

## Pharma and life sciences tax news: Vol. 8, No. 9 September 29, 2009

### Medical device industry not alone in opposing Baucus health reform bill's \$4 billion annual fee on the sector

Senate Finance Committee Chairman Max Baucus's healthcare reform bill, "America's Healthy Future Act," has invoked strong opposition from Democrats and Republicans even though he spent months working with both parties to draft the bill, hoping it would find broader support than the House's reform proposal.

The chairman already has backed down on some provisions of the bill he introduced Sept. 16, but the main concern for medical device companies remains. The bill would impose a \$4 billion annual fee on medical device<sup>1</sup> manufacturers and importers to help raise revenue to cover the \$856 billion, 10-year cost of reform.

Several senators, including Amy Klobuchar and Al Franken of Minnesota, John Kerry of Massachusetts, and Evan Bayh and Dick Lugar of Indiana, have spoken out against the bill, raising concerns that the fee would stifle innovation and threaten jobs. These senators represent states where major medical device companies have a strong presence.

#### Background

The Baucus bill proposes to raise revenue by assessing fees on the healthcare industry. The annual fees would be apportioned among specified industry sectors based on relative market share of covered domestic sales for the preceding year. The nondeductible fees would be effective beginning in calendar year 2010, with respect to domestic covered sales in 2009.

- A \$4 billion annual fee would be apportioned among domestic and foreign manufacturers and importers of medical devices offered for sale in the United States.
- A \$2.3 billion annual fee would be apportioned among pharmaceutical manufacturers and importers.
- A \$6 billion annual fee would be apportioned among US health insurance providers. This fee would not apply to self-insured employers.
- A \$750 million annual fee would be apportioned among clinical laboratories.

Medical device companies' covered domestic sales would include US sales of medical devices regulated by the Food and Drug Administration (FDA) and subject to premarketing and postmarketing regulatory controls. The fee would not apply to sales attributable to FDA Class I

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<sup>1</sup>Definition from the Chairman's Mark: A product labeled, promoted or used in a manner that meets the definition in section 201(h) of the Federal Food, Drug, and Cosmetic Act. For these purposes, a device is — an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

products or devices intended for use on animals. Class 1 medical devices present the lowest risk of potential harm to patients and have the least amount of regulatory control.

The draft bill would require any covered medical device company to report annually its covered domestic sales for the prior calendar year to the Secretary of the Treasury. The Secretary would establish individual assessments by determining the relative market share for each company — its covered domestic sales as a percentage of the total reported covered domestic sales for all covered entities. In determining each company's relative market share, covered domestic sales will be taken into account as follows: 0 percent of sales up to \$5 million; 50 percent of sales over \$5 million and up to \$25 million; and 100 percent of sales over \$25 million.

## Latest Developments

Markup on the Baucus bill began Sept. 22 in the Senate Finance Committee. The Chairman's Mark drew well over 500 proposed amendments, including some that would eliminate or lower the industry fees and others that would raise them. Modifications to the Chairman's Mark issued Sept. 22 left fee provisions intact except for striking the annual fee on clinical laboratories.

Stephen J. Ubl, president and CEO of the Advanced Medical Technology Association (AdvaMed), issued a statement opposing what he called the "unfair and counterproductive \$40 billion tax on medical devices" [over 10 years]. Ubl said that the tax would "sharply cut the resources available for research and development of life-saving medical treatments."<sup>2</sup>

AdvaMed noted that the annual fee would amount to nearly half of the \$9.6 billion the industry spent on research and development in 2007. It also would exceed the amount of venture capital dollars invested in device companies in 2007 (\$3.7 billion) and would be four times the amount the industry raised with 2007 IPOs.<sup>3</sup>

Commenting on the Class 1 exclusion, AdvaMed stated that "scores of consumer products and medical devices used by millions of Americans every day" would be taxed. Examples included contact lenses and battery-powered breast pumps. Manual breast pumps and eye glasses would be excluded.

*The Wall Street Journal* reported that some senators — specifically Chairman Baucus — were "troubled" that the medical device industry did not come up with a dollar amount that it was willing to concede to help finance healthcare reform. The pharmaceutical industry proffered \$80 billion; and hospitals, \$155 billion. The medical device industry drew criticism for suggesting that the government levy a tax on hospital purchasing groups.<sup>4</sup>

Despite the fact that the \$4 billion annual fee is not tax deductible, the Joint Committee on Taxation estimates it would generate only \$29.9 billion in additional revenues during fiscal years 2010 through 2019 after accounting for certain adjustments and payment lags.<sup>5</sup>

Consumers would likely bear part of the fees in the form of higher prices for medical devices. How the final legislation tiers the \$4 billion fee according to sales volumes could have an impact on medical device companies' plans to merge or purchase other firms. Higher sales volumes would translate into higher fees, making it potentially disadvantageous for companies to expand.

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<sup>2</sup> "AdvaMed Statement on Chairman's Mark," AdvaMed Press Release, Sep. 16, 2009.

<sup>3</sup> Ibid.

<sup>4</sup> Alicia Mundy, "Medical-Device Makers Scramble to Avert New Fees in Health Bill," *The Wall Street Journal*, Sept. 15, 2009, <http://online.wsj.com/article/SB125297599091410349.html>.

<sup>5</sup> Joint Committee on Taxation, "Estimated Revenue Effects of the Revenue Provisions Contained in the Chairman's Mark, as Modified, of the 'America's Healthy future Act of 2009,' Scheduled for Markup by the Committee on Finance on September 22, 2009," Sept. 22, 2009.

## What Can Taxpayers Do?

- Give the Baucus proposal top-level attention. Assess how the fee would affect your company's bottom line and ability to compete in foreign markets.
- Evaluate your company's best course of action if the proposal were to become law.
- Be prepared to engage in the debate and help Congress understand the consequences of this proposal for your company and employees.
- Stay in touch with AdvaMed. Because the legislation is still in flux, the tiers within the \$4 billion fee that have zero or discounted fees may change. Industry groups may get the opportunity to help shape the final tiers either in the Senate or in conference if both houses pass legislation.

## For Further Information

PricewaterhouseCoopers, "Finance Chairman Baucus proposes health care reform bill with revenue offsets," Pharma and Life Sciences Tax News, Vol. 8, No. 6, [http://www.pwc.com/en\\_GX/gx/pharma-life-sciences/publications/tax-news/finance-chairman-baucus-health-care-reform-revenue-offsets.jhtml](http://www.pwc.com/en_GX/gx/pharma-life-sciences/publications/tax-news/finance-chairman-baucus-health-care-reform-revenue-offsets.jhtml).

"Chairman's Mark: America's Health Future Act of 2009," [http://finance.senate.gov/sitepages/leg/LEG%202009/091609%20Americas\\_Healthy\\_Future\\_Act.pdf](http://finance.senate.gov/sitepages/leg/LEG%202009/091609%20Americas_Healthy_Future_Act.pdf).

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