

Remarks of Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
“The Importance of PIC/S in our Globalized World”
40th Anniversary of PIC/S
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Good afternoon—and thank you so much for inviting me here today. What an honor it is not only to be part of the 40th anniversary of PIC/S, but also to lead an agency that is now a proud and official Participating Authority. Many people from the U.S. Food and Drug Administration and from PIC/S worked very hard to vet FDA and to make FDA membership a reality, and I am very happy that FDA is now a PIC/S member. I am also delighted to be here today to talk with you about the importance of PIC/S in our globalized world.

There can be no doubt that PIC/S is a global leader in helping to ensure the quality of drugs. And you have had a tremendous impact by focusing on a set of key issues, importantly including international cooperation and collaboration in critical areas such as Good Manufacturing Practice standards, technical training, and quality systems of inspectorates—all essential to protecting the health of individuals and the public health of nations throughout the world.

What is perhaps most impressive is that you’ve created a high-functioning, cooperative arrangement among so many regulatory authorities from around the world. By bringing us together, you provide us with opportunities to share ideas and information and to exchange everything from inspection reports to recall alerts to visions of global drug quality. And you give us the chance to discuss science; to brainstorm smart, new approaches for protecting people from falsified and potentially deadly products; and to overcome common challenges that range from challenges in science to challenges in resources.

For those of you in the room who are considering becoming members of PIC/S, I want to share with you a little about FDA’s experience. Becoming a member of PIC/S was a long road for us. Our application was distinct because FDA is a very large organization with some 12,000 employees and a broad mandate that includes regulating not only pharmaceuticals, but also foods, medical devices, veterinary feeds and medicines, and tobacco.

Though not always easy, the PIC/S application process helped FDA to mature as an organization. The process required us to engage in rigorous self-examination. We improved our quality systems, focused on gaps in our regulatory processes, and became more cohesive internally. We are better for it.

We also believe the application process was challenging and illuminating for PIC/S. Because FDA’s system is different from the European system, it took a lot of work to consider how to compare our system to those of many of the existing members. There was a great deal of productive dialogue, and we very much appreciated the candor and openness of the PIC/S assessment team.

They were tough, but they were fair, and were willing to accept that different systems could be comparable and could get us to the outcome to which we all aspire. While it was a thorough, at times challenging process, I think we all believe that it was well worth it in the end and that by working closely together in this way, we have all deepened our appreciation of what really matters and how to achieve it—and we are all stronger for having persevered. We hope that these efforts will encourage other countries that are considering applying to be PIC/S members.

We at FDA are excited and honored to be a part of PIC/S, and we look forward to the benefits—networking with our counterpart regulatory authorities, sharing training opportunities, promoting quality systems, as well as participating in Quality Circles and other committees and working groups. We are also committed to investing in PIC/S. Among other things, we will make our experts available to help, and we are excited to host a PIC/S seminar in the near future.

Today, PIC/S is more important than ever, given the realities of globalization. In the U.S., a stunning 80 percent of the active pharmaceutical ingredients in our drugs come from outside our borders and about 40 percent of the finished drugs themselves.

And, the world is poised for even further globalization. There are macro trends at work that are impacting global commerce, and the cumulative effect of these trends will ensure that, ten years in the future, commerce in the products we all regulate will be even further transformed. Undoubtedly, the pressure to reduce costs and increase productivity will lead companies to continue to move manufacturing activities to new and different locations, looking for less costly sites and global supply chains to reduce production costs.

These realities challenge virtually all nations and make us increasingly connected and interdependent. In the U.S., at FDA, we tell Americans that there is no longer such a thing as an American drug supply; there is a global drug supply. Those of you sitting in this room fully understand the global nature of drugs today, the vulnerabilities this creates, and the challenge it poses for regulators who are dedicated, as you are, to protecting your citizens from unsafe, ineffective, and poor quality drugs.

At the same time, globalization and outsourcing have redrawn the path that drugs navigate to reach the citizens of all of our countries, and the supply chain from manufacturer to consumer has become more and more complex...involving a web of re-packagers and redistributors, including those online, that make oversight significantly more difficult.

This complex global supply chain creates new vulnerabilities in the lifecycles of the products we regulate and provides greater opportunities for the distribution of unsafe and ineffective products, including the unintentional introduction of contaminants or other quality concerns, as well as the harm caused by intentional fraud, counterfeiting, and economic or other ill-intended adulteration. And it presents many new national and international health security threats.

In recent years in the U.S., we have experienced events, as many of you have—some clearly deliberate and some unintended—that had serious consequences for life, health, and safety, as well as for trade, commerce, and the economy. The most notable of these for drugs involved contaminated heparin. I'm sure that many of you were personally involved in dealing with the

potential for heparin contamination in your own countries. In the U.S., FDA publicly referred to the heparin crisis as a “wake up call.” It was an alert not only for FDA, but also for U.S. citizens, companies and politicians. I assure you, FDA is now more aware than ever of the threats around us. But, we cannot address them alone.

Certainly as U.S. FDA Commissioner, I spend a lot of time grappling with these issues. They have major implications for how we fulfill our mission to promote and protect the health of the American people. It is clear to me that the U.S. FDA—and many of our regulatory counterparts around the world—have to continue to evolve to meet the demands of globalization.

