

- [Drugs](#)
- [Drug Safety and Availability](#)

## Section Contents Menu

### [Drug Safety and Availability](#)

- [Drug Alerts and Statements](#)
- [Medication Guides](#)
- [Drug Safety Communications](#)
  
- [Drug Shortages](#)
- [Postmarket Drug Safety Information for Patients and Providers](#)
- [Information by Drug Class](#)
- [Medication Errors](#)
- [Drug Safety Podcasts](#)
- [Safe Use Initiative](#)
- [Drug Recalls](#)
- [Drug Supply Chain Integrity](#)

# North Carolina: Caldwell County Manager, Bobby White

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

Public Health Service  
Food and Drug  
Administration  
Rockville MD 20857

April 5, 2004

Mr. Bobby White  
Caldwell County Manager  
P.O. Box 2200  
Lenoir, North Carolina 28645

Dear County Manager White:

I am writing at the suggestion of the North Carolina Board of Pharmacy to reinforce concerns the Board raised with you about Caldwell County's nascent Canadian drug importation program for county employees and dependents that facilitates the purchase of unapproved, illegal drugs from foreign pharmacies. We strongly believe that the endorsement of this practice by a public official undermines one of our nation's key consumer protection statutes and places 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 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.

Under current Federal law, if a county government establishes a drug importation program, the drugs that county employees and dependents will purchase from the Canadian pharmacies to which they are referred will clearly be illegal in virtually all instances. However, our concerns are far greater than that. For example,

- A number of Canadian pharmacies that promote and sell drugs to Americans have been found substantially lacking in contemporary standards for safe pharmacy practices. I have attached our recent letter to Minnesota Governor Tim Pawlenty, summarizing in some detail the inadequacies of those pharmacies found by his own pharmacy board officials when they visited Canadian internet pharmacies.
- In response to the deficiencies described in the Minnesota pharmacy board inspections, the Canadian pharmacies acknowledged those problems and committed to correcting them. In this country, "we'll do better next time" has not been an acceptable means of regulating our drug supply. Indeed, any of the almost three dozen deficiencies found by the Minnesota officials could have resulted in a fine, license suspension, or license revocation for a U.S. pharmacy.
- The drugs that your employees would purchase from these pharmacies 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 will be sending your employees to buy drugs whose assurance of safety comes only from the commercial operators that profit from those sales.

I must also take note of possible tort liability concerns that a public entity could be subject to if a citizen purchases an unapproved, illegal drug on that entity's advice, and suffers an injury as a result. Most Canadian internet pharmacies have bold disclaimers intended to deflect responsibility for injury to their American customers. If you do, indeed, provide incentives for your employees to purchase foreign drugs, I urge you to at least include a warning that the drugs are not necessarily approved by American medical authorities and may thus be unsafe for use.

There are many other ways that the County could pursue for providing affordable, but safe, medications to its citizens. We and others in the Federal government are ready to work with you to implement these approaches for the people of Caldwell County. 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.

As I noted earlier, Canadian drug regulators have said repeatedly that they will not assure that drugs exported from Canada meet American safety requirements. In contrast, the United States Food and Drug Administration does accept responsibility under the Federal Food, Drug, and Cosmetic Act for the safety and efficacy of drugs it approves and regulates. We confidently recommend those drugs to patients and physicians as products that have been proven to be safe and effective medical therapies. And we do not recommend that citizens purchase unregulated and unapproved drugs from foreign businesses.

As a native North Carolinian myself, I fully understand the long tradition of caring public officials such as those in Caldwell County finding creative and effective ways to serve their constituents. But please understand that we here at the FDA sincerely believe the use of unregulated foreign drugs poses a real and distinct risk to American citizens. We would be happy to discuss those concerns further with you at your convenience.

Sincerely,

William K. Hubbard  
Associate Commissioner for Policy and Planning

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Page Last Updated: 09/10/2009

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