

Import Safety: Safety at the Speed of Life

Prologue Series



WHAT IS PAST
IS PROLOGUE

Michael O. Leavitt

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Prologue Series

I have come to understand that public service is a generational relay. Many of the most profound problems are not ours to solve in finality, but rather to incrementally improve during our temporary stewardship.

Three foundation goals thus form the basis for my public service: to leave things better than I found them; to plant seeds for the next generation; and to conclude my work knowing I have given my all.

For nearly sixteen years, my life has evolved in four year terms. I was elected three times as Governor of Utah. Some of what I consider our accomplishments were initiated in my first term, but fully matured in my third. Likewise, some seeds planted in my third term are only now beginning to flower.

Living in four year cycles has taught me the importance of choosing priorities and impressed the need for urgency. Time passes quickly.

I am currently in my fifth year as a member of President George W. Bush's Cabinet. I served first as the Administrator of the Environmental Protection Agency and now as Secretary of Health and Human Services. The constitutional constraints on the President's service imposed limits on what initiatives I might see to completion. However, I view it as my obligation to lead with a longer horizon in mind.

Over time, I have developed a set of tools useful in keeping a long-term vision in mind while managing the day-to-day problems. One such tool is establishing a 5,000 Day Vision, with a 500 Day Plan.

The 5,000 Day Vision is our aspiration for various long-term outcomes. The 500 day plan is more granular, listing what needs to be done now to bring about the larger vision. Both are recalibrated periodically.

As my stewardship comes to a close, it is time to plant seeds for the next generation. I intend to write and deliver a series of formal speeches to convey some of the 5,000 Day Vision and share what I see on our approaching horizon.

I call these speeches *The Prologue Series*. There is a statue behind the National Archives that I look at nearly every day as I drive between HHS and the White House. The statue, the work of Robert Aitken, is called "The Future." It depicts a woman looking up to the horizon from a book as if to ponder what she has just read. At the base of the statue are the words from Shakespeare's *The Tempest* "What is past is prologue."

I have titled this speech in *The Prologue Series*: "Import Safety: Safety at the Speed of Life."

Michael O. Leavitt
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U.S. Department of Health and Human Services
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in Washington, DC

On August 8, 2008, the world will gather for the 29th Olympiad in Beijing, China. Those who participate and watch these games will be a part of the largest, most extraordinary collaboration of nationhood and humanity that exists in our world today.

Three out of every five people on the planet will watch as athletes from 200 countries join in this peaceful celebration of sport and personal achievement. It is a marvelous moment for mankind and a force for good in our world.

During my service as Governor of Utah, I witnessed, in a powerful way, the effort, strength, sheer talent, beauty, and grace of Olympic athletes. The setting was the 2002 Olympic Winter Games in Salt Lake City. It was the first major world gathering after September 11th.

The Olympic motto is three Latin words — “*Citius, Altius, Fortius*” — which mean “Faster, Higher, Stronger.” These words capture the spirit of the Olympic movement, a movement that dares people to break records and to achieve their personal best.

The first of the words in the Olympic motto has particular importance to import safety. That word is *citius*. It means faster, swifter, quicker. It is the Olympic aspiration of speed. Speed is a value that is ingrained in many Olympic athletes, but victory requires another virtue — safety.



In global commerce, as in the Olympics, things happen fast, they have to — but speed without safety carries great risk.

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Apolo Anton Ohno is arguably the finest short-track speed skater who has ever lived. Short-track speed skating is one of my favorite Olympic sports, a cross between ballet and roller derby. Short-track racers sprint around an oval track wearing helmets and skintight suits. The grace and swiftness of their movement is counterbalanced by some quite spectacular crashes that occur at high speeds.

During the 2002 Games, I watched the 1000-meter, medal-round race where five skaters participated, including Apolo Ohno and a very colorful Australian named Steven Bradbury. What Ohno and Bradbury had in common were colorful personalities. Ohno sported a signature goatee, and Bradbury displayed spiky blonde hair.

I spent time with both of them, and they are terrific guys. Ohno was the most likely to win, Bradbury the least. In fact, Bradbury's presence in the medal round involved luck. He advanced from the first trial round because of a disqualification. He got through the second round because four skaters crashed.

