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United States Senate

COMMITTEE ON THE JUDICIARY
WASHINGTON, DC 20510-6275

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January 22, 2013

VIA ELECTRONIC TRANSMISSION

The Honorable Jacob Lew
Chief of Staff to the President of the United States
The White House
1600 Pennsylvania Avenue NW
Washington, DC 20500

Dear Mr. Lew:

As a strong proponent of transparent financial relationships between doctors and pharmaceutical and medical device companies, I write today to express my disappointment that the administration continues to delay implementation of the Physician Payments Sunshine Act (Sunshine Act), which Congress passed in March 2010 as part of the Patient Protection and Affordable Care Act.

While many interactions between medical professionals and the pharmaceutical and medical device industry are vital to the advancement of medical science and patient care, the Sunshine Act was developed after numerous investigations and hearings revealed that large sums of money were going to physicians for questionable purposes. Some of these payments were the subject of a federal criminal inquiry resulting in more than \$300 million in fines and legal costs paid by the major orthopedic medical device manufacturers.¹ Ultimately, Congress passed the Sunshine Act in response to growing concerns over industry payments to physicians and their potential negative effects on patient care and efforts to restrain healthcare costs, as evidenced by a growing body of research.

This month, a journal of the American Medical Association published a study that found doctors who received food, drinks or drug samples from pharmaceutical manufacturers were more likely to prescribe brand-name drugs over generic equivalents than doctors who received no such incentives. According to the authors, "certain physician-industry relationships were significantly, positively associated with accommodating patient requests for brand names. Physicians who received industry-

¹ Barnaby J. Feder, "U.S. Settles With Hip and Knee Makers," New York Times, Sept. 27, 2007.

provided food and/or beverages in the workplace and samples were significantly more likely to accede to patient demands for brand-name drugs. Also, physicians who meet with industry representatives to stay up to date are more likely to give in to patient requests for brand names. These findings are likely the result of the fact that industry gifting of food and beverages coincides with ‘up-to-date meetings’ with drug representatives; thus, these factors work together to increase the likelihood that physicians will prescribe a brand name and clearly serve a marketing function.”²

The Sunshine Act required that CMS release final regulations by Oct. 1, 2011, so that pharmaceutical and medical device manufacturers could begin collecting payment data by Jan. 1, 2012, and submitting data to the Department of Health and Human Services by Mar. 31, 2013. Congress designed the law so that the data would be publicly available by Sept. 30, 2013. Unfortunately, the final regulations are now more than **15 months overdue**. At best, the public may miss an entire year’s worth of data collection—perhaps more. This is unacceptable.

These delays are disrupting the considerable efforts of the pharmaceutical and medical device manufacturers that are already investing in systems to comply with the law, as well as voluntary efforts of universities and even the National Institutes of Health to promote more transparent relationships between physicians and industry.

I urge you to release these final rules without further delay. If the regulations are not going to be released by January 24, 2013, then please provide a date by which they will be issued and an explanation for the delay. Should you have any questions regarding this letter, please contact Erika Smith of the Judiciary Committee at (202) 224-5225.

Sincerely,



Charles E. Grassley
Ranking Member
Committee on the Judiciary

² Campbell EG, Pham-Kanter G, Vogeli C, Iezzoni LI. Physician Acquiescence to Patient Demands for Brand-Name Drugs: Results of a National Survey of Physicians. JAMA Intern Med. 2013;():1-3. doi:10.1001/jamainternmed.2013.1539. <http://archinte.jamanetwork.com/article.aspx?articleid=1555818>