From: Jeannette Barrett
To: Jennifer Altier
Sent: 9/27/2012 9:28:59 AM
Subject: Fw: APS Corporate Member Advisory Meeting Agenda
Attachments: 12 advisory meeting agendaFinal.pdf; 12-APS Adv Mtg List Participants-Staff.pdf; Physician Payment Sunshine Act.pdf

Jeannette A. Barrett, PhD
Sr. Medical Dir, Actavis
Sent from blackberry, please forgive typos!

From: Heather Deja [mailto:hdeja@ampainsoc.org]
Sent: Wednesday, September 19, 2012 05:52 PM
To: Randi Romanek <RRomanek@Connect2amc.com>
Cc: Heather Deja <HDeja@Connect2amc.com>
Subject: APS Corporate Member Advisory Meeting Agenda

Hello APS Executive Committee Members and APS Corporate Members:

We have received a good response for the upcoming APS Corporate Member Advisory Meeting. Currently there will be 7 companies represented at this meeting. Also in attendance will be the APS executive committee and the APS management staff. The meeting will be professionally facilitated by Terri Theisen of Theisen Consulting, LLC.

The meeting will take place on Thursday, September 27, 2012 from 10 am to 3:30 pm in the Yeager & Wright room of the Hilton Rosemont/Chicago O'Hare, 5550 North River Road, Rosemont, IL 60018. Attached is the participant list, the meeting agenda and a document regarding the Physician Payment Sunshine Act that we would like you to review before the meeting. Please note the program will begin at 10:30 am.

If your plans have changed and you can no longer attend the meeting, please let us know immediately. If you have not responded regarding your attendance please let us know immediately. Please respond to Heather Deja by email hdeja@ampainsoc.org or phone at 847/375-3676.

We look forward to seeing you.

Sincerely,

Randi

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American Pain Society
RESEARCH
EDUCATION
TREATMENT
ADVOCACY

American Pain Society
Planning Session
September 27, 2012
10:30 AM – 3:30 PM
Hilton Rosemont

Meeting Purpose

- *To review and assess the relationship between the American Pain Society and the corporate members;*
- *To identify collaborative opportunities and overlapping interests with the corporate members of the American Pain Society;*
- *To discuss governmental and regulatory changes that affect us all; and*
- *To determine the best ways to work together in the future.*

AGENDA

10:30 – 10:50 AM Welcome & *State of Society* Address/Review of Materials

Roger Fillingim, Ph.D., President

10:50 – 11:00 AM Agenda Overview & Charge for the Day

Terri Theisen, Theisen Consulting LLC
Facilitator

11:00 – 1130 AM Overview of the 2011 IOM Report…*Relieving Pain in America*

Charles Inturrisi, PhD, Past President and IOM Committee Member

11:30 – 11:50 Putting Recommendations into Action
Group Discussion:
Based on the strategic activities of APS the and the recommendations of the IOM report (reviewed this morning),

- *Which initiatives offer the best opportunities going forward?*
- *What are the steps that you feel corporate member companies can take to put the recommendations into action?*
- *How do you, as a corporate member, see yourself working with nonprofits such as APS? What would you like to see accomplished during the next 1-3 years by working together?*

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11:50 – 12:30	Groups Report Back on Their Pre-Lunch Discussion: Opportunities for Working Together *Small groups report back on their conversations.*
12:30 – 1:15 PM	Lunch
1:15 – 2:00 PM	What impact will the implementation of the Sunshine Act have our relationship in the future? *Group Discussion:* • *How should APS work with your companies?* • *Will we need to work differently and how will that look?* • *What do you need from APS to continue working with and supporting the organization?*
2:00 – 2:15 PM	Break
2:15 – 3:00 PM	Groups Report Back/Discussion & Agreement *Each group presents its recommendations from the previous discussion; those recommendations are noted, and consensus developed through facilitation.*
3:00 – 3:25 PM	Summary of Today's Work/Next Steps
3:25 – 3:30 PM	Closing Remarks & Thanks