The skaters took their marks. The starter gun sounded. The skaters sprinted through the first straightaway and then fell into a ballet-like glide for eight laps, leaning in unison around each curve.

Going into the last turn of the final lap, Ohno and another skater were stride for stride. The crowd was on its feet. Suddenly, skates bumped, legs flared, and a domino collision left four skaters sprawled on the ice, each banging into the sideboards, just feet from the finish line.

All but Steven Bradbury, who up to that point, was a distant fifth. He skated by the wreckage to victory as the first Australian to ever win a gold medal at the Winter Games.

As a side note, I spoke with Steven the next day in the athletes' village. I wished him good luck in his next race, to which he replied, "You know mate, I think I've used all of my lucky charms." We later joked that he was "slow enough to win the gold."

This illustrates an important lesson. In the Olympics, athletes will take extraordinary steps to achieve maximum speed, sometimes sacrificing safety. This produces both heroic results of victory and dramatic crashes of defeat.

Great sport, but dramatic crashes — when you are dealing with people’s health — are not an option — we must combine both speed and safety.

An executive of a large American retail firm told me that one of its core values is represented by the phrase, “Speed is life.”

This connotes the need to be nimble, innovative, and responsive to the need for change in both business operations and consumer preferences.

Too frequently we see product safety problems resulting in unnecessary expense, sickness, injury, and even the loss of life. To the consumer the result is harmful, even tragic. To countries, companies and categories of products, the impact on a reputation can be devastating.

In global commerce, as in the Olympics, things happen fast, they have to — but speed without safety carries great risk.

The unsettling stream of product safety problems we are experiencing is a reflection of the most profound change in commercial patterns in human history — the globalization of trade.

This opening of world markets has brought enormous benefits to consumers: lower prices, greater variety, and more choice.

Nowhere is this more evident than in the produce industry.

I met a produce manager named Dan in Detroit. I can remember his name because he told me he was “Dan the produce man.” He has been in the grocery business for three decades.

I asked him what has been the most significant change he has seen. He immediately responded with four words, “It’s what consumers want.”



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A typical grocery store carried 173 produce items in 1987 and now carries 558 produce items.
—FDA Food Protection Plan

It is a fundamental challenge for all nations. We need to develop new tools and strategies equal to the new challenges we face.

It used to be a big deal each year when fresh peaches arrived. They would put up signs and place ads in the local paper. Not anymore.

Now he sells peaches almost every month of the year. During the winter, plums, nectarines, and grapes pour into this country from Latin America. We eat big, bright red strawberries in January without a second thought.

Americans walk into almost any produce department in the country and purchase what used to be seasonal items, at a reasonable price, any time of the year.

It is the speed of life — our lives, our demands on an ever-growing global market.

It's anything, anywhere, anytime.

My point is that as long as Americans want to enjoy fresh produce from around the world, buy medicine, wear low-cost clothing, drive foreign-made cars, use electronic products designed and built off our shores, purchase affordable furniture, and otherwise participate in the bounties of a global economy, our import system will become increasingly complex.

This is the value of global trade. The challenges we face are the result of a global market beginning to mature.

Last year, the United States imported more than \$2 trillion worth of products, an amount that exceeds the entire gross domestic product of France. This is approximately \$6,500 for every man, woman, and child in the U.S. These products were brought into the United States by more than 800,000 importers, through over 300 ports-of-entry. All projections indicate that this volume will continue to skyrocket over the coming years.

Just as the volume of trade has changed, so must the strategies to regulate safety. Simply scaling up our current inspection strategy will not work. This is not a problem unique to the United States. It is a fundamental challenge for all nations. We need to develop new tools and strategies equal to the new challenges we face.

A year ago, President Bush directed a Working Group of his Cabinet to conduct a comprehensive review of our import safety practices. He appointed me Chair. Our review involved teams from throughout the federal government, with extensive help from the private sector. We conducted the most complete policy review ever on this subject by our government.

