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U.S. Food and Drug Administration



U.S. Department of Health and Human Services

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Department of Health and Human Services

Public Health Service
Food and Drug Administration
Rockville MD 20857

August 4, 2004

The Honorable Thomas M. Menino
Mayor of Boston
Mayor's Office Boston City Hall
One City Hall Plaza
Boston, Massachusetts 02201

Dear Mayor Menino:

I write to express our concerns about the new program Boston is implementing that will encourage city employees and retirees to purchase foreign unapproved prescription drugs. When you met with us several months ago, we explained to you that unapproved foreign drugs were outside of the Food and Drug Administration's regulatory jurisdiction, and that we had substantial fears about exposing your city's citizens to drugs of unknown origin and quality.

I would like to reiterate some of our earlier concerns, as well as make additional points that I hope you will consider. First, as we explained in our meeting with you, sixty-five years ago Congress enacted the Food, Drug, and Cosmetic Act as a means of establishing a drug safety system requiring that drugs be carefully tested before marketing, produced under exacting standards overseen by the FDA, and dispensed by state-licensed pharmacies and pharmacists. That regulatory system has enabled Americans to have the safest, most advanced drug supply in the world, and our citizens can purchase medicines within this country with great assurance of getting a properly tested and manufactured drug that will successfully treat their condition. Drugs made or distributed in other countries are not necessarily subject to FDA's strict regulatory standards, and we have no way to assure that drugs imported from such places are safe and effective. We are troubled that you would actively promote such unproven and unregulated drugs to your employees and retirees.

The fact that the drugs you plan to import may come from Canada does not obviate our concerns. It is often assumed that a drug sold by a Canadian pharmacy is the same or very similar to American drugs, since Canada has a regulatory system analogous to our own. However, it is important to note that drug products must be made with great care and to exact specifications, without which drugs containing the same active ingredients may vary significantly. In fact, FDA has gone to great lengths to ensure that the generic version of a drug is the same--is absorbed into the body, enters the bloodstream, and has the same therapeutic

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such drugs will be the "same," even if they contain the same active ingredient, and thus, such drugs may be unsafe in a number of ways. In fact, the Agency has no way to assure that the drugs actually come from Canada and recent reports indicate that these products may be supplied from all over the world.

Second, you have chosen Total Care Pharmacy of Calgary, Alberta as the city's preferred pharmacy for your Meds by Mail program. Although the drugs that your citizens will purchase from Total Care Pharmacy will in almost all cases be illegal under federal law, our concerns extend even beyond that critical fact. Substantial concerns have been raised about Total Care's willingness to abide both by appropriate pharmacy standards and by its own agreements with jurisdictions that have previously identified Total Care as a supplier. As you know, the states of Wisconsin and Minnesota have included Total Care on their state's list of recommended Canadian pharmacies for state residents to utilize in purchasing unapproved foreign prescription drugs. Wisconsin entered into a specific, detailed agreement with Total Care in hopes of assuring the quality and safety of drugs imported from Total Care. Total Care agreed not to send to state residents drugs for which there was no U.S.-approved equivalent, generic drugs (which tend to be cheaper in the U.S. than in Canada), and medicines that require refrigeration or cannot otherwise be safely shipped by mail. Unfortunately, Total Care has not even complied with the terms of this agreement. For example,

- The Pharmacy Society of Wisconsin found in March that almost half of the drugs sold by Total Care violated the agreement with the state (e.g., drugs dispensed that had no approved version in the U.S.). Despite warning letters from the Wisconsin state government, those violations continued in April and May.
- During June and July, FDA inspectors in our Chicago District Office examined incoming packages from Total Care to confirm the Pharmacy Society's finding and to ascertain if the violations were continuing. We found that 54 of 78 drug shipments from Total Care to Wisconsin residents violated the terms of their agreement.

In sum, Total Care is selling drugs to Americans that can be purchased less expensively here in the United States (and not informing them of that fact). It is selling drugs that are considered risky in a variety of ways, and that it agreed not to export to America. This is disturbing information that demonstrates an ongoing pattern of putting U.S. citizens at risk, and is even more alarming because the violations continue despite repeated warnings from the state of Wisconsin.

I have attached our [recent letter](#) to Wisconsin Governor Doyle on this matter, which provides greater detail about our concerns. I will also note the disclaimers that both you and Total Care provide to those seeking these imported drugs. Specifically, although the City of Boston is encouraging its employees to seek health care from an unregulated foreign entity, it "accepts no legal liability, with respect to any product offered, or pharmaceutical care provided, by Total Care Pharmacy." Moreover, Total Care requires the patient to sign an acknowledgement that the pharmacy is "not responsible for any ... damage whatsoever and howsoever caused, arising out of or in connection with the use of the site . . . including personal injury." No properly licensed American pharmacy of which I am aware requires such a disclaimer and, indeed, both FDA and pharmacies in this country stand behind the quality of the legal drugs sold in the United States.

Let me close by once again thanking you for traveling to Washington to meet with me and my colleagues. It is obvious that you are seeking answers to a vexing societal problem: providing

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we recognize the depth of that concern and are doing whatever we can here at the FDA to provide affordable medications, principally by assuring that less expensive generic versions of brand name drugs get on the market as rapidly as possible. But we must be cautious and deliberate when considering proposals to address this problem to ensure that any changes do not require American citizens to give up the "gold standard" in drug safety that has become a hallmark in this country. I am confident we can work cooperatively towards solutions that will not be a disservice to the people of Boston.

I would be happy to meet again with you or your advisers to discuss these matters further at your convenience.

Sincerely,

William K. Hubbard
Associate Commissioner for Policy
and Planning

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