American Pain Society

RESEARCH
EDUCATION
TREATMENT
ADVOCACY

APS Corporate Member Advisory Meeting
Thursday, September 27, 2012
Hilton Rosemont/Chicago O'Hare
Rosemont, IL

Meeting Participant List

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Physician Payment Sunshine Act: Senate Special Committee on Aging Roundtable "Let the Sunshine in: Implementing the Physician Payment

Sunshine Act" Posted: 13 Sep 2012 03:47 AM PD

The U.S. Senate Special Committee on Aging held a roundtable discussion entitled, "**Let the Sunshine in: Implementing the Physician Payments Sunshine Act**." As we have written many times over the last four years, the Physician Payment Sunshine Act (Sunshine Act)—Section 6002 of the Affordable Care Act (ACA)—requires public disclosure of the financial relationships between physicians and applicable manufacturers, including pharmaceutical, medical device and biologics companies.

The law also required the Department of Health and Human Services (HHS) to establish reporting procedures for manufacturers to submit information, as well as procedures for making that information available to the public, by October 1, 2011. While the Centers for Medicare and Medicaid Services (CMS) issued a **proposed rule** in December 2011, the law has yet to be implemented.

The roundtable was moderated by Dr. Mark McClellan, Director, Engelberg Center for Health Care Reform at the Brookings Institution, and former CMS Administration and Commissioner of the Food and Drug Administration. Senators Charles Grassley (R-IA) and Chairman of the Aging Committee **Herb Kohl** (D-WI)—co-authors of the Sunshine Act—made opening remarks. Senator Richard Blumenthal (D-CT) also made comments. While the CMS representative was in attendance, he not able to give substantive comment on the finalization of the rule—frequently noting he could not speak on a particular area or timeline. Other round table members and their written statements included:

Diane Biagianti, Vice President, Chief Responsibility Officer, Edwards Lifesciences, Irvine, CA

Niall Brennan, Director, Policy and Data Analysis Group, Centers for Medicare and Medicaid Services, Washington, DC

Daniel Carlat, MD, Project Director, Pew Charitable Trusts, Washington, DC

Jeremy Lazarus, MD, President, American Medical Association, Washington, DC

Elizabeth O'Farrell, Senior Vice President, Policy and Finance Eli Lilly & Company, Indianapolis, IN

Douglas Peddicord, Ph.D., Executive Director, Association of Clinical Research Association (ACRO), Washington, DC

Charles Rosen, MD, Clinical Professor of Orthopedic Surgery, University of California, Irvine School of Medicine, Orange, CA

James H. Scully, Jr., MD, Medical Director and CEO, American Psychiatric Association, Arlington, VA

Both Kohl and Grassley expressed their disappointment that almost one year after the statutory deadline to implement the Sunshine Act, and over two years since the passage of the ACA, CMS has still not issued a finalized rule. They both expressed reaching out to CMS numerous times over the past year get a timeline for implementation for CMS, which has said it expects a final rule by the end of the year.

Interestingly, Grassley expressed concern that "rumors" indicated that the rule was final, and that the Office of Management and Budget (OMB), which must review all regulations before they can be finalized, is stalling the rule until after the presidential election. Grassley expressed his frustration, and noted the consequences the delay was having on industry and consumers due to the lack of guidance. He recognized how companies need to buy and implement systems to track payments, train their employees, and ensure proper use of such systems.

Kohl noted that the bill was "never meant to be burdensome." However, consumers and manufacturers have been left "in the dark" without a final rule. Accordingly Kohl and Grassley urged CMS to finish the rules "and ensure that the definitions and guidelines are clear and workable for industry and patients alike … and the information is available to the public … easily understood, and provide[d with] enough context for patients to understand why their doctors' names appear on this website.

