



HAPPY BIRTHDAY FDA

In honor of its 100th year, the FDA has created a Website that provides a quick study on FDA history and offers some fun features. Read all about the agency's humble beginnings in 1906 as the Bureau of Chemistry. Check out the many milestones FDA has placed in the history books over the last century. And if you're up to the challenge, test your FDA I.Q.

Q: About what drug, first approved in 1960, did a FDA advisory committee once note that "never would so many people take such a potent drug voluntarily over such a long period for a reason other than to cure disease"?

- a. extra-strength pain relievers
- b. long-acting cough syrup
- c. birth control pill

Q: What crusading supporter of national food and drug regulation in the early 1900s became the first to lead what later became the Food and Drug Administration?

- a. Charles A. Browne
- b. Carl L. Alsberg
- c. Harvey W. Wiley

Q: The Bureau of Chemistry, the earliest version of what later became FDA, was a part of what federal department?

- a. Agriculture
- b. Labor
- c. Treasury

Answers: (c.) birth control pill; (c.) Harvey W. Wiley; (a.) Agriculture

SOURCE: FOOD AND DRUG ADMINISTRATION, ROCKVILLE, MD

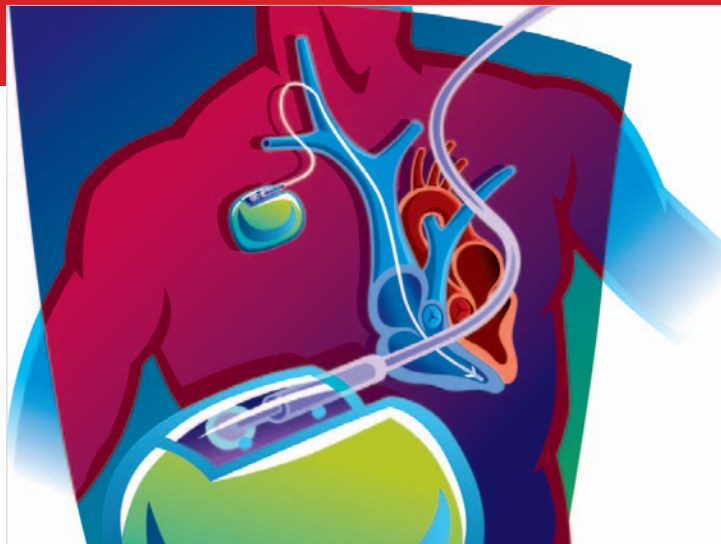
DEVICE TRENDS

Five Issues Expected to Shape the Industry

In 2005, the device industry registered an average 12% growth in sales over 2004, with a few companies growing as much as 25%. Smaller industry players were buoyed by the Medical Device User Fee Stabilization Act of 2005, which raised the revenue cap on industry players defined as small businesses from \$30 million to \$100 million. This allows many more developing companies to pay lower fees (\$98,650 vs. \$259,600 for a novel device) when submitting applications for approval to the FDA.

Booz Allen Hamilton Inc. has identified five major, interrelated trends shaping the device industry in 2006 and beyond.

1. Cost pressures: With their seemingly high price tags and



constant product innovation, medical devices present high-profile targets for cost-cutting efforts.

2. Efficiency in Innovation: In a market driven by innovation but under great cost pressure, the efficiency of research and development becomes key.

3. Outsourcing and Offshoring: Companies will increasingly outsource, not only manufacturing and clinical trials but also development, to such lower-cost locations as China and India.

4. Networked Automation:

Pushed by cost, clinical necessity, and technological opportunities, the industry is moving inexorably to a healthcare future that is highly automated, digitized, and networked.

5. Growth in Consumer-Directed Health: In 2005, insurers and health plans were boldest in their moves on consumer-directed health plans (CDHPs), while providers continued to underestimate their impact. The CDHP sector, overall, is predicted to garner the largest portion of new health plan enrollees.

SOURCE: BOOZ ALLEN HAMILTON INC., NEW YORK

NOTABLE POST

Former HHS Secretary Lends Expertise to Biopharm Company

Tommy G. Thompson, former Secretary of Health and Human Services and four-term Governor of Wisconsin, joins Alfacell Corp. as Special Advisor.

Secretary Thompson is chairing the newly created Alfacell Business Policy Committee, which includes members of the company's senior management team and board of directors. The committee is focused on advancing and executing strategies associated with key initiatives in areas such as finance, government relations, and regulatory affairs, as well as corporate governance and development.

The Bloomfield, N.J.-based biopharmaceutical company focuses on the discovery, development, and commercialization of novel ribonuclease (RNase) therapeutics for cancer.



"I am extremely pleased to serve in this new role with Alfacell, a rising company with an unwavering commitment to developing potential breakthroughs in the treatment of cancer," Mr. Thompson states. "I became familiar with Alfacell as Governor of Wisconsin, where the company manufactures its products. I look forward to working closely with Kuslima Shogen and the strong management team at Alfacell."

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Top 10 Business Issues for the Healthcare Industry in 2006

- 1 Medicare and the Drug Medicare Plan
- 2 Care and Coverage of the Uninsured
- 3 The Rise of the Healthcare Consumer
- 4 Focus on Prevention: Wellness is In; Fat is Out
- 5 Calls for Patient Safety to Drive Health IT Investments
- 6 Diminishing Drug Pipeline
- 7 Pay for Performance
- 8 Report Card Fever
- 9 Technology Backbone
- 10 Labor Shortages

SOURCE: PRICEWATERHOUSECOOPERS LLP, NEW YORK