S. HRG. 112–664

LET THE SUNSHINE IN: IMPLEMENTING THE PHYSICIAN PAYMENTS SUNSHINE ACT

ROUNDTABLE

BEFORE THE

SPECIAL COMMITTEE ON AGING

UNITED STATES SENATE

ONE HUNDRED TWELFTH CONGRESS

SECOND SESSION

WASHINGTON, DC

SEPTEMBER 12, 2012

Serial No. 112–22

Printed for the use of the Special Committee on Aging

Available via the World Wide Web: http://www.fdsys.gov

U.S. GOVERNMENT PRINTING OFFICE
76–453 PDF WASHINGTON : 2013

For sale by the Superintendent of Documents, U.S. Government Printing Office
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LET THE SUNSHINE IN: IMPLEMENTING THE PHYSICIAN PAYMENTS SUNSHINE ACT

WEDNESDAY, SEPTEMBER 12, 2012

U.S. SENATE,
SPECIAL COMMITTEE ON AGING,
Washington, DC.

The Committee met, pursuant to notice, at 2:31 p.m. in Room SD–562, Dirksen Senate Office Building, Hon. Herb Kohl, chairman of the committee, presiding.

Present: Senators Kohl [presiding], Blumenthal, and Grassley.

OPENING STATEMENT OF SENATOR HERB KOHL, CHAIRMAN

The CHAIRMAN. Good afternoon. We thank you all for coming here, especially Senator Grassley.

Today we will discuss the Physician Payments Sunshine Act, a law that Senator Grassley and I worked on together. Unfortunately, the Sunshine Act's implementation is a year late, which is both troublesome as well as not acceptable.

In November 2010, Senator Grassley and I asked Secretary Sebelius about implementing the Sunshine Act according to the timeframe in the law. Almost two years later, I'm disappointed to say, we're still asking these same questions. Industry, doctors, and consumers deserve better. I have repeatedly requested that CMS provide a timeline for implementation. Secretary Sebelius and CMS tell us that the rule will be finalized by the end of the year, so we expect CMS to honor that commitment, and hopefully CMS can get this done even sooner.

The Sunshine Act ensures the openness and transparency of the financial ties between doctors and the drug and medical device industries. These financial relationships are valuable and lead to new therapies and technologies, but the public has a right to know about these financial ties.

As many stakeholders who worked with Senator Grassley and me to develop the law know, the Act was never meant to be burdensome. In fact, many medical device and drug companies are already releasing information about payments to doctors voluntarily or as required by state law.

The Federal law set reasonable timelines requiring rules on how to operate the Sunshine Act by October 1st of last year, and to date CMS has not finalized the rules, leaving consumers and manufacturers in the dark. We urge CMS to finish the rules and ensure that the definitions and guidelines are clear and workable for industry and patients alike.

Most importantly, the information must be made available to the public, must be easily understood and provide enough context for patients to understand why their doctors' names appear on the website.

All the stakeholders, consumer and industry groups together, want a fair rule and want it issued now. That is why we're here today, to give CMS and all the players a chance to discuss how best to make the Sunshine law a reality and to ensure that CMS is listening to the questions and concerns these companies and groups bring to the table.

With that, I invite Senator Grassley to provide his opening statement before we turn this roundtable over to Dr. McClellan.

STATEMENT OF SENATOR CHUCK GRASSLEY

Senator GRASSLEY. Thank you, Mr. Chairman. I thank you for your leadership, and particularly I thank you for your bipartisanship on this effort and how you conduct the work of your committee.

I thank everybody in the room for coming, particularly those at the table here who have to do the hard work and prepare for it, and particularly for Dr. McClellan leading the discussion.

In 2007, I began conducting extensive oversight and seeking disclosure of industry financial ties with groups, including taxpayer-funded research, physicians, medical schools, medical journals, continuing medical education companies, and patient advocacy nonprofit organizations. We exposed numerous cases where there were vast disparities between drug company payments received and reported by leading medical researchers.

Just two examples. At Stanford University, the Chairman of Psychiatry received an NIH grant to study a drug while partially owning as much as $6 million in stock in a company that was seeking FDA approval of that drug. After exposure, the NIH removed the individual from the grant. At Harvard University, three professors failed to report almost a million dollars each in outside income while heading up several NIH grants. In response to my oversight, Harvard revised the conflict of interest policies and conducted an internal investigation of these professors.

These problems led to the Physician Payment Sunshine Act. The Sunshine Act establishes a nationwide standard requiring drug, device, and biologic makers to report payments to doctors to the Department of Health and Human Services. It requires information about those payments to be posted online in a user-friendly way for public consumption. It also establishes a penalty as high as $1 million for knowingly failing to report the information.

Now, as we all know, the legislation was ultimately included in Section 6002 of the Patient Protection and Affordability Act. CMS was eventually tasked with carrying out the Sunshine Act. The agency had until October 1st, 2011 to issue regulations. When CMS failed to meet the deadline, Senator Kohl and I wrote to CMS about why it failed to meet the deadline. We asked for a timetable for issuing the preliminary regulations and implementing the Act.

CMS' response was incomplete and very uninformative. There was no explanation for the delay and no indication of the expected completion date. At the time of the response, the U.S. Government

had just settled with a medical device maker for $2.4 million over allegations of kickbacks to doctors to use the company's product. The payments to doctors are the kind that might be prevented through disclosure as soon as the Sunshine Act is in place.

Senator Kohl and I then scheduled a hearing to force the agency to publicly explain why the rule was taking so long. Not surprisingly, because it happens so often around this town, not only with CMS but with so many other bureaucracies, on the eve of the hearing CMS finally issued the proposed rule. For the most part, I was very pleased with CMS' proposed rule. CMS stuck to the goals and the integrity of the Sunshine Act, providing clarification where it was needed.

However, many questions remain on the technical aspects of the rule and how the data will be presented. I have said from the very beginning, if the information provided to the public is not concise, easily readable and understandable, then we have all failed the American taxpayer.

It has now been nearly nine months since the proposed rule was issued, and CMS cannot tell us when they plan to issue the final rule. The longer we wait, the more the taxpayers miss out on the benefits of public disclosure.

CMS is simply dragging its feet on implementing the Sunshine Act. But why? Because it doesn't make sense, the dragging of the feet. Rarely do you find all stakeholders, including consumer groups, industry, professional medical organizations and provider organizations, MedPAC, the Institute of Medicine, and Congress all on the same side of the issue. In fact, industry and consumer groups sent a letter to CMS October the 25th last year urging full implementation of the Sunshine Act. Yet, still, there is delay.

Our efforts to engage with CMS on the implementation of the Sunshine Act have met with resistance and silence, just like Congress passing a law doesn't make any difference around this town. Why is CMS so unwilling to being open and transparent with the implementation of the process? It seems to me that the public's business ought to be public. That's what democracy is all about. That's what our government is all about.

I am never one to put a lot of stock into rumors. But one that keeps popping up is that CMS has completed the final rule and sent it over to OMB, but OMB will not issue the final regulation until after the election.

Now, that doesn't make sense, but that is what people are saying. CMS needs to clarify if there is any truth to this rumor. Is the rule at OMB or not? Is it being held up until after the election? If so, why?

We need to find out what the hold-up is, deal with it, and get the job done. After all, how long have we been on this? It's five or six years since the investigation started, three years since the law was passed. The American people deserve the full disclosure and transparency that this law promises; and more importantly, the people we expect to comply with it, meaning the industry, needs certainty about what the specifics of the rule will be so that compliance can begin. The time for delay is over.

Today's roundtable is geared towards gaining a better understanding from CMS officials on why they have failed to implement

the Sunshine Act, their anticipated release of the regulations, and the consequences facing industry due to the lack of guidance from CMS. You kind of get back to something very basic. You know, a lot of people in this country may not like what government tells them, but they ought to tell them so they know what the situation is.

Due to the structure of the law, companies must establish an internal data collection system and educate all employees on the new requirements. However, companies do not have the luxury of going to Best Buy and purchasing the latest data collection system off the shelf. Companies build the systems. They must train and educate their employees on the proper use of the system in order to properly capture the necessary data. Many companies have already begun piloting these systems to ensure that they are capturing all the relevant information, and I thank them who are doing that for doing that. However, with the lack of recognized practices from CMS on how to move forward, companies cannot prepare to fully meet the letter of the law.

Lastly, as I did at the beginning, I want to thank our participants in today's roundtable. Collectively, these participants represent the government agency in charge of carrying out the intent of the law, the industry the law is intended to regulate, the consumer groups representing the patients the law is intended to help and protect, and various experts in the field, all of you folks at the table.

It is my sincere hope that CMS is prepared to be open and honest about where it is in the process and why it has failed to implement the law in a timely manner. Letting the sunshine in and making information public is basic to accountability. The sooner we can properly implement this law, the sooner we can establish greater accountability for patients and consumers, especially in medical research.

Thank you, Mr. Chairman. Thank you.

The CHAIRMAN. Thank you very much, Senator Grassley.

We now turn the roundtable over to Dr. Mark McClellan, and we thank you for moderating this roundtable.

Dr. McClellan previously served as Administrator for the Centers for Medicare and Medicaid Services, as well as the Commissioner of the Food and Drug Administration.

I know this conversation will be productive, and we thank the panelists, each and every one of you, for joining this discussion.

Dr. McClellan, the roundtable is now in your hands.

Dr. MCCLELLAN. Chairman Kohl, thank you very much for that introduction. I would like to especially thank you and Senator Grassley for all your work over the years on the Physician Payment Sunshine Act and working to have it implemented effectively. It has been a real privilege for me personally to have the opportunity to work with you not only on this issue but on many other issues of importance to older Americans and the financing of health care, and the quality of health care in this country. It's a real pleasure to be part of this effort to try to bring everyone along together on moving forward on implementing the Sunshine Act as effectively as possible.

I think everybody here—and I had a chance to read the statements and hear through my staff from many of you—everybody here agrees with the goal of the Sunshine Act, bring transparency to the health care system through accurate disclosure of payments and other transfers of value between different participants in it, physicians, teaching hospitals, GPOs, manufacturers and others.

As CMS said in its proposed rule on the Act, "collaboration among physicians, teaching hospitals and industry manufacturers may contribute to the design and delivery of life-saving drugs and devices. However, while some collaboration has been official, payments from manufacturers to physicians and teaching hospitals can also introduce conflicts of interest that may influence research, education and clinical decision-making in ways that compromise clinical integrity and patient care, and may lead to increased health care costs. Financial ties alone do not signify inappropriate relationships. However, transparency can shed light on the nature and extent of relationships and may dissuade inappropriate conflicts of interest from developing."

So that's the purpose behind the rule, and this development of the rule has been, and I think will be a challenging task for CMS, and striking the right balance and involving all stakeholders in what has been an iterative process, and I expect from the engagement of everyone here will continue to be an iterative and constructive process, and hopefully the dialogue that we have today can contribute in a constructive way to helping all of this effort move forward.

I'm here to moderate. There are a lot of people around the table. I know many of you in this room who have been deeply involved in the issues related to the Sunshine Act for some time. So we're going to try to make this as informative and fast-moving a process as possible.

I want to start out by discussing some of the key issues involved in the Sunshine Act and respond to some of the questions and key points that the senators raised at the outset. All of this, again, is to highlight why it's so important for CMS to get it right. And then we'll hopefully have some time to discuss ways to present the information involved, ways to address the effort and the burden involved in reporting, ways to make as much of an impact at as low of a cost as possible from the implementation of the Sunshine Act.

So to do that, I'm going to need the help of everyone around this table, and I'd like to start by asking each of you to introduce yourself.

Elizabeth, maybe we can start down at your end, just a brief introduction, and then we'll come back to the statements.

Please do press the button, right.

Ms. O'FARRELL. Hi. I'm Liz O'Farrell, and I'm with Eli Lilly and Company, where I'm Senior Vice President of Finance and Policy.

Dr. LAZARUS. Dr. Jeremy Lazarus. I'm President of the American Medical Association.

Dr. CARLAT. Dr. Daniel Carlat. I am the Director of the Pew Prescription Project with the Pew Charitable Trusts.

Ms. BIAGIANTI. Diane Biagianti, Vice President of Edwards Lifesciences, Chief Responsibility Officer.

Mr. BRENNAN. Niall Brennan, CMS.

Mr. PEDDICORD. Doug Peddicord. I serve as Executive Director of ACRO, the Association of Clinical Research Organizations.

Dr. ROSEN. I'm Charles Rosen. I'm a clinical professor of orthopedic surgery at UC-Irvine and President and Co-Founder of the Association for Medical Ethics.

Dr. SCULLY. Good afternoon. I'm Jay Scully. I'm the Medical Director and Chief Executive Officer of the American Psychiatric Association.

Dr. MCCLELLAN. Again, thanks to all of you for being here. Now I would like to get to those 1-minute opening statements, and I'd like to thank everyone for preparing the statements they did for the record and encourage everybody here, if you haven't had a chance to look at them already, very informative on the topics involved today.

So I'd like to go alphabetically on these, starting, Diane, with you.

DIANE BIAGIANTI, VICE PRESIDENT, CHIEF RESPONSIBILITY OFFICER, EDWARDS LIFESCIENCES, IRVINE, CA

Ms. BIAGIANTI. Chairman Kohl, Senator Grassley, and Dr. McClellan, thank you very much for the opportunity to participate in this roundtable. We commend you for your continued efforts to ensure that the Physician Payment Sunshine Act is promptly and effectively implemented as part of the Affordable Care Act.

Edwards Lifesciences is a California-based medical technology company that has maintained global leadership in the science of heart valves and hemodynamic monitoring for several decades. We support transparency because strong collaboration between scientists, engineers, entrepreneurs, and the clinical community is key to innovation. It was the close collaboration between a cardiothoracic surgeon and an engineer that created the first commercially available artificial heart valve more than 50 years ago. That was the beginning of our company and almost all the products we have made since then were created as a result of this kind of collaboration.

Based on our belief that the greater transparency will help the public better appreciate what we do with clinicians, Edwards Lifesciences decided four years ago to become the first medical device company to initiate a voluntary payment disclosure program. We appreciate the opportunity to participate here today and hope our experience with transparency will help answer your questions and inform the dialogue.

Most importantly, we hope our answers underscore three key points: first, that the process of medical device innovation is unique. Device companies are extremely dependent on the input and guidance from clinicians as we invent and improve upon the products we make.

Number two, we support transparency and the need for a final rule to issue as soon as possible. We are confident that CMS will take into consideration the extensive comments provided by the various stakeholders and will provide clear guidance for companies to comply with the law.

And third, patients and the public need to be provided with the opportunity to understand what these payments are for, an oppor-

tunity to provide meaningful context surrounding a transfer of value that's critical to avoid further confusion and possible misrepresentation of what can be very important collaboration.

Thank you.

Dr. MCCLELLAN. Great. Thanks very much, Diane.

I thought I was going to go in alphabetical order. But now, if you don't mind, I'll let CMS be saved for last. So that means next up is Dan.

DANIEL CARLAT, MD, PROJECT DIRECTOR, PEW CHARITABLE TRUSTS, WASHINGTON, DC

Dr. CARLAT. Thank you. Thank you, Dr. McClellan, Senator Kohl and Senator Grassley.

The prescription project has focused on issues related to physician-industry relationships and transparency for quite a while now. Before I became the director of the prescription project, I was a practicing psychiatrist and a publisher of CME material and journals, and before that I worked with the pharmaceutical industry in different contexts, both speaking and research.

The Pew Health Group has been a strong proponent of the Physician Payment Sunshine Act since 2007, and has worked in a bipartisan fashion with pharmaceutical and device companies, medical associations, and consumer groups to support its passage and its implementation.

We support the Sunshine Act so strongly because of an essential principle really of medical ethics, which is that we must treat our patients based on the best medical evidence, and that our treatment decisions should not be inappropriately influenced by financial considerations.

So I look forward to today's discussion, and I'm quite optimistic that we can move forward with the final regulations quite rapidly, as Senator Kohl and Senator Grassley had hoped. Thank you.

Dr. MCCLELLAN. Dan, thanks very much, and thanks for all the work that Pew is doing on this important set of issues.

I'm going to go a little bit out of order again and turn now to Senator Blumenthal. Thank you for joining us for this roundtable today and, please, if you'd like to make a statement to help us start out, that would be great.

STATEMENT OF SENATOR RICHARD BLUMENTHAL

Senator BLUMENTHAL. Well, I actually relish those occasions when I don't have to say anything and I can just listen, and I want to listen. Rachel Pryor is my staff person with me today.

I want to thank Senators Kohl and Grassley for their leadership on this issue. For all of us who have been involved in consumer protection and advocating consumer causes, as well as anyone who is interested in lowering the cost of health care, this issue is so critical, and I think this kind of conversation is very important to achieving the important ends of the legislation.

I will be very interested in knowing more about what can be done not only to improve the law but, most important, improve its enforcement. I'm very interested in enforcement, in implementation, administration, which often makes the law real in people's lives. And I think that disclosure, sunshine, full transparency, the

more the better, and really just want to thank all the participants today for your contributions, and everyone else who is here today, for the work that you're doing on this common cause. I very much hope it is a common cause, and I believe it is. Thank you.

Dr. MCCLELLAN. Senator, thanks very much for your comments, and especially for your leadership on this important set of issues.

I'd now like to turn to Jeremy.

JEREMY LAZARUS, MD, PRESIDENT, AMERICAN MEDICAL ASSOCIATION, WASHINGTON, DC

Dr. LAZARUS. Thank you. I'm Dr. Jeremy Lazarus, a board-certified psychiatrist in private practice in Denver, Colorado, and President of the AMA.

We appreciate the opportunity to provide our views and to discuss with other stakeholders the AMA's concerns and recommendations concerning implementation of the Sunshine Act. We support efforts to increase transparency. We provided ongoing input and supported the final version of the Sunshine Act after important modifications were made to the legislation designed to ensure that the reporting did not impose a regulatory and paperwork burden on physicians, protected physician due process rights, and provided a meaningful picture of physician-industry interactions.

Our goal is to work with all of you to streamline the regulatory burden, ensure accurate and fair reporting, and ensure adequate time to conduct outreach and education on the final rule to physicians. We're very hopeful that today's discussion will advance resolution of key questions and areas of concern that we have with the proposed rule. Thank you.

Dr. MCCLELLAN. Thanks very much, Jeremy.

And next up, Liz.

ELIZABETH O'FARRELL, SENIOR VICE PRESIDENT, POLICY AND FINANCE, ELI LILLY & COMPANY, INDIANAPOLIS, IN

Ms. O'FARRELL. Good afternoon. At Lilly, we believe that physician payment transparency, when done accurately and with relevant context, is good for all stakeholders. Through developing our current payment registry, where we disclose all financial relationships, payments and transfers of value to physicians, we learned how operationally complex this is. I'm concerned that the draft regulations, along with an overly-aggressive implementation timeline, will result in confusing, inconsistent and inaccurate interpretations of the data.

This is why we're recommending a phased approach which we believe will enable a high percentage of payments to be accurately captured in the proposed timeline.

In addition to timing, there are four areas where the current draft regulations are both operationally unmanageable for manufacturers and will create confusion for the public.

First, indirect payments should be reportable only when the manufacturer controls or implements the selection of the physicians engaged by the third party.

Second, meal allocations must be factual and workable. We should not attribute value to someone who does not actually receive a meal.

Third, the exclusion for patient materials should explicitly encompass all educational items and services provided to covered recipients for the direct benefit of the patient.

Lastly, we ask for the definition of "applicable manufacturer" to align with the statutory definition and only include our subsidiaries who are operating in the United States.

In 2011, we disclosed $216.5 million on our registry. This encompassed 1.1 million transactions with 102,000 physicians. It took us 23 months to design, implement and validate our registry. To broaden our registry to meet the requirements of the draft regulations, we estimate it would take a minimum of 180 days, and we're starting from a position of strength and experience. Many companies are starting disclosure for the first time.

I really appreciate the opportunity to be here this afternoon and look forward to the discussion. At Lilly, we firmly believe that transparency, when done in the right way, is good for all of us.

Dr. MCCLELLAN. Liz, thanks, and I appreciate you summing up some of your experience as well. We are going to, obviously, come back to a lot of the issues that you and the other presenters have brought up in these opening comments.