One interesting exchange happened when Senator Blumenthal asked if CMS could specifically reaffirm the time line for implementation of the bill including the date of data collection. CMS acknowledged that this was a difficult question to answer as they were still in the clearance process, but they were hopeful that some data collection will occur in 2013. Senator Blumenthal was not pleased with the use of the word hope and was encouraging CMS to provide more certainty.

Consequently, Dr. McClellan focused the hearing on several major areas of concern:

1. Continuing medical education (CME)
2. Payments for direct and indirect research
3. Indirect payments/third party payments
4. Implementation
5. Public reporting, online website
6. Process for resolving payment reporting disputes between manufacturers and doctors

Continuing Medical Education (CME)

As they acknowledged, CMS received numerous comments regarding CME and the impact the Sunshine Act may have on CME stakeholders. **American Medical Association (AMA) President Jeremy A. Lazarus, MD**, provided substantial comments indicating AMA's support for excluding certified CME payments from Sunshine Act reporting. He noted that CMS's proposed inclusion of certified CME is inappropriate because "the statutory language does not support such an interpretation."

With respect to CME, Lazaurs noted how AMA's House of Delegates adopted an ethics policy on Financial Relationships with Industry in CME proposed by AMA's Council on Ethical and Judicial Affairs (CEJA), which identifies the core ethical principles of transparency, independence, and accountability. The policy provides practical ethical guidance to maintain the independence and integrity of continuing professional education and promote public trust.

The AMA agreed that other educational activities including those that are characterized as CME (but which are not certified) could be subject to reporting as there could be direct transfers of value to individual physicians and industry could control and/or influence the content of the educational materials. He explained, however, that certified CME is independent and manufacturers have no control or input into the content, the speakers, slides or the attendees. In light of the foregoing, the AMA asserted that **certified CME is not covered by the Sunshine Act and CMS should make this clear.**

Of interest, AMA noted that previous versions of the Sunshine Act, actually required reporting on CME or other educational programs. Accordingly, because the statute does not include a reference to CME, AMA argued that the statutory language is clear "and certified CME does not involve transfers that trigger reporting."

On a similar note, **Eli Lilly** maintained that indirect payments—which CME would fall under—be reportable only when the applicable manufacturer controls or influences the selection of the covered recipients engaged by the third party. Lilly noted that requiring such third party payment reporting based on CMS' proposed standard would "require substantial changes in its existing processes to achieve." Further, "such an expanded approach would challenge the independence of third parties and their justifiable interest in protecting their own dealings and compensation arrangements as proprietary and confidential."

Only one panel member—Dr. Charles Rosen, Clinical Professor of Orthopedic Surgery, University of California, Irvine School of Medicine was against the idea of exempting certified or accredited CME from reporting. Dr. Rosen, however, seemed to have a misunderstanding of the accredited CME process for accredited providers that receive grants or support from pharmaceutical and device manufacturers. In fact, Dr. Rosen repeatedly referred to the entity as the ACGME instead of the Accreditation Council for

Continuing Medical Education (ACCME) not graduate medical education.

Nevertheless, the strong support offered by the AMA, and the agreement among other panel members—including the lack of any other real objection to a certified CME exemption—demonstrated a clear consensus that certified CME is beyond the intent of Congress and the scope of the Sunshine Act.

45-Day Review, Dispute Resolution

AMA expressed its concern that the proposed rule does not require manufacturers to provide physicians with the option of an ongoing opportunity to check reports nor does it indicate that the agency or some other independent third party will arbitrate disputes between physicians and manufacturers. They were also concerned with having only the 45-window once a year to challenge reports. AMA noted that 45 days is a minimum, and that when disputes occur, Congress showed no intent that such disputed payments still be reported in the same time frame. As a result, AMA maintained that the proposed rule would deny physicians substantive and procedural due process rights.

Instead, AMA asked that CMS provide physicians with ongoing access to reports to make modifications and establish a neutral arbiter to resolve disputes. AMA's concern was that inaccurate reporting could mislead people, leading to government investigations, disciplinary actions, and other adverse consequences to physicians.

