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2009 SUNSHINE ACT REFLECTS CONGRESSIONAL INTENT TO REGULATE DRUG, DEVICE INDUSTRY AGGRESSIVELY

Congress has renewed its efforts to require public disclosure of the financial relationships that drug and device manufacturers have with physicians. Senators Charles Grassley (R-Iowa) and Herb Kohl (D-Wisconsin) recently introduced the Physician Payments Sunshine Act of 2009 ("2009 Sunshine Act"). The 2009 Sunshine Act calls for manufacturers to report annually to the U.S. Department of Health and Human Services ("HHS") payments to physicians that exceed $100 per year. As introduced, the 2009 Sunshine Act reverses course on concessions that the drug and device industry had negotiated into past versions of similar legislation and, by doing so, signals a greater willingness by the new Congress to confront perceived abuses in the drug and device industry through aggressive regulation.

2009 SUNSHINE ACT WOULD MANDATE PUBLIC DISCLOSURE OF PHYSICIAN TIES

The 2009 Sunshine Act would require manufacturers of any drug, device, biological, or medical supply that is eligible for Medicare, Medicaid, or SCHIP coverage to report annually, beginning March 31, 2011, any payment or other transfer of value to a physician, medical practice, or group practice that exceeds $100 per year. HHS would then be required to make all of the reported information available over the internet in a user-friendly, searchable format. Manufacturers would face fines ranging from $1,000 to $10,000 for each payment that is not reported (up to $150,000 annually), and, if a manufacturer were found to have knowingly violated its reporting requirements, it would incur penalties of $10,000 to $100,000 for each payment not reported (up to $1 million annually).

The 2009 Sunshine Act defines payment broadly to include one or more transfers having an aggregate value of more than $100 per year, including everything from meals, entertainment, and travel expenses to consulting fees, honoraria, and profit distributions. Notably, manufacturers would not need to report educational materials that directly benefit patients, product samples for patient use that may not be sold, or in-kind contributions used for charity care.

Additionally, under the proposed legislation, manufacturers would be allowed to delay reporting payments made pursuant to a product development agreement for services provided in conjunction with the development of a new drug, device, biological, or medical supply or in connection with a clinical trial. In these instances, a manufacturer could delay reporting the financial relationship until the first report after FDA approval or two years, whichever is earlier.

Reports filed by manufacturers under the 2009 Sunshine Act would need to include information, such as:

- The name of the physician, medical practice, or group practice that received the payment.
- The recipient's business address.
- The value of the payment.
- The date(s) on which the payment was made.
- The form of payment, such as cash or cash equivalent; in-kind items or services; or stock, stock options, or any other ownership interest, dividend, or profit.
- The nature of the payment, such as whether it was a consulting fee, honoraria, food, travel, education, research, royalty, or license or ownership interest.
- The name of the drug, device, biological, or medical supply if the payment is related to a specific drug, device, biological, or medical supply.

The 2009 Sunshine Act would also require manufacturers and group purchasing organizations to report ownership or investment interests held by physicians or their immediate family members (other than those interests in the form of publicly traded securities or mutual funds).

2009 SUNSHINE ACT DIFFERS SIGNIFICANTLY FROM PAST DISCLOSURE LEGISLATION

Congress first addressed the disclosure of the financial relationships between drug and device manufacturers and physicians when it considered the Physician Payments Sunshine Act of 2007. Throughout 2008, the passage of that prior legislation appeared increasingly likely as drug and device manufacturers secured key concessions from Congress aimed at preempting state disclosure laws and limiting the number and scope of required reports. As noted, the 2009 Sunshine Act significantly modifies, if not eliminates, many of these earlier concessions.

Most importantly, the 2009 Sunshine Act backs away from the preemption provision that the industry had secured in past drafts of disclosure legislation. In May 2008, a working draft of the 2007 legislation was released that broadly preempted state disclosure requirements, such as those adopted by Massachusetts, Minnesota, and other states. As introduced, the 2009 Sunshine Act only preempts duplicate state reporting requirements but allows states to impose additional reporting obligations on drug and device manufacturers. This means that drug and device manufacturers will likely have to develop compliance systems for a hodgepodge of potentially contradictory state and federal reporting requirements.