In my role as Chair, I visited ports and post offices, freight hubs and fruit stands, supermarkets and seaports. I listened, probed, toured, and took in the totality of America's import system. I met with leaders from India, Vietnam, People's Republic of China, Australia, Mexico, Canada, El Salvador, Costa Rica, Panama, Nicaragua, Guatemala, Honduras, Singapore, the largest economies of the European Union, and the European Commission to discuss import safety.

The scale and complexity of global commerce amazed me. So did the need for change. We provided a comprehensive report to the President; the most important thing we said was this:

Mr. President,

We have a good system of product safety today, but it is not adequate for the future, and we need a fundamental change in our strategy.

In the past, we have stood at our borders attempting to apprehend products that don't meet our expectations.

We cannot inspect our way to product safety without bringing trade to a standstill. Our new strategy must be to extend our borders and ensure that quality and safety are built into the products we import.

We will do this by rewarding producers that have products certified to meet our standards. Their goods will receive expedited entry into our country.

We will make clear to those who don't that they can expect enhanced scrutiny.



Approximately 15 percent of the overall U.S. food supply by volume is imported.

—USDA Economic Research Service

"We recommend working with the importing community to develop approaches that consider risks over the life cycle of an imported product, and that focus actions and resources to minimize the likelihood of unsafe products reaching U.S. consumers"

—Strategic Framework for Import Safety



A centerpiece of our new strategy is to encourage, leverage, and build upon such voluntary third-party efforts. We are not inventing a new concept. It already exists. And it works.

You can read the report and 50 specific recommendations we made at importsafety.gov. They are important, but the real transformation comes from the change in our basic strategy.

I want to illustrate this by talking about the shrimp business. I was in Vietnam recently and Central America two weeks ago — both are big producers and exporters of shrimp. I met with representatives of the shrimp industry in both places.

We talked about the impact on their product when a shipment gets detained at our border. Delays create huge costs and often disrupt or even close affected businesses.

Members of the shrimp industry independently decided that they needed to develop a set of quality and safety standards, and a way to verify compliance with those standards. They did this because their consumers needed to know that their products were safe and of high quality.

They developed a formal, voluntary collaboration that produced a set of industry standards and certification process. A centerpiece of our new strategy is to encourage, leverage, and build upon such voluntary third-party efforts. We are not inventing a new concept. It already exists. And it works.

We observed independent certification being used in many sectors of the import world. Until now, we have not integrated this capacity for improvement into our regulatory responsibility. This needs to be a government-wide strategy; ultimately, it should apply to all product lines.

Since FDA has responsibility for the safety of a significant share of our imports, I would like to outline the way we are transforming the Food and Drug Administration to harness the power of this new vision.

In the future, products from those firms that have standards and certification processes that we trust will be given expedited entry and access to U.S. consumers. The FDA will be freed to focus its enforcement resources on those suppliers that don't have certified products.

I'm pleased to announce today that FDA is establishing a pilot with the shrimp industry to help learn how to evaluate third-party certification programs, and implement them in the field.

So we are saying clearly: "We want you to have access to American consumer markets — we want to have access to yours. To do so, you need to meet American standards of quality and safety. If you can demonstrate through a process we trust, that your products meet the safety standards that we have mutually agreed upon, we'll be your partners in speed."

Can you see the linkage that connects speed and safety?

Speed is accomplished when trust has been established. Trust happens only with complete transparency. Transparency requires standards, and standards require collaboration.

This is a key point — a change born of the global market — collaboration is the new frontier of human productivity. I believe learning better collaborative skills is a requirement for success in this century. It is a proven method of solving complex problems, and it's hard work.

In my 16 years of public service, every significant step of meaningful progress has come as a result of collaboration. Collaboration does not eliminate tensions, but it minimizes them.

Collaboration does not take away hard choices, but it improves the acceptance of the decisions made. Collaboration does not create instant success, but it has accelerated progress.

In the context of product safety, collaboration will not only be necessary for developing product standards, but in implementing many other parts of the plan as well. Governments must collaborate with governments. Departments within governments — law enforcement, trade, border security and health agencies, for example — must collaborate with each other. Even competitors must cooperate in some circumstances.

Imports of seafood rose from less than 50 percent of U.S. seafood consumption in 1980 to more than 75 percent today.