Covered Recipient Notification/Preview: Under Edwards Lifesciences' voluntary disclosure program, we provide physicians with reasonable notice and a preview of the information we plan to publish on our website. This gives them a better understanding of the process, sets their expectations so that they can respond to patient inquiries, and provides them an opportunity to verify our data. CMS's draft regulation appropriately contemplates the need for a dispute resolution process prior to publication by CMS, and we believe that providing a minimum amount of time for a reasonable "back-and-forth" between the manufacturer and physician is necessary once CMS makes the data available to physicians.

Accurate Attribution, Meals

AMA and several others took issue with CMS' proposal to attribute a transfer of value/payment to a physician even when a physician did not receive value directly (and even in some instances indirectly) based on employment, affiliation, or association with an entity or person that did receive a direct transfer. AMA noted, however, that the Sunshine Act provides for actual transfers of value to a covered physician, not estimates. CMS' proposal to apportion payments among physicians in the organization or institution could result in grossly misleading reporting.

Physicians employed by a large organization or institution could have funding and transfers imputed to their report that they cannot reject, did not receive directly (or even indirectly), and for which they have no knowledge so they are unable to effectively challenge it. AMA also strongly opposed CMS' proposal to

attribute to a physician transfers of value or payment that are made to other individuals where the physician personally did not request the transfer, it was not designated on their behalf, and they did not receive it.

In particular, this issue was addressed regarding the provisions of meals or food. Lilly maintained that the meal allocation methodology in the proposed rule is unworkable and inappropriate in several ways:

(1) It would require applicable manufacturers to undertake the operationally unmanageable task of identifying and attributing value to physicians that do not partake in a meal but are employed by or associated with a group practice or department;

(2) It would require allocation of meal expenses to physicians with whom the applicable manufacturer does not actually interact (and may be legally restricted from interacting); and

(3) It would force attribution to physicians and/or teaching hospitals of meal value provided to non-physician employees, functionally broa-dening the statutory definition of "covered recipient."

Lilly asserted that the final rule should not force manufacturers to attribute value to anyone who does not actually receive a meal because it is factually inaccurate and therefore misleading and will result in disputes and confusion regarding the reliability and accuracy of the reported data. Further, "requiring manufacturers to identify affiliations and employment relationships for persons attending business meals adds an inordinate level of complexity in record keeping and related processes, which will substantially increase the burden and cost relative to the added benefits of these incremental disclosures. Finally, flexibility will be necessary to address variables such as opt-outs, excess food, and no-shows."

Implementation

Diane Biagianti, Vice President and Chief Responsibility Officer Edwards Lifesciences Corporation, expressed her concern about implementing the Sunshine Act, noting that it took over 6 months to revamp and automate their systems, processes and procedures to meet the requirements under the law. She also noted that it may also take several months to adjust their current reporting systems – and launch an effective employee training program – if they have not guessed properly on what CMS will require.

She recognized that other manufacturers, who may not have their own voluntary program or the resources to implement fully in anticipation of the final regulations, may not be in as enviable position as Edwards in terms of preparation. Biagianti noted that a majority of medical device companies in the U.S. are small to midsized businesses that are less likely to have the resources to do this quickly.

As the first medical device company to implement such a program on a voluntary basis, she noted how Edwards was "challenged to develop the policies that would apply to our own reporting program, to develop the systems and processes to manage the data, and to work out discrepancies in the unexpected

situations that can sometimes arise through the normal course of business."

While Edwards was able to build and test their system for compliance, she noted how the company is "not as large and complex compared to some others." Nevertheless, she explained how Edwards still had to "develop systems to merge data from different financial reporting systems around the world to ensure that if any of our global operations incur an expense related to a U.S. physician, we are able to accurately capture and report that information." On this point, she noted the difficulty of reporting and aggregating without a unique indemnification number for each physician. As a result, she recommended that CMS should publish a list of unique identification numbers for teaching hospitals and physicians.

