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FDA Law Update BLOG
Current Issues Affecting FDA-Regulated Companies

FDA Law Update

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New Taxes for Pharmaceutical and Medical Device Manufacturers/Importers/Distributors

Manufacturers

As part of the recently enacted Patient Protection and Affordable Care Act ("PPACA") – known to most as Healthcare Reform Legislation, new taxes will be imposed on manufacturers of "branded prescription drugs" and most medical devices. These taxes are in addition to the fees already charged by the Food and Drug Administration ("FDA") for review of full new drug applications for drugs and 510(k)'s and Premarket Approval Applications for medical devices. And unlike user fees, the taxes will not be paid to FDA but assessed by the Department of Treasury and paid to support health insurance coverage.

The Medical Device Tax

The medical device tax is straightforward. It is a 2.3% excise tax based on the price that the medical device product is sold for. The tax is paid by either the U.S. importer (of foreign manufactured products) and the U.S. manufacturer in case of a U.S. manufactured medical device. The tax goes into effect for sales on and after January 1, 2013. The tax will be codified at Section 4191 of Chapter 32 of the Internal Revenue Code. The following medical devices are exempt:

- eyeglasses
- contact lenses
- hearing aids
- devices sold at retail to the general public for individual use

It remains unclear at this point how the Department of Treasury will assess and collect the tax; the PPACA does not so specify. Unlike the pharmaceutical tax, there is no indication of how Treasury is to obtain the sales information on which tax will be assessed.

The Pharmaceutical Tax

Unlike the medical device tax, the new tax on pharmaceuticals is complicated at best, and convoluted at worst. It applies only to "branded prescription drugs", which are defined as any product approved under Section 505(b) of the Federal Food Drug and Cosmetic Act ("FFDCA") that bears an Rx legend required by Section 503(b) of the FFDCA; the only exception is an orphan drug approved *only* for orphan indications. Generic drug sales are excluded, as those drugs are approved under Section 505(j) of the FFDCA; Rx products approved under Section 505(b)(2), of FFDCA, although quasi-generic in nature, are, however, subject to the tax.

These fees will not be paid to FDA, but will be transferred by Treasury Department to the Federal Supplementary Medical Insurance Trust Fund set up by PPACA to support health insurance coverage. The tax will first be paid in 2012 for the year 2011. The law requires the payment date be no later than September 30th of each year, which is the Federal Government fiscal year end.

The fee computation is convoluted. It goes like this. The fee is calculated by determining first "the percentage of sales taken into account." If the aggregate sales of a company's "branded prescription drugs" are less than $5 million, the percent is 0%. If between $5 million and $125 million, then it is 10%. If between $125 million and $225 million, then it is 75%. If more than $400 million, then it is 100%. See Section 9008(a)(2) of the PPACA. The fee is then calculated based on a company's percent amount of all manufacturers "sales taken into account", as that percent of an "applicable amount" for each year-which is as follows:

2011 – 2.5 billion
2012 – 2.8 billion
2013 – 2.8 billion
2014 – 3 billion
2015 – 3 billion
2016 – 3 billion
2017 – 4 billion
2018 – 4 billion
2019 – after – 2.8 billion.

See Section 9008(a)(4) of PPACA. The "sales taken into account" are based on reporting by government agencies (HHS, Veterans Affairs and Department of Defense) to the Department of Treasury and by any other source available to them. There are no new reporting obligations on pharmaceutical manufacturers. The fees are considered excise taxes treated under Section 275(a)(6) of the Internal Revenue Code. The law requires the Treasury Department to publish guidance "necessary to carry out the purpose of this Section". Section 9008(i).

As indicated, this is complex, if not convoluted. The following example may help.

Say the amount of sales reported to Treasury for a company's "branded prescription drugs" is

$100 million. The percent taken into account is then 10% of that or $10 million. Say the total of all "sales taken into account" for all manufacturers is $25 billion. The company's percent is 10 million divided by 2.5 billion or 0.004%. If the sales remain the same, for 2011 the company pays 0.004% of the "applicable amount" for 2011-2.5 billion, or $10 million. If the same were true for 2012, they will pay 0.004 percent of 2.8 billion or $11,200,000.

There are numerous potential issues raised by the scheme, foremost among them is how a pharmaceutical company can verify the validity of the information on which the tax is based, since it is not self reported – but reported to Treasury by HHS, Veterans Affairs and the Department of Defense. In addition, the law states that if more than one person is liable for payment of a tax, all such persons are jointly and severally liable for payment of the tax. See Section 9008(d)(3).

Conclusion

There are many issues that the Treasury Department will need to address to assess and collect these new taxes. Companies with distribution agreements will need to address responsibility for payment of the taxes in license and distribution agreements, and address issues such as joint and several liability. Pharmaceutical and medical device companies should be aware of these new taxes for budgeting and legal issues and should monitor this blog for further developments.

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