—FDA Food Protection Plan



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Indeed, the changing import environment for our increasingly global food supply demands a new approach to import safety

—John D. Flores, Ph.D.
Institute of Food Technologists

A collaborative spirit, skill set, and commitment is a pre-requisite for leadership and success in the 21st century global marketplace.

And, in my judgment, a collaborative spirit, skill set, and commitment is a pre-requisite for leadership and success in the 21st century global marketplace.

When we presented our import safety plan to the President, I told him it would require additional money. The President committed to seeking additional funding. Congress has made a down payment that will support crucial steps, including expanding FDA's international presence and improving its scientific and information-technology infrastructure. But it will require sustained investment over the next several years to achieve long-term import safety.

Legislative action is also needed.

We need Congress to provide the FDA with authority to mandate third-party certification in certain high-risk categories when voluntary measures aren't working.

Having laid out a long-term vision and strategy, I want to acknowledge that changes of this magnitude take time. Solutions take time to implement. But we have to keep steady pressure on the change pedal.

In the limited time left in this Administration, there are several things I plan to complete.

In the United States, our biggest trading partners are now Canada, China, and Mexico, in that order. Chinese products made up about one-sixth of all U.S. imports.

Recognizing that, we have signed and begun to implement two landmark Memoranda of Agreement with the Chinese government: one concerning food and feed, and the other, drugs and medical devices.

These strong, action-oriented documents call for specific steps and set clear deadlines for achieving them. Once implemented, they will enhance the safety of scores of items the American people consume on a daily basis.

We recently signed a Memorandum of Understanding with the Vietnamese government. We are working with Indian

authorities to support their pharmaceutical regulatory priorities. We have committed to share information and collaborate with our Mexican and Canadian partners on food and drug recalls. And we are developing an agreement with Central American governments that will improve product safety for consumers in the U.S. and abroad.

FDA's work is often underappreciated in this country. Countries around the world recognize FDA as the "gold standard" when it comes to food and drug safety. Under Commissioner Andrew C. von Eschenbach's leadership, FDA is building on that "gold standard" by reaching out to new frontiers and globalizing the FDA.

FDA is opening an office in China with staff in three cities: Beijing, Shanghai, and Guangzhou. We are currently negotiating to do the same in India, with plans for additional FDA offices in multiple areas of Latin America, Europe, and the Middle East.

And we are changing how we do business. The traditional role of FDA as approver stands strong. How and where we do that is undergoing change.

The origin of all product standards, certification and inspection of goods does not need to start with FDA; it can start with the industry and in other countries as it did with shrimp.

This is a fundamental shift in government's role. The 21st century role of FDA is as convener and arbiter, as well as verifier and enforcer.

Will FDA be an aggressive enforcement entity? Yes. In fact, FDA's enforcement resources will be better funded and more focused on the producers who have not demonstrated trustworthiness.

Will FDA be adopting safety standards as a regulator? Yes. But we will encourage industry to collaboratively develop standards for FDA to review. If they don't meet the scientific rigor, we won't accept them until they do.

Solutions take time to implement. But we have to keep steady pressure on the change pedal.

The 21st century role of FDA is as convener and arbiter, as well as verifier and enforcer.

The United States must transition from an outdated "snapshot" approach to import safety, in which decisions are made at the border, to a cost-effective, prevention-focused "video" model that identifies and targets critical points in the import life cycle where the risk of the product is greatest, and then verifies the safety of products at those important points.

—Action Plan for Import Safety

This is a very exciting vision: common standards, common certification, and shared inspections. Safer products. Lower costs.

FDA regulates \$49 billion in imported food¹ annually. Approximately 189,000 registered foreign facilities manufacture, process, pack, or hold food consumed by Americans.
—FDA Food Protection Plan

While the United States is the largest economic player in the food and drug market, there are other nations with excellent systems in which we have great confidence.

In the past, each nation has conducted separate inspections. The result is great redundancy as several countries inspect the same plant — for essentially the same things, while too much time lapses between visits.

We are going to change that.