In other words, this is a moment for leaders and experts around the world—particularly those in this room today—to come together and collaborate even more than ever before. We have a shared interest in ensuring the safety and quality of drugs and a shared responsibility for that safety and quality. Working together to monitor and improve safety and quality globally will benefit all the citizens of the world. Our jobs are getting harder but they are more important than ever before.

We must continue to work together in a proactive, rather than reactive, manner in dealing with potential threats. Together, we must continue to develop improved approaches to secure the supply chain and avoid illegal shipments and falsification of drugs.

We can set common goals based on common needs—and rely on each other to leverage resources and to improve drug quality worldwide. We need not have identical systems in order to rely upon and trust each other. We simply must have enough confidence in each other’s systems to use data and activities of counterpart regulators as we would our own.

We can also work together to assure that regulators around the globe have common Knowledge, tools and practices, so that they can best work together. The more we can make our work comparable and interchangeable, the more we can leverage each other’s efforts.

Together, we can all do our jobs that much better, for as you know, no one country is capable of inspecting the world on its own, nor can we assure quality with inspections alone. As manufacturers and distributors strategically relocate to countries with lower operational costs—and often countries with less mature regulatory systems and historically less active engagement in drug quality assurance—all PIC/S members must continue to think strategically about how we can pool our resources and truly work together for the common good.

A recent example of such an approach is probably worth mentioning. In this case, the U.S. FDA relied on the European Directorate for the Quality of Medicines to place a firm under Import Alert and prevent its active pharmaceutical ingredient from entering our country. We made this decision solely on EDQM’s information, even though FDA had never inspected the manufacturing site. To make this decision, which was an unprecedented one for us, we learned about the deficiencies by monitoring an EU database; requested and reviewed EDQM’s establishment inspection report; and had detailed technical discussions with the inspectors. Now, we are working to conduct a joint inspection of the firm with EDQM.

FDA also works together with the European Medicines Agency and its member state inspectorates on drug product inspections, and with EMA and the Australian Therapeutic Goods Administration on active pharmaceutical ingredient manufacturer inspections in various parts of the world. We collaborate with many other counterparts as well, including many represented here today.

These are all important steps because they show how we can multiply our impact by working together.

FDA also took an important step forward this past week in our own information-sharing efforts. We made public our COMSTAT database, which contains our inspection results. This means that every country, as well as every citizen, now has the benefit of knowing whether FDA has previously inspected a manufacturing facility and whether we found the facility to be in or out of compliance with our requirements and standards.

Whether you are a current PIC/S member, applying, or just thinking about applying, we encourage all countries represented in this room to take advantage of this information because you may learn from our databases and decide not to duplicate our inspectional efforts.

At FDA, we have thought a great deal about what our strategy should be to confront the risks and challenges of globalization. We know that we must work together with our counterparts in global coalitions of regulators in all of our commodity areas—foods, drugs, medical devices, veterinary medicine, and tobacco. PIC/S is, in fact, such a global coalition when it comes to inspectorates responsible for GMPs for human and animal drugs. And we are excited to explore and further develop with you the additional impact we can have as a collaborative team.

We also believe that global data-information systems and networks are imperative, so that we can proactively share data with our partners. This would begin with inspectional results or GMP certificates and hopefully extend to include inspection reports and inspection schedules. With time, it should expand to allow real-time global sharing of information about emerging threats and quality trends. With advanced risk analytics, we can achieve global vigilance on drug quality issues so that we can all coordinate and more effectively work together to maximize the protection of our citizens.

In addition, we at FDA know we must also begin to leverage the efforts of private sector third parties, so that we can effectively allocate FDA resources based on risk. We must also leverage the efforts of industry, which has a vital stake in assuring the quality of its products. We will be exploring even more intensively in the future how we can strengthen our engagement and make these advances.

This is an exciting time for all of us—and we have a lot left to do. We at FDA realize that we can learn so much from our colleagues here at PIC/S, our new partner... As we together move toward our shared global vision, we hope that, individually and collectively, you will teach us, support us, and help us to figure out how to be an active, collaborative, and fully productive part of the international GMP inspectorate enterprise so that, together, we can create a safety net that

ensures drug quality worldwide. Again, please let me say how honored, excited, and humbled we are to be here.

In turn, I am confident that we will make significant and continuing contributions to this important collaborative enterprise. And I think that this is a critical moment.

As I stand here today, I do feel the urgency to challenge all of you—and to challenge ourselves—to figure out how we can, together, have the greatest impact on assuring drug quality, safety, and efficacy globally. We must always focus on the public health outcomes we achieve. We know that, every day, some of those in the manufacturing and distribution chains for these products cut corners in small or large ways. They gain a competitive advantage or a monetary windfall from this non-compliance. But, they put our citizens at risk, and we cannot tolerate that.

And even under the best of circumstances, and with all good intentions, mistakes get made.

Now is the time for us to come together and rise to these challenges. This is a vision that I think all of us share—a vision that is essential in promoting the future of public health—and a vision that none of us can achieve alone.

Thank you again for your kind invitation to join you today. And I wish you the greatest of success for this meeting and for many, many years to come.