Right now, though, let me go on to Doug.

DOUGLAS PEDDICORD, PH.D., EXECUTIVE DIRECTOR, ASSOCIATION OF CLINICAL RESEARCH ORGANIZATIONS (ACRO), WASHINGTON, DC

Mr. PEDDICORD. Dr. McClellan, thanks very much.

Again, my name is Doug Peddicord, and I serve as Executive Director of the Association of Clinical Research Organizations, or ACRO, which represents the world's leading clinical research organizations, CROs. Our member companies provide a range of services across the entire spectrum of development for new drugs, biologics and medical devices, from pre-clinical, proof-of-concept and first-demand studies, through post-approval and pharmaco-vigilance research.

With more than 75,000 employees engaged in research activities around the world, ACRO member companies conduct more than 11,000 clinical trials involving nearly 2 million research participants every year. We are involved in half of all clinical trials that take place worldwide.

Since passage of the Affordable Care Act, we have worked with industry, CMS and other stakeholders to try to ensure a regulation that will be fair to doctors and hospitals, useful to patients and consumers, and not discourage research participation.

Let me begin by saying that ACRO argued, and we continue to believe, that fair market payments made for legitimate research activities should have been excluded from the provisions of 6002. It's worth noting that several states Sunshine statutes exclude from reporting payments made for such bona fide research activities.

Our concern is that failing to exempt those payments for research activities from the requirements will have deleterious effects on the research enterprise in the United States. A 2010 survey of U.S. physicians who conduct clinical trials, investigators, showed that 24 percent would be less likely to participate in research or would not participate at all if the revenues, the gross revenues, not

revenues in excess of expenses or profits but gross revenues, which is what the proposed rule will require, were disclosed by HHS.

A major reason for this, we believe, is physician concern that the data will be highly susceptible to misinterpretation. Stated differently, the survey finding suggests that the U.S. is in danger of losing one-quarter of its clinical investigators, which will slow innovation and delay the delivery of needed treatments for patients.

I very much look forward to the conversation today.

Dr. MCCLELLAN. All right. Thanks very much, Doug.

Chuck.

CHARLES ROSEN, MD, CLINICAL PROFESSOR OF ORTHOPEDIC SURGERY, UNIVERSITY OF CALIFORNIA, IRVINE SCHOOL OF MEDICINE, ORANGE, CA

Dr. ROSEN. Thank you. I'm President and Co-Founder of the Association for Medical Ethics, and we believe in and supported the Sunshine Act from the beginning. We believe in the transparency of people, doctors, reading research papers, knowing whether the authors had $10,000 for research support or $1 million in stock options, and believe that patients should have the right to know about their physicians.

There is no restriction in the Sunshine Act that I know of, nor in our policy, of how much anybody gets from anybody for anything, whether it's $10 a day or $1 million a day. This is purely transparency and openness.

The concerns that I have thus far are about the continuing medical education exemption, that the idea somehow of industry-sponsored continuing medical education payments to physicians via a third party should somehow be exempt I think will gut the Sunshine Act. To say that this will discourage somehow medical education in this country having these marketing seminars—and as Marcia Angell, the previous editor of the New England Journal of Medicine said, these are for marketing, not education—will somehow collapse the education system in this country I think is a little bit silly.

Also, I'm concerned about the pre-FDA research that's done that exempts any of the authors from having transparency of their payments under the guise of somehow trade secret, or somehow it's competitive getting researchers. I think that will gut a lot of the Sunshine Act if that's allowed.

And just the last point, I have noticed being here that a lot of questions are being made about how difficult it is to set up this database and so forth. I can tell you, for the last five months at AME, with personal funds between me and my co-founder of AME, Gemma Cunningham, we put in $600,000, hired 18 programmers over the last five months, have downloaded a searchable database of every transaction between pharmaceutical and medical device companies to physicians for the past seven years, including the DPA of the ortho companies from five years ago, and it's searchable and it's free on our website. It's the largest in existence.

So I would dispute that this is such a difficult thing to download and do at CMS, and we certainly don't have the capabilities that CMS does, and we've done it.

Dr. MCCLELLAN. Just for the people who may be going to their laptops now, the web address for your organization?

Dr. ROSEN. Ethicaldoctor.org.

Dr. MCCLELLAN. Okay. Thanks very much.

And next up is Jay.

JAMES H. SCULLY, JR., MD, MEDICAL DIRECTOR AND CEO, AMERICAN PSYCHIATRIC ASSOCIATION, ARLINGTON, VA

Dr. SCULLY. And last. Thank you, Mark.

As I said, I'm Jay Scully with American Psychiatric. When I came into my current position, we were already concerned about these issues and were hearing from our members, particularly our younger members, that there was a problem in our relationship and how we primarily dealt with the funding of education. I expect one of the reasons you invited me here is that we don't have a disclosure problem because we don't do it anymore.

So, I'll tell you what happened: we were getting commendations from the accrediting CME body for the way we managed the industry-supported programs—highly valued by a lot of our members. But concerns were raised by the public and by our members, and the public trust was just too important to us.

So, in 2008, we decided we would phase out any industry funding for our CME programs, which we did at some cost. Four years later, it's working pretty well. We have a problem that we still are working on, which is we want access to the best experts. Sometimes those best experts are in the pharma labs. So, we still are working on that. We're working with them, and we're making progress in that area—particularly with the university-based folks who get pharma money. I'll talk about research in a second maybe in more detail.

So, we did the separation. Again, we love marketing. We love advertising from pharma. We just want to make clear that it's not education. We live in a market-based economy. That's how we get the new products and the great advances we've made, and we need that from our colleagues in the pharmaceutical industry. We just want to be clear about when it's marketing and when it's education.

So, it works for us. With the Sunshine Act, though, one of the things we've done is our own disclosures, which have been quite extensive—particularly in our guidelines groups who produce the clinical guidelines. And one of the things we've learned is that the research dollars and how they're managed in various institutions is very complicated. Some money may go directly to the researcher and into their personal funds. Others go to the university or the organization and are never seen by the researcher. So how does that get dealt with?

Furthermore, a lot of money is spent on free medicines that are to be researched and studied. Is that going to be reported as the doctor's income, the money for those things? This is a problem we have had with our own disclosure system.

We also, as everybody else does, want to make sure there's a fair, formal dispute resolution that goes into the rules for the Sunshine Act so that everybody is clear that these things are not reported until discrepancies have been dealt with, so bad data doesn't go up.

It gets confusing sometimes, so it needs to be done, especially around the research dollars.

I'll stop there. We can talk later.

Dr. MCCLELLAN. Thanks. And I want to thank everyone for the conciseness of their opening statements. Again, we are going to come back to discuss all these issues in more detail.

First, though, let me turn to Niall for some opening comments from the CMS perspective.

NIALL BRENNAN, DIRECTOR, POLICY AND DATA ANALYSIS GROUP, CENTERS FOR MEDICARE AND MEDICAID SERVICES, WASHINGTON, DC

Mr. BRENNAN. Thank you, Mark. I'd like to thank the senators and their staff for convening this roundtable. CMS is certainly looking forward to the input of folks here at the roundtable.

As you know, we published an NPRM for the Sunshine Act on December 19th, 2011, with a 60-day comment period, which ended on February 17th, 2012. At the conclusion of the comment period, we had received over 300 highly substantive and technical comments from a wide range of stakeholders covering almost every section of the proposed rule.

We continue to meet extensively with stakeholders. We met with them both prior to the NPRM and subsequent to the NPRM to give them an opportunity to amplify their comments to us, and we like to think that we have been as open and transparent as possible in that regard.

While there were a lot of comments, some certainly were commented on more than others: continuing medical education, the treatment of indirect research payments, the process for resolving disputes between physicians and manufacturers.

In May of this year we announced that in light of the extensive comments, and again to try and be as transparent as possible to folks affected by this provision, that we would not require data collection by applicable manufacturers or group purchasing organizations before January 1st of 2013, which would give us additional time to address the operational and implementation issues in a thoughtful manner.

We continue to assess the requirements for the program to ensure that we can accurately and effectively collect and publish the data, as intended by statute. I think many of the participants already have alluded to the complexity of a lot of the underlying issues and the need to get it right before it becomes a real and tangible program, and that's what we're focused on.

We're working very hard on finalizing the regulations and rulemaking around this particular provision. We're in parallel starting to gear up on implementation and considering the various systems and programmatic decisions that have to be taken into account in order to operate this program effectively and efficiently.

We remain committed to the goals of the statute and look forward to talking to you all today.

Dr. MCCLELLAN. Great. Thanks, Niall, and I think we're all looking forward to that discussion.

I do want to get into some more of the specifics around the issues that all the panelists have raised, but maybe I could start with

just, Niall, a follow-up for you. We heard that everyone here is very interested in moving forward with clarity about the final rule as soon as possible. It sounds like, from what you said, you're in the midst of a lot of work based on the extensive comments that you received. You said there's a parallel process with both getting the final rule and getting to some of the systems work that needs to be done.

Anything else you can add at this point, even though you're in this rulemaking process, on plans and on how those parallel processes are likely to move forward?

Mr. BRENNAN. Well, I am relatively limited in what I can say, Mark, because we are in a rulemaking process. We're working very hard. We are discussing things extensively with both our lawyers and OIG as required by the statute, and my colleague, Shantanu Agrawal, who is the Chief Medical Officer at the Center for Program Integrity, is also in the audience, and CPI are starting to gear up on many aspects relating to implementation.

Dr. MCCLELLAN. Okay. Thanks for that. And with that process coming, I think one of the useful ways to spend some of our time together today is to make sure we're all up to speed as much as possible on what some of those key issues are and what kinds of preparations different stakeholders can do for that final rule and the systems to implement it that, as you say, are coming in the not-too-distant future.

There has been, as you heard from a number of the participants around the table, a good deal of experience with some kinds of reporting and transparency around payments. There also were a lot of views and I think informed perspectives on some of the challenges in both producing these reports and in their use and interpretation, and I'd like to go through all of those issues as best we can in the time that we have together today.

So let me start with the what, what should be reported and what some of the key issues are there, and I'd like to particularly focus on the areas that you all emphasized in your written statements, in your opening comments around reporting research payments, around reporting CME, and around reporting meals. Those are not the only things that are covered here, but they seem to have been a big part of the comment process and some of the tougher issues in getting to effective implementation.

So maybe we can start with research and, Doug, let me turn to you. I appreciate your point in the statement that research perhaps should be included—research should be excluded. Research is not going to be excluded under the law. So given that, any further comments you'd like to elaborate on about how to get research reporting as effective as possible?

Mr. PEDDICORD. Sure, Mark, and I think we're obviously recognizing that research is not likely to be excluded. In our written statement, one of the things we provided was a chart of the flow of research payments and data collection related to those payments, which in some ways very much underlies this question of direct versus indirect payments and how do we capture what it is that is being paid for what.

I think one of the things that it is relatively uncommon for applicable Manufacturer A to write a big check to Doctor B to perform

research services. In fact, it is more often the case that payments, like NIH grants that flow through research institutions, are likely to flow through other intermediaries, including CROs, in the commercial side of the world also. As a matter of fact, our companies work with something over 500 manufacturers each per year, and so we have a very broad range of experience with what those payments are going for.

What those payments go for is everything from what I would call goods, laboratory tests and the like, to services, physical examinations, to essentially professional and administrative services like record-keeping and data collection and data reporting. I think one of the things that the rule needs to do better than it does in the proposed version is to, in fact, separate out those categories.

That's what I think the direct and indirect payments idea is trying for, but I think as written within the proposed rule, we were left very much concerned with the issue of the potential for double and triple counting. If what we end up doing is we count a direct payment made to a physician and an associated, what would be called indirect, payment made to the institution, are those amounts the same? Are they different? Do we get—are we asking for greater levels of granularity than we, in fact, now have?

So, for instance, lots of times now, a payment gets made to a physician practice. Two of those physicians might be investigators in a research project. The other eight of the physicians in the practice are not. We don't necessarily know how they divide up their money, and it's not something that we are likely to need to capture, except if the rule requires us to capture it.

So I'll stop at the major question of I think direct/indirect needs to be much clearer, and I will make one particular plea, which is probably as much to the industry as to CMS, which is that this is an area that cries out for a great deal of standardization. The notion that every manufacturer is developing a different system for capturing a relatively small number of data elements is really problematic, and I think it will be really problematic for CMS as well because if it can't get standard data elements in, it's unclear to me how it will create a database that really will be useful and informative for patients and consumers.

Dr. MCCLELLAN. I want to pick up on that point about informative for the public. That is, obviously, the bottom-line goal of the legislation. And while, as you pointed out, many of the financial flows here are complex, there are not that many categories, and standards could be helpful in making it interpretable to the public.

Standards development is something that happens in a lot of areas. You don't necessarily have to wait for the government to do it for you. Industry, other stakeholders working together, can often make progress on this.

Jay, you all have a lot of experience with thinking about these research issues, and I know you commented extensively on it in your written comments. In terms of making this information as useful as possible to the public, any thoughts about what standardization might involve and how to get there? Do we really need entirely to wait on CMS to get the rule out?

Dr. SCULLY. No. I think it would be great if industry—and here primarily it's universities and some institutes that are not univer-

sity-based, but primarily universities–reports, but in what categories? If I get a $9 million grant from Acme Pharmaceuticals to do a study, do I buy a condo in the Caribbean, or is this for research associates? Is this for the medications that we're studying, and I don't get anything into my personal accounts?

Still, the public may need to know I'm doing research for Acme Pharmaceuticals. That's fine. But it needs to be done in a way that's useable information for people.

What we've discovered, because in addition to the CME business, in our guidelines world—and I think a lot of professional societies are doing this—we have divestiture. You can't be running our guidelines on the treatment of depression if you're getting a lot of money from a drug company, even though you may be the world expert. So we struggled with that.

Clearly, disclosure is important, but we're saying there are some limits, you know, and you really can't have any money. If our guidelines are used—Acme Drugs, for the treatment of this—are used with this particular drug, that needs to be pretty clearly pristine. We're very clear about that.

So if you're a researcher, can you do it? We think so, as long as you're not individually—as long as we can disclose that, that you have been doing research for this in your university and it's dealt with in a particular way and you're not getting personal money.

But if you are, so what is personal money and how is that dealt with? Is your salary dependent upon it? If you're bringing in so many dollars to the university, they'll raise your salary? Lots of complicated things need to be worked out before somebody is tagged with "Dr. Scully gets a million dollars from Acme Drugs."

Dr. MCCLELLAN. Let me ask Dan, since you all have thought about this a lot as well. Any further thoughts given the comments you've heard about reporting on research, how to make that as useful as possible to the public without being unduly burdensome or have the kind of adverse effects on the conduct of research that Doug and others have articulated?

Dr. CARLAT. So we have to realize, of course, that there are two great truths as far as these research payments go. One is that research is really the life blood of medical progress and nurtures medical care. So all these research payments are good and we need to maintain them, and we certainly need to develop a system in which we're not going to over-inflate the payments that physicians are receiving, as you said.

On the other hand, and this speaks to the heart of the Sunshine Act, when a physician does take payments from a drug company, that does set up a potential conflict of interest.

My own personal experience, having run clinical trials—and this is a situation somewhat different from what you were saying, Jay—working for a CRO. A CRO got a grant. A CRO hired me, and probably other doctors, within a private practice setting. So I would recruit patients for an anti-depressant trial as part of my private practice. I would receive an enrollment fee of $5,000 per patient that I enrolled in the trial.

So here you have a potential conflict of interest where, on the one hand, as a physician, I'm there for my patient to provide the best possible care. On the other hand, I'm getting paid a fair

amount of money to enroll them in the trial. So from the perspective of the consumer, from the perspective of the patient, deciding to be in a clinical trial is complicated enough because there are risks involved, right? And certainly one of the things that we want to disclose to them is that, in cases where there are financial incentives, that those financial incentives are in place so they can have that information. They do deserve that information, in addition to all the other information that they get about the research trial.

Dr. SCULLY. You're trying to convince the patient to enroll in the trial, you need to let them know you're making money when they go in the trial. That's an ethical issue between you and the patient, as well as the public at large.

Dr. MCCLELLAN. It sounds like some opportunities for really promoting transparency here, and I'm glad there's some common ground.

I do want to move on, though, because we have so much to cover. So let me turn to continuing medical education, also very important for effective medical care. I know there has been some important discussion and maybe some differences of opinion around what and how should be reported on CME.

Jeremy, you talked about this at some length and highlighted in your statement a range of ethical guidance that AMA and other professional organizations have in place to help assure appropriateness of CME. Given all of that, what should be exempt from reporting in terms of CME?

Dr. LAZARUS. Thanks, Mark. Well, I think what should be exempt is what's written in the statute and the ACA, and that is that certified CME—I think we need to clarify the difference between certified CME, in which there are already significant firewalls between the granting organization, whether it's pharma or the device manufacturer and whoever is providing the CME, and the recipients of that CME, as opposed to more promotional or marketing kinds of activities.

And we already have very extensive ethical guidelines from the AMA, from the Council on Ethical and Judicial Affairs, on how physicians should take a look at their relationships with industry. But we think if you exempt the certified CME, that would be the best way to go. And again, that is what is written in the statute. So that's what we would propose.

Dr. MCCLELLAN. And, Chuck, I know you care deeply about these issues as well. Your thoughts on the same topic of what should and shouldn't be reported in terms of CME?

Dr. ROSEN. I'm not sure of the reasons for exempting certified CMEs since they are industry-funded CMEs as well. The ACCME for some reason allows industry-funded CMEs to be certified, and there are non-certified CMEs that are industry funded. So just to say they're certified, I don't think that's reasonable either, because they are going to be industry funded. In fact, I think the ACCME should not be funding, should not be certifying industry-funded CMEs, because they are marketing.

Dr. LAZARUS. Mark, could I just respond a bit? I think it's important to recognize that the certified CME, the pharmaceutical or device manufacturers, have no impact in terms of who is chosen as speakers, they have no impact on the content of the presentations,

they don't give PowerPoint slides. And indeed, it may be that the recipients of that education might not know who is doing the funding. So it is quite a different kind of continuing medical education than more promotional activities.

Dr. MCCLELLAN. I appreciate the back and forth, but given how much we have to cover, I do want to move on. I'm going to turn over the questioning just for a moment to Senator Blumenthal.

I understand you have a specific question that you'd like to ask.

Senator BLUMENTHAL. I really appreciate that, and I apologize if I'm repeating something that has already been discussed.

But I'd like to ask Director Brennan whether you can state specifically or reaffirm what the timeline will be. There was a delay, obviously, from 2012 to 2013 for beginning data collection. But I wonder if you could just lay out for the record now so that we know with certainty what the timeline will be for each of the stages, 2013 January for data collection, 2014 for posting anything else that you think ought to be clarified here?

Mr. BRENNAN. Thank you, Senator. That's a somewhat challenging question for me to answer because we're still in the clearance process, and even if you look at the comments from folks like Elizabeth today regarding the length of time that industry would like between publication of a final rule and actual collection of data, some folks feel that 180 days is appropriate, some folks feel that 90 days is appropriate, some folks feel that 120 days is appropriate.

Certainly, we do hope to get the final rule out as soon as possible. We do hope to build in an appropriate period of time for manufacturers and covered recipients to get ready to collect the data and be reported on, and we certainly hope that some of that data collection would occur in 2013.

Senator BLUMENTHAL. You hope that some of it will occur in 2013? Maybe you could just repeat that. You hope that it will occur in 2013?

Mr. BRENNAN. I hope that some of the data collection will occur in 2013, yes.

Senator BLUMENTHAL. Okay. You know, I don't mean to be too preemptory about this issue because I'm not the author of the bill, and Senator Kohl I think has left. But Congress mandated some dates here, and we very much welcome hopes, but I think that some finality and certainty and commitment is to be expected. I don't want to put you on the spot now, but I'm going to ask for the record that you come back to us with a commitment to a date certain as soon as possible. That's just my request. I think it's a legitimate and understandable request.

I know that there are complexities and difficulties, but there is more than just a hope on the part of Congress. There was a deadline that was set.

Mr. BRENNAN. Thank you.

Dr. MCCLELLAN. Thank you, Senator. And Chairman Kohl and Senator Grassley I think also made the same point very clearly.

