

Written Testimony Submitted to Health and Human Services Task force on Drug Importation by Thomas M. Menino, Mayor of Boston, April 30, 2004

The price of prescription drugs is a major problem for many of our citizens. It is a major problem for purchasers, such as cities, who cannot afford prices that rise so much faster than inflation. More importantly, it is a problem for those who are uninsured or underinsured. I have taken a leading role in the effort to place the issue of drug pricing on the national agenda through active support for importation. I organized a meeting of Northeastern mayors early this year to discuss importation. Some of these cities have started importation programs. In Boston, I am completing the development of a pilot implementation program designed to demonstrate that importation can be safe. I believe that you, as task force members, will also find that importation can be made safe, if you have the will to do so.

The broader issues of drug pricing and access will of course frame the discussion that you are leading. It is this discussion that is most important. The debate about this set of issues needs to be given greater attention by this administration. The pharmaceutical industry must also realize that this is an issue that will not go away and must be addressed in a manner that is sensitive to the needs of consumers. Pricing must be made more equitable internationally and domestically.

Drug Pricing and Access

I believe the Medicare Prescription Drug, Improvement, and Modernization Act left significant gaps in coverage. Perhaps more important, however, the Act only deals with those covered by Medicare. While roughly 12 million Medicare recipients lack drug coverage, 53 million non-Medicare recipients are without such benefits.

Those without health insurance, or with limited prescription coverage, are asked to pay the most for their prescription medicines. Those with insurance receive the benefit of volume discounts. Those least able to afford it are asked to pay the most. Given how critical drugs have become in overall medical care, this approach to pricing is just plain wrong.

The issue of pricing is tricky. Pharmaceutical companies need to be able to earn enough to justify the risk and expense of research and development. It is unfair that US consumers are the ones that are asked to pay for research and development for new drugs for the whole world. Part of the problem is that some other countries are not paying their fair share to support research and development (R&D). The US government should do more to pressure other industrialized countries to fairly reflect the cost of R&D in their price regulation mechanisms. This would help relieve pressure on US prices.

The need for R&D investment, and our own desire for newer, better medicines must, however, be balanced against the necessity of making these newer medications available and affordable. In recent years, this balance has shifted. Over the past two

decades a number of federal policy changes have significantly expanded the effective patent protection period for new drugs. With this, prices and profits have risen. Much of this is good. Many new drug treatments have been developed. But I fear that the balance has shifted too far.

Part of the solution needs to be a reevaluation of pricing within the US market. A broad mechanism for keeping prices affordable for all, not just those with great insurance provided by their employer, needs to be created. I am not advocating for price controls. I prefer a voluntary approach wherein manufacturers limit pricing disparities between the uninsured and insured. Voluntary effort on the part of the industry to expand and simplify free drug programs could be a significant part of this effort.

Failing that, the role of taxpayer money (through NIH grants) should be accounted for. Studies have shown that somewhere between 70 and 90% of leading drugs have been developed with the use of taxpayer supported research money. Other studies indicate that only 15% of the basic research studies to develop new drugs have been funded by the industry. Perhaps drugs developed with NIH research funding should be obligated to offer reduced prices for certain needy groups.

A remedy must be found. Importation is not in and of itself a solution to this larger dilemma. It may, however, be part of a solution. At a minimum it makes clear that pricing is often inequitable and forces a debate about possible solutions.

Importation and Safety

As a committee, you are charged with determining if importation can be safe. The answer is yes.

The Food and Drug Administration (FDA) has publicly argued, in the words of Associate Commissioner Pitts, that “the flood gates can’t be opened only part way.” They have viewed the question before you as an all or nothing proposition: seal the border tight or beware the massive flood tide of imported drugs.

This is nonsense. The Medicare Prescription Drug, Improvement, and Modernization Act gives the Secretary of Health and Human Services the authority to establish any regulations necessary on importation. The secretary has the authority to define and limit importation as needed to assure its safety.

The FDA will, I am sure, present to you today a variety of problems that they say are risks of importation. Their argument is, however, overly broad. Their risk list is a laundry list of issues that might happen. Even they will admit that these risks (such as counterfeiting) occur occasionally within the current US drug system. The FDA uses a list of limited examples in an effort to indict all importation, while most people see this only as evidence that some paths of importation are risky.

A program and regulatory scheme can be designed to minimize risks and lead US citizens away from websites that source from unknown origins. Today people are ignoring the FDA's advice because they see the FDA's arguments as too broad. They see the FDA's effort as fear mongering and overreaching. I believe the FDA's credibility in this area must be reestablished, but the only way it will be regained is to permit and regulate a controlled form of importation.

How then can importation or re-importation be safe? Let me assume that the decades old policy of allowing US residents to carry limited quantities of medicines across the border will continue. The issue is what standards and policing are necessary to make mail order or larger scale importation safe.

Type of drug: Such importation should be limited to drugs that have generally been authorized for sale in the US, having passed FDA standards and trials. Some allowance should be made, however, for variances in coloring and fill agents. Controlled substances and other restricted drugs should not be imported.

Manufacturing location: Importation should be limited to drugs manufactured in FDA approved production facilities. This represents a substantial portion of the name brand drugs that are currently the subject of individual importation activities. The FDA does currently not certify batches not destined for the US, but easily could, as long as they are produced in an FDA approved facility.

Packaging: Exporters of drugs should be required to package and ship drugs following US packaging and labeling standards (although a review should be done to see where some US standards may be overly specific). Exporters that are interested in the US market will conform their practices to meet these standards if provided with an authorized market.

Exporter qualification: Importation should be limited to exporters that meet specific criteria and agree to FDA oversight. These entities should be required to certify chain of custody and storage standards and risk de-certification for non-compliance.

Counterfeiting: Counterfeiting is a real problem, but it is a problem in the US already. Frankly, there are many more instances of counterfeiting in the US than in Canada. Importation can open some additional avenues for counterfeiting, but the supply chains in some countries (such as Canada) are tighter than our own. Importation could be limited to countries with tight supply chains and stringent domestic regulation.

Reciprocal agreements: Reciprocal agreements with Canada (and other selected industrialized states) could permit the FDA to have confidence in some suppliers and drugs coming from these markets. The FDA already relies to a limited extent on others review of manufacturing facilities. Reciprocal agreements can establish the level of confidence necessary for importation.

Pilot Programs

It may be appropriate to establish a few different pilot projects to test the viability of this approach. Depending on the model of importation, wholesale or individual (retail), it may also be appropriate to restrict drugs that require significant medication management, have a history of severe drug interactions, are injectible, or are temperature sensitive.

In Boston, we have been developing a pilot project that includes these restrictions (and others) and is designed to integrate imported medicines and US distributed medicines into an electronic, point of service drug utilization review mechanism which will catch drug interactions and patient-specific drug concerns. Such a pilot would be an effective way for HHS to test the viability of controlled importation. I hope that HHS will actively review authorizing a few pilots as part of this yearlong study process that you are engaged in.

Conclusion

The pharmaceutical industry has done amazing things for us in developing new drugs that do so much. But we are reaching the point that too many cannot afford these life-saving drugs. A balance needs to be reached where new drug development is encouraged, but consumers are not left without needed medicines. The current mechanisms for this are not sufficient. The industry must develop alternatives, and the federal government should be prodding the industry to do so. I hope this task force will lead to a broader national discussion about how to better balance profits and affordability.

Importation is not a complete solution for the overall issue of drug pricing and access. But importation can be made safe and will provide a short-term way of offering price reductions to consumers who are priced out of the current market.

Thank you for the opportunity to testify.