspection information-sharing developed through PIC/S. Other jurisdictions have also created a tiered approach to facility inspections, adjusting the length and depth of the inspection based on the degree of risk associated with the particular facility, enabling those countries to quickly conduct a large number of inspections of low-risk sites.

New and innovative approaches to enhance regulatory effectiveness, including the PREDICT system and the opening of foreign offices, have been met with some success. However, there is a need to move beyond these efforts and to think strategically across FDA and a network of regulators worldwide about what is needed to effect a substantial enhancement of global product safety.

IV. FDA IS PURSUING A STRATEGY WITH FOUR PRIMARY COMPONENTS TO ADDRESS THE COMING CHALLENGES

In order to cope with the magnitude of the fundamental shifts on the horizon, FDA is committed to substantially and fundamentally revising its approach to global product safety and quality. Over the next decade, FDA will transform itself from a domestic agency operating in a globalized world to a truly global agency fully prepared for a regulatory environment in which product safety and quality knows no borders.

To achieve this transformation, the agency is developing an international operating model that relies on enhanced intelligence, information sharing, data-driven risk analytics, and the smart allocation of resources through partnerships. The new approach rests on four core building blocks:

- 1) FDA, in close partnership with its foreign counterparts, will assemble global coalitions of regulators dedicated to building and strengthening the product safety net around the world.
- 2) With these coalitions, FDA intends to develop a global data information system and network in which regulators worldwide can regularly and proactively share real-time information and resources across markets.
- 3) FDA will continue to expand its capabilities in intelligence gathering and use, with an increased focus on risk analytics and thoroughly modernized IT capabilities.
- 4) FDA will effectively allocate agency resources based on risk, leveraging the combined efforts of government, industry and public- and private-sector third parties.

FDA and its partners around the world have already taken steps to set the foundation for the work ahead. Bilateral relationships with regulatory counterparts and collaborative workplans exist with several countries. Interactions with foreign counterparts in the development of common standards and capabilities have been immensely helpful in building positive working relationships with a number of different countries. Engagement in these discussions has also given FDA valuable insight into the challenges that others have been facing. The lessons and successes from

its involvement in programs like the Codex Alimentarius Commission, International Conference on Harmonisation (ICH), PIC/S, and Global Harmonization Task Force (GHTF) are critical building blocks for the collaboration envisioned in this strategy for global product safety. In addition, there is urgency to effect change that enhances global product safety and quality given the major shifts already well underway.

A. FDA will partner with foreign counterparts to create global coalitions of regulators focused on ensuring and improving global product safety

Increasingly, national borders no longer define the challenges of ensuring product safety and quality. FDA and its foreign counterparts have acknowledged this reality and undertaken efforts to increase collaboration among regulators and standardization of manufacturing requirements and inspection procedures. As the agency moves forward, FDA envisions a much deeper engagement, beginning with a core group of partners. The primary aim of this effort would be to develop procedures for more comprehensive and systematic information sharing and coordinated deployment of resources. This would be achieved in a timely manner by focusing on comparability—elements or features of a regulatory system that give confidence it will produce comparable safety outcomes to the benchmark system. Focusing on comparability will be faster and likely more effective than harmonization, in which a regulator only recognizes the similarities of a peer system.

Traditionally FDA has had close cooperation with a series of regulatory partners via bilateral agreements. While FDA has built strong relationships with its counterparts, a broader and more comprehensive model is required going forward to achieve the change required. Global coalitions are not new and there are several models operating today that successfully govern global commerce. For example, the International Civil Aviation Organization (ICAO) was formed to promote global cooperation and common standards to ensure safe, secure, and efficient civil air traffic. ICAO has successfully operated for over 60 years and now has more than 190 members.

In the medical products context, several models exist today. For example, PIC/S was formed in 1970 to strengthen cooperation in the field of inspections with a view to maintaining mutual confidence and promoting quality assurance. PIC/S has grown significantly since formation and now has over 35 members (including the U.S. as of January 2011). Similarly, earlier this year, senior leaders of the GHTF decided to create an expanded global regulators' forum for medical devices. The forum's objective is to promote convergence across global device safety activities. This will extend GHTF's traditional role of developing and leveraging guidance documents to engagement with countries that are, or are likely to become, influential in medical device manufacturing and regulation.