Although it was pointed out that a recent survey of industry executives said they were somewhat ready with implementing the Sunshine Act, this survey may have little value given that such comments were based off the proposed rule and much is likely to change between now and the finalized version.

Identifying Covered Recipients

Concern was also expressed about accurately capturing transfers of value to third parties "*At the request of or designated on behalf of. . .*" covered recipients. For example, individual clinicians may set up or work for small businesses that manage the financial transactions related to their consulting arrangements. Sometimes these businesses have names that provide data managers with little indication of any association with a physician (e.g., "Pinetree, LLC"). Even with aggressive employee training and education, it can be very challenging to identify every construct that could be used to manage a physician practice. Moreover, it is generally unknown by a medical device company how much, if any, of the compensation paid to the entity is received by the physician.

In the interest of time, it was recommended that CMS take the approach proposed by AdvaMed: where a transfer of value is reportable to the Internal Revenue Service as gross income attributed to a covered recipient by the medical device company, it should qualify for reporting by that company under the Sunshine provisions. In his written comments, **Daniel Carlat, MD**, Director of the Prescription Project for Pew Charitable Trusts, said that such an approach "allows for a possible scenario in which physicians could deliberately create LLCs or other entities so that the payments would be reported under a corporate name, as a way of avoiding disclosure under their own names."

Context of Payments

Many panel members also emphasized the importance of manufacturers being able to provide ample opportunity to voluntarily provide meaningful context surrounding a transfer of value. For example, information regarding the contribution an expert physician provided to a research project related to a disease she is uniquely familiar with could be very valuable to a patient's understanding of that physician's clinical capabilities. Some suggested including different web pages for research payments so

the public understood the context more.

Research Payments – Direct and Indirect

Douglas Peddicord, Ph.D., Executive Director, Association of Clinical Research Association (ACRO), Washington, DC, spoke primarily about the reporting of research payments. He expressed his concern about research payment reporting by noting that 24% of doctors in the U.S. who conduct clinical research would be less likely to participate in the research if revenues (not revenues in excess of expenses or "profits" but gross revenues which is what CMS's proposed rule requires) were disclosed, according to a 2010 survey. Losing this many researchers will slow innovation and delay the delivery of needed treatments for patients.

In contract research organizations (CROs), nearly all payments made to physicians and teaching hospitals on behalf of applicable manufacturers are "pass-throughs" for research; that is, the conduct of clinical trials. On average, CROs work with more than 500 research sponsors – applicable manufacturers – annually. Payments can be made for basic research activities – for screening and recruiting patients, for engaging with the individual in the informed consent process, for administering test articles and monitoring patient reactions, for performing medical procedures, record-keeping and data submission, and the myriad activities involved in following a research protocol that is meant to produce accurate data for the evaluation of the safety and efficacy of a new drug, biologic or medical device by the FDA and other regulators.

ACRO pointed to many inconsistencies with CMS' proposal to report direct and indirect research payments, and urged CMS to exclude indirect payments from reporting. While the Act requires reporting indirect payments and transfers that are made to a third party at the request of the physician or designated on behalf of the physician, "many payments related to research, such as travel and food costs, are not made at the request of a covered recipient or designated on behalf of a covered recipient, but are entirely incidental and thus, not reportable under the Act."

Instead, ACRO a standard for research payments or transfers of value that provides that in instances where a manufacturer (or CRO on its behalf) does not know the value of specific payments or imputed benefits that are presumed to flow to individual covered recipients and the payment or transfer is not made at the request of a covered recipient or designated on behalf of a covered recipient, such payments or transfers are not reportable. To illustrate, to the extent that a manufacturer's visibility into payments for research stops at the physician practice group or teaching hospital – and does not continue down to the specific dollar amount (whether gross or net 'payment') that ultimately flows to investigator A or B or C, the report that should be made to the Department by the manufacturer is of the total amount paid to covered recipients and there should not be any further effort required to derive or impute sub-amounts or divisions among physician recipients, to the extent that the manufacturer is not aware of those payments

or transfers of value today.

