



JEB BUSH  
GOVERNOR

STATE OF FLORIDA

# Office of the Governor

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June 27, 2006

Ms. Sue Cobb  
Secretary of State  
Florida Department of State  
R. A. Gray Building  
500 South Bronough Street  
Tallahassee, FL 32399

Dear Secretary Cobb:

By the authority vested in me as Governor of Florida, under the provisions of Article III, Section 8 (a), of the Constitution of Florida, I do hereby transmit House Bill 371, with my signature, enacted during the 108<sup>th</sup> Session of the Legislature of Florida, since statehood in 1845, during the Regular Session of 2006 and entitled:

An act relating to prescription drugs...

This bill creates the Cancer Drug Donation Program, provides an alternative definition of pedigree paper for closed-loop wholesale drug distributions, and creates a general exception to the pedigree paper requirement for drop ship distributions.

The safety of Florida's drug supply has been one of my primary concerns throughout my term as Governor. In 2003, I requested the impaneling of a statewide grand jury to examine the safety of prescription drugs in Florida. The grand jury noted, among other observations, that the secondary wholesale distribution market was the principal source of adulterated drugs. The recommendations of the grand jury were codified in Committee Substitute for Committee Substitute for Senate Bill 2312, passed that same year.

Since then, there have been marked improvements in assuring the safety of our drug supply:

- Civil and criminal penalties for adulterating prescription drugs have been strengthened;
- Licensing and regulation of wholesale distributors has been tightened resulting in a sharp decline in the number of licensed distributors; and,
- Pedigree regulations have created incentives for direct purchase from manufacturers and have substantially decreased the confusing multiplicity of ownership transfers that used to be common in the distribution of drugs.

As the July 1 deadline approaches for implementation of the second phase of pedigree requirements, some unanticipated consequences of the current law have become evident. Significant among these is the silence of current law regarding "drop ship" transactions, wherein a manufacturer directly ships prescription drugs to an end user, while billing a wholesale distributor for the transaction. Drop ships are used in a multitude of situations, such as for antibiotic or oncology prescription drugs that have low production volumes or unusual handling



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Ms. Sue Cobb  
June 27, 2006  
Page Two

requirements. These situations will be hampered by full pedigree requirements, but Floridians depend daily on the ready availability of these life-saving drugs. House Bill 371 will clearly--and narrowly--authorize these transactions.

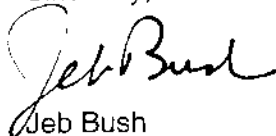
In addition, for the sale of drugs directly from a manufacturer, through a wholesaler, to an end user, House Bill 371 will require meaningful documentation, including both a sworn statement and detailed records maintained by the distributors, so that regulators can identify any problems that may occur and prosecutors can pursue wrongdoing. House Bill 371 focuses the full pedigree on those transactions that involve the secondary market. Such "sideways movements" are generally acknowledged as the chief source of adulterated drugs; House Bill 371 will narrow the application of full pedigree to these transactions.

Thus, House Bill 371 will incentivize direct purchase transactions, thereby enhancing safety. Most importantly, House Bill 371 does not weaken the enhanced civil and criminal penalties and stronger wholesale distribution permit requirements contained in the 2003 law.

I have tremendous respect for those who have expressed concern with the changes in pedigree laws that House Bill 371 includes. Like them, I am committed to a safe and secure drug supply and determined to preserve laws that prevent adulteration or diversion of prescription drugs. It is only because I am convinced this bill that will enhance rather than weaken these safeguards that I am taking this action.

I hereby transmit with my approval House Bill 371.

Sincerely,



Jeb Bush