Additionally, the 2009 Sunshine Act does not limit its applicability to large-scale manufacturers. Under the 2007 legislation, manufacturers with $100 million or less in annual sales had no reporting obligations. As drafted, the 2009 Sunshine Act's reporting requirements would extend to any entity engaged in the "production, preparation, propagation, compounding, conversion, processing, marketing or distribution of a … drug, device, biological or medical supply" and any subsidiary or affiliate of such an entity. Similarly, the 2007 legislation imposed no reporting requirements on aggregate payments to a physician of less than $500. The 2009 Sunshine Act lowers this threshold to $100.

SUNSHINE ACT DOES NOT PROHIBIT PAYMENT ARRANGEMENTS

The 2009 Sunshine Act does not prohibit any specific type of payment that a drug or device manufacturer may make to physicians. The 2009 Sunshine Act merely establishes minimum disclosure requirements that would bring into

public view the marketing practices and financial relationships of drug and device manufacturers. The significance of these disclosure requirements will likely differ based on who examines the required reports. Hospitals and other organizations that employ physicians may find the reports useful in monitoring potential conflicts of interest that may interfere with their missions or a physician's independent medical judgment. Members of the media will likely find the reports noteworthy as well for purposes of writing about perceived conflicts of interest among local physicians.

Review of these financial relationships by state and federal law enforcement agencies, however, may result in much more than a damaged reputation. The reports will almost certainly be scrutinized for potential violations of federal and state anti-kickback statutes, false claims acts, and other laws having far-ranging civil and criminal penalties. For example, in 2008, the U.S. Department of Justice reported that it had recovered more than $694 million by settling allegations of illegal incentives and improper conduct by just one device manufacturer and two pharmaceutical companies. If passed, the 2009 Sunshine Act would arm investigators with greater access to information about potentially problematic financial relationships and may provide investigators with a head start in pursuing charges for alleged misconduct.

2009 SUNSHINE ACT IMPOSES SIGNIFICANT COMPLIANCE BURDEN

Drug and device manufacturers will likely incur significant compliance costs if the more rigorous disclosure requirements of the 2009 Sunshine Act are adopted in their present form. The $100 reporting threshold, together with the absence of a broad preemption provision and the difficulty of valuing non-monetary items and services, will require the development of comprehensive reporting policies for geographically diverse work forces, work force training relating to the policies, and sophisticated processes for monitoring compliance. Adhering to voluntary codes of conduct that the industry has developed may alleviate this compliance burden. In December 2008, AdvaMed announced that its board of directors had approved a significantly revised code of ethics regulating relationships between its members and health care professionals. The revised code, among other items, prohibits providing entertainment or recreation to health care providers, establishes guidelines for its members to follow in developing royalty arrangements, and provides greater clarity and guidance regarding consulting agreements. (For more information on the revised AdvaMed code of ethics, see Frank E. Sheeder, III, and Keri L. Tonn, *AdvaMed's Revised Code of Ethics on Interactions with Health Care Professionals Scheduled to Be Effective July 1, 2009*, which is available at http://www.jonesday.com).

The significance of the 2009 Sunshine Act for drug and device manufacturers likely extends beyond its reporting requirements. The reversal of many provisions in the 2009 Sunshine Act that the drug and device industry found favorable in prior versions reflect a desire by the new Congress to regulate the drug and device industry more aggressively. The next phase of this more aggressive regulation may be increased attention to proposals to ban certain financial relationships entirely, monitor consumer advertising more closely, impose stricter regulatory approval processes for drugs and devices, or create federally funded academic detailing programs.

The 2009 Sunshine Act has been referred to the U.S. Senate Finance Committee, which has not yet scheduled any hearings on the legislation. Observers, however, believe that the 2009 Sunshine Act will likely pass on its own or as part of Medicare reform legislation that is anticipated later this year.

LAWYER CONTACTS

For further information, please contact your principal Firm representative or one of the lawyers listed below. General email messages may be sent using our "Contact Us" form, which can be found at www.jonesday.com.

Stephen G. Sozio
Cleveland
1.216.586.7201
sgsozio@jonesday.com

Frank E. Sheeder III
Dallas
1.214.969.2900
fesheeder@jonesday.com

R. Christopher Cook
Washington
1.202.879.3734
christophercook@jonesday.com

Heather M. O'Shea
Chicago
1.312.269.4009
hoshea@jonesday.com

Toni-Ann Citera
New York
1.212.326.8376
tcitera@jonesday.com

Travis F. Jackson
Columbus
1.614.281.3833
tfjackson@jonesday.com