ACRO also recognized the tremendous compliance burden regarding tracing research payments, not only for manufacturers but on the physicians and hospitals who would be asked to report back to manufacturers the distribution of both direct and indirect payments to-the-penny, because that is the level of transparency that manufacturers will now believe they must have. ACRO noted that CMS clearly underestimated the costs of dealing with such compliance and that the proposed rule "would force physicians to function as accountants or auditors to verify financial information that has nothing to do with the delivery of care or conduct of research within a medical practice or hospital."

ACRO also maintained that for research, all payments and transfers of value associated with a research project should be aggregated under the category of research, even if some of the transfers of value come in the form of food, travel, equipment, and the like—arguing against the "nature of payment" segregable categories. Simply, if a payment or transfer of value occurs incidentally to a research project, the transfer of value would not occur at all absent the physician's participation in the research project. Thus, to the extent that such payments or transfers are tracked to specific covered recipients, "the travel, food and other costs should be reported as research payments."

ACRO made an important point about bundling such payments: for those researchers whose payments would be delayed for four years, it would be misleading and inconsistent with the intent of the law to publish travel payments for researchers who's other payments for research would not be published. ACRO was also concerned about the potential for double and even triple counting of research payments that flow "directly" to teaching hospitals and "indirectly" to intermediary organizations and then "indirectly" again down to physician investigators.

In addition, ACRO recommended that physicians who are employees of a CRO or who provide research services on a contract basis to a CRO should be excluded similar to how physician employees of applicable manufacturers are excluded. Thus, ACRO proposed the following: "Any physician, except for a physician who is an employee... of an applicable manufacturer, or in the case of payments or transfers of value for research, an employee of or a person who provides research services on a contract basis to a CRO entity."

Finally, ACRO reaffirmed is position that fair-market payments made for legitimate research activities should have been excluded from the provisions of Section 6002. They pointed to several state sunshine laws with such requirements for payments for bona fide research activities.

The final rule should allow at least 180 days from publication until the commencement of data collection.

Lilly recommended that the final rule provide applicable manufacturers with at least 180 days to

implement the final rule, noting that it took up to 23 months to file its first full quarterly publication, as well as modifications that would need to be made to comply with the Sunshine Act. Lilly noted a series of necessary steps required to implement any change to business processes: first the requirements must be clearly defined (which cannot occur until the final regulation is issued), then the requirements must be translated into required changes on various impacted processes, then those required changes need to be built into documented procedures and configured into IT systems, then those modified IT systems must be tested and validated to ensure they do what they are supposed to do, then the people who use those procedures and systems must be trained. Each and all of these steps must occur and must occur in linear order to effect the required changes. Consequently, the more the final rule requires changes to the business and IT system rules already in place, the more complex the implementation implications for manufacturers and the more lead time that necessarily will be required.

Phased Approach

Lilly urged CMS to look at the phased implementation of Lilly's corporate integrity agreement (CIA) requirements and consider a three phase approach to enable manufacturers and CMS to manage the complexity of data collection and reporting in a more measured and controlled manner and to reduce the risk of error or incomplete reporting.

Phase I, for which data collection could commence in early 2013, could include all direct payments from manufacturers to physicians and teaching hospitals. These direct payment data are the most readily identifiable and accessible in most company systems. It was recommended that Phase 1 direct payments not include payments for research made to CROs or payments to reimburse expenses as the processes needed enable detailed reporting of these payments do not usually exist. This would cover about 70% of all payments.