Based on a review of existing governance models there are several key principles that must be established for a successful global coalition. First, the coalition needs an overarching organizing body to facilitate regulation and promote key functions. Second, sovereignty should be maintained and respected, and nations should maintain control of their own borders, markets, and standards. Third, the coalition should rely on common science-based standards as a baseline for judging the other members' effectiveness at product quality and safety assurance. Fourth, the coalition should focus on comparability and not equivalence, as public health impact and outcomes are more important than identical standards. Finally, it will be essential to establish clear membership standards supported by an effective auditing process to ensure member compliance.

The building of global coalitions is consistent with the direction of FSMA. The new law explicitly

recognizes that all food safety agencies, domestic and foreign, need to work together in an integrated way to achieve our public health goals. The law directs FDA to develop a comprehensive plan to expand the capacity of foreign governments and their industries, including training of foreign governments and food producers on U.S. food safety requirements, the mutual recognition of inspection results, and the sharing of electronic data. FDA is explicitly authorized to rely on inspections of other Federal, State, and local agencies to meet its increased inspection mandate for domestic facilities. FSMA also allows FDA to enter into interagency agreements to leverage resources with respect to the inspection of seafood facilities, both domestic and foreign, as well as seafood imports.

B. FDA will work to build a global data-information system and network and proactively share data with peers

It will be essential to FDA's quality and safety efforts that the agency be able to aggregate and utilize multiple sources of information as inputs to intelligence and regulatory analysis to identify potential threats. This is a key enabler of more sophisticated risk assessments and models than are currently possible. In order to share information efficiently within the agency as well as with domestic and foreign counterparts, FDA will develop or locate systems capabilities and processes to manage the secure, smooth exchange of information. As a first step, the agency will work with coalition partners to identify critical data elements needed to inform risk models and standardize the reporting of this information to allow for the seamless and automated flow of data. Internally, it will work to make necessary changes and build new capabilities that enable the agency to transmit information to and receive information from a wide variety of sources. Through the development of robust global coalitions, FDA will work with its partners to craft a process for regular, systematic information exchange that will provide an ongoing input into FDA's risk modeling, various analyses, and, ultimately, the deployment of agency resources to achieve greater public health impact.

The most effective global coalitions have built sophisticated systems to share data across markets. Interpol, the International Criminal Police Organization, has developed sophisticated data systems that allow broad, timely intelligence sharing to facilitate law enforcement across participating agencies worldwide. Interpol has also successfully developed systems that facilitate information exchange between members of varying technological expertise. The World Meteorological Organization (WMO) has established tightly managed data standards to ensure quality and homogeneity through non-real time data assessments. Global product safety coalitions of the future must possess similar capabilities. While FDA may be hindered by legal restrictions on its ability to share data in the absence of a legislative change, a global data-information system will be a critical enabler to building effective and empowered global coalitions.

C. FDA will expand its capabilities in intelligence gathering and use, with an increased focus on risk analytics and thoroughly modernized IT capabilities

With an ever-growing roster of manufacturers and producers to monitor, FDA plans to build deeper capabilities in intelligence gathering and risk analytics. Scaling the current model for regulatory operations is simply not viable from a resource utilization standpoint. Intelligence capabilities will give FDA a more sophisticated understanding of the potential threats facing U.S. consumers with the ultimate goal of detecting and addressing risks before they materialize into public health harms. FDA must first identify the signals and warnings of potential risks that it will monitor and then focus the organization on gathering the intelligence that will monitor the signals.

In addition, analytics capabilities will allow FDA to interpret and act on the intelligence gathered. To enhance its analytics capabilities, the agency will work to provide advanced training to current analytics experts as well as bring in new employees with significant analytical talent and experience to complement and fill needs not met by current staff. To build the necessary support infrastructure, FDA will focus on creating or identifying IT tools that allow experts to quickly access and analyze data across the various information resources available. At the heart of FDA's effort to be a smarter, more proactive safety agency lies the analytical horsepower to make timely, effective decisions.

D. FDA will effectively allocate agency resources based on risk, leveraging the combined efforts of government, industry, and public- and private sector third parties

One of the most fundamental changes that FDA will undertake is a more effective deployment of its own global safety resources. The agency will continue executing the broad range of surveillance, intervention, and enforcement activities that are currently its primary tools for preventing product-related harms. As FDA evolves and continues to become a more agile, forward-looking, intelligence-driven organization, these activities will be more directly aligned against a robust set of risk-based priorities, with agency staff spending a more significant share of their energies on the products and producers around the globe that represent the greatest potential harm to public health. At the same time, FDA will maintain broad-based oversight of the entire range of products within its purview by developing compliance and inspection programs that contemplate enlisting public and private third parties to conduct audits and other oversight activities on behalf of FDA.

