



December 16, 2009

The Honorable Harry Reid
Majority Leader
U.S. Senate
Capitol Building, S-221
Washington, D.C. 20510-7020

The Honorable Max Baucus
Chairman, Committee on Finance
U.S. Senate
Dirksen Senate Office Building, SD-219
Washington, D.C. 20510-6200

The Honorable Tom Harkin
Chairman, Committee on Health,
Education, Labor and Pensions
U.S. Senate
Dirksen Senate Office Building, SD-428
Washington, D.C. 20510

The Honorable Christopher Dodd
Chairman, Committee on Banking, Housing and
Urban Affairs
U.S. Senate
Dirksen Senate Office Building, SD-534
Washington, DC 20510-6075

Dear Senators Reid, Baucus, Harkin and Dodd:

As the Senate continues its health care reform efforts, we respectfully request that the exemption of certain classes of medical devices from the proposed fee on device manufacturers be maintained in the Senate bill. We also ask that these important exemptions be included in the final conference package on health care reform.

Although we do not support taxing medical devices or imposing non-deductible fees on the medical device industry, we do appreciate that size of the fee has been reduced by \$20 billion over 10 years and that the language currently under consideration in the Senate would exclude some medical devices from the fee based on their FDA classification. Specifically, Class I devices are exempted, along with Class II devices that retail for \$100 or less. The House legislation, however, only exempts those items sold through retail.

While some may argue that the FDA product class is not a perfect delineation, the Senate exemption is a fairer approach to address the types of devices within Class I and the patients and providers that rely on them for critical patient care needs.

- Class I devices include products such as tongue depressors, cotton swabs, wound care dressings, ostomy pouches, and hearing aids.
- If imposed on certain Class I devices, any tax or fee based on sales would likely be passed on directly to patients and could have a significantly negative impact on patient care quality. For example, the majority of hearing aid sales (72%) are not paid for by insurance, but are paid for by individuals as an out of pocket expense. Any tax will drive up costs to these patients, regardless of whether they had medical insurance under previous plans or new plans created by the legislation.
- Many Class I devices are low margin products. Any significant tax or fee could be higher than profit margins, which are often 1% or less. Imposing this tax or fee based on sales of such products would be highly regressive when appropriately viewed in the context of relative profitability.

As you continue your debate in the Senate, we urge you to resist making any changes to the class I medical device fee exemption. We also respectfully request that the Senate medical device tax language with the Class I exemption be adopted, along with the House or Senate retail sales exemption, when the legislation is considered in conference.

Sincerely,

Academy of Doctors of Audiology
Adenna
Alexander Graham Bell Association for the
Deaf and Hard of Hearing
American Academy of Audiology
American Academy of Otolaryngology –
Head and Neck Surgery
American Speech-Language-Hearing
Association
American Tinnitus Association
Coloplast
ConvaTec Inc.
Dental Trade Alliance
Healthcare Distribution Management
Association
Health Industry Distributors Association
Hearing Industries Association
Hill-Rom

International Hearing Society
3M
National Association for the Support of
Long Term Care
PSS World Medical, Inc
Smith & Nephew
Welch Allyn