Phase II could reasonably commence 6-12 months later and could include all reimbursed expenses as well as any indirect research payments made by CROs. Reimbursed expenses are suggested to be separated from Phase I because reporting of such expenses will likely require modifications to billing and invoicing practices, expense re-categorization to align to Sunshine Act definitions and requirements, and modifying IT systems to ensure that elements of such reimbursements get reported under the proper categories with the proper associated level of detail, all as dictated by the yet-to-be-issued final rule. By the end of Phase II, there could be over 90% visibility into disclosure required under the Sunshine Act.

Finally, Phase III could commence 12-18 months after Phase I and would complete the Sunshine Act reporting requirements by adding disclosure of any non-cash transfers of value. Non-cash transfers of value would include transfers such as business meals, travel and educational materials for physician benefit. Importantly, these non-cash value transfers represent a very small percentage of total value transfers to be reported under the Sunshine Act. Specifically, for Lilly, in 2011, of all the value reported on Lilly's payment registry, only 8% represented non-cash value. On the other hand, to capture this data

for such reporting requires significant business process modifications. For instance, for some non-cash items, new processes will be required to first assign a market value, then to record the distribution at the individual recipient level, and to train personnel to identify situations where such capture is required.

Patient Materials

The Sunshine Act expressly excludes educational materials intended for patient use from reporting. In the proposed rule, however, CMS states that this exclusion is limited to written or electronic materials and does not include services or other items. CMS's interpretation of the statutory exclusion for educational materials is unnecessarily restrictive, and as a result, Lilly expressed concerne that the continued availability of patient-centered programs and services (e.g., patient assistance programs or patient starter kits) would be jeopardized, with a potential negative impact on patient care.

Accordingly, Lilly urged the final rule to (1) explicitly interpret the exclusion more broadly to encompass any materials, including programs, services, and items provided to covered recipients for the direct use or benefit of patients or (2) further clarify that such programs, services, and items do not need an express exclusion because they do not constitute transfers of value to covered recipients.

The Definition of 'Applicable Manufacturer'

Lilly expressed concern with the definition of "applicable manufacturer" requiring tracking and reporting of payments outside the U.S. because such foreign affiliates are not preparing to report under the statute. As a result, Lilly urged CMS to define the term to include only manufacturers operating in the U.S.

Significant Paperwork Burden on Physicians

AMA expressed its concern that the current proposed rule would impose a paperwork burden on all physicians who will need to maintain ongoing records of every activity they engage in so they are able to ensure accurate reporting, and that CMS "greatly underestimated" the amount of time physicians will spend reviewing and challenging cumulative reports.

Conclusion

Ultimately, many of the speakers recognized the importance of physician industry relationships, but emphasized that transparency is necessary for patients, and hoped to achieve a reasonable and effective way of approaching it through the Sunshine Act.

There was considerable amount of agreement amongst the participants which should help move the process along.

After the hearing it was much clearer that creating rules to accurately guide the management, collection

and reporting process is complex and it is no wonder it has taken this amount of time for CMS to come up with the final rule. Collection of data will be complicated and implementation will be time consuming. As Mark McClellan noted there are some days he misses being CMS administrator and others he doesn't and this may be one of those days.

Novartis and University of Pennsylvania Announce Research Collaborative

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The collaboration between academia and industry has led to some of the world's greatest and most innovative breakthroughs in medicines and medical devices. Frequently, life sciences companies rely on members of academia to conduct the basic research and clinical trials that may eventually lead to the research, development and approval of products that companies submit to the Food and Drug Administration (FDA).

In addition, there has been a recent trend for companies to invest in collaborative partnerships with academic medical centers to pursue research and development of innovative new drugs and treatments. For example, last year, a new **drug research** collaboration was **announced** between pharmaceutical giant **Pfizer** and the **University of California San Diego**, which could deliver up to $50 million to local scientists over the next five years, speed the delivery of promising therapies to patients and help refill the fast-depleting pipeline of the world's largest pharmaceutical manufacturer. And earlier this year, Merck **announced** a collaboration to create the California Institute for Biomedical Research (Calibr), an independent, not-for-profit organization--501(c)(3).

