

By the Committee on Fiscal Resource and Senator Kirkpatrick

314-2156-99

1 A bill to be entitled
2 An act relating to economic development;
3 expressing legislative intent to foster the
4 development of the health technology industry;
5 amending s. 499.015, F.S.; exempting certain
6 medical device manufacturers from specified
7 registration and fee provisions of the Florida
8 Drug and Cosmetic Act; requiring documentation
9 to support such exemption from the act;
10 requiring the State University System and the
11 University of Miami to report to the
12 Legislature on evaluation of certain business
13 incubator, clinical trial, intellectual
14 property, and technology transfer activities;
15 requiring consultation with specified entities
16 as part of such evaluation; encouraging the
17 State Board of Community Colleges to continue
18 its efforts on the development of curriculum to
19 support the workforce needs of the health
20 technology industry; directing Enterprise
21 Florida, Inc., and the Department of Banking
22 and Finance to evaluate ch. 517, F.S., to
23 determine its impact on the ability of health
24 technology firms to raise capital; providing an
25 effective date.

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27 WHEREAS, Enterprise Florida, Inc., has a sector
28 strategy devoted to Florida's health technology industry, and
29 WHEREAS, the health technology industry represents a
30 valued and growing sector of Florida's economy, and
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1 WHEREAS, the health technology industry employs more
2 than 250,000 Floridians at a high average wage and is a
3 significant contributor to state and local tax revenue, and

4 WHEREAS, the health technology industry is dominated by
5 small employers and entrepreneurs that look to the state, its
6 communities, economic development organizations, community
7 colleges, and universities to provide an environment that will
8 nurture its development, and

9 WHEREAS, the health technology industry improves the
10 quality of life for all Floridians, and

11 WHEREAS, the Florida Legislature recognizes the
12 importance of this industry to our state, NOW, THEREFORE,

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14 Be It Enacted by the Legislature of the State of Florida:

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16 Section 1. It is the intent of the Legislature to
17 encourage and facilitate the location and expansion of the
18 state's health technology industry. This industry sector
19 creates high-wage, value-added jobs that strengthen and
20 diversify the state's economy.

21 Section 2. Subsections (8) and (9) are added to
22 section 499.015, Florida Statutes, 1998 Supplement, to read:

23 499.015 Registration of drugs, devices, and cosmetics;
24 issuance of certificates of free sale.--

25 (8) Notwithstanding any requirements set forth in ss.
26 499.001-499.081, a manufacturer of medical devices who is
27 registered with the Federal Food and Drug Administration is
28 exempt from this section and s. 499.041(6) if:

29 (a) The manufacturer's medical devices are approved
30 for marketing by, or listed with, the Federal Food and Drug
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1 Administration in accordance with federal law for commercial
2 distribution; or
3 (b) The manufacturer subcontracts with a manufacturer
4 of medical devices to manufacture components of such devices.
5 (9) However, the manufacturer must submit evidence of
6 such registration, listing, or approval with its initial
7 application for a permit to do business in this state, as
8 required in s. 499.013 and any changes to such information
9 previously submitted at the time of renewal of the permit.
10 Evidence of approval, listing, and registration by the Federal
11 Food and Drug Administration must include:
12 (a) For Class II devices, a copy of the premarket
13 notification letter (510K);
14 (b) For Class III devices, a Federal Food and Drug
15 Administration premarket approval number;
16 (c) For a manufacturer who subcontracts with a
17 manufacturer of medical devices to manufacture components of
18 such devices, a Federal Food and Drug Administration
19 registration number; or
20 (d) For a manufacturer of medical devices whose
21 devices are exempt from premarket approval by the Federal Food
22 and Drug Administration, a Federal Food and Drug
23 Administration registration number.
24 Section 3. The State University System and the
25 University of Miami shall evaluate the feasibility of
26 establishing additional health technology business incubators
27 similar to the University of Florida's Sid Martin
28 Biotechnology Institute at appropriate state universities or
29 the University of Miami, and the feasibility of enhancing and
30 expanding current facilities to support health technology
31 companies. The State University System and the University of

1 Miami shall evaluate establishing cooperative clinical trial
2 programs in conjunction with their medical schools. The State
3 University System shall also evaluate and recommend ways to
4 support, improve, encourage, and facilitate the creation of
5 and the collaboration with Florida-based businesses in
6 licensing State University System intellectual property, and
7 the collaboration of State University System employees with
8 Florida businesses in research and technology transfer
9 efforts. The State University System and the University of
10 Miami shall consult with the Health Technology Advisory
11 Council of Enterprise Florida, Inc., and Bio+Florida as part
12 of these evaluations and recommendations. The State
13 University System and the University of Miami shall report
14 their recommendations to the Governor, the President of the
15 Senate, and the Speaker of the House of Representatives by
16 December 1, 1999.

17 Section 4. The State Board of Community Colleges is
18 encouraged to continue its efforts to develop health
19 technology curricula to support the industry's workforce
20 needs. The State Community College System shall report its
21 results to the Governor, the President of the Senate, and the
22 Speaker of the House of Representatives by December 1, 1999.

23 Section 5. Enterprise Florida, Inc., and the
24 Department of Banking and Finance are encouraged to continue
25 their efforts to enhance opportunities for small-capital
26 formation in Florida while providing appropriate protections
27 for Florida investors. Enterprise Florida, Inc., and the
28 Department of Banking and Finance shall evaluate chapter 517,
29 Florida Statutes, to determine its impact on the ability of
30 Florida's Health Technology firms to raise capital.

31 Section 6. This act shall take effect July 1, 1999.

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STATEMENT OF SUBSTANTIAL CHANGES CONTAINED IN
COMMITTEE SUBSTITUTE FOR
SB 2468

This committee substitute removes the bill's tax exemption for the health technology industry and reduces the fiscal impact of the bill to insignificant. It also amends recommendations to Community Colleges and Enterprise Florida concerning industry promotion.