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# New Hampshire: Governor Craig Benson

Department of Health and Human Services logo Department of Health and Human Services

Public Health Service  
Food and Drug  
Administration  
Rockville MD 20857

March 31, 2004

Via Fax: (603) 271-7630

The Honorable Craig Benson  
The Governor of New Hampshire  
Office of the Governor  
107 North Main Street  
Room 208  
Concord, New Hampshire 03301

Dear Governor Benson:

It has come to our attention that you may endorse the purchase by citizens of New Hampshire of unapproved, illegal drugs from a foreign pharmacy, specifically CanadaDrugs.com of Winnipeg, Manitoba. We are writing to express our concern over this possibility. We strongly believe that the endorsement by a public official such as yourself would undermine one of our nation's key consumer

protection statutes and place your constituents at unnecessary risk of harm from unregulated pharmaceuticals.

As you may know, sixty-five years ago Congress enacted the Food, Drug, and Cosmetic Act to create a strong drug regulatory system requiring that drugs be carefully tested before marketing, produced under exacting standards overseen by the Food and Drug Administration, and dispensed by state-licensed pharmacies and pharmacists. That regulatory system has enabled our citizens to have the safest, most advanced drug supply in the world, and every day in this country millions of patients are successfully treated by safe and effective medications. Drugs made or distributed in other countries, including Canada, are not necessarily subject to our strict regulatory standards, and we have no way to assure that drugs imported from such places are safe and effective. FDA has, therefore, been vigilant in protecting unknowing patients from those who would lure our citizens to buy unproven, unregulated drugs from foreign countries.

The drugs that your citizens will purchase from the Canadian pharmacies to which you refer them will clearly be illegal in virtually all instances. However, our concerns are far greater than that. Indeed, the report to your Health and Human Services Director arising from a visit to a Canadian pharmacy that was found to be "acceptable" is telling. For example,

- The "inspection" of CanadaDrugs.com was apparently carried out by a Department of Corrections employee and by an employee of a chain drugs store in New Hampshire, not by trained, experienced inspectors from your Board of Pharmacy.
- The inspectors' report noted their apparent satisfaction that CanadaDrugs.com was accredited by the Internet and Mail order Pharmacy Accreditation Commission, a voluntary "accrediting" body with no legal standing and no Federal or State regulatory or enforcement authority. Nor would FDA or the National Association of Boards of Pharmacy endorse such a program.
- The visit determined that CanadaDrugs.com has no malpractice insurance. But then, perhaps they need none, as their "terms of service" require the patient to sign a statement that "CanadaDrugs.com will not be liable for damages arising from personal injury or death" from the use of drugs sold by that business. Since New Hampshire citizens sent to Canadadrugs.com will apparently have no recourse from the dispensing pharmacy if injured by such drugs, who will accept responsibility for any injuries arising from use of the unapproved, illegal drugs marketed by CanadaDrugs.com?
- The drugs that your citizens will purchase from any foreign pharmacies that you designate have not been manufactured, shipped or held within the oversight of the FDA, and Canadian drug regulators have said repeatedly that they will not assure that drugs exported from Canada meet American safety requirements. So you would be sending your citizens to buy drugs whose assurance of safety might come only from the commercial operators that profit from those sales, since CanadaDrugs.com disclaims any safety assurance.
- Despite the fact that New Hampshire law does not permit a pharmacy in New Hampshire from accepting a prescription faxed by a patient, you are apparently considering recommending that such faxes be accepted by Canadian pharmacies selling drugs to your citizens.
- Although generic versions of brand name drugs are usually less expensive in the United States, your "program" would apparently encourage the sale of Canadian generic drugs to your citizens. And your "inspectors" report notes that many of the Canadian generics are not approved for sale in the United States, and thus cannot be FDA-approved, U.S.-manufactured

drugs. This is further acknowledgement of the intention to encourage the sale of illegal, unapproved drugs that will cost your citizens more than they would pay at a legitimate, New Hampshire-licensed pharmacy.

There are many other ways that the state could pursue providing affordable, but safe, medications to your citizens, and we would welcome the opportunity to explain our thinking on that. We and others in the Federal government are ready to work with you to implement these approaches for the people of New Hampshire. These approaches include: promoting access to FDA-approved generic drugs, which are proven safe and effective, account for the majority of prescriptions filled in the U.S., and generally cost less than the generic drugs sold in Canada; disease management programs to help educate patients and practitioners about low cost ways to meet medical needs; and implementation of the new Medicare Drug Discount Program, which will become effective in June and will enable seniors who lack medical coverage to obtain medicines at reduced prices. Please contact me if you would like to discuss these further and we will be pleased to arrange a meeting.

Meanwhile, you should also know that we are working diligently to respond to our mandate from Congress to assess whether and how foreign drugs could be imported while providing assurances of their safety and effectiveness. Surgeon General Richard Carmona is chairing a Task Force on Importation, which was created by the Secretary of Health and Human Services (HHS), to advise and assist HHS in determining how drug importation might be conducted safely and its potential impact, positive and negative, on the health of American patients, medical costs and the development of new medicines. The task force intends to consider the public health questions posed by Congress in a way that is fair, public, and evidence-based. Indeed, the Surgeon General has begun a series of meetings with the various stakeholders in this important area, and we hope that you will provide your advice to the task force as it conducts its work.

We would be happy to discuss our concerns further with you at your convenience.

Sincerely,

William K. Hubbard  
Associate Commissioner for  
Policy  
and Planning

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