I'm announcing a policy initiative where FDA will work more closely with foreign regulators who have systems of inspection and regulation we trust. The principle will be collaborative information gathering, individual decision making.

As part of that effort, FDA has initiated a pilot project with our colleagues in the European Union and Australia to jointly plan, allocate, and conduct international pharmaceutical inspections. This will begin with inspections of active pharmaceutical ingredient manufacturing. These are the “starting products” of many of the medicines we all use.

Through this new collaboration, FDA and these trusted colleagues can spread our inspection net wider by leveraging our respective resources. We will be inspecting some, the Australians others, the European Union still others. We will then share information. This just makes good sense. Facilities will be inspected more often and we can all focus more resources on those products that present higher risk.

This is a very exciting vision: common standards, common certification, and shared inspections. Safer products. Lower costs.

Finally, we need the private sector to step up big-time to initiate, lead, and participate in the development of consensus-based standards and independent certification. You have a responsibility to your consumers and to the integrity of your industry. Together we have a unique opportunity to influence the future of product safety.

I would like to close by sharing one more story about safety, speed, and Olympic athletes. This one is a tale of devotion to the safety of our country and sheer speed on ice. It is about a true hero of the 2002 Olympic Winter Games — Derek Parra, a Mexican-American speed skater from San Bernardino, California.

Prior to the Games, Derek was an employee at Home Depot working in the flooring and electrical department. He is a regular guy who at the time would eat Fig Newtons the night before each race.

This regular guy represented our country during the 2002 Games in two monumental ways. In the opening ceremony, Parra was chosen as one of eight U.S. athletes who carried in the tattered flag that flew over the World Trade Center. In his book, *Reflections on Ice*, he wrote about this experience. Let me share an excerpt:

When it came time to begin the procession I touched the flag for the first time and felt a physical sensation unlike anything I had ever experienced. If it is possible to feel your soul being touched that is what I felt. As we carried the flag out before the capacity crowd and worldwide television audience the silence was deafening. I've never before heard such stillness. I was some place emotionally I had never been before; some place spiritually I didn't know existed. While in this instance that flag represented so much death, it seemed also to stand for life, love and the hope of a nation.

I was there and he is right. Powerful words about the safety of our homeland from a great Olympian.

A few days later, Parra fulfilled the hope of a nation by demonstrating that nice guys do finish first. He had a breathtaking and world-record-setting performance in the 1,500-meter race. In a stunning time of one minute 43.95 seconds, he bested the favorite skater from the Netherlands and captured gold for the United States.

After winning the race Parra said, “You give up so much, hoping for a moment like this, and it happens.”

We owe it not only to our consumers, but, of course, our farmers, ranchers and producers as well. As we must work with our trading partners to share best practices and agree on common standards of science-based approaches for food safety.

—Chuck Conner
Deputy Secretary of Agriculture



We will achieve safety and speed by harnessing the power of consumers who rapidly and harshly punish those who produce poor products.

He skated the perfect race. He embraced safety, mastered the ice, and skated at the speed of life. His fleet power made him at that moment the best in the world ... ever.

In the next 12 to 24 months something far more significant than an Olympic gold medal is at stake. It is the future of product safety in the United States. There are two competing and divergent philosophies ready for battle. This battle is not entirely about safety; it is a surrogate battle about U.S. philosophy on trade.

I believe that opening world markets has brought enormous benefits to consumers — lower prices, greater variety, and more choice. We will achieve safety and speed by harnessing the power of consumers who rapidly and harshly punish those who produce poor products. The game plan is to develop high, science-based standards, demand absolute transparency, reward independent certification, and rigorously enforce high-risk products.

Others would have government inspect everything. They want to stop products at the border and increase point-of-entry government inspection. Not only does such a course mean higher costs and taxes, it means consumers would be denied timely access to an abundance of safe products at lower prices. Frankly, underneath their government-centric view lurks the spirit of protectionism and the illusion that they can use the inspection process to slow or reverse global trade.

If you care about the future of the United States in the global market, you have to weigh in here. Now is the time. This is the medal round.

In a global market there are three ways to approach change: You can fight it and fail; you can accept it and survive, or you can lead it and prosper.

We are the United States of America; let us lead.

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