We have also written **several times** about the University of California, San Francisco Chancellor Susan Desmond-Hellmann, who advocates for establishing closer relationships with industry in order to spark new ideas, fund research, access high-tech equipment and speed medical advances to patients.

Following in the footsteps of these collaborative partnerships, drugmaker **Novartis** and the **University of Pennsylvania** recently announced a research and licensing agreement that aims to bring to market a new approach to fighting cancer that has shown promising results in early trials, reported the **New York Times**. The arrangement is being announced as major pharmaceutical companies **are cutting back on their deals with biotech firms** and collaborating increasingly with universities instead. Agreements between pharmaceutical companies and biotech companies totaled $18.9 billion in the first seven months of this year, a decline from the $22.7 billion in deals that were done over the same period a year ago, according to a recent report by the venture capital firm Burrill & Company.

Penn is a leading center for viral vector research, and did the first clinical trial several years ago using adenoviral vectors to replace mutant genes in patients with inborn errors of metabolism. Under the leadership of Dr James Wilson this center has pioneered the use of viral vectors.

The alliance seeks to build on the recent results of an experimental treatment that trains a person's immune system to kill cancer cells. Scientists at the university announced last year significant results in several patients with advanced chronic lymphocytic leukemia who were treated using the new technique, **including two who went into complete remission**.

The treatment uses a disabled form of the HIV-1 virus to carry cancer-fighting genes into the patients' T-cells, a type of white blood cell that fights viruses and tumors. Although the study involved patients with leukemia, researchers hope to apply the approach to treat patients with a variety of cancers. Other trials are under way for lymphoma, mesothelioma, myeloma and neuroblastoma.

Included in the deal is a commitment by Novartis to contribute $20 million to build the Center for Advanced Cellular Therapies, which will be devoted to studying the new treatments, on the campus. Novartis and Penn say the deal will combine the intellectual resources of the university with the commercial wherewithal of the company, a major drugmaker. Penn is granting Novartis an exclusive worldwide license to the technologies, and Penn will receive royalty payments.

"Penn's intellectual resources, combined with a pharmaceutical industry leader like Novartis, offer a powerful symbiotic relationship in our mutual goal of finding more effective treatments for cancer," J. Larry Jameson, dean of the Perelman School of the Medicine at the University of Pennsylvania and executive vice president for the Health System, said in a statement announcing the deal.

The downside, said G. Steven Burrill, chief executive of Burrill, is that Novartis and other companies will be taking on more risk by getting involved in research at its earliest phases. "Now they're going to own all of the development, both the risk and the cost," he said.

In addition to the New York Times article, Pharmalot posted an **interview** about the new partnership with *Mark Fishman, who is president of the Novartis Institutes for BioMedical Research.*

Fishman explained that the deal with Penn is different than most agreements with academic entities because it is a "multi-part contract." Novartis has "an investigational potential drug, plus the ability and the willingness to do to the work around the actual manufacturing of this, which is not part of the usual, standard relationship with a university. Plus, what's even more exciting is the ability to keep this in new directions of research around immunotherapy, in general." He also added that this agreement is another way Novartis is trying to grow and expand their translational research focus.

The rest of the interview focused on the particular drugs Novartis will be developing in collaboration with Penn. Fishman noted that the goal of this collaborative effort is to not only make the CARt systems as

effective as possible, but for other cancers as well. Other cancers Novartis is working on B-cell malignancies such as CLL (chronic lymphocytic leukemia). Novartis also wants to start studying CARt-19 for other cancers that express CD-19, such as acute lymphocytic leukemia, or diffuse large B-cell lymphomas. Then, over time, Fishman said the company would want to identify antigens on other tumors that would be amenable to this type of targeting.

Ultimately, Penn and Novartis should be applauded for this collaboration and other academic medical centers and companies should follow in their footsteps. The more companies can begin to work together and collaborate on finding new ways to approach diseases such as cancer, the better chances patients have for receiving timely and effective treatment.