

BRIEFINGS



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Late Filed Amendment to House Bill 371 Compromises the Florida Prescription Drug Protection Act of 2003

Florida TaxWatch Recommends Governor VETO the Bill and Administratively Enact Two Good Key Provisions

Florida TaxWatch has encouraged the Legislature to make full use of standing and interim committees to review proposed legislation to avoid floor amendments offered in the waning hours of legislative sessions.¹ Floor amendments are not inherently harmful if filed timely and subjected to full floor debate. However, floor debate about an amendment considered in the final hour before adjournment of a session cannot be thorough enough particularly if the issue is complex or affects public safety.

Adequate notice and legislative deliberations are critical to representative democracy because the transparency of committee proceedings and staff analysis processes may reveal unintended, harmful or costly consequences. The committee process allows stakeholders to research positions and to prepare testimony in support or opposition to bills.²

An 11:06 PM Amendment on the Last Day of Session Could Compromise Enforcement of Drug Counterfeiting Laws and Restrict Competition in Pharmaceutical Wholesaling

Similar to Budget Turkeys, the last minute amendment to HB 371 is another example of lack of full deliberation and process transparency. The bill as amended is now awaiting signature, veto or inaction by the Governor. The Senate floor amendment³ at issue was adopted at 11:06 PM on

¹ Florida TaxWatch has criticized earmarked state appropriations for projects that were not properly vetted within the legislative committee process or identified through established statutory planning or project selection procedures. TaxWatch, Governors and legislative leaders of both parties term these budget items “Budget Turkeys.” See our most recent publication, *The 2006 Turkey Watch Report*, available at www.floridatxwatch.org.

² In Florida, legislative committee staff prepares a bill analysis that summarizes the bill, describes what the bill does, cites relevant research, and notes any issues relative to feasibility of administration or compliance costs.

³ See details about the various versions of the bill prior to the amendment and Senate Amendment 422560 ultimately incorporated into the engrossed or final bill at <http://www.myfloridahouse.gov/Sections/Bills/billsdetail.aspx?BillId=32048&>

May 5, 2006 and will compromise enforcement of drug counterfeiting laws and restrict competition in wholesale distribution of prescription drugs in Florida. The amended bill largely exempts major drug wholesalers from more detailed record keeping that will be required of all other wholesalers beginning July 1, 2006 pursuant to the Florida *Prescription Drug Protection Act of 2003* (act).⁴ Certain other provisions of the floor amendment intended to provide record-keeping flexibility for drop shipment of time-sensitive fast expiring drugs needed for patient emergencies had transparency and serve a public and taxpayer purpose. Proponents of drop ship record flexibility had pursued the issue before the Department of Health and other state agencies for over a year before resorting to the legislative process. **We believe that with the Governor's full endorsement, the proper distribution of unopened cancer drugs together with drop shipment record flexibility, can and should be achieved administratively.**

The amended bill substantially altered the 2003 act, which stemmed from concerns surrounding a statewide grand jury investigation of prescription medicine thefts and the manufacture and distribution of adulterated or counterfeited drugs. Lax or non-existent record keeping from the manufacturer through the wholesale and retail distribution chains was a major factor in drug counterfeiting and manipulative distribution.⁵ The Legislature's Office of Program Policy Analysis and Government Accountability (OPPAGA) also had reported on the growing dimensions and methods of counterfeiting and diversion of drugs including the cruel and insidious dilution of drugs for cancer and HIV/AIDS patients.⁶ The record keeping provisions central to the act were premised on the statewide grand jury report, OPPAGA findings, State Department of Health input, and legislative hearings. After Florida enacted the 2003 reforms, states such as Nevada viewed the legislation as model and advised against any prospect of changes to the pedigree requirements.⁷

Before being amended, HB 371 was meritorious—its sole purpose had been to allow unopened cancer drugs not needed by original patients to be distributed to patients who could not afford them. The amendment so substantially changed the bill's purpose that the Senate, pursuant to its rules, had to change the bill's title because it was no longer a measure to provide relief to cancer victims. Significantly, the Florida division of the American Cancer Society urged the Governor to veto the bill because of the Society's concern about the late amendment's effects on the safety of the drug supply in Florida.⁸

⁴ Chapter 2003-155, LAWS OF FLORIDA.

⁵ The Governor petitioned the Supreme Court to convene the grand jury. See "Petition for Order to Impanel a Statewide Grand Jury," *In Re: Statewide Grand Jury*, No. SC02-2645 (December 20, 2002).

⁶ Office of Program Policy Analysis and Government Accountability, Report No. 03-18, *Counterfeit and Diverted Drugs Threaten Public Health and Waste State Dollars* (February 2003). Available at: <http://www.oppaga.state.fl.us/reports/health/r03-18s.html>. See also OPPAGA *Progress Report: Legislature Strengthens Pedigree Paper, Wholesaler Permit Requirements to Better Ensure Safe Prescription Drugs*, Report No. 05-49 (October 2005) <http://www.oppaga.state.fl.us/reports/health/r05-49s.html>.

