Colleagues,

Thank you for the opportunity to comment on this issuance. Details follow:

The Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act imposes a yearly fee on the pharmaceutical manufacturing industry for each calendar year beginning on or after January 1, 2011. The annual fee ranges from $2.5 billion to $4.1 billion for all affected entities in total. A part of the fee will be allocated to individual entities on the basis of the amount of their name brand prescription drug sales for the previous year as a percentage of the industry's branded prescription drug sales for the same period.

An entity's portion of the annual fee becomes payable to the Treasury. The requirement triggers once a pharmaceutical manufacturing entity has a gross receipt from branded prescription drug sales to any specified government program. The receipts may be in accordance with coverage under any government program for each calendar year beginning on or after January 1, 2011. An entity's portion of the annual fee is payable no later than the end of the 3rd quarter of the applicable calendar year. The annual fee isn't tax deductible. 720-50-05-2

The Financial Accounting Standards Board issued a proposed Accounting Standards Update (ASU), Other Expenses (Topic 720): Fees Paid to the Federal Government by Pharmaceutical Manufacturers - Consensus of the FASB Emerging Issues Task Force. This issuance was to address questions concerning how pharmaceutical manufacturers should recognize and classify fees mandated in the Acts in the income statements.

The amendments in the proposed ASU specify that upon recognition of the liability, the annual fee would be:

- Recognized over the calendar year payable employing a straight-line method of allocation unless another method better allocates the fee over the calendar year payable
- Presented as an operating expense. pp. 1

If approved, the amendments in the proposed ASU would be effective for calendar years beginning after December 31, 2010, when the fee initially activates.

Major questions are as follows:
(1) Do you agree with the scope of the fee?
(2) When should the fee be recognized?
(3) Should the fee be classified as an operating expense?
(4) Are any additional disclosures in order?

Critique:

Question 1: This fee is significant. It's difficult to match this fee against the government's costs in the area of pharmaceuticals. There is uncertainty as to whether or not generic drugs are free of this excise tax. There is no objective way to determine whether or not this fee is excessive as presented. In theory, an excise tax is an internal tax levied on the manufacture, sale or consumption of a commodity within a country. If the result of this
excise tax is to limit the use of pharmaceuticals in physician treatment plans, there could be some benefit to patients or HMOs.

Question 2: The fee is recognized as an operating expense. Alternative accounting might require estimates. Such estimates might cause reported earnings to be unpredictable to pharmaceutical manufacturers. These fees may be construed as excise taxes. The new taxes may result in cost subsidies of the sick to subsidize health care for other sick people. In addition, the legislation calls for an increase in the Medicaid drug rebate that drug manufacturers must pay to Medicaid. The increase in the rebate may cause manufacturers to pass on cost increases to consumers. Although the increased Medicaid drug rebate differs from an excise tax, the economic incidence of an increased rebate also falls disproportionately on consumers in the form of higher drug prices.

Question 3: The fee may be classified as an operating expense or a process of setting up estimates may be employed. The non-deductibility of the annual fee may not be an attractive feature for manufacturers.