Senator BLUMENTHAL. Well, again, I apologize if I came in late.

Dr. MCCLELLAN. No. Look, it's a very important issue that everybody around the table agrees. The sooner this can be done and done right, the better. There are some days when I really miss

being CMS administrator, and there are some times and some questions when I don't.

[Laughter.]

Senator BLUMENTHAL. And a lot of days when you don't miss it, right?

[Laughter.]

Dr. MCCLELLAN. But I appreciate Niall committing to get back to you with as much clarity as he can as soon as possible on this set of issues.

Senator BLUMENTHAL. Thank you.

Dr. MCCLELLAN. Thank you.

In the meantime, I do want to try to make sure that we're getting up to speed as much as possible on what these key issues that you're working through are. One other key area of reporting that has generated an awful lot of comments and some of the favorite anecdotes about who gets charged for the bagels and so forth is the reporting on meals and the methods included.

Liz, you've got some experience with this from the work that you all have been doing in your reporting already. Any thoughts that you can give on how to do this right? It is a significant—maybe it's not the biggest part, but it is a significant part of financial arrangements.

Ms. O'FARRELL. And I'll talk a little bit about how we've done it and what some of my concerns are with the proposed methodology now.

We currently attribute the value of a meal consumed by a physician on our registry. So, for example, if we bring in $100 worth of food and 10 people are eating, and 2 of those are physicians, we will allocate $10 to each of them.

Now, just that from a technology and systems perspective, and communication and training, to get to that point with our registry took changes to our expense reporting system, training to our sales reps, and also training—we made sure that every physician understood for our data collection date that we were going to be attributing value to anything that was received after that point. Also for speaker programs, if they attend a meal, we obviously allocate that.

Where we get very concerned with the draft regulations is to think about allocating that—go back to that $100 again—not the whole $100 to the physicians who have an ownership interest in that practice, or to try to attribute that at speaker programs.

Why is that so complicated? Well, first of all, when we go into an office, we don't necessarily know who all of the physician owners are, and even if the sales rep knows that, our systems and technology don't know that. So we're concerned about being able to accurately do that.

Second of all, if you are a physician who has said I'd like to listen to what you have to say but I'm not going to take any food from you, we have lost the opportunity to even have a discussion if we're bringing food for anyone because we no longer can have a physician actually opt out of receiving anything of value from us.

And I think thirdly, one of our biggest concerns is that in some bigger practices, there may actually be a physician that we don't call on because we don't have a product or an indication for that

physician, and the last thing we want to do is attribute value to that physician on our registry when not only did they not eat the meal but they are actually somebody we shouldn't call on.

I think within this—and as I said, we've been doing this for a while—we have a dispute process.

I think the other thing you have to look at is the downstream implications of adding complexity. If you are attributing to a physician a meal that that physician ate, and they understand in advance that that's attributable, you really don't have much of a dispute if you do that correctly. When you broaden that to attributing a much larger amount than what they know they actually consumed, you're going to increase the disputes.

And when you go to the extreme of attributing expense to someone who didn't even see you and didn't take the food, we're going to see so many more disputes that are going to be very hard to reconcile.

So those are the major issues. We continue to look at the simpler you can have it, the better your accuracy is going to be, the more understandable it's going to be.

Dr. MCCLELLAN. I did hear or see some head-nodding around the table with that. Dan, you all have thought about these issues as well, and there are some issues here, questions of balance about getting accuracy and completeness versus fairness and burden.

Dr. CARLAT. Speaking as someone who used to go into some of the offices giving talks—I would come with the reps who would provide the platters of sandwiches and what-not—it seemed to me that it was a relatively simple matter, and maybe there are elements in place that make it more difficult than common sense would dictate. But it seemed to me a relatively straightforward matter for the drug rep to see which physicians were actually eating a sandwich or a bagel, to put that in their information-keeping system, and then to attribute that amount of expense.

Similarly, when I go to meetings these days, everybody has a badge and a bar code, practically on their forehead these days, but they have it on the badge. So as they walk in to pick up their box lunch, they're being scanned. It seems that the technology is pretty straightforward to make sure, again, that the reporting of meals is accurate and not over-reported.

Ms. O'FARRELL. I would say I agree with you on what you said. It is—if we know who has eaten and we can attribute the meal to that, that's what we do today. We had to make changes to our system to enable us within the expense reporting system to ensure that we were picking up the right physicians, because from knowing who the physician is to actually knowing that you got the right one in the system, there's a lot of validation and work behind that. But you're right, that is more straightforward.

Where it becomes less straightforward is in the interpretation in the draft regulations which would say it's not just about attributing it to the physicians that I see right now, but now I have to attribute it to whatever physicians happen to have an ownership interest in that practice whether I saw them or not, and even knowing who those ownership interests are is very problematic.

Dr. MCCLELLAN. Jeremy, a quick comment on this, and Doug, and then I want to move on from what gets reported to some other issues.

Dr. LAZARUS. I'm basically in agreement with what's been said. I think physicians should be "billed" for what they eat and not for what they don't eat. So if they're not actually getting that meal or that bagel, it shouldn't be attributed to them. It should be the direct meal that they got, not more than that.

Dr. MCCLELLAN. Okay. And Doug?

Mr. PEDDICORD. So just a quick comment, since the notion of common sense came up before.

[Laughter.]

Dr. MCCLELLAN. We like common sense.

[Laughter.]

Mr. PEDDICORD. At the risk of saying the obvious—I'm not sure that the real point of Sunshine, actually, is to employ lawyers and consultants and financial managers so that we end up with this level of silliness around there should be a no-bagel table and a bagel table. We actually think that, at least in the research sphere, if we bring together 10 physicians for a study initiation meeting, and we keep them in a room to train them on the study from 9:00 to 3:00 and we feed them, we think the meal is entirely incidental to the research and simply should be reported under research and should not be segregated out.

I think this idea of segregating out, especially at the level of $5 and $10, is part of what then gets us to this notion of physicians disputing at the end of the year "I really couldn't possibly have eaten that many meals from applicable Manufacturer A."

I think there is a need for some sort of common sense here. I know meals are a real issue, but I also don't want to make them the focus of the regulation. I think patients care about what financial relationships are and if there is a conflict, as opposed to if people are being incidentally fed during a time where they are providing a service.

Dr. MCCLELLAN. All right. That's actually a good transition to what I want to talk about next. There have been some great comments on what gets reported, some very useful perspectives on that and how to move forward. Next is how it gets reported. So as Doug was just emphasizing in his comments, what really matters here is the public getting an accurate understanding of what's going on with these financial supports.

A key part of that is presentation. The law and CMS' proposed regulation envisions a website that's easily searchable. Fortunately, as in some of the other issues we've discussed, this is not something where we need to start from zero. We've got some good experience and some examples already.

So, Chuck, let me turn back to you to start off this discussion, since you've already been involved in trying to compile some of this information in a useable way for the public. What is most important in getting this right? What are the things that should be part of this website, and are there ways to get going on moving towards implementing that now, even as we're waiting for the final regulation?

Dr. ROSEN. I thoroughly agree that the reporting should be accurate, whatever system is worked out, and it accurately reflect whatever compensation the physician has gotten, whatever form or not. I encourage and believe in that. Nobody really cares about bagels, frankly. I mean, that's not the whole thing. It's often trivialized and jokes are made about it to sort of denigrate the Sunshine Act, it's all about bagels and cream cheese and eggs in the morning.

Well, it's not. I guess that's gotten caught up in it, but nobody really cares if you ate $300 worth of bagels last year.

Dr. MCCLELLAN. So when you're designing this website and presenting this information, what would you really want to——

Dr. ROSEN. Well, all we did was take the data as it's listed by the companies under their categories and did not change anything and put it in. That's all we did, and we developed programs to access it every two weeks to update it, automatic programs. So we didn't change it. As far as the details on how to break it out and how to list it out, I'll leave that up to the decision-makers, what's going to be listed and how you're going to be listed.

I think accurately it should list just what the physician gets. I think that what the physician gets personally should be listed because we're talking about people writing papers and research that affect the entire country and all patients and a very public stance, and you have no right to say, well, that's public, but I can't tell you about the financial stuff, that's private. You can't have one side public on the other side, and I don't know why it's a problem reporting a big salary from a company. I'd be glad to report a large salary from any companies out there. I don't right now, but if——

Dr. MCCLELLAN. Duly noted. But in all seriousness, I appreciate the emphasis that you're putting on getting the most important information out and making that clear. Again, a number of the companies here have some experience in doing that. Maybe, Diane, you talked before about how devices are different in some ways. Devices do involve a lot of back-and-forth interaction in their development and further innovation with the practicing physicians, and there are a lot of financial arrangements tied up in that. Your thoughts on how to make this public reporting as clear and useful as possible?

Ms. BIAGIANTI. When you first asked that question, Dr. McClellan, my first thought was the challenges that we had faced in our voluntary disclosure program and some of the challenges I perceive that CMS will have as well in aggregating the data. I understand from Ms. O'Farrell that Lilly has had the same issues, and that is how do you identify, uniquely identify the health care practitioner or the physician, and that is something that we struggle with as an industry. There is no unique identifier for each physician. You can use the NPI. There's not necessarily one for all physicians. You can use their state licensing number, but they may have multiple state licensing numbers. So how do you aggregate the data so that you are accurately and completely reporting the data?

From CMS' perspective, how are they going to aggregate data from multiple manufacturers who may be reporting a different identifier, NPI, state license number? How do we make sure that happens?

So our suggestion has been it would be very helpful to have a unique identifier from CMS for industry to use to ensure that we are capturing accurately the data associated with an individual physician, as well as CMS can aggregate that data appropriately, and patients have access to that information. So that was one immediate reaction I had to your question.

In terms of the data and what would be helpful to patients on the CMS website, definitely searchability is going to be very helpful. It doesn't help to show what Lilly has paid, what Edwards has paid. What they want to see is searchability by a doctor's name. So that's critical and, again, goes to aggregation.

And also the ability to add context around those transactions. If our whole purpose is to provide clarity to the public and to patients around what those collaborations look like, it is not going to be helpful if we're just providing numbers. We have to explain the context around those collaborations so that there's an understanding of what that means.

Dr. MCCLELLAN. And is there a straightforward way to do that based on your experience?

Ms. BIAGIANTI. Based on our experience, we have not gone transaction by transaction because our voluntary payment program is not transaction by transaction. So I don't have a clear answer, but context around an individual transaction is probably going to be helpful.

Dr. MCCLELLAN. Okay. Liz, you all have a website that provides information on transfers of value and the specific dollar amounts and has some of this kind of categorization and context built in. Your thoughts about how to do this right?

Ms. O'FARRELL. I think for us the most important—and we spent, I'm not going to say as much time on the context on our website as we did on tracking the data, because we spent a lot of time getting the data reported. But we did put a lot of time and effort into the context of our website. We wanted to really make sure that a reader of the data would have the ability to really understand why we work with different health care professionals, the context of our work there.

For example, for research, we do disclose all of our payments, including research, and we disclose both the entity paid and the principal investigator. That shows that, first of all, the check, the actual payment, for the most part went to an institution, not a person; and then we have a lot of words, context around what does it mean to be a principal investigator. What does that mean? What does this number mean relative to what that person may or may not have received? Even indicating that sometimes that person may have received nothing, the physician, because they're an employee of the institute. And that, I think, has been very well received by the research. We have that kind of context with everything. We actually have a video of our chief medical officer in the U.S. talking about the work that we do.

We also have evolved with our current registry to being very downloadable and searchable. We feel like if our information is going to be out there, we want people to be able to get everything out of it that they can. So we offer multiple ways to search, to look

up different transactions, or we aggregate. We don't have it at the transaction level, but in the different buckets.

I think the last is we really do look at the categories. We spend a lot of time on what are the categories. So we agree, research is research, and if you're going to disclose—if you're going to be paying for meals while you have somebody who is in a start-up meeting or something, that that is all really research, and we have also a lot of context on our website about what that means and why.

So I can't highlight enough how important it is to spend the time to put that context, because just looking at the numbers can be very misleading. I also think that it's important to understand that people need to be able to search and download and really look at this data. I think that this is also a key for CMS, then, to make sure that you are providing a lot of clear guidance on what a bucket is, what's in research, what's in meals, what's in speaker programs, because if you want it to be able to be aggregated across the different manufacturers, it's really important that we've got good definitions bucket by bucket, not dictionary definitions but real-life definitions, so we all know that we're submitting things the right way to you so you can aggregate.

Dr. MCCLELLAN. And, Niall, again, I know you're limited in what you can say, but any thoughts from CMS about what should go into the website and what should go into providing context for people who are using it?

Mr. BRENNAN. Well, we're very aware of the need to present context with these numbers. We certainly intend to conduct extensive outreach and education to make sure the information is presented in the appropriate way. Also, I think CMS has a fair amount of experience in this area of presenting complex information via web tools such as Hospital Compare, the Plan Finder tools, and obviously the upcoming exchange implementation. So CMS has invested a lot in translating complex issues to consumer and patient audiences over the years, and we'd certainly hope to leverage that going forward as we present the information on a website.

Dr. MCCLELLAN. Thanks. Let me ask anybody else here—this is a very important topic, context and how the information is presented. So I just want to make sure I don't miss any important ideas, but please do keep it brief.

Dr. LAZARUS. Just a couple of comments, Mark. First, I think it's incredibly important from our point of view that for the individual physician, that there should be direct payments. Those are the things that we think the public wants to know about, the direct payments, and not to go beyond the statute.

The context is important. I think the context for us is also that we would have an opportunity to also have a place on the website to comment on our view of what was reported.

And in addition to that, we didn't get into the dispute resolution part of it, and hopefully if the issue of more direct payments is taken care of, there will be less disputes. But if there are disputes, there should be an opportunity for the physician to have an opportunity to say that on the website.

The last part of it is that we talked a lot about research. We would suggest that you consider a separate section of the public

website that only is about research, and that might separate out some of these issues, make it more clear.

Dr. MCCLELLAN. So distinguishing that from CME?

Dr. LAZARUS. Yes, not a non-certified CME.

Dr. MCCLELLAN. Right.

Dr. LAZARUS. So that it's clear that there are different buckets, and the public would be more clear about whether it's research, promotional marketing, and we hope certified CME doesn't make it into it.

Dr. MCCLELLAN. You did make that clear.

Jay, and then Chuck.

Dr. SCULLY. I just wanted to follow along that we think that the dispute resolution business needs to be settled before the numbers are put on the website, rather than have that go on when misinformation is——

Dr. MCCLELLAN. Although some disputes may take some time to settle.

Chuck.

Dr. ROSEN. The spirit of the Sunshine Act, I believe, is that money for what physicians do that goes to them be reported. Because it stops at some intermediary and is sort of laundered a little bit doesn't mean it can't be reported. So I think if the CMEs are excluded, tens of millions of dollars are now going to go through CMEs to physicians and avoid the reporting requirements of the Sunshine Act.

Also, certified CMEs—I mean, let's be realistic. This is where speakers that are paid by companies will talk about off-label uses of products. No emails will be sent. There will be no documentation. That's kind of the part of it in a lot of these, and to say that they're all sort of pure and they're certified and there's a firewall, that really just is not realistically, in my opinion, what happens. It's kind of a wink-wink, nod-nod, we'll have a CME down in the Caribbean.

Dr. MCCLELLAN. I appreciate the perspective on this. It seems like there are a number of areas where there is substantial agreement. This may be one, for handling certified CME, where there just isn't, and that's another reason why Niall's got a tough job.

Dan.

Dr. CARLAT. Just a quick point of agreement. I had some time with Eli Lilly's website, which is an excellent site. Pew has commissioned surveys of consumers. Consumer Reports has published surveys. There have been some peer-reviewed surveys published in 2012 in a couple of peer-reviewed journals. Overwhelmingly, what we see in these surveys is that the main concern that consumers have with these payments is the marketing payments. So, for example, 72 percent of the Consumer Reports survey respondents said that they were very uncomfortable with doctors giving promotional talks, particularly when they were giving promotional talks for a company whose drug they were prescribing.

So I would say that, again, I would agree with a lot of what's been said here, that the buckets need to be very clear.

Dr. MCCLELLAN. And it is nice to know that there is at least some experience that can be drawn on to get at least the most important buckets off to a good start in this program.

I do want to turn, in the time that we have left, to another set of issues, and that's implementation. So we talked some about what. We talked some about how. But carrying out the implementation of this website and this ability to obtain transparent information about financial arrangements has a whole set of issues in itself. We've talked about some of them already. There are issues related to standards, what gets reported how, given the complexities of some of these arrangements. We've talked about data systems. Niall even noted that this is a parallel effort, in addition to just working out the details of the final regulation.

A third issue that some of you have already emphasized is education and outreach to the physicians involved, to the people who need to do the reporting, and to the public that's going to be using these tools.

So I'd like to spend a lot of our remaining time on these very important implementation issues, and we can stipulate at the beginning that for the implementation questions that I know many of you are most interested in—what's the date of the final regulation and what's the date of data collection—I think we're not going to get those exact dates today. It sounds like it is going to be in the not-too-distant future.

With that said, it seems like there's a lot that can be done now to help make sure that we're as prepared as possible to enable this to go smoothly. With that in mind, I would appreciate some comments from you all who have already made some investments in getting ready for Sunshine implementation to talk about what can be done now and what are still important unanswered questions given the proposed rule and the uncertainty that exists.

I'm not sure who the best person is to start with on this. Maybe I'll go back to Liz and Diane since you all have some direct experience with these kinds of systems.

Ms. O'FARRELL. Thank you. As I said, and we actually brought a couple of visuals as well, we started our CIA implementation of our registry, which encompasses all payments and transfers of value, and it took about 23 months to get from the point of really starting, understanding what the requirements were going to be, understanding our business processes, making the appropriate changes both to business processes, communication, training, and to the approximately 30 source systems that we have that feed all this.

We also had the luxury of already having the Sunshine Act to look at. So as we went through that process, we tried very hard to mirror or to make sure we were accommodating what we thought the interpretation of the Sunshine Act would be, and really felt that after this work we would be pretty much ready for Sunshine, with a few exceptions that we knew. TOV from CROs we knew we didn't get that in and we'd have to work on that.

So when the draft regulations came out, we were really surprised by the difference between where we were and a lot of those that I talked about in my opening statement.

So a lot of the timelines from the implementation standpoint for companies will go back to how complex the rule is, how broad the transactions that we have to cover are. We believe that an implementation timeline similar to what we've gone under with our vol-

untary first disclosure and then CIA, which is really starting with payments that are much more direct, that we have control of internally in our system—we still may have to make some system modifications, but that you can actually control and get out there, that most companies should be able to do that within a maximum of 180 days, and in Lilly's case that would provide about 70 percent of the transactions. It's not going to get the bagels, but I agree with you. I'm sorry, I mean 70 percent of the value. On our registry, less than 5 percent of our $216 million is meals, but that's about half our transactions. So the cost/benefit there is pretty off balance.

Then we believe that you could give people time, then, to start looking at some of the more difficult implementation challenges, including CROs. As Dr. Scully said, we have learned that it is very challenging to work with CROs and get the data. I do think we're going to have an opportunity as an industry to standardize some of that, versus companies under CIAs going one off. But we have some CROs that it took a year of renegotiating the contracts and getting that data in from them. Just as in any other industry, there are more sophisticated CROs and less sophisticated CROs.

And then going to a third phase, if it's still necessary to capture the transfer of value of the meal, attributions, et cetera, putting that in the third phase. For us, that's only about 8 percent in total reimbursed expenses, plus the meals. So that can always be up for debate, but right now I think it is required.

But we believe that if you can phase something like this in, you can get a lot of the value early on, allow CMS to get what would actually be fewer transactions with that value, to implement that into their website, and then see how the dispute resolution process works, et cetera, and then move to increasing types of transactions.

Dr. MCCLELLAN. Thanks. And next, Diane, tell me about how this fits with your experience, this kind of phased approach.

Ms. BIAGIANTI. Yes. So I would echo some of Liz's comments in terms of implementation. You know, we started voluntary disclosure four years ago. So we got a little bit of a jump on the rest of the industry; in fact, quite a bit of a jump. And that's really worthwhile noting. For a company like Edwards that has done this voluntarily, we have learned from that experience. We have gone through iterations on our systems and processes. For someone who has been subject to a CIA, there has definitely been a lot of work done, a lot of time to develop those systems.