⁷ April 24, 2006 letter to the Florida Legislature and Stephanie Feldman Aleong of Nova Southeastern University from Louis Ling, General Counsel to the Nevada State Board of Pharmacy.

⁸ J. Taylor Rushing, *Battle Over Drug Law Goes to Governor*, Florida Times Union, June 8, 2006.

The Amendment Jeopardizes Enforcement of the Prescription Drug Protection Act of 2003

Effective July 1, 2006, state law as currently written requires all wholesalers of all listed drugs to compile “pedigrees” informing subsequent buyers of the details about previous sales transactions (lot number, date of each transaction, buyers and sellers). The prescription distribution business is already heavily regulated because of the necessity to protect users from the dangerous effects of adulterated, counterfeited, or misused drugs. Records of shipments and sales have been required for many years, but neither as detailed in content nor to the extent required by the new pedigree provision. Pedigrees allow for the tracing of final units of drugs in the last-stage dispenser’s sale back to the selling wholesalers’ inventories as it moved down or sideways through the sales chain from the original manufacturer’s production run. Pedigrees enhance the ability of authorities to target investigations toward drug transactions whose pedigrees are missing, appear suspicious or do not reconcile with collateral records reflecting the transaction history of the suspect production lot. This is a more efficacious surveillance process than was possible under previous law. Investigators had to announce their investigations and ask distributors blindly to produce distribution records, which gives a violator the opportunity to control release of information to investigators and time to bury potentially damaging records among stacks of extraneous paper, or to destroy, conceal, alter or even falsify records. The Florida Attorney General, while urging the Governor to veto HB 371 because of the amendment, termed pedigrees, “the fingerprints by which public health officials and pharmacists can trace the path of drugs.”⁹

However, the questionable amendment exempted from the detailed pedigree regulations wholesalers (direct purchasers) who buy directly from manufacturers and sell directly to a pharmacy or dispenser. These larger direct purchasers will only be required to certify that their products were purchased directly from the manufacturer and in turn will be sold directly to pharmacies or dispensers even if the products changed locations several times within the direct purchaser’s system. The exemption eliminates, and thus weakens, the more detailed pedigree trail for these major distributors who wholesale the bulk of pharmaceuticals in the state and is counter to the consumer protection intent of the reform.

Some pharmacy retail chains and health providers supported provisions of the amendment related to “drop shipping”—whereby a dispenser orders directly from a third-party supplier, which in turn ships directly to the local dispenser. The 2003 act was inflexible and did not exempt drop shipping from record pedigrees, which appeared to be a hindrance to the cost-effective delivery of certain types of drugs. The flexibility permitted by the bill for drop ship record keeping could save dispensers and taxpayers alike and is a very beneficial process. Medical businesses that made use of drop shipping to order time sensitive drugs needed in smaller quantities had made repeated efforts to get the Department of Health to allow record-keeping flexibility through administrative rule and as a last resort used HB 371 as a vehicle. According to a trade group representing retail pharmacies, the drop ship issue became “caught up in an effort by the wholesalers to change the pedigree procedures as they related to wholesale

⁹ May 16, 2006 letter from the Honorable Charlie Crist, Attorney General, to Honorable Jeb Bush, Governor.

distributors. This change ultimately held up the drop shipment issue until very late on the last night of the session.”¹⁰

The Amendment Hinders the Wholesale Market

The amendment affects the competitiveness of the wholesale prescription business in Florida in two ways:

- Unlike direct purchasers who will not be required to prepare pedigrees, drug wholesalers who do not always buy directly from manufacturers and who buy from other wholesalers will be required to do so. This does not create a level business playing field in a market that is already highly contentious.
- Exempt direct purchasers have no incentive to sell to competing smaller wholesalers and are not required to do so. Direct purchasers would avoid selling to other wholesalers because these transactions will require generation of costly pedigree records. Exempt direct purchasers would want to maintain their lower costs and their dominant and exclusive market position. Any undue restriction of competition is likely to increase consumer costs unnecessarily and in the case of widely used and expensive prescription drugs, this could cost millions of dollars, if not tens of millions of dollars, annually. Furthermore, unnecessary restriction of competition is almost always a bad deal for taxpayers as it adds costs and reduces meaningful consumer choices.