FDA intends to establish a review and audit infrastructure to verify the integrity of the information that it receives from public and private third parties and to ensure that the agency can rapidly take follow-up enforcement measures or actions where needed. In addition, industry's own safety monitoring efforts will also be a critical support for more comprehensive oversight. By balancing its own resources with the additional capacity afforded by leveraging these public and private third parties, FDA will achieve greater coverage of the public health risks that exist and create the flexibility to quickly shift its attention to the most pressing dangers as they arise.

Increased reliance on audits conducted by public and private third parties aligns with FDA efforts to enhance oversight of medical devices. Soon after passage in 2002 of the Medical Device User Fee Modernization Act, FDA launched a program to permit agency-accredited third parties to inspect device manufacturers. A 2006 FDA-Health Canada pilot program authorized accredited third parties to conduct facility inspections that meet FDA and Health Canada regulatory requirements. And more recently, FDA published a draft guidance allowing manufacturers to submit third-party reports of inspections conducted under International Organization for Standardization 13485:2003. FDA is currently building on these efforts to create a single audit program for medical devices.

The increased use of public and private third parties is also consistent with the spirit of the recently passed FSMA, which directs FDA to establish a program through which accredited public or private third parties can certify that compliance with U.S. food safety standards. This certification may be used to facilitate the entry of imports and may be required as a condition of entry for certain designated high risk products. (The audits performed under this section will however not be considered inspections under section 704 of FDA's Act.)

V. IMPLEMENTING THE PATHWAY TO GLOBAL PRODUCT SAFETY AND QUALITY

Implementing the pathway will require a concerted effort involving all parts of FDA and multiple external stakeholders (global regulators, industry, states, White House, etc.). For implementation of the strategy to be successful, FDA will undergo a paradigm shift to become a global agency. Implementing an effort of this nature will be complex and take multiple years; however, it is important to establish early momentum and support for the effort, to ensure that it launches with a critical mass of resources and attention from key stakeholders. To achieve this, FDA will focus on two areas in the coming year.

A. Establishing the framework and approach for broader data sharing and use of third parties

It will be essential for FDA's broader product safety efforts that the agency be able to aggregate multiple sources of information as inputs to intelligence analysis to proactively identify threats. In order to share information efficiently with both domestic and foreign counterparts, the agency needs to develop or identify systems, capabilities, and processes to manage this exchange. Building the appropriate IT infrastructure will be critical.

Furthermore, scaling the current model for regulatory operations is simply not viable from a resource standpoint. FDA instead must shift to a model which more aggressively utilizes reliable public and private third parties to conduct inspections and other oversight activities.

While making this shift will be a multi-year effort for FDA, it will be essential to quickly establish the framework and approach for capturing this opportunity.

B. Establishing the Global Coalitions of Regulators

Over the next 12 months FDA aims to partner with foreign counterparts to create global coalitions of regulators. Effective and well-functioning coalitions are critical to the successful implementation of the Pathway to Global Product Safety and Quality. Key activities will include:

- Determining the governance structure for the coalitions (roles, mandates, operating model, funding mechanism, etc.)
- Identifying initial partners, with a goal of expanding over time
- Conducting discussions with key emerging economies that may not be part of the initial group
- Identifying early high priority topics for agreement

CONCLUSION

FDA is committed to addressing its challenges and those of the future by implementing a strategy to enhance global product safety and quality, and in doing so more effectively fulfill its mission.

The essence of this strategy marries creative international coalitions with cutting-edge investigative tools to continue to provide the consistently high level of safety and quality assurance the public expects—and deserves. FDA will continue to partner with other federal agencies, the states, and nations around the world. It will also look to Congress to modernize its antiquated authorities so that FDA's legal tools keep pace with globalization.

To meet these ambitious goals and achieve a true and lasting paradigm shift, FDA will engage all stakeholders in a process that will unfold over several years. Success will require boldness, creativity, and patience. It will not be easy, but it is imperative. Global supply chains, international trade, foreign sourcing, and terrorism remind us daily that the rest of the world will not stop and wait for regulators to catch up. It is incumbent upon FDA to engage its international counterparts, industry, and stakeholders worldwide to blaze the Pathway to Global Product Safety and Quality.

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