For the medical device industry, we are very unique in our size. We are not pharma. We have very, very small medical device companies. Edwards is probably one of the bigger ones with respect to that. So it's going to take companies a different amount of time based on that diversity of the population in the device industry.

Again, we started quite a while ago, so we learned from that.

Dr. MCCLELLAN. Is that sort of phased by company size, as opposed to type of activity?

Ms. BIAGIANTI. Actually, what I'm suggesting is that companies are going to need time to get started. So for us, we have learned companies are going to have to go through this painful process of how to do it, and for smaller companies it's going to be very painful. So as the med device and pharma has suggested, at least 180

days is what we really think is appropriate for the industry in general.

In terms of Edwards, even though we had gone through voluntary disclosure, once the proposed regs came out, we sat down and we looked at what those requirements would mean to Edwards, and it involved a significant amount of system processes development, training, and it took us at least six months to get there.

Dr. MCCLELLAN. And you have some of those details in your written statement, which I appreciate.

Ms. BIAGIANTI. Yes.

Dr. MCCLELLAN. Dan, you all have—in your statement you reviewed some of the published work in this area, some of the surveys that Deloitte and others have done about readiness for implementation. So we'd appreciate your comments about the implementation challenges.

We ended up focusing a lot on timeline, and specifically on time to data submission, but I want to emphasize that while that's really critical, I do want this discussion to be broader than that. To the extent you can get to other issues like education and outreach about using the data, I'd like to make sure we talk about that, too; and I'm going to get to everybody else as well.

Dr. CARLAT. Thank you. As we've looked closely at the existing transparency regulations, I think we've learned three points that are important to this discussion.

The first one is that consumers are not ignoring this information when it's out there. So, for example, ProPublica, which is a journalism website, aggregated data from 12 companies and put it on a website. These are large companies, accounting for 40 percent of all drug sales in the U.S. And they started that site in 2010, and they've had 5 million hits on that site in over two years. Consumers want the data.

The second thing is that we've learned that these programs, even though there's been concern, these programs really are not harming the industry, they're not harming research. For example, in Minnesota, which is the state that has the longest-running transparency provision, 1993, Minnesota has developed a very thriving medical device industry, as you know. My own home state of Massachusetts passed a gift ban and a disclosure law in 2008, and again there were concerns that the biotech field would flee the state, alarmist editorials and what-not. And as it turned out, just the opposite has occurred. So we've had four or more companies—Novartis, AstraZeneca, Biogen, another that escapes my mind—that have made very large investments in the state after that happened.

And then finally, I think it's important when we start talking about phasing things in, which worries us a lot about delaying this even further, these regulations are not carved in stone. So take the example of, say, Vermont. Vermont has had, since 2008 or 2009, a disclosure law and regulation in effect. After they released their regulations, the Attorney General's Office had conference calls and a lot of communication with stakeholders, and as they had that communication, they got feedback from stakeholders, and they altered their guidance accordingly in order to make sure that things weren't excessively burdensome or just that things were fine-tuned.

So I think that we have to keep that in mind as well before we talk about delaying the release of these regulations further.

Dr. MCCLELLAN. I think I'll just pick up on that, Niall, in a question for you. I'm not sure it's the usual way, but a very common way for CMS to proceed with regulations in complex areas like this one is you do the proposed rule, you get all the comments back, maybe even more than you expected, and it takes longer than you expected, you do the final rule, and then there are still a lot of things that need to be clarified that people may not fully understand, and that does usually respond well to some kind of process. CMS has done open-door forums. They have sometimes held mini-conferences or workshops around implementation. There might be some regulatory guidance written or other kinds of questions and answers.

Is that in the cards in this case? Any planning at CMS for what happens after the final regulation is out to resolve what will probably be some further questions and need for clarification?

Mr. BRENNAN. So again, I can't really get into specifics, but I don't see why we would approach sub-regulatory guidance around this particular provision differently than we've done it for many, many other activities. We recognize the complexity. We recognize the sizeable lift it will be for applicable manufacturers and covered recipients in the first year, and we do want to work to make it as painless a process as possible.

Dr. MCCLELLAN. Let me go back now to get maybe some physician perspectives on this. Again, a big part of implementation success is going to be physicians being aware of what's coming, why, and why the choices that were made in this regulatory process were made.

Jeremy, your thoughts about how to make that education outreach process work as well as possible? I know the way to make it work easiest is if CMS follows your recommendations. But beyond that, regardless of what happens, there is a lot, or at least some things, that physicians are going to need to know about what's coming, and where are we on informing them?

Dr. LAZARUS. Right. Well, we did have CMS come in and meet with a group of our states and specialties, which was very helpful. We still are waiting for the final rule, obviously. Of course, if CMS listens to us, that would make it a lot easier. If it's simpler, the better. Less complex is better. But once it's done, we think it will take us about six months to try to educate the physician population about what's going on. We'll put something up on the website. We'll put it out on our communications vehicles across the country. But I think it's going to take some time to get the information out.

But rather than put it out in a half-baked way, which is going to make things very confusing for physicians, we want to see the final rule so we can tell them what they're up against, what they do need to keep track of, and what they don't.

Dr. MCCLELLAN. And, Doug from the standpoint of individuals or health professionals participating in leading research efforts, education plans for them?

Mr. PEDDICORD. Let me make just a comment or two, and then try to touch the education piece.

Dr. MCCLELLAN. Okay.

Mr. PEDDICORD. One is that I want to be strongly supportive of the notion of research as a clearly delineated bucket and in some ways separately reported with its own context.

The other is just to comment that CROs are increasingly the project management infrastructure for the enterprise. So on the other side of Liz and Diane's companies are companies in the middle. So Diane talked about a year's worth of time to renegotiate contracts with CROs and looking at her 30 source systems for where she's going to get the data. So it will now be the company in the middle that's dealing with Lilly and 499 other manufacturers, which is what gets me back to my issue around levels of standardization; because again, I think it's going to be impossible for CMS to construct a meaningful database if it has discordant data elements coming in.

So with that said, I think what's happening at the level of physicians, I think one of the things that certainly a number of CROs, that are very much involved in physician recruitment, are doing is educating around reporting and the notion that dollars will be reported. I don't think people care—I don't think people really do worry about the notion that dollars are reported. What they worry about is dollars that they haven't seen being reported as attributed to them. That's a different issue.

So I think we're in the process of educating new physicians, and what I think we're trying to deal with is those concerns that come up out of that survey. We shouldn't really lose—25 percent of current investigators should not say, gee, I would be less likely to be engaged in research if revenues are going to be reported. I mean, we really can't tolerate that because that's a lot of investigators to lose.

So I think that leaves us and the manufacturers in need of educating physicians, along with physician societies and the like, because we really can't afford that.

Dr. MCCLELLAN. And beyond CMS, I know following your comments and finalizing the rule, are there some steps, further steps that CMS can take, that you all can take, that others can take to handle these education issues which we know will be coming?

Mr. PEDDICORD. Well, I think certainly within the rule itself, I think CMS needs to provide levels of guidance that are actually intended for the physician population. So physicians have certain questions around are these revenues going to be reported to the Internal Revenue Service? Does this begin to show up on my tax return? I mean, physicians ask lots of questions. So I think within the rule, the discussion section and the guidance around that, and the FAQs that CMS puts out, because ultimately those disputes are going to go to manufacturers and to CMS, both. So I think a really good FAQ section is going to be very much needed.

Dr. MCCLELLAN. And as I think Dan emphasized, since this is probably going to be an iterative process even if CMS tries their best to get those FAQs done right in the regulation, it seems likely that some things are going to be missed, some further clarifications are needed, and it seems like everyone is willing to engage in a collaboration through further work on FAQs, through some regulatory guidance, or at least through giving some quick feedback to CMS

to help with those education efforts. It seems like that's going to be very important.

Any other comments about key implementation issues? I want to turn to one other implementation topic——

Dr. SCULLY. Just a note, that in the education world there are a lot of other things being learned. You may have noticed there's a fair amount of ferment going on in health care and what physicians' roles will be, and our relationship with CMS in other areas. There's a lot going on. So this will be one, probably not the highest priority for our folks.

Dr. MCCLELLAN. That's right, a lot else happening now.

Ms. O'FARRELL. Could I add one thing?

Dr. MCCLELLAN. Yes. Go ahead, Liz.

Ms. O'FARRELL. I referred to this in my opening statements as well. Under our CIA, we have been very clear in reporting on physicians where we influence or control the selection of the physician. So what that doesn't broaden to is every vendor that we use who may or may not be using a licensed physician to do work for them on our behalf, a consulting firm, a law firm, a training development company that we go to get training and they need to use a physician to review some of the training, for example.

If that doesn't change in the final regulations and the knowledge standard stays and there's an expectation that we would know and take reasonable efforts to know what every vendor that we engage is doing with any kind of health care professional or licensed physician, and then have an obligation to attribute some value for that work and publish it, the implementation timelines are—we don't believe that that's manageable operationally at all, and the implementation timelines are very short.

Where I get concerned about the iterative process—and I appreciate that, and we've had that with the OIG, and we want a venue to be able to come forward and say is this the right interpretation, is this a different way. But some of these, you can't go back and change a business process retroactively. You just can't. Once you've done it, you've done it. And so some of these, we're going to have to have really good clarity before day one, because we can have a discussion for 90 days, 100 days, and if it comes back that the answer is different than what we're hoping, we have no way to go back and change our business processes to start tracking that.

So I think that's where we have to understand that an open discussion for all the implementation items is good, but you can never go back and recreate transactions or change your business processes retroactively.

Dr. MCCLELLAN. Liz, you and Doug both particularly highlighted this concern around this. Doug said payments that you don't know are going to be attributed on your behalf.

Dan, this is something that I think you all commented on as well. Any thoughts about how to resolve this implementation issue?

Dr. CARLAT. The overall comment that we made—and you've mentioned the Deloitte survey that we had looked up. Deloitte surveyed pharmaceutical executives recently and asked them how prepared are you for the Sunshine provisions. Eighty-eight percent of those respondents said they were at least 50 percent prepared, and a third said that they were 100 percent prepared.

We realize that, of course, in that survey the respondents didn't know exactly what the Sunshine rules would end up being. So there may have been——

Dr. MCCLELLAN. It may have been a test of optimism.

[Laughter.]

Dr. CARLAT. I think the bottom line is that they were fairly optimistic, and given the fact that virtually all drug and device companies have had to report this data for certain states, we're fairly confident that they've developed reporting systems that have been able to work.

Dr. MCCLELLAN. There is a good deal of experience out there to draw on.

Just so you all know what's coming, I do want to make sure you get a chance to get out everything you think is important. So in a few minutes before we wrap up, I'm going to ask you all, give you all a minute or two to highlight any points that you want to make sure that people in general, or Niall, or others in particular take away from this discussion, and any other issues that we haven't brought up yet. So I'll be turning to you all for that in just a few minutes as we get closer to wrapping up.

I did want to come back before then to one more implementation issue, and that's that many of you have stressed the importance of standards. As I mentioned at the outset, this is a challenge in lots of different areas of health care, where the information involved is complex and the responses are often a combination of actions by CMS and their coding decisions and things like that, but also a lot of leadership from industry and other stakeholders involved to try to get to consensus to solve these practical problems.

So, Niall, first to you. You mentioned the work on data systems that you're thinking about in parallel to the final regulation, and CMS has to rely on a lot of information technology, information management vendors in this process. Is there anything you can say now about what's going on in this regard? I know that the final regulation isn't out, but if there's some technical work being done around data structure and things like that, maybe that's something that would benefit from even more collaboration.

Mr. BRENNAN. Obviously, there are two types of implementation challenges. There are the implementation challenges that applicable manufacturers face, and there are the implementation challenges that CMS face, and those are overlapping. But realistically, the applicable manufacturers face their implementation challenges on a slightly more aggressive timeline than CMS does because when the data collection begins, as the law specifies, applicable manufacturers have to collect data for an entire calendar year and then submit it to CMS on March 31st of the following calendar year.

So there are definitely great challenges for applicable manufacturers, not that CMS' challenges are any less, but they're different. We'll be receiving a standardized data template from hundreds of applicable manufacturers and GPOs containing potentially hundreds of millions of lines of data, and as some of the other panelists have alluded to, our big challenge will be accurately aggregating the data in a way that we're sure that all the right dollars are going to all the right physicians, accurately and efficiently estab-

lishing a review, a secure review, an appeal process for physicians to be able to review those results and let us know if they agree with them or not; and if not, work with applicable manufacturers to come to resolution; and then finally, presenting it in a consumer-friendly and accessible manner on a website.

So that's how we're approaching our side of the implementation challenge. Obviously, Mark, as a former CMS administrator, you know our goal is to try and avoid duplication of systems and building other silos. So there's a lot of activity across the agency around building out or examining the build-out of provider portals and how does authentication work and security, different things like that. So those are the types of actions that we're taking right now to get our implementation ducks in a row.

Dr. MCCLELLAN. So before we wrap up, I'll see if there are any further thoughts on this issue of system support and standards for effective implementation of these requirements as soon as possible.

Chuck.

Dr. ROSEN. I think the work lies more with industry's template of how to work out what the accuracy of the payments are, and they should be very accurate, and there's no disagreement about that.

I don't understand why it would be a problem for CMS to aggregate the data and collect it. We've done it, and we're nobody, and we've collected all the data for seven years, and we haven't even gotten cooperation of any of the companies to send it to us. We've had to query the systems, and all 75 or 80 companies have different systems. Some are better than others.

So I don't understand where there's an issue of, when CMS gets the data on some template, why it can't be put up the next day, frankly. We have security. We have all these things on our website.

In the summary note, I also want to mention, talking about what you said, that doctors should know about this, there's no penalty to getting money, no matter how much it is. There's no part of the Sunshine Act that says you cannot get this amount of money for whatever thing you do. The companies don't like it because sometimes, most of the time it's with products that are a little iffy, that you don't want people to know are not necessarily independently validated. The vast majority of products are very good. In fact, they're very good that people name them after themselves. But I don't know what the defensible reason is for not accurately listing money that you've received from a company, which is the basis of the Sunshine Act.

Dr. MCCLELLAN. I think that is the goal that we're headed for.

Any other thoughts about things that could be done now to get to more standard, effective templates for this reporting so that the program can hit the ground running?

Dan.

Dr. CARLAT. So there's been a whole cottage industry of IT businesses that are providing software solutions for companies. If you go to any of the meetings, you'll see whole exhibit halls now filled with these companies. That's good for the economy.

One of them is for the dispute resolution process. There are a couple of companies that are creating physician portals so that you don't have to get into a position of that terrible 45-day window be-

fore the information goes public. There will be software available to create portals for doctors to go in to look up exactly what they've been reported, how many hundreds of dollars have been reported, and then to communicate with the company if they disagree. So that's just one example of many different solutions out there.

Dr. MCCLELLAN. Thanks. I appreciate all the comments on all the topics. We are coming close to the end of our time. I have a minute or two for you all to highlight any final issues. You don't need to restate everything that you've already stated or that's in your written statement, just any points that we haven't discussed as much as you'd like that you'd like for people here to take away.

Liz, can I start with you?

Ms. O'FARRELL. I will restate that I think the implementation timeline is very aggressive for companies that do not already have any kind of reporting in place.

One thing that we didn't talk about today is the definition of applicable manufacturer, and we really believe that it needs to be limited to the subsidiaries operating in the United States. We currently have processes in place to track and disclose U.S.-based physicians who are asked to go outside the U.S. and present or be on an advisory board with one of our outside-the-U.S. affiliates. We feel pretty good about those processes, and we believe that those are valid processes to require.

But to try to extend that to any U.S.-licensed physician who happens to be asked by one of our foreign affiliates to come in and do work for them—so you have a French-based physician who also has a U.S. license, and to try to get that French affiliate to put a process in place to track those type of transactions we believe is meaningless to the public and would require such a level of infrastructure that 180 days, 360, it would be unable to be done in that short a time.

Dr. MCCLELLAN. Thank you.

Jeremy.

Dr. LAZARUS. Thanks. I think the one thing that didn't come up is the potential impact on the individual physician if the data is not accurately reported, and that's why we are hopeful that we'll be able to follow the statute in terms of the direct reporting, some of the things I talked about before, and also so that there is an ongoing dispute resolution process between the physicians and the manufacturers. As Dan said, there is already the ability to do that so the physicians can be aware of what the reports are going to be, get those disputes ironed out before they get up on the public website.

And also the thing I think we didn't talk about, and I was glad that Niall talked about it, is that there should be a dispute resolution process if there is a disagreement, and we think that it should either be CMS or an independent agency. But, hopefully that can get done and that 45-day window is more of a rolling window so that there can be an opportunity for physicians to dispute inaccurate reporting. Thank you.

Dr. MCCLELLAN. Thanks, Jeremy.

Dan.

Dr. CARLAT. Thank you. I think the only thing that I'd like to emphasize is from the consumer perspective. The information is

going to be interpreted in very different ways depending on the doctor's relationship and depending on the consumer. For example, I have a colleague who I was meeting with at my last professional meeting who gives talks to companies. He's made up to a million dollars a year giving talks. He gives a printout to each of his patients detailing each one of his talks, all the companies that he works for, and he tells me that not a single patient has left his practice because they value the trust in the relationship.

On the other hand, in the December 2011 issue of Health Affairs Journal, there's a story from Maran Wolston, a woman with multiple sclerosis, who worked with a neurologist who offered her to be in a clinical trial, pressured her to be on a couple of medications, one of which caused terrible side effects. She wasn't sure about the level of trust. She looked him up in the Minnesota database and found that he had made $300,000 from two companies that made drugs that she had taken, which made her seek a different physician.

So I think the point is here that consumers are going to be interpreting the data in very different ways, but they deserve to get this data. It's important data for them to have.

Dr. MCCLELLAN. Thanks very much, Dan.

Diane.

Ms. BIAGIANTI. I would just add a couple of points, some that we've already talked about. Most of the things that concern Edwards with implementation are certainly the indirect payments which we've all discussed, and that is a big operational burden for device manufacturers, pharmaceutical manufacturers. So that is a big issue.

Certainly the issues or the potential disputes that may come from physicians with respect to misrepresentation of the allocation, whether it be meals that they don't feel are appropriately allocated to them, or whether it's the clinical research that they don't feel is appropriately identified or allocated to them when they haven't been paid.

So those are the biggest issues we see, and that leads to the dispute resolution process. We do think there does need to be an appropriate amount of time. We can't yet guess how many disputes will come in as a result of this process. It's very different than the voluntary disclosure program that we've implemented, so we can't yet guess what time is needed to give physicians significant time to dispute it, but then we need to add on a separate, segregated time period, a time for the manufacturers to do their research and to work before that gets publicized.

Dr. MCCLELLAN. Great. Thank you.

I'll save you for actually the next to last word. I get the last word.

Doug.

Mr. PEDDICORD. Well, let me just say, I think well implemented, Sunshine will illuminate the triangular relations between biopharma companies and doctors and patients. What that means is that it will illuminate interests, the vast majority of which are not conflicts of interest. They are interests. People have a right to understand the interests that each of the participants have. But

again, that doesn't represent, necessarily represent a conflict of interest.

We've been pleased to be part of a national dialogue on health care innovation which has very much been looking at these issues around conflict and potential conflict and how to manage that. I think the principles that came out of that dialogue, and it's a dialogue across industry and patient groups and the like, was that those relations should be built on four principles. They should benefit patients, first of all. They should preserve the autonomy of health care professionals. They should be transparent. And they should build accountability into the mix.

And so with that in mind, what's important to note is that Sunshine doesn't replace ethics, that when a physician enrolls a patient in a clinical trial, for instance, the disclosure of interests is not a replacement for the physician behaving appropriately and ethically. I don't think we should suggest that informing the patient of financial interests somehow prevents people from doing bad things. That's not the point of Sunshine. Sunshine should be about transparency and interests. Again, without some interest, there won't be even the potential for a conflict of interest. So, with that said——

Dr. MCCLELLAN. Thank you very much.

Chuck.

Dr. ROSEN. Being the only orthopedist on this panel, I'm sure there will be a bunch of jokes about that.