Relative to whether pedigree requirements should apply to large wholesale distributors as they do to secondary wholesalers, a US Food and Drug Administration task force reported that stakeholders supported universal applicability of pedigrees:

*There was near complete agreement that all wholesalers, not just non-authorized distributors, should be responsible for passing pedigree information.*¹¹

Florida TaxWatch concurs with the U.S. Federal Drug Administration Counterfeit Drug Task Force Report 2006 Update, which states: “...a universal e-pedigree (i.e., a pedigree passed by all wholesalers, not just those who are not authorized distributors of record) that documents the movement of every prescription drug product from the manufacturer to the dispenser would be an important step in preventing counterfeit drugs from entering the drug supply chain.”¹²

Prescription drugs accounted for 18.2% of total 2004-05 Medicaid services costs in Florida. Florida Medicaid prescription drug expenditures increased from \$1.4 Billion in fiscal year 2000-01 to \$2.5 Billion in 2004-05.¹³ The Legislature and Agency for Health Care Administration have been aggressive in negotiating price concessions and slowing the growth rate of such costs, which had been rising by an annual rate of 21.2% between 1995 and 2000, but slowed to 15.1%

¹⁰ *Pharm Alert, 2006 Session Wrap-Up*, “Pedigree Papers,” Florida Chain Drug Council.

¹¹ June 8, 2006, *FDA Counterfeit Drug Task Force Report: 2006 Update*, p. 15, available at <http://www.fda.gov/counterfeit/>.

¹² June 8, 2006, *FDA Counterfeit Drug Task Force Report: 2006 Update*, p. 12, available at <http://www.fda.gov/counterfeit/>.

¹³ Office of Program Policy Analysis and Government Accountability, Report No. 06-07, *Inflated Pricing and Confidential Information Prevent Medicaid from Ensuring Lowest Prescription Drug Prices* (January 2006). Available at: <http://www.oppaga.state.fl.us/reports/health/r06-07s.html>.

from 2001 to 2005. However, there are strong indications that the drug industry is resisting efforts to contain Medicaid costs. In a January 2006 report, the Legislature's Office of Program Policy Analysis and Government Accountability (OPPAGA) observed, "the state's ability to obtain the lowest possible prices for prescription drugs is hindered by inflated manufacturer pricing information and lack of access to confidential information."¹⁴

The pedigree provisions as contemplated by the Prescription Drug Protection Act of 2003 will improve the transparency of transactions within the prescription drug distribution market and the late amendment that exempted the bulk of wholesale transactions in Florida from pedigrees is potentially harmful to cost control and market competition.

Florida TaxWatch Concurs with the Attorney General and Former Director of the Florida Office of Drug Control Calls for a VETO and Administratively Enact the Proper Distribution of Unopened Cancer Drugs Together with Drop Shipment Record Flexibility

In a May 16, 2006 letter to the Governor, Attorney General Charlie Crist requested the Governor to veto HB 371 citing "the late night amendments that were so unrelated that a title amendment to the cancer drug donation bill was necessitated..."¹⁵ In addition, Secretary of Corrections, James McDonough, recommended a veto. McDonough is the former Director of Florida's Office of Drug Control and former head of the White House Office of National Drug Control Policy.¹⁶

Florida TaxWatch concurs with the Attorney General and Secretary McDonough's recommendations and urges that the Legislature remove the amendment in question and restore the intent of both the cancer drug bill and the Prescription Drug Protection Act of 2003. Affected distributors and providers may still be able to pursue expediting drop shipping and flexible record keeping through the Department of Health administrative rule process or through the Governor's emergency powers. Florida TaxWatch recommends that the Governor and administration take appropriate and immediate steps to resolve the drop ship issue and provide proper distribution of unopened cancer drugs to patients who cannot afford them as soon as possible. Furthermore, the 2007 Legislature should enact the drop ship flexibility and proper distribution of unopened cancer drugs provisions in law.

There are far more equitable and responsible ways to serve the prescription drug needs of our citizens and the taxpayers of Florida than by improperly restricting competition and creating an unlevel playing field in a market that is both highly contentious and of utmost importance to Florida. The uncertainty surrounding the effect of the late amendment suggests a veto because conservative thinking demands, "When in doubt, keep it out." The state should apply record-keeping requirements needed by law enforcement to all wholesale distributors as was intended by the well-thought-out Prescription Drug Act of 2003. It is important that actions taken by Florida be viewed as a model for the nation and other states. The taxpaying citizens of Florida deserve and expect nothing less.

¹⁴ OPPAGA, Report No. [06-07](#), p.2.

¹⁵ May 16, 2006 letter from Attorney General Crist to Governor Bush.

¹⁶ May 18, 2006 email from Secretary James McDonough to Governor Bush.

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Florida TaxWatch's research recommends productivity enhancements and explains the statewide impact of economic and tax and spend policies and practices on citizens and businesses. Florida TaxWatch has worked diligently and effectively to help state government shape responsible fiscal and public policy that adds value and benefit to taxpayers.

This diligence has yielded impressive results: since 1979, policy makers and government employees have implemented three-fourths of Florida TaxWatch's cost-saving recommendations, saving the taxpayers of Florida more than \$6.2 billion--approximately \$1,067 in added value for every Florida family.

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