October 25, 2011

Secretary Kathleen Sebelius
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Sebelius:

We are writing to urge you to fully implement Section 1128G of the Social Security Act, the Physician Payments Sunshine Provision, which was added as Section 6002 of the Patient Protection and Affordable Care Act (PPACA).

This provision requires that manufacturers of drugs, devices, biologics or medical supplies, or their subsidiaries that sell these products in the United States, report to Health and Human Services (HHS) certain payments made to physicians and teaching hospitals. It reflects the recommendation by major medical, consumer and industry groups, as well as MedPAC and the Institute of Medicine, that Congress pass federal legislation to bring transparency to the financial relationships between pharmaceutical and medical device companies, and health professionals and teaching hospitals.

This federal transparency provision has support from diverse stakeholders, including consumer and patient groups, professional medical associations, provider organizations, and industry.

As you move forward to implement this provision, we ask you to work quickly. The legislation required HHS to establish, by October 1, 2011, reporting procedures for applicable manufacturers to submit information to you, as well as procedures for making such information available to the public.

We also request that HHS follows the requirement in the law to engage stakeholders and allow public comment on any procedures established related to the submission and public reporting of information under Section 6002 of PPACA. The law states that the Secretary is required to "consult with the Inspector General, affected industry, consumers, consumer advocates and other interested parties to ensure that the information made available to the public is presented in the appropriate context."

Many companies have already invested significant resources in preparing to comply with the Sunshine provision. To comply with the law, covered entities must begin to collect the information required by Section 6002 of PPACA beginning January 1, 2012. They must submit to HHS the required information on March 31, 2013. However, delays in establishing procedures for the submission and public reporting of the required information will make it increasingly challenging for manufacturers to know whether they are meeting their statutory obligation as they begin to collect data in 2012. Given that Congress intended that industry have three months to complete implementation based on the government procedures following the

October 1, 2011 statutory date to implement the new provisions, we request that a similar time period be permitted following establishment of final procedures for the submission and public reporting of 2012 information for companies to achieve full compliance. An absence of established procedures could harm both the companies who are trying to comply with the law and the public who stands to benefit from increased transparency of these relationships.

This provision had bipartisan champions in Congress and has the support of both consumer groups and industry. Full implementation of this law will protect patients and help restore trust in our health care system.

Sincerely,

Advanced Medical Technology Association (AdvaMed)
Biotechnology Industry Organization (BIO)
Community Catalyst (CC)
Consumers Union (CU)
Medical Imaging & Technology Alliance (MITA)
Pew Health Group (PHG)
Pharmaceutical Research and Manufacturers of America (PhRMA)

cc: Donald M. Berwick, MD, MPP, CMS Administrator