



May 13, 2010

The Honorable Charlie Crist  
Governor, State of Florida  
The Capitol  
400 S. Monroe Street  
Tallahassee, FL 32399-0001

Dear Governor Crist:

On behalf of the board and membership of the Florida Medical Manufacturers' Consortium (FMMC), and the 470 medical device manufacturers in our state, we urge you to support and sign HB 5311, relating to the Department of Health.

HB 5311 remedies a long-overdue regulatory flaw and burden for medical device and component manufacturers in Florida. Under current law and regulations, the Florida Department of Health (DOH) directly duplicates the extensive regulation of the medical device industry by the federal Food and Drug Administration (FDA), by requiring all medical device manufacturers (including component manufacturers) to obtain a permit (\$1,200 biennial fee) and submit to a facility inspection every two years. Medical device manufacturers must also register their facility with the FDA and submit to an inspection every two years as well.

The medical device industry is perhaps one of the most regulated industries in the world; and, in the United States, the industry is robustly regulated by the FDA through a comprehensive set of rules and regulations, and widespread acceptance of international standards (eg, ISO 13485) for good manufacturing practices and quality systems. The state-level regulation of the medical device industry by DOH is unnecessary and contributes little to the public health and safety of our citizens.

This duplicative and ineffective state regulation creates a competitive disadvantage for Florida medical manufacturers: it imposes an unnecessary "tax" and promotes a confusing regulatory environment. Many manufacturers have relayed instances where DOH inspectors have cited violations and enforced rules incorrectly and/or contrary to FDA regulations. DOH inspectors, who are only required to hold pharmacy degrees, receive no specialized training on the medical device industry and its FDA rules and regulations.

HB 5311 removes this unnecessary and burdensome layer of regulation for Florida medical device manufacturers.

This legislation is an important economic development issue for Florida's medical manufacturers. Florida is home to the nation's 2<sup>nd</sup> largest medical device sector – encompassing 470 device manufacturers (and hundreds more component manufacturers) employing more than 20,000 Floridians, paying an average annual wage of \$55,500. With the exception of California, none of Florida's key competitor states require state-level permitting and inspection of medical device facilities.

Joining with the Manufacturers Association of Florida, the Florida Economic Development Council, the Tampa Bay Partnership, the Manatee County Chamber of Commerce, BioFlorida, and others, we urge you to sign HB 5311 into law.

Sincerely,

A handwritten signature in black ink, appearing to read "Geary A. Havran". The signature is fluid and cursive, with a long horizontal stroke at the end.

Geary A. Havran  
Chairman

cc: Bob Brown-Barrios, Governor's Office of Policy & Budget