Maybe the dollar limit is too low. Maybe it uses up too much of the industry effort to ferret out $200 or less, and it should be somehow differentiated and more focused on money that's over $200 or $500 or $1,000.

And just a final word, the Sunshine Act will not hurt but will improve legitimate research and physician education. It will not hurt physicians to be transparent for the reasons Dr. Carlat elucidated. I think there's a fear of this transparency that's unwarranted and exaggerated by some.

Dr. MCCLELLAN. Thank you.

Jay.

Dr. SCULLY. Patients deserve to know this information. We all agree to that. The information needs to be accurate. That's some of the concerns about Murphy's Law that still exists. If things can go wrong, they will go wrong. And it hasn't come up, the estimate that for an office practice, the cost per year for reviewing this is $72 is a fantasy if there's a dispute.

Dr. MCCLELLAN. Thank you.

And with that, I'd like to turn to Niall for the next to the last word for the roundtable.

Mr. BRENNAN. Well, I don't know if people know, but I used to work for Brookings a couple of years ago, so him having the last word is just like old times.

We appreciate the opportunity to be a part of the roundtable. We think the feedback was excellent. I don't think it's an exaggeration to say there's probably nobody in this room who would like to see the final rule come out more than me.

[Laughter.]

So we hope that we can make that happen very soon.

Dr. MCCLELLAN. Great. Thanks, Niall.

Niall does get the award for the toughest question of the day, and it came from Chairman Kohl or Grassley and Senator Blumenthal. I know it was on everyone's mind. I appreciate your being here for this discussion.

But I also appreciate all the rest of you taking time to answer a lot of challenging questions and to keep this moving. Everybody stayed within their time limits. That doesn't happen often in events that I moderate, especially on such a challenging topic as this.

I think that's a testament to both how important and meaningful this issue is and how much everyone who is involved in it does want to see this move forward and succeed.

This roundtable will definitely not be the last word, but I hope it's been helpful in advancing the discussion, and I, for one, look forward to what happens next, and I want to thank all of you, and the senators especially, for their continued involvement and their keeping their hearts behind effective implementation of the Sunshine law.

Thank you all very much.

[Applause.]

[Whereupon, at 4:29 p.m., the hearing was adjourned.

APPENDIX

Statement of

Diane Biagianti
Vice President and Chief Responsibility Officer
Edwards Lifesciences Corporation

Submitted for the Record

to the

Special Committee on Aging
United States Senate

"Let the Sunshine in:
Implementing the Physician Payments Sunshine Act"

September 12, 2012

Chairman Kohl, Ranking Member Corker, and Senator Grassley, thank you for the opportunity to appear before you today to participate in this Roundtable, , "Let the Sunshine in: Implementing the Physician Payments Sunshine Act." As the Chief Responsibility Officer for Edwards Lifesciences and on behalf of our company, I commend you for your continued efforts to ensure that the Physician Payments Sunshine Act, included as Section 6002 of the Patient Protection and Affordable Care Act (PPACA), is promptly and effectively implemented.

Edwards Lifesciences is a California-based medical technology company that has maintained global leadership in the science of heart valves and hemodynamic monitoring for several decades. As a medical device manufacturer with sales in the U.S., Edwards is one of the thousands of companies that will be required to comply with the Sunshine provisions. We have been and remain strong supporters of this legislation, which requires manufacturers to annually disclose qualified transfers of value to U.S. physicians and teaching hospitals exceeding $100 cumulatively. As you know, the Department of Health and Human Services (HHS) was required under the law to establish reporting procedures for applicable manufacturers to submit information, as well as procedures for making that information available to the public. We appreciate your leadership on this legislation, and your continued efforts to ensure the law is implemented in a timely manner.

We understand the challenges that the Centers for Medicaid and Medicare Services (CMS) face in working through the complicated implementation details surrounding data reporting of certain transfers of value for U.S. physicians and teaching hospitals. Like Members of this Committee, as well as CMS, we are somewhat frustrated with the time it can take to develop clear guidelines for this process. CMS should be commended for their efforts over the last two years to reach out to interested stakeholders and engage in a consultative approach to developing their draft regulations. Despite the guidance you, your staff and Committee staff put into crafting the Sunshine provisions, we know from our company's experience that transitioning from concept to implementation can be very challenging. Based on the quantity and quality of public comments submitted in response to the draft regulations, we believe that CMS should have clear guidance on how a final rule will maximize clarity for those of us who must comply with the law. We know that CMS appreciates how important clarity will be to an effective regulation.

With that said, we are now almost a year beyond the statutory requirement for a final regulation, and more than eight months behind the deadline for implementation of the law. We would like to see CMS release a well-thought out regulation as soon as possible, as delay may be contributing to additional confusion and possible wasted expense. In the absence of a rule, manufacturers have had to guess as to what will be required of them in preparation for an implementation date sometime in the near future. Further delay will thwart the purpose of the law, causing more confusion about the appropriate role of physicians in the collaboration process.

Edwards Lifesciences has some relevant experience with this subject. For the past four years, we have been tracking and reporting financial relationships with U.S. physicians on a voluntary basis. Despite Edwards Lifesciences' own extensive experience with implementing a disclosure program, we spent over 6 months revamping and automating our systems, processes and procedures to meet the requirements under the law and may need several months to adjust our current reporting systems – and

launch an effective employee training program – if we have not guessed properly on what CMS will require of us. 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 our company in terms of preparation. It is worthwhile to note 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.

We undertook our voluntary program because we strongly believe the public must have full confidence in the important and necessary relationship between the medical device industry and the physician community. Many of the best ideas for new therapies and iterative improvements to existing technologies result from collaboration between physicians, engineers, and entrepreneurs. Edwards has always been proud of its relationships with clinicians, which led to the development of the first commercially available artificial heart valve and the establishment of our company more than 50 years ago. Medical innovation is dependent on these financial partnerships, and we believe that bringing transparency to these relationships will help the public better understand the critical role they play in the advancement of medical technology and patient care.

In late 2008, Edwards announced its plans to publicly disclose its financial transactions with physicians who receive $5,000 or more a year in consulting fees, royalties, honoraria and other transfers of value from Edwards. We began tracking this data on January 1, 2009, and have published it annually beginning in the second half of 2009 . In addition to the primary purpose of providing transparency, launching this voluntary program in advance of a federal mandate helped inform us and our ability to engage in the debate as we learned from our experience. As the first medical device company to implement such a program on a voluntary basis, we were 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. During the legislative process, we were able to share with your staff and other stakeholders some of the insights we gained in the early stages of the development of our program.

Because of our early start, our road to compliance with the federal mandate is fairly unique. We have built and tested the systems necessary to comply with most of the requirements of the Sunshine provisions, but we are not a large and complex company compared to some others. We can appreciate how difficult a process it will be for some companies to prepare to comply with the law. Indeed, if a company has not already invested in the systems, changed its policies and procedures, communicated those changes, trained appropriate personnel , as well as begun testing the data, it is likely that they will have difficulty timely reporting and assuring data integrity for their reports to CMS when those become required under regulation.

During the past three years, Edwards has built the systems to track and manage accounts payable, purchasing and expense reporting activities to ensure that we capture all payments to U.S. physicians that may add up to the minimum reporting threshold. As a global company with sales in more than 100 countries, we needed 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. This presented many challenges. For instance, in an absence of unique identification numbers for each

physician, we had to manage the challenge of verifying that transactions are appropriately matched (or not) to individuals that have similar names or where their names may have been misspelled. We have found that we needed to convert financial reporting systems that were originally built to help our company track and report financial information solely for accounting and tax compliance purposes, so this was no easy task.

Our experience has illuminated a number of issues that may present ongoing challenges to covered entities as we strive to develop a national policy that fair and accurately characterizes the financial relationships between medical technology companies and clinicians. We have provided CMS with comments on the proposed regulation through our trade association, AdvaMed, and remain concerned about a number of key issues that we hope will be adequately addressed through the final regulation. Among those concerns are:

1. ***Identifying Covered Recipients***: Accurately capturing transfers of value to third parties "*At the request of or designated on behalf of. . .*" covered recipients can be difficult. For example, we learned through our own program that 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.

   This is a complex issue that we've worked with other stakeholders to try to solve. Unfortunately, we believe there lacks consensus in this area, although there is promise that a reasonable approach could be found in time. While it is important the regulation captures relevant transactions , we believe that only a very small population of transactions will fail to be captured as a result of these types of situations, yet the burden on companies to try to ensure this data is captured will be significant. At this point, it is more important to get a final regulation out as quickly as possible so that manufacturers can have time to prepare for implementation in a timely manner. In the interest of time, we recommend that CMS and this Committee take the approach proposed by AdvaMed in this case: 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. It is possible that this approach could still result in difficulty identifying covered recipients if physicians wish to intentionally avoid the intent of this law. Therefore, unless CMS has already developed a better solution, we would urge CMS and Congress to view this aspect of the regulation as an ongoing process and to remain open to developing further clarification through additional guidance or regulation. We urge you and the Committee to continue your oversight of this important issue.

2. ***Context***: It is important that manufacturers are provided 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. Without sufficient details justifying the reported expenditure, patients and the public may unfairly conclude that the mere existence of a financial relationship is suggestive of an inappropriate relationship that would compromise the integrity of the physician and his/her judgment. CMS should ensure that it develops an information system capable of handling data submissions in their appropriate context. Correspondingly, CMS should seek adequate resources to ensure that this information is easily accessible to the public and is displayed in a user-friendly manner when it is published for the first time. We are extremely concerned that appropriate planning and funding for adequate systems to accomplish these goals has not occurred by the federal government, and we urge you and the Committee to continue your efforts to remedy this situation.

3. ***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.

4. ***Unique Individual or Entity Identification***: It is important that companies appropriately attribute expenses to the correct covered recipient. To assist companies in accurately identifying individual physicians or teaching hospitals, CMS should publish a list of unique identification numbers for teaching hospitals and physicians.

We understand that the behavior of some individuals and a few companies in the past has caused some to question the nature of relationships between industry and physicians. However, we know that high ethical standards and close collaboration between the two can and must exist. Our experience with the voluntary program at Edwards demonstrates that we can provide information required to assess these relationships. The overall goal of this program must be to increase public understanding of industry-physician relationships so that patients can feel confident in their physician's medical advice.

Edwards looks forward to working with the Committee, Congress, and CMS to ensure that stakeholders have prompt and consistent access to the information required by this law. Thank you for the opportunity to participate in this Roundtable discussion, and we welcome any questions you or your staff may have.

Written Statement for the Record

Roundtable on Implementation of the Physician Payments Sunshine Act
U.S. Senate Special Committee on Aging
September 12, 2012

Dr. Daniel J. Carlat
Director, Pew Prescription Project
Pew Health Group, The Pew Charitable Trusts

Chairman Kohl, Ranking Member Corker and members of the Special Committee on Aging, thank you for the opportunity to testify about the importance of implementing the Physician Payments Sunshine Act (the "Sunshine Act") as quickly as possible.

The Sunshine Act will bring critical and much needed transparency to the financial relationships between physicians and pharmaceutical manufacturers and medical device companies, and it has the broad support of diverse stakeholders, including consumer groups, industry groups and leaders within the medical profession. Industry trade organizations have publicly weighed in on the need to move forward with transparency measures contained within the Sunshine Act. Congress recognized the importance of making these relationships transparent when it included the Physician Payments Sunshine Act in the Patient Protection and Affordable Care Act (2010). Yet, despite an October 1, 2011 statutory deadline, the final regulation implementing the Sunshine Act has not been released.

The Pew Charitable Trusts is driven by the power of knowledge to solve today's most challenging problems. Pew applies a rigorous, analytical approach to improve public policy, inform the public and stimulate civic life. Based on research and critical analysis, the Pew Health Group seeks to improve the health and well-being of all Americans.

The Sunshine Act requires pharmaceutical and medical device companies to publicly report their gifts and payments to physicians and teaching hospitals. Medical products are central to modern health care, and academic-industry collaboration is vital for their development. At the same time, it is essential that the use of these products be guided by sound evidence and good science. Every patient deserves the safest, most effective treatment.

The drug and medical device industries spend heavily to influence a physician's choice of

products. Estimates of the exact amount vary, but pharmaceutical companies alone spend tens of billions of dollars per year on marketing.[1] According to a study published in 2010 in the Archives of Internal Medicine, 84 percent of U.S. physicians have some kind of financial relationship with industry, including receiving payments, drug samples or, most often, free meals or gifts.[2] About 14 percent of physicians reported being paid by one or more companies for services such as serving on speaker bureaus, consulting or enrolling patients in clinical trials.

The influence of pharmaceutical marketing is well established.[3,4] Leaders within the medical profession have recognized these impacts and called for transparency. A major Institute of Medicine (IOM) report in 2009, entitled "Conflict of Interest in Medical Research, Education and Practice,"[5] emphasized that some financial relationships between physicians and industry raise concerns about the risk of bias in clinical decisions. For example, companies have paid some physicians large but generally undisclosed amounts to give talks to other physicians, whose prescribing practices were then tracked by company sales representatives. Drug samples and other gifts to physicians by company sales representatives are major marketing tools that evidence suggests influence prescribing choices. The IOM concluded that conflicts of interest "present the risk of undue influence on professional judgments and thereby may jeopardize the integrity of scientific investigations, the objectivity of medical education, the quality of patient care, and the public's trust in medicine."

An optimal reporting system will ensure that all payments are reported clearly enough for consumers to understand what the numbers mean. For example, companies fund research in a variety of ways, sometimes by paying doctors directly, and other times by paying hospitals which then pass the funds on to doctors in charge of the research. It is important that in both cases, whether the payment to doctors is direct or indirect, that consumers be informed when doctors are receiving research payments from industry. This is not to suggest that research payments are undesirable. Indeed, these collaborations are vital, but the financial relationships should be

[1] Gagnon MA, Lexchin J. The cost of pushing pills: A new estimate of pharmaceutical promotion expenditures in the united states. PLoS Med. 2008;5:el

[2] Campbell EG, Rao SR, DesRoches CM, et al. Physician Professionalism and Changes in Physician-Industry Relationships from 2004 to 2009. Archives of Internal Medicine. 2010; 170 (20)

[3] Wazana A. Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift? JAMA. 2000; 283(3)

[4] Dana J, Loewenstein G. JAMA. 2003; 290

[5] Institute of Medicine. Conflict of Interest in Medical Research, Education and Practice. IOM Report Brief. April 2009

transparent.

A related issue is that some stakeholders have suggested that only IRS-reportable payments should be reported. However, this 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. The intent of the law is to ensure that the financial relationship between companies and physicians is reported, and there should be no third party structures that might serve to obscure the reporting of such payments. Without language clarifying that all payments to physicians should be captured, whether IRS-reportable or not, there is the potential for undermining comprehensive reporting of payments.

Pew is committed to working with industry, CMS, Congress, and other stakeholders to ensure the system is as strong as it can be. The issues we discuss above should not be a reason to delay the final regulations. Failure to fully implement this law as quickly as possible runs counter to the clear intent of Congress in passing the law, which was to start tracking payments as of January 1, 2012. The Sunshine Act was passed 2 ½ years ago after years of discussion, which provided ample time for companies to set up tracking and compliance systems. Similar state transparency laws have been in place since the early 1990s. Many companies are already disclosing payments, either voluntarily or as a condition of legal settlements with the Department of Justice. In fact, most companies are already substantially prepared for the disclosure requirements. A recent Deloitte survey of pharmaceutical executives found that 88 percent of companies reported being at least 50% prepared for Sunshine Act compliance requirements, with 33% of companies being 100% prepared.[6] Companies will be able to begin reporting payment data by January of 2013 if the final regulations are released soon. Stakeholders agree that it is important to begin the data collection process soon so that CMS can test the new system and can address any technical issues that will arise as quickly as possible.

The intent of the Sunshine Act is to protect patients and restore trust in the medical profession. The Pew Health Group urges the Administration to avoid further delay and act quickly to implement this important consumer protection legislation.

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[6] Deloitte. Physician Payment Sunshine Act: Physicians and life sciences companies coming to terms with transparency? 2012

Statement for the Record

of the

American Medical Association

to the

Special Committee on Aging
United States Senate

RE: Roundtable on the Physician Payments Sunshine Act September 12, 2012

Presented by: Jeremy A. Lazarus, MD

September 12, 2012

(202) 789-7426
Division of Legislative Counsel

Statement for the Record

of the

American Medical Association

to the

Special Committee on Aging
United States Senate

RE: Roundtable on the Physician Payments Sunshine Act

Presented by: Jeremy A. Lazarus, MD

September 12, 2012

The American Medical Association (AMA) appreciates the opportunity to provide its views and to discuss with other stakeholders the thematic issues surrounding the implementation of the Physician Payment Sunshine Act (Sunshine Act) provisions of the Patient Protection and Affordable Care Act (ACA). We commend Chairman Kohl, Ranking Member Corker, Senator Grassley, and members of the Committee for convening this Roundtable to ensure impacted stakeholders and the agency charged with the implementation of the Sunshine Act, the Centers for Medicare & Medicaid Services (CMS), have the opportunity to fully discuss key areas of concern related to the implementation of the Sunshine Act. Below we have outlined areas of concern in the proposed rule as well as recommended modifications to ensure that the final rule comports with the statute as well as congressional intent. We look forward to working with CMS and other stakeholders in order to streamline the regulatory burden, ensure accurate and fair reporting, and allow adequate time to conduct outreach and education on the final rule to physicians.

Background

In brief, the AMA supports efforts to increase transparency. To that end, the AMA worked with Congress on the Sunshine Act and we supported the final version of the legislation after important modifications were made to minimize the regulatory and paperwork burden on physicians, to safeguard physician due process rights, and ultimately to provide an accurate and meaningful picture of physician-industry interactions.

The Sunshine Act modifications ultimately reflected a considered decision to avoid a "boil the ocean" approach to transparency reporting that would create more questions than answers, increase disputes, and impose a substantial administrative burden.

It is important to note, however, that while not all transfers are subject to reporting under the Sunshine Act, the AMA provides ethical guidance that covers all transfers—including indirect ones.

The AMA was founded with the purpose of establishing ethical standards for all physicians. First developed in 1847, the AMA *Code of Medical Ethics* (AMA *Code*) undergoes continual revision, guided by the AMA Council on Ethical and Judicial Affairs (CEJA). The opinions contained in the AMA *Code* establish core standards of conduct for the medical profession that address relevant issues in medical practice. The AMA *Code* constitutes the most comprehensive source of ethical guidance for physicians and serves as the primary compendium of medical professional ethical statements in the United States.

The AMA believes that physician relationships with industry should be transparent, meaningfully independent, and focused on benefits to patients. The AMA supports providing information that physicians and the public need to make informed, critical judgments about physician-industry relationships. In addition, the AMA supports practices that ensure that a physician's clinical judgments are objective and evidence based and that a physician's interactions with industry are transparent.

In previous testimony before the Committee in 2007, we outlined the AMA's clear ethical guidelines that govern physician interaction with industry. In brief, based on the AMA *Principles of Medical Ethics* (*Principles*) and the AMA *Code*, physicians' responsibility to their patients is paramount. This means that physicians must not place their own financial interests above the welfare of their patients and their medical recommendations must not be inappropriately influenced by financial considerations. We are including an overview of relevant AMA policy on the topic. In 2011, the AMA's House of Delegates, a deliberative body comprised of representatives from state medical associations and medical specialty societies, adopted ethics policy on Financial Relationships with Industry in Continuing Medical Education proposed by CEJA. CEJA's report on this matter identified the core ethical principles of transparency, independence, and accountability. The report's recommendations provide practical ethical guidance to maintain the independence and integrity of continuing professional education and promote public trust. A copy of the report is attached.

The AMA, along with other stakeholders in the medical profession, continues to take appropriate measures to reduce the actual or perceived conflicts-of-interest that might arise from industry transfers of value to physicians, in order to safeguard the delivery of quality health care based on the best available science, thus earning and maintaining the trust of patients.

The focus of the roundtable is on the implementation of the Sunshine Act; however, the Sunshine Act does not set ethical standards for the medical profession nor does it codify fraud and abuse or program integrity laws. The AMA is concerned to the extent that the Sunshine Act requirements are characterized as establishing ethical standards governing conflict of interests, for example, and/or designed to identify fraud and abuse. **While the transparency reporting undoubtedly could provide information in some cases on transfers that violate professional ethical codes or even federal and state fraud and abuse laws, the purpose of the Sunshine Act registry is not to supplant the role of the profession in regulating ethical conduct or to create new fraud and abuse laws.**

There is a danger in conflating these issues since it could lead to a public perception that most, if not all, transparency reports are prima facie evidence of unethical or illegal behavior. This perception has the potential to chill beneficial collaboration and information exchange between physicians and industry. For example, we would not want a stigma associated with industry-physician collaborations that facilitate the clinical application of knowledge we are rapidly gleaning about the human genome. New technologies and discoveries such as molecular pathology diagnostics have the potential to revolutionize the practice of medicine as we know it. Physician decisions are heavily dependent on the quality of the scientific information available, provided to them, in part, by industry and federal regulators. There remains a need for interactions between physicians and industry to ensure the free flow of valid scientific information. When the information is accurate and complete, physicians have the necessary tools to make the right treatment decisions. If information is not properly provided by industry, or if physicians never receive such information, necessary and appropriate medical care can be jeopardized.

Areas of Concern with the Proposed Rule

The AMA submitted a sign-on comment letter to the Sunshine Act proposed rule along with 49 medical specialty societies and 43 state medical associations. The sign-on comment letter is attached. In addition, the AMA joined a sign-on letter submitted by national organizations involved in Continuing Medical Education (CME) in the United States, including Accreditation of CME Providers, granting of CME Credit for CME activities, and fulfillment of the responsibility of the Profession of Medicine to self-regulate in the arena of CME. The sign-on comment letter is also attached. The following five areas provide a high level summary of the AMA's concerns and recommended changes to the proposed rule.

CMS is Required to Publish Accurate Transparency Reports.

CMS has proposed a process that is unlikely to ensure accurate reporting or a reasonable opportunity to correct false, misleading, or inaccurate reports by severely limiting the ability of physicians to review and challenge incorrect reports. 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. In

addition, the agency proposes to severely restrict the ability of physicians to challenge reports with a compressed 45 day window once a year even though the statute provides that 45 days is the minimum amount of time allotted to challenge the reports before these reports are made public. **We oppose limiting a physician's ability to challenge the accuracy of reports to the "current" and prior reporting year within a compressed 45-day window each year.** There is no statutory support for this provision and it is inconsistent with the Congress' intent to ensure such reports are accurate. **The ACA provides that before a report is made public, physicians are to have 45 days to review and submit corrections, at a minimum. This does not apply to corrections after the reports are made public. Congress intended that disputes would not delay publication, but never provided that all disputes were to be compressed into a 45-day once a year period. The rule as proposed would deny physicians substantive and procedural due process rights.**

In light of the current state of technology, **industry has the capability to allow for real-time updates and modification of reports. Instead of compressing the challenge period into a short period of time that could require significant allocation of staff resources during this condensed period, it is reasonable to require manufacturers and CMS to allow modification and correction of reports on an ongoing basis as part of their normal workflow. In sum, the statute does not establish a maximum 45-day window in which to challenge the accuracy of transparency reports and we do not support CMS imposing such an arbitrary limitation on the due process rights of physicians.**

We strongly urge CMS to re-structure the process that the agency has outlined and require industry to provide physicians with ongoing access to reports and establish a neutral arbiter to resolve disputes. The proposed rule opens the door to the real possibility that a large number of physicians could become the victims of false, inaccurate, or misleading reporting and suffer significant damages including investigation by government and private entities, potential disciplinary actions, public censure, ridicule, and destruction of professional reputation and livelihood.

CMS is Not Authorized by Statute to Expand Reporting to Indirect Transfers (Not Otherwise Specified in Statute)

Although the statute limits reporting to direct payments/transfers of value to physicians except in carefully specified circumstances, CMS has expanded the category of transfers subject to reporting to a broad category of indirect transfers. The current statute contains a number of differences from the original bills S. 2029, *"Physician Payments Sunshine Act of 2007"* and H.R. 5605, "*Physician Payments Sunshine Act of 2008.*" The original bills would have explicitly required that manufacturers report a payment or other transfers of value made "directly, indirectly, or through an agent, subsidiary, or other third party." This language was not included in the ACA version of the Sunshine Act. A new subsection was added once the original language was struck in order to capture when reporting on indirect payments and transfers would be required. These situations include those instances where manufacturers are transferring payment or value to a third party at

the request of the physician or designated on behalf of the physician. This closes an obvious potential loophole to avoid reporting. The purpose was not to create a back door by which a vast, complicated, and confusing number of transfers with questionable relevance would be added to the reporting requirement. The proposed regulation would impose a significant paperwork burden while obscuring significant interactions between industry and physicians.

Certified Continuing Medical Education (CME) is Excluded from Reporting by Statute

CMS has proposed reporting standards that will include indirect transfers that occur through certified CME even though the statutory language does not support such an interpretation. The AMA agrees 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. **Certified CME is independent and manufacturers have no control or input into the content, the speakers, or the attendees. In light of the foregoing, certified CME is not covered by the Sunshine Act and CMS should make this clear.** The law includes a broad category of educational activities that are subject to reporting.

We urge CMS to exclude from reporting certified CME as this is a reasonable interpretation of the statute as well as the legislative history. As discussed above, earlier versions of the Sunshine Act, S. 2029 and H.R. 5605, required reporting on a far larger universe of transfers/payments including all indirect transfers/payments and for "participation in a medical conference, continuing medical education, or other educational or informational program or seminar, provision of materials related to such a conference or educational or informational program or seminar, or remuneration for promoting or participating in such a conference or educational or informational program or seminar." The statute does not include a reference to CME and limits the universe of indirect transfers/payments that are reportable. The statutory language is clear and certified CME does not involve transfers that trigger reporting.

CMS is Required to Ensure Accurate Attribution and Is Not Allowed to Use Estimates

CMS has proposed attributing 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. The ACA provides for actual transfers of value to a covered physician, not estimates. CMS' proposal to estimate or impute attribution even where there is no direct transfer or a qualifying indirect transfer is beyond its statutory authority, violates basic principles of due process, and is inconsistent with the changes to the legislation as reflected in the final statute. **Congress did not direct CMS to develop reports that provide an approximation of the value transferred by manufacturers to physicians nor did Congress intend that transfers of value made by manufacturers to an organization or entity that employ physicians would be attributed to a physician without regard to whether they received the transfer, requested the transfer, or it**

was designated on their behalf. CMS has proposed that where an organization receives a payment or transfer of value, it will be apportioned among the physicians in the organization or institution. This, of course, 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. We also strongly oppose 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. **CMS is required to direct manufacturers to document and report only those payments and transfers made directly to physicians or those specified indirect transfers/payments requested by the physician or designated on their behalf.**

The Proposed Rule Imposes a Significant Paperwork Burden on Physicians

CMS has underestimated the paperwork requirements of ensuring that industry accurately reports transfers. The process as outlined in the proposed regulation imposes ongoing and time intensive paperwork obligations on physicians if the proposed rule remains unchanged when CMS issues a final regulation. CMS has provided a very limited estimate and analysis of the burden associated with the information collection requirements for physicians. While we strongly believe this estimate would be alleviated by requiring industry to provide ongoing physician access to reports, the current proposed rule would impose a paperwork burden on <u>all</u> physicians who will need to maintain ongoing records of every activity they engage in so they are able to ensure accurate reporting. This is not an overstatement given the large universe of indirect reporting requirements contained in the proposed rule. We believe that CMS has greatly underestimated the amount of time physicians would need to review cumulative reports and to challenge them before they were posted given the resources physicians would likely need to dispute inaccurate, false, and misleading reports.

The AMA appreciates the opportunity to provide our views to the Special Committee on Aging and we look forward to working with CMS and other stakeholders to promote the goal of transparency in a meaningful manner.

AMA Policy Overview

AMA believes that relationships with industry should be transparent, meaningfully independent, and focused on benefits to patients, including

- providing the information physicians and the public need to make informed, critical judgments about physician-industry relationships
- ensuring that physician's clinical judgments are objective and evidence based
- monitoring interactions with industry to help ensure transparency and independence

AMA has supported efforts to promote public transparency in the interactions between industry and physicians.

The AMA continues to strongly support certified CME which ensures that industry does not influence the content of continuing education for physicians as well supports access to independent information about drugs and devices (so called "independent physician education or academic detailing).

The AMA has recently adopted policy specifically concerning the Affordable Care Act Physician Payment Sunshine Act provisions:

> That our AMA (1) continue its efforts to minimize the burden and unauthorized expansion of the Sunshine Act by CMS; and, (2) recommend to CMS that a physician comment section be included on the "Physician Payments Sunshine Act" public database. Substitute Resolution 223, Physician Payment Sunshine, A-12.

AMA policies cover issues in physician-industry relationship across clinical practice, medical research, and physician education

Clinical practice

- E-5.075 and D-315.988, address access to patients' medical records and physician prescribing data[1]
- E-8.047, provides guidance for physicians when industry representatives are present during clinical care, e.g., technical assistance in the use of devices[2]
- E-8.061, requires physicians to decline inappropriate gifts from industry, such as payments to defray costs of participating in continuing medical education or token consulting or advisory arrangements[3]
- H-410.953, sets out ethical principles for the design of clinical practice guidelines[4]

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[1] https://ssl3.ama-assn.org/apps/ecomm/PolicyFinderForm.pl?site=www.ama-assn.org&uri=%2fresources%2fdoc%2fPolicyFinder%2fpolicyfiles%2fHnE%2fE-5.075.HTM; https://ssl3.ama-assn.org/apps/ecomm/PolicyFinderForm.pl?site=www.ama-assn.org&uri=%2fresources%2fdoc%2fPolicyFinder%2fpolicyfiles%2fDIR%2fD-315.988.HTM

[2] https://ssl3.ama-assn.org/apps/ecomm/PolicyFinderForm.pl?site=www.ama-assn.org&uri=%2fresources%2fdoc%2fPolicyFinder%2fpolicyfiles%2fHnE%2fE-8.047.HTM

[3] https://ssl3.ama-assn.org/apps/ecomm/PolicyFinderForm.pl?site=www.ama-assn.org&uri=%2fresources%2fdoc%2fPolicyFinder%2fpolicyfiles%2fHnE%2fE-8.061.HTM

Medical research

- E-8.031 and E-8.0315, provide guidance for managing conflicts of interest in biomedical research, such as disclosing financial relationships to prospective subjects and avoiding compromising financial interests with the sponsor concurrent with involvement in research (e.g., purchase of stock)[5]

- H-460.914, calls for transparent, responsible reporting of clinical trials[6]

- D-460.979, urges AMA to collaborate with industry to develop guidelines for open scientific communication[7]

Physician education

- E-9.0115 and E-9.011, provide guidance re financial relationships with industry in the context of continuing medical education[8]

- D-295.955, addresses educating medical students about industry[9]

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[4] https://ssl3.ama-assn.org/apps/ecomm/PolicyFinderForm.pl?site=www.ama-assn.org&uri=%2fresources%2fdoc%2fPolicyFinder%2fpolicyfiles%2fHnE%2fH-410.953.HTM

[5] https://ssl3.ama-assn.org/apps/ecomm/PolicyFinderForm.pl?site=www.ama-assn.org&uri=%2fresources%2fdoc%2fPolicyFinder%2fpolicyfiles%2fHnE%2fE-8.031.HTM; https://ssl3.ama-assn.org/apps/ecomm/PolicyFinderForm.pl?site=www.ama-assn.org&uri=%2fresources%2fdoc%2fPolicyFinder%2fpolicyfiles%2fHnE%2fE-8.0315.HTM

[6] https://ssl3.ama-assn.org/apps/ecomm/PolicyFinderForm.pl?site=www.ama-assn.org&uri=%2fresources%2fdoc%2fPolicyFinder%2fpolicyfiles%2fHnE%2fH-460.914.HTM

[7] https://ssl3.ama-assn.org/apps/ecomm/PolicyFinderForm.pl?site=www.ama-assn.org&uri=%2fresources%2fdoc%2fPolicyFinder%2fpolicyfiles%2fDIR%2fD-460.979.HTM

[8] https://ssl3.ama-assn.org/apps/ecomm/PolicyFinderForm.pl?site=www.ama-assn.org&uri=%2fresources%2fdoc%2fPolicyFinder%2fpolicyfiles%2fHnE%2fE-9.0115.HTM; https://ssl3.ama-assn.org/apps/ecomm/PolicyFinderForm.pl?site=www.ama-assn.org&uri=%2fresources%2fdoc%2fPolicyFinder%2fpolicyfiles%2fHnE%2fE-9.011.HTM

[9] https://ssl3.ama-assn.org/apps/ecomm/PolicyFinderForm.pl?site=www.ama-assn.org&uri=%2fresources%2fdoc%2fPolicyFinder%2fpolicyfiles%2fDIR%2fD-295.955.HTM

AMA POLICY

The HOD adopted policy specifically concerning the Affordable Care Act Physician Payment Sunshine Act provisions:

> That our AMA (1) continue its efforts to minimize the burden and unauthorized expansion of the Sunshine Act by CMS; and, (2) recommend to CMS that a physician comment section be included on the "Physician Payments Sunshine Act" public database. Substitute Resolution 223, Physician Payment Sunshine, A-12.

Clinical practice

E-5.075 and D-315.988, address access to patients' medical records and physician prescribing data

E-5.075 Confidentiality: Disclosure of Records to Data Collection Companies
Data collection from computerized or other patient records for marketing purposes raises serious ethical concerns. In some cases, firms have sought to amass information on physicians' prescribing practices on behalf of pharmaceutical houses for marketing purposes. Often, physicians are offered incentives such as computer hardware and software packages in return for agreeing to such an arrangement. They may be told that data-collecting software does not capture patients' names. These arrangements may violate principles of informed consent and patient confidentiality. Patients divulge information to their physicians only for purposes of diagnosis and treatment. If other uses are to be made of the information, patients must give their permission after being fully informed about the purpose of such disclosures. If permission is not obtained, physicians violate patient confidentiality by sharing specific and intimate information from patients' records with commercial interests. Arrangements of this kind may also violate Opinion 8.061, "Gifts to Physicians From Industry." Finally, these arrangements may harm the integrity of the patient-physician relationship. The trust that is fundamental to this relationship is based on the principle that the physicians are the agents first and foremost of their patients. (I, II, IV) Issued June 1994; Updated June 1998.

D-315.988 Use of Physician and Patient Prescribing Data in the Pharmaceutical Industry
Our AMA will (1) work to control the use of physician-specific prescribing data by the pharmaceutical industry as follows: (a) implement a suitable "opt-out" mechanism for the AMA Physician Masterfile governing the release of physician-specific prescribing data to pharmaceutical sales reps by including appropriate restrictions in the AMA data licensing agreements; (b) communicate to physicians the resources available to them in reporting inappropriate behavior on the part of pharmaceutical sales representatives and the work the AMA has done and will continue to do on their behalf; and (c) work with Health Information Organizations (HIOs) to describe to physicians how their prescribing data are used and work to create access for physicians to view reports on their own prescribing data to enhance their clinical practice; and (2) assume a leadership position in both developing a Prescribing Data Code of Conduct for the Pharmaceutical Industry that dictates appropriate use of pharmaceutical data, behavior expectations on the part of industry, and consequences of misuse or misconduct, and in convening representatives from HIOs and the pharmaceutical companies to promulgate the adoption of the code of conduct in the use of prescribing data. (BOT Rep. 24, I-04; Reaffirmed in lieu of Res. 624, A-05; Reaffirmation A-09; Reaffirmed: Res. 233, A-11)

E-8.047, provides guidance for physicians when industry representatives are present during clinical care, e.g., technical assistance in the use of devices

E-8.047 Industry Representatives in Clinical Settings
Manufacturers of medical devices may facilitate their use through industry representatives who can play an important role in patient safety and quality of care by providing information about the proper use of the device or equipment as well as technical assistance to physicians.
Because of their obligation to protect their patients, physicians must strive to prevent industry representatives from breaching patient privacy and confidentiality, and seek to verify that they are properly credentialed and do not exceed the bounds of their training. Physicians may fulfill these obligations by satisfying themselves that the facility has suitable mechanisms in place to accomplish these functions.
Physicians or their designees must disclose to patients the anticipated presence and roles of industry representatives during clinical encounters, and obtain patients' approval. This requires neither disclosure of the representative's specific identity nor a formal informed consent process. (I, IV, V) Issued November 2007 based on the report "Industry Representatives in Clinical Settings," adopted June 2007.

E-8.061, requires physicians to decline inappropriate gifts from industry, such as payments to defray costs of participating in continuing medical education or token consulting or advisory arrangement

E-8.061 Gifts to Physicians from Industry
Many gifts given to physicians by companies in the pharmaceutical, device, and medical equipment industries serve an important and socially beneficial function. For example, companies have long provided funds for educational seminars and conferences. However, there has been growing concern about certain gifts from industry to physicians. Some gifts that reflect customary practices of industry may not be consistent with the Principles of Medical Ethics. To avoid the acceptance of inappropriate gifts, physicians should observe the following guidelines: (1) Any gifts accepted by physicians individually should primarily entail a benefit to patients and should not be of substantial value. Accordingly, textbooks, modest meals, and other gifts are appropriate if they serve a genuine educational function. Cash payments should not be accepted. The use of drug samples for personal or family use is permissible as long as these practices do not interfere with patient access to drug samples. It would not be acceptable for non-retired physicians to request free pharmaceuticals for personal use or use by family members. (2) Individual gifts of minimal value are permissible as long as the gifts are related to the physician's work (eg, pens and notepads). (3) The Council on Ethical and Judicial Affairs defines a legitimate "conference" or "meeting" as any activity, held at an appropriate location, where (a) the gathering is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse (one or more educational presentation(s) should be the highlight of the gathering), and (b) the main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented. An appropriate disclosure of financial support or conflict of interest should be made. (4) Subsidies to underwrite the costs of continuing medical education conferences or professional meetings can contribute to the improvement of patient care and therefore are permissible. Since the giving of a subsidy directly to a physician by a company's representative may create a relationship that could influence the use of the company's products, any subsidy should be accepted by the conference's sponsor who in turn can use the money to reduce the conference's registration fee. Payments to defray the costs of a conference should not be accepted directly from the company by the physicians attending the conference. (5) Subsidies from industry should not be accepted directly or indirectly to pay for the costs of travel, lodging, or other personal expenses of physicians attending conferences or meetings, nor should subsidies be

accepted to compensate for the physicians' time. Subsidies for hospitality should not be accepted outside of modest meals or social events held as a part of a conference or meeting. It is appropriate for faculty at conferences or meetings to accept reasonable honoraria and to accept reimbursement for reasonable travel, lodging, and meal expenses. It is also appropriate for consultants who provide genuine services to receive reasonable compensation and to accept reimbursement for reasonable travel, lodging, and meal expenses. Token consulting or advisory arrangements cannot be used to justify the compensation of physicians for their time or their travel, lodging, and other out-of-pocket expenses. (6) Scholarship or other special funds to permit medical students, residents, and fellows to attend carefully selected educational conferences may be permissible as long as the selection of students, residents, or fellows who will receive the funds is made by the academic or training institution. Carefully selected educational conferences are generally defined as the major educational, scientific or policy-making meetings of national, regional, or specialty medical associations. (7) No gifts should be accepted if there are strings attached. For example, physicians should not accept gifts if they are given in relation to the physician's prescribing practices. In addition, when companies underwrite medical conferences or lectures other than their own, responsibility for and control over the selection of content, faculty, educational methods, and materials should belong to the organizers of the conferences or lectures. (II)
Issued June 1992 based on the report "Gifts to Physicians from Industry," adopted December 1990 (JAMA. 1991; 265: 501); Updated June 1996 and June 1998.

Clarification of Opinion 8.061
Scope Opinion 8.061, "Gifts to Physicians from Industry," is intended to provide ethical guidance to physicians. Other parties involved in the health care sector, including the pharmaceutical, devices, and medical equipment industries and related entities or business partners, should view the guidelines as indicative of standards of conduct for the medical profession. Ultimately, it is the responsibility of individual physicians to minimize conflicts of interest that may be at odds with the best interest of patients and to access the necessary information to inform medical recommendations.

The guidelines apply to all forms of gifts, whether they are offered in person, through intermediaries, or through the Internet. Similarly, limitations on subsidies for educational activities should apply regardless of the setting in which, or the medium through which, the educational activity is offered.

General Questions (a) Do the guidelines apply only to pharmaceutical, device, and equipment manufacturers?

"Industry" includes all "proprietary health-related entities that might create a conflict of interest."

Guideline 1 Any gifts accepted by physicians individually should primarily entail a benefit to patients and should not be of substantial value. Accordingly, textbooks, modest meals, and other gifts are appropriate if they serve a genuine educational function. Cash payments should not be accepted. The use of drug samples for personal or family use is permissible as long as these practices do not interfere with patient access to drug samples. It would not be acceptable for non-retired physicians to request free pharmaceuticals for personal use or for use by family members.

(a) May physicians accept gram stain test kits, stethoscopes, or other diagnostic equipment?

Diagnostic equipment primarily benefits the patient. Hence, such gifts are permissible as long as they are not of substantial value. In considering the value of the gift, the relevant measure is not the cost to the company of providing the gift. Rather, the relevant measure is the cost to the physician if the physician purchased the gift on the open market.

(b) May companies invite physicians to a dinner with a speaker and donate $100 to a charity or medical school on behalf of the physician?

There are positive aspects to the proposal. The donations would be used for a worthy cause, and the physicians would receive important information about patient care. There is a direct personal benefit to the physician as well, however. An organization that is important to the physician-and one that the physician might have ordinarily felt obligated to make a contribution to-receives financial support as a result of the physician's decision to attend the meeting. On balance, physicians should make their own judgment about these inducements. If the charity is predetermined without the physician's input, there would seem to be little problem with the arrangement.

(c) May contributions to a professional society's general fund be accepted from industry?

The guidelines are designed to deal with gifts from industry which affect, or could appear to affect, the judgment of individual practicing physicians. In general, a professional society should make its own judgment about gifts from industry to the society itself.

(d) When companies invite physicians to a dinner with a speaker, what are the relevant guidelines?

First, the dinner must be a modest meal. Second, the guideline does allow gifts that primarily benefit patients and that are not of substantial value. Accordingly, textbooks and other gifts that primarily benefit patient care and that have a value to the physician in the general range of $100 are permissible. When educational meetings occur in conjunction with a social event such as a meal, the educational component must have independent value, such as a presentation by an authoritative speaker other than a sales representative of the company. Also, the meal should be a modest one similar to what a physician routinely might have when dining at his or her own expense. In an office or hospital encounter with a company representative, it is permissible to accept a meal of nominal value, such as a sandwich or snack.

(e) May physicians accept vouchers that reimburse them for uncompensated care they have provided?

No. Such a voucher would result directly in increased income for the physician.

(f) May physicians accumulate "points" by attending several educational or promotional meetings and then choose a gift from a catalogue of education options?

This guideline permits gifts only if they are not of substantial value. If accumulation of points would result in physicians receiving a substantial gift by combining insubstantial gifts over a relatively short period of time, it would be inappropriate.

(g) May physicians accept gift certificates for educational materials when attending promotional or educational events?

The Council views gift certificates as a grey area which is not per se prohibited by the guidelines. Medical textbooks are explicitly approved as gifts under the guidelines. A gift certificate for educational materials, ie, for the selection by the physician from an exclusively medical textbook catalogue, would not seem to be materially different. The issue is whether the gift certificate

gives the recipient such control as to make the certificate similar to cash. As with charitable donations, preselection by the sponsor removes any question. It is up to the individual physician to make the final judgment.

(h) May physicians accept drug samples or other free pharmaceuticals for personal use or use by family members?

The Council's guidelines permit personal or family use of free pharmaceuticals (i) in emergencies and other cases where the immediate use of a drug is indicated, (ii) on a trial basis to assess tolerance, and (iii) for the treatment of acute conditions requiring short courses of inexpensive therapy, as permitted by Opinion 8.19, "Self-Treatment or Treatment of Immediate Family Members." It would not be acceptable for physicians to accept free pharmaceuticals for the long-term treatment of chronic conditions.

(i) May companies invite physicians to a dinner with a speaker and offer them a large number of gifts from which to choose one?

In general, the greater the freedom of choice given to the physician, the more the offer seems like cash. A large number of gifts presented to physicians who attend a dinner would therefore be inappropriate.

There is no precise way of deciding an appropriate upper limit on the amount of choice that is acceptable. However, it is important that a specific limit be chosen to ensure clarity in the guidelines. A limit of eight has been chosen because it permits flexibility but prevents undue freedom of choice. Each of the choices must have a value to the physicians of no more than $100.

(j) May physicians charge for their time with industry representatives or otherwise receive material compensation for participation in a detail visit?
Guideline 1 states that gifts in the form of cash payments should not be accepted. Also, Guideline 6 makes clear that, in the context of the industry-physician relationship, only physicians who provide genuine services may receive reasonable compensation. When considering the time a physician spends with an industry representative, it is the representative who offers a service, namely the presentation of information. The physician is a beneficiary of the service. Overall, these guidelines do not view that physicians should be compensated for the time spent participating in educational activities, nor for time spent receiving detail information from an industry representative.

Guideline 2 Individual gifts of minimal value are permissible as long as the gifts are related to the physician's work (eg, pens and notepads).

(a) May physicians, individually or through their practice group, accept electronic equipment, such as hand held devices or computers, intended to facilitate their ability to receive detail information electronically?
Although Guideline 2 recognizes that gifts related to a physician' s practice may be appropriate, it also makes clear that these gifts must remain of minimal value. It is not appropriate for physicians to accept expensive hardware or software equipment even though one purpose only may pertain to industry-related activities of a modest value.

Guideline 3 The Council on Ethical and Judicial Affairs defines a legitimate "conference" or "meeting" as any activity, held at an appropriate location, where (a) the gathering is primarily dedicated, in both time and effort, to promoting objective scientific and

educational activities and discourse (one or more educational presentation(s) should be the highlight of the gathering), and (b) the main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented. An appropriate disclosure of financial support or conflict of interest should be made.

Guideline 4 Subsidies to underwrite the costs of continuing medical education conferences or professional meetings can contribute to the improvement of patient care and therefore are permissible. Since the giving of a subsidy directly to a physician by a company's sales representative may create a relationship which could influence the use of the company's products, any subsidy should be accepted by the conference's sponsor who in turn can use the money to reduce the conference's registration fee. Payments to defray the costs of a conference should not be accepted directly from the company by the physicians attending the conference.

(a) Are conference subsidies from the educational division of a company covered by the guidelines?

Yes. When the Council says "any subsidy," it would not matter whether the subsidy comes from the sales division, the educational division, or some other section of the company.

(b) May a company or its intermediary send physicians a check or voucher to offset the registration fee at a specific conference or a conference of the physician's choice?
Physicians should not directly accept checks or certificates which would be used to offset registration fees. The gift of a reduced registration should be made across the board and through the accredited sponsor.

Guideline 5 Subsidies from industry should not be accepted directly or indirectly to pay for the costs of travel, lodging, or other personal expenses of physicians attending conferences or meetings, nor should subsidies be accepted to compensate for the physicians' time. Subsidies for hospitality should not be accepted outside of modest meals or social events held as a part of a conference or meeting. It is appropriate for faculty at conferences or meetings to accept reasonable honoraria and to accept reimbursement for reasonable travel, lodging, and meal expenses. It is also appropriate for consultants who provide genuine services to receive reasonable compensation and to accept reimbursement for reasonable travel, lodging, and meal expenses. Token consulting or advisory arrangements cannot be used to justify the compensation of physicians for their time or their travel, lodging, and other out-of-pocket expenses.

(a) If a company invites physicians to visit its facilities for a tour or to become educated about one of its products, may the company pay travel expenses and honoraria?
This question has come up in the context of a rehabilitation facility that wants physicians to know of its existence so that they may refer their patients to the facility. It has also come up in the context of surgical device or equipment manufacturers who want physicians to become familiar with their products.

In general, travel expenses should not be reimbursed, nor should honoraria be paid for the visiting physician's time since the presentations are analogous to a pharmaceutical company's educational or promotional meetings. The Council recognizes that medical devices, equipment, and other technologies may require, in some circumstances, special evaluation or training in proper usage which can not practicably be provided except on site. Medical specialties are in a better position to advise physicians regarding the appropriateness of reimbursement with regard to these trips. In

cases where the company insists on such visits as a means of protection from liability for improper usage, physicians and their specialties should make the judgment. In no case would honoraria be appropriate and any travel expenses should be only those strictly necessary.

(b) If the company invites physicians to visit its facilities for review and comment on a product, to discuss their independent research projects, or to explore the potential for collaborative research, may the company pay travel expenses and an honorarium?
If the physician is providing genuine services, reasonable compensation for time and travel expenses can be given. However, token advisory or consulting arrangements cannot be used to justify compensation.

(c) May a company hold a sweepstakes for physicians in which five entrants receive a trip to the Virgin Islands or airfare to the medical meeting of their choice?

No. The use of a sweepstakes or raffle to deliver a gift does not affect the permissibility of the gift. Since the sweepstakes is not open to the public, the guidelines apply in full force.

(d) If a company convenes a group of physicians to recruit clinical investigators or convenes a group of clinical investigators for a meeting to discuss their results, may the company pay for their travel expenses?

Expenses may be paid if the meetings serve a genuine research purpose. One guide to their propriety would be whether the National Institute of Health (NIH) conducts similar meetings when it sponsors multi-center clinical trials. When travel subsidies are acceptable, the guidelines emphasize that they be used to pay only for "reasonable" expenses. The reasonableness of expenses would depend on a number of considerations. For example, meetings are likely to be problematic if overseas locations are used for exclusively domestic investigators. It would be inappropriate to pay for recreation or entertainment beyond the kind of modest hospitality described in this guideline.

(e) How can a physician tell whether there is a "genuine research purpose?"

A number of factors can be considered. Signs that a genuine research purpose exists include the facts that there are (1) a valid study protocol, (2) recruitment of physicians with appropriate qualifications or expertise, and (3) recruitment of an appropriate number of physicians in light of the number of study participants needed for statistical evaluation.

(f) May a company compensate physicians for their time and travel expenses when they participate in focus groups?

Yes. As long as the focus groups serve a genuine and exclusive research purpose and are not used for promotional purposes, physicians may be compensated for time and travel expenses. The number of physicians used in a particular focus group or in multiple focus groups should be an appropriate size to accomplish the research purpose, but no larger.

(g) Do the restrictions on travel, lodging, and meals apply to educational programs run by medical schools, professional societies, or other accredited organizations which are funded by industry, or do they apply only to programs developed and run by industry?

The restrictions apply to all conferences or meetings which are funded by industry. The Council drew no distinction on the basis of the organizer of the conference or meeting. The Council felt

that the gift of travel expenses is too substantial even when the conference is run by a non-industry sponsor. (Industry includes all "proprietary health-related entities that might create a conflict of interest.")

(h) May company funds be used for travel expenses and honoraria for bona fide faculty at educational meetings?

This guideline draws a distinction between attendees and faculty. As was stated, "[i]t is appropriate for faculty at conferences or meetings to accept reasonable honoraria and to accept reimbursement for reasonable travel, lodging, and meal expenses."
Companies need to be mindful of the guidelines of the Accreditation Council on Continuing Medical Education. According to those guidelines, "[f]unds from a commercial source should be in the form of an educational grant made payable to the CME sponsor for the support of programming."

(i) May travel expenses be reimbursed for physicians presenting a poster or a "free paper" at a scientific conference?

Reimbursement may be accepted only by bona fide faculty. The presentation of a poster or a free paper does not by itself qualify a person as a member of the conference faculty for purposes of these guidelines.

(j) When a professional association schedules a long-range planning meeting, is it appropriate for industry to subsidize the travel expenses of the meeting participants?

The guidelines are designed to deal with gifts from industry which affect, or could appear to affect, the judgment of individual practicing physicians. In general, a professional society should make its own judgment about gifts from industry to the society itself.

(k) May continuing medical education conferences be held in the Bahamas, Europe, or South America?

There are no restrictions on the location of conferences as long as the attendees are paying their own travel expenses.

(l) May travel expenses be accepted by physicians who are being trained as speakers or faculty for educational conferences and meetings?

In general, no. If a physician is presenting as an independent expert at a CME event, both the training and its reimbursement raise questions about independence. In addition, the training is a gift because the physician's role is generally more analogous to that of an attendee than a participant. Speaker training sessions can be distinguished from meetings (See 5d) with leading researchers, sponsored by a company, designed primarily for an exchange of information about important developments or treatments, including the sponsor's own research, for which reimbursement for travel may be appropriate.

(m) What kinds of social events during conferences and meetings may be subsidized by industry?

Social events should satisfy three criteria. First, the value of the event to the physician should be modest. Second, the event should facilitate discussion among attendees and/or discussion between attendees and faculty. Third, the educational part of the conference should account for a

substantial majority of the total time accounted for by the educational activities and social events together. Events that would be viewed (as in the succeeding question) as lavish or expensive should be avoided. But modest social activities that are not elaborate or unusual are permissible, eg, inexpensive boat rides, barbecues, entertainment that draws on the local performers. In general, any such events which are a part of the conference program should be open to all registrants.

(n) May a company rent an expensive entertainment complex for a evening during a medical conference and invite the physicians attending the conference?

No. The guidelines permit only modest hospitality.

(o) If physicians attending a conference engage in interactive exchange, may their travel expenses be paid by industry?

No. Mere interactive exchange would not constitute genuine consulting services.

(p) If a company schedules a conference and provides meals for the attendees that fall within the guidelines, may the company also pay for the costs of the meals for spouses?

If a meal falls within the guidelines, then the physician's spouse may be included.

(q) May companies donate funds to sponsor a professional society's charity golf tournament?

Yes. But it is sensible if physicians who play in the tournament make some contribution themselves to the event.

(r) If a company invites a group of consultants to a meeting and a consultant brings a spouse, may the company pay the costs of lodging or meals of the spouse? Does it matter if the meal is part of the program for the consultants?

Since the costs of having a spouse share a hotel room or join a modest meal are nominal, it is permissible for the company to subsidize those costs. However, if the total subsidies become substantial, then they become unacceptable.

Guideline 6 Scholarship or other special funds to permit medical students, residents, and fellows to attend carefully selected educational conferences may be permissible as long as the selection of students, residents, or fellows who will receive the funds is made by the academic or training institution. Carefully selected educational conferences are generally defined as the major educational, scientific, or policy-making meetings of national, regional, or specialty medical associations.

(a) When a company subsidizes the travel expenses of residents to an appropriately selected conference, may the residents receive the subsidy directly from the company?

Funds for scholarships or other special funds should be given to the academic departments or the accredited sponsor of the conference. The disbursement of funds can then be made by the departments or the conference sponsor.

(b) What is meant by "carefully selected educational conferences?"

The intent of Guideline 6 is to ensure that financial hardship does not prevent students, residents, and fellows from attending major educational conferences. For example, we did not want to deny cardiology fellows the opportunity to attend the annual scientific meeting of the American College of Cardiology or orthopedic surgery residents the opportunity to attend the annual scientific meeting of the American Academy of Orthopedic Surgeons. However, it was not the intent of the guideline to permit reimbursement of travel expenses in other circumstances, such as when conferences or symposia are designed specifically for students, residents, or fellows. Funds are limited to travel and lodging expenses for attendance at major educational, scientific, or policy-making meetings of national, regional, or specialty medical associations.

Guideline 7 No gifts should be accepted if there are strings attached. For example, physicians should not accept gifts if they are given in relation to the physician's prescribing practices. In addition, when companies underwrite medical conferences or lectures other than their own, responsibility for and control over the selection of content, faculty, educational methods, and materials should belong to the organizers of the conferences or lectures.

(a) May companies send their top prescribers, purchasers, or referrers on cruises?

No. There can be no link between prescribing or referring patterns and gifts. In addition, travel expenses, including cruises, are not permissible.

(b) May the funding company itself develop the complete educational program that is sponsored by an accredited continuing medical education sponsor?

No. The funding company may finance the development of the program through its grant to the sponsor, but the accredited sponsor must have responsibility and control over the content and faculty of conferences, meetings, or lectures. Neither the funding company nor an independent consulting firm should develop the complete educational program for approval by the accredited sponsor.

(c) How much input may a funding company have in the development of a conference, meeting, or lectures?

The guidelines of the Accreditation Council on Continuing Medical Education on commercial support of continuing medical education address this question.

Issued 1992. Updated December 2000, June 2002, and June 2004 (Food and Drug Law Journal, 2001;56(1):27-40).

H-410.953, sets out ethical principles for the design of clinical practice guidelines

H-410.953 Ethical Considerations in the Development of Medical Practice Guidelines
Medical practice guidelines help inform physician judgment and decision making by physicians and patients. Practice guidelines also have significant potential to meaningfully inform efforts to provide care of consistently high quality for all patients and to help shape development of sound public policy in health care. To achieve those ends, practice guidelines must be trustworthy. Patients, the public, physicians, other health care professionals and health administrators, and policymakers must have confidence that published guidelines are the ethically and scientifically

credible product of development processes that are rigorous, independent, transparent, and accountable.
To that end, the development or updating of medical practice guidelines should meet the following expectations:
1. Guidelines/updates are developed independent of direct financial support from entities that have an interest in the recommendations to be developed.
2. Formal, scientifically rigorous methods and explicit standards are adopted for the review and weighting of evidence, the integration of expert judgment, and the strength of clinical recommendations.
3. Guideline panels have access to appropriate expertise among members or consultants, including not only relevantly qualified clinical experts but also appropriately qualified methodologists, representatives of key stakeholders, and, ideally, one or more individuals skilled in facilitating groups.
4. Ideally, all individuals associated with guideline development will be free of conflicts of interest during the development process and will remain so for a defined period following the publication of the guideline.
5. Formal procedures are adopted to minimize the potential for financial or other interests to influence the process at all key steps (selection of topic, review of evidence, panel deliberations, development and approval of specific recommendations, and dissemination of final product). These should include: a) required disclosure of all potential conflicts of interest by panel members, consultants, staff, and other participants; b) clearly defined criteria for identifying and assessing the seriousness of conflicts of interest; and c) clearly defined strategies for eliminating or mitigating the influence of identified conflicts of interest (such as prohibiting individuals from participating in deliberations, drafting, or voting on recommendations on which they have conflicts) in those limited circumstances when participation by an individual with a conflicting interest cannot be avoided.
6. Guidelines are subject to rigorous, independent peer review.
7. Clear statements of methodology, conflict of interest policy and procedures, and disclosures of panel members' conflicts of interest relating to specific recommendations are published with any guideline or otherwise made public.
8. Guidelines are in the first instance disseminated independent of support from or participation by individuals or entities that have a direct interest in the recommendations. (BOT Rep. 2, A-11)

Medical research

E-8.031 and E-8.0315, provide guidance for managing conflicts of interest in biomedical research, such as disclosing financial relationships to prospective subjects and avoiding compromising financial interests with the sponsor concurrent with involvement in research (e.g., purchase of stock)

E-8.031 Conflicts of Interest: Biomedical Research

Avoidance of real or perceived conflicts of interest in clinical research is imperative if the medical community is to ensure objectivity and maintain individual and institutional integrity. All medical centers should develop specific guidelines for their clinical staff on conflicts of interest. These guidelines should include the following rules: (1) once a clinical investigator becomes involved in a research project for a company or knows that he or she might become involved, she or he, as an individual, cannot ethically buy or sell the company's stock until the involvement ends and the results of the research are published or otherwise disseminated to the public; (2) any remuneration received by the researcher from the company whose product is being studied must

be commensurate with the efforts of the researcher on behalf of the company; and (3) clinical investigators should disclose any material ties to companies whose products they are investigating, including financial ties, participation in educational activities supported by the companies, participation in other research projects funded by the companies, consulting arrangements, and any other ties. The disclosures should be made in writing to the medical center where the research is conducted, organizations that are funding the research, and journals that publish the results of the research. An explanatory statement that discloses conflicts of interest should accompany all published research. Other types of publications, such as a letters to the editor, should also include an explanatory statement that discloses any potential conflict of interest. In addition, medical centers should form review committees to examine disclosures by clinical staff about financial associations with commercial corporations. (II, IV) Issued March 1992 based on the report "Conflicts of Interest in Biomedical Research," adopted December 1989 (JAMA. 1990; 263: 2790-2793); Updated June 1999 based on the report "Conflicts of Interest: Biomedical Research," adopted December 1998.

E-8.0315 Managing Conflicts of Interest in the Conduct of Clinical Trials

As the biotechnology and pharmaceutical industries continue to expand research activities and funding of clinical trials, and as increasing numbers of physicians both within and outside academic health centers become involved in partnerships with industry to perform these activities, greater safeguards against conflicts of interest are needed to ensure the integrity of the research and to protect the welfare of human subjects. Physicians should be mindful of the conflicting roles of investigator and clinician and of the financial conflicts of interest that arise from incentives to conduct trials and to recruit subjects. In particular, physicians involved in clinical research should heed the following guidelines: (1) Physicians should agree to participate as investigators in clinical trials only when it relates to their scope of practice and area of medical expertise. They should have adequate training in the conduct of research and should participate only in protocols which they are satisfied are scientifically sound. (2) Physicians should be familiar with the ethics of research and should agree to participate in trials only if they are satisfied that an Institutional Review Board has reviewed the protocol, that the research does not impose undue risks upon research subjects, and that the research conforms to government regulations. (3) When a physician has treated or continues to treat a patient who is eligible to enroll as a subject in a clinical trial that the physician is conducting, the informed consent process must differentiate between the physician's roles as clinician and investigator. This is best achieved when someone other than the treating physician obtains the participant's informed consent to participate in the trial. This individual should be protected from the pressures of financial incentives, as described in the following section. (4) Any financial compensation received from trial sponsors must be commensurate with the efforts of the physician performing the research. Financial compensation should be at fair market value and the rate of compensation per patient should not vary according to the volume of subjects enrolled by the physician, and should meet other existing legal requirements. Furthermore, according to Opinion 6.03, "Fee Splitting: Referral to Health Care Facilities," it is unethical for physicians to accept payment solely for referring patients to research studies. (5) Physicians should ensure that protocols include provisions for the funding of subjects' medical care in the event of complications associated with the research. Also, a physician should not bill a third party payer when he or she has received funds from a sponsor to cover the additional expenses related to conducting the trial. (6) The nature and source of funding and financial incentives offered to the investigators must be disclosed to a potential participant as part of the informed consent process. Disclosure to participants also should include information on uncertainties that may exist regarding funding of treatment for possible complications that may arise during the course of the trial. Physicians should ensure that such disclosure is included in any written informed consent. (7) When entering into a contract to perform research, physicians should ensure themselves that the presentation or

publication of results will not be unduly delayed or otherwise obstructed by the sponsoring company. (II, V) Issued June 2001 based on the report "Managing Conflicts of Interest in the Conduct of Clinical Trials," adopted December 2000 (JAMA. 2002; 287: 78-84).

H-460.914, calls for transparent, responsible reporting of clinical trials[10]

H-460.914 Influence of Funding Source on Outcome, Validity, and Reliability of Pharmaceutical Research
Our AMA: (1) policy is that all medical journal editors and authors should adhere to the revised CONSORT (Consolidated Standards for Reporting of Trials Group) Statement and Uniform Requirements for Manuscripts Submitted to Biomedical Journals; (2) recommends that (a) the Department of Health and Human Services establish a comprehensive registry for all clinical trials conducted in the United States; (b) every clinical trial should have a unique identifier; and (c) all results from registered clinical trials be made publicly available through either publication or an electronic data-repository; and (3) urges that Institutional Review Boards consider registration of clinical trials to an existing registry as condition of approval. (CSA Rep. 10, A-04)

D-460.979, urges AMA to collaborate with industry to develop guidelines for open scientific communication

Physicians and Clinical Trials
Our AMA will (1) work with the Pharmaceutical Research and Manufacturers of America, the American Academy of Pharmaceutical Physicians, and all other appropriate organizations to develop guidelines that would eliminate the use of restrictive covenants or clauses that interfere with scientific communication in agreements between pharmaceutical companies or manufacturers of medical instruments, equipment and devices, and physician researchers; and (2) take all appropriate action to protect the rights of physician researchers to present, publish and disseminate data from clinical trials. (Res. 610, I-04)

Physician education

E-9.0115 and E-9.011, provide guidance re financial relationships with industry in the context of continuing medical education

E-9.0115 Financial Relationships with Industry in Continuing Medical Education
In an environment of rapidly changing information and emerging technology, physicians must maintain the knowledge, skills, and values central to a healing profession. They must protect the independence and commitment to fidelity and service that define the medical profession.

Financial or in-kind support from pharmaceutical, biotechnology or medical device companies that have a direct interest in physicians' recommendations creates conditions in which external interests could influence the availability and/or content of continuing medical education (CME). Financial relationships between such sources and individual physicians who organize CME, teach in CME, or have other roles in continuing professional education can carry similar potential to influence CME in undesired ways.

CME that is independent of funding or in-kind support from sources that have financial interests in physicians' recommendations promotes confidence in the independence and integrity of

[10] https://ssl3.ama-assn.org/apps/ecomm/PolicyFinderForm.pl?site=www.ama-assn.org&uri=%2fresources%2fdoc%2fPolicyFinder%2fpolicyfiles%2fHnE%2fH-460.914.HTM

professional education, as does CME in which organizers, teachers, and others involved in educating physicians do not have financial relationships with industry that could influence their participation. When possible, CME should be provided without such support or the participation of individuals who have financial interests in the educational subject matter.

In some circumstances, support from industry or participation by individuals who have financial interests in the subject matter may be needed to enable access to appropriate, high-quality CME. In these circumstances, physician-learners should be confident that vigorous efforts will be made to maintain the independence and integrity of educational activities. Individually and collectively physicians must ensure that the profession independently defines the goals of physician education, determines educational needs, and sets its own priorities for CME. Physicians who attend CME activities should expect that, in addition to complying with all applicable professional standards for accreditation and certification, their colleagues who organize, teach, or have other roles in CME will:

(a) be transparent about financial relationships that could potentially influence educational activities.
(b) provide the information physician-learners need to make critical judgments about an educational activity, including:
(i) the source(s) and nature of commercial support for the activity; and/or
(ii) the source(s) and nature of any individual financial relationships with industry related to the subject matter of the activity; and
(iii) what steps have been taken to mitigate the potential influence of financial relationships.
(c) protect the independence of educational activities by:
(i) ensuring independent, prospective assessment of educational needs and priorities;
(ii) adhering to a transparent process for prospectively determining when industry support is needed;
(iii) giving preference in selecting faculty or content developers to similarly qualified experts who do not have financial interests in the educational subject matter;
(iv) ensuring a transparent process for making decisions about participation by physicians who may have a financial interest in the educational subject matter;
(v) permitting individuals who have a substantial financial interest in the educational subject matter to participate in CME only when their participation is central to the success of the educational activity; the activity meets a demonstrated need in the professional community; and the source, nature, and magnitude of the individual's specific financial interest is disclosed; and
(vi) taking steps to mitigate potential influence commensurate with the nature of the financial interest(s) at issue, such as prospective peer review. (I, V) Issued November 2011 based on the report "Financial Relationships with Industry in Continuing Medical Education," adopted June 2011.

E-9.011 Continuing Medical Education
Physicians should strive to further their medical education throughout their careers, for only by participating in continuing medical education (CME) can they continue to serve patients to the best of their abilities and live up to professional standards of excellence. Fulfillment of mandatory state CME requirements does not necessarily fulfill the physician's ethical obligation to maintain his or her medical expertise.

Attendees. Guidelines for physicians attending a CME conference or activity are as follows: (1) The physician choosing among CME activities should assess their educational value and select

only those activities which are of high quality and appropriate for the physician's educational needs. When selecting formal CME activities, the physician should, at a minimum, choose only those activities that (a) are offered by sponsors accredited by the Accreditation Council for Continuing Medical Education (ACCME), the American Academy of Family Physicians (AAFP), or a state medical society; (b) contain information on subjects relevant to the physician's needs; (c) are responsibly conducted by qualified faculty; (d) conform to Opinion 8.061, "Gifts to Physicians from Industry." (2) The educational value of the CME conference or activity must be the primary consideration in the physician's decision to attend or participate. Though amenities unrelated to the educational purpose of the activity may play a role in the physician's decision to participate, this role should be secondary to the educational content of the conference. (3) Physicians should claim credit commensurate with only the actual time spent attending a CME activity or in studying a CME enduring material. (4) Attending promotional activities put on by industry or their designees is not unethical as long as the conference conforms to Opinion 8.061, "Gifts to Physicians from Industry," and is clearly identified as promotional to all participants. Faculty. Guidelines for physicians serving as presenters, moderators, or other faculty at a CME conference are as follows: (1) Physicians serving as presenters, moderators, or other faculty at a CME conference should ensure that (a) research findings and therapeutic recommendations are based on scientifically accurate, up-to-date information and are presented in a balanced, objective manner; (b) the content of their presentation is not modified or influenced by representatives of industry or other financial contributors, and they do not employ materials whose content is shaped by industry. Faculty may, however, use scientific data generated from industry-sponsored research, and they may also accept technical assistance from industry in preparing slides or other presentation materials, as long as this assistance is of only nominal monetary value and the company has no input in the actual content of the material. (2) When invited to present at non-CME activities that are primarily promotional, faculty should avoid participation unless the activity is clearly identified as promotional in its program announcements and other advertising. (3) All conflicts of interest or biases, such as a financial connection to a particular commercial firm or product, should be disclosed by faculty members to the activity's sponsor and to the audience. Faculty may accept reasonable honoraria and reimbursement for expenses in accordance with Opinion 8.061, "Gifts to Physicians from Industry."

Sponsors. Guidelines for physicians involved in the sponsorship of CME activities are as follows: (1) Physicians involved in the sponsorship of CME activities should ensure that (a) the program is balanced, with faculty members presenting a broad range of scientifically supportable viewpoints related to the topic at hand; (b) representatives of industry or other financial contributors do not exert control over the choice of moderators, presenters, or other faculty, or modify the content of faculty presentations. Funding from industry or others may be accepted in accordance with Opinion 8.061, "Gifts to Physicians from Industry." (2) Sponsors should not promote CME activities in a way that encourages attendees to violate the guidelines of the Council on Ethical and Judicial Affairs, including Opinion 8.061, "Gifts to Physicians from Industry," or the principles established for the AMA's Physician Recognition Award. CME activities should be developed and promoted consistent with guideline 2 for Attendees. (3) Any non-CME activity that is primarily promotional must be identified as such to faculty and participants, both in its advertising and at the conference itself. (4) The entity presenting the program should not profit unfairly or charge a fee which is excessive for the content and length of the program. (5) The program, content, duration, and ancillary activities should be consistent with the ideals of the AMA CME program. (I, V) Issued December 1993; Updated June 1996.

D-295.955, addresses educating medical students about industry

D-295.955 Educating Medical Students about the Pharmaceutical Industry

Our AMA will strongly encourage medical schools to include: (1) unbiased curricula concerning the impact of direct-to-consumer marketing practices employed by the pharmaceutical industry as they relate to the physician-patient relationship; and (2) unbiased information in their curricula concerning the pharmaceutical industry regarding (a) the cost of research and development for new medications, (b) the cost of promoting and advertising new medications, (c) the proportion of (a) and (b) in comparison to their overall expenditures, and (d) the basic principles in the decision making process involved in prescribing medications, specifically using evidence based medicine to compare outcomes and cost effectiveness of generic versus proprietary medications of the same class. (Res. 303, A-05)

REPORT 1 OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS (A-11)
Financial Relationships with Industry in Continuing Medical Education
(Reference Committee on Amendments to Constitution and Bylaws)

EXECUTIVE SUMMARY

Relationships between medicine and industry—such as pharmaceutical, biotechnology, and medical device companies—have driven innovation in patient care, contributed to the economic well-being of the community, and provided significant resources (financial and otherwise) for professional education, to the ultimate benefit of patients and the public. The interests and obligations of medicine and industry diverge in important ways, however. An increasingly urgent challenge for both partners is to devise ways to preserve strong, productive collaborations for the benefit of patients and the public at the same time they each take clear, effective action to avoid relationships that could undermine public trust.

This report examines financial relationships between medicine and industry in the specific context of continuing medical education. It summarizes the ethical foundations of medicine's obligation to ensure that physicians acquire and maintain the knowledge, skills, and values that are central to the healing profession. The report analyzes the ethical challenges that can be posed when physicians who organize, teach in, or serve other roles in continuing medical education have financial relationships with companies that have a direct interest in physicians' recommendations and illustrates strategies for mitigating the potential of such financial relationships to influence professional education in undesired ways. It identifies core ethical principles of transparency, independence, and accountability and provides practical ethical guidance to maintain the independence and integrity of continuing professional education and promote public trust.

REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Report 1-A-11

Subject: Financial Relationships with Industry in Continuing Medical Education

Presented by: John W. McMahon, Sr., MD, Chair

Referred to: Reference Committee on Amendments to Constitution and Bylaws (Patricia L. Austin, MD, Chair)

Relationships between medicine and industry—such as pharmaceutical, biotechnology, and medical device companies—have driven innovation in patient care, contributed to the economic well-being of the community, and provided significant resources (financial and otherwise) for professional education, to the ultimate benefit of patients and the public.[1,2] The interests and obligations of medicine and industry diverge in important ways, however. An increasingly urgent challenge for both partners is to devise ways to preserve strong, productive collaborations for the benefit of patients and the public at the same time they each take clear, effective action to avoid relationships that could undermine public trust.

As relationships between medicine and industry have evolved, major national organizations, such as the Institute of Medicine (IOM)[3] and the Association of American Medical Colleges (AAMC)[4,5,6] have explored the challenges that these relationships can pose in research, clinical care, education, and beyond. Key stakeholders, including (among others) the Accreditation Council for Continuing Medical Education (ACCME),[7] the Council of Medical Specialty Societies (CMSS),[8] and the Pharmaceutical Research and Manufacturers Association (PhRMA)[9] have developed guidance to help their constituents sustain appropriate, productive, and professional interactions.

The American Medical Association was founded on the vision that as medical professionals, physicians should represent the highest standards of competence, integrity, and professionalism. This report carries that vision forward. It examines ethical aspects of medicine-industry relationships in continuing medical education (CME), explores ethical challenges that can be posed by financial relationships from the perspective of physicians, and provides guidance for members of the medical profession who attend or who organize, teach in, or serve other roles in CME.

The Council on Ethical and Judicial Affairs recognizes that pharmaceutical, biotechnology, and medical device companies are not the only entities with which financial relationships can raise concerns. CEJA likewise recognizes that CME is not the only domain of potential concern. However, narrowing our focus to CME allows us to explore the complex considerations at stake in a manageable context and to provide practical ethical guidance on issues that increasingly challenge physicians as professionals.

* Reports of the Council on Ethical and Judicial Affairs are assigned to the Reference Committee on Amendments to Constitution and Bylaws. They may be adopted, not adopted, or referred. A report may not be amended, except to clarify the meaning of the report and only with the concurrence of the Council.

LIFELONG LEARNING & MEDICINE'S DUTY TO EDUCATE

> *Publicly in his oath and privately in his encounter with the patient, the physician professes two things—to be competent to help and to help with the patient's best interests in mind.*
>
> — Edmund Pellegrino[10]

The practice of medicine is inherently a moral activity, founded in a "covenant of trust" between patient and physician.[10,11,12] The respect and autonomy that medicine enjoys rest on the profession's commitment to fidelity and service in the patient-physician relationship. To sustain that commitment, medicine must ensure that physicians acquire and maintain the knowledge, skills, and values that are central to the healing profession. In return, society grants medicine considerable authority to set the ethical and professional standards of practice and the autonomy to educate practitioners.[13,14]

The special moral character of the interaction between patient and physician arises from the need—illness or the prevention of illness—that brings the patient into the relationship. Physicians are granted extraordinary privileges to intervene in patients' lives. Patients entrust to physicians the care of their bodies and the protection of sensitive information revealed in confidence for the purpose of seeking healing. Educating current and future generations of physicians to fulfill the responsibilities that flow from the patient-physician relationship is the foundation of medicine's status as a caring and competent profession. Thus medicine's ethical duty to educate cannot be delegated to others.

Individual physicians have an ethical obligation to dedicate themselves to "continue to study, apply, and advance scientific knowledge" and to "maintain a commitment to medical education."[15] As professionals, practicing physicians are expected to commit themselves to lifelong learning and to maintain their clinical knowledge and skills through CME and other professional development activities.[16] That commitment is reflected not only in ethical expectations and standards, but also in requirements for licensure and specialty certification, as well as hospital credentialing.

Physicians and the patients who rely on them must be confident that treatment recommendations and clinical decisions are well informed and reflect up-to-date knowledge and practice. CME activities that are pedagogically sound, scientifically grounded, and clinically relevant are essential to ensure that physicians can provide the high quality of care their patients deserve. To achieve these goals, medicine has an ethical obligation to ensure that the profession independently sets the agenda and defines the goals of physician education; controls what subject matter is taught; determines physicians' educational needs; and takes steps to ensure the independence of educational content and of those who teach it. The importance of doing so may extend well beyond continuing education—as one commentary noted, "[w]hat is at stake is nothing less than the privilege of autonomy in our interactions with patients, self-regulation, public esteem, and a rewarding and well-compensated career."[17]

CONTINUING MEDICAL EDUCATION

Continuing medical education today takes place in an environment that includes "promotional" activities, "certified CME," and noncertified CME. Promotional activities lie outside the scope of the present analysis and recommendations. As defined by the Food and Drug Administration (FDA), these are activities developed by or on behalf of a commercial entity and under the substantive influence of that entity to provide information on the therapeutic use of a product or

service. They are governed by the labeling and advertising provisions of the Food, Drug, and Cosmetic Act,[18,19] and may constitute protected commercial speech.

"Certified CME" refers to educational activities developed and implemented in compliance with the certification requirements of the American Medical Association Physician Recognition Award (PRA) CME Credit System or the accrediting policies of the American Academy of Family Physicians or American Osteopathic Association.[20] Certified CME meets the requirements for Category 1 credit under AMA's PRA program, including compliance with Accreditation Council for Continuing Medical Education (ACCME) standards and with relevant AMA ethics policy.[21]

Beyond these formal categories lie activities designed to inform and educate practicing physicians that are neither promotion nor certified CME. These other activities may or may not be commercially supported, may or may not voluntarily adhere to AMA policy or ACCME Standards for Commercial Support℠ (even if they are not formally certified or offered by formally accredited providers), and may or may not be recognized by licensing bodies or credentialing boards as fulfilling CME requirements.

Physician involvement is critical in CME. Individually and collectively, physicians play key roles in educating their peers, as teachers, content developers, organizers of CME, or in other capacities.

Financial Relationships with Industry in CME

In the context of continuing medical education, relationships with industry that may pose challenges for the independence and objectivity of physician education include not only direct industry support of CME activities, but also financial relationships between industry and individual physicians involved in CME as faculty, content developers, or in other capacities.

Industry support for CME has declined in recent years, but commercial funding still accounts for approximately 40 percent of overall CME-related revenue, ranging from less than one percent to just over 60 percent across accredited CME providers.[22] A growing number of accredited providers—20 percent as of July 2009—no longer accepts any commercial support at all.[23]

Industry support helps to meet the costs of CME activities in the face of uncertain funding from other sources[24] and may help make CME more accessible, especially for physicians in resource-poor communities.[25] Industry engagement and support can be especially helpful in ensuring affordable CME when educational activities need high cost, sophisticated, rapidly evolving technology or devices. Along with lower costs, industry support may encourage greater participation than would otherwise be the case by providing amenities. As yet there is no peer-reviewed evidence to support or to refute the effect of industry funding on accessibility of or participation in CME activities.[26]

However, there is growing concern within and outside medicine that industry funding for CME could have undesirable effects, including potentially biasing content toward funders' products and influencing the overall range of topics covered.[27,28,29,30] Importantly, where patients' health and public trust are concerned, the perception of bias, even if mistaken, can be as potentially damaging as the existence of actual bias.

Influence, Evidence & Ethics

Whether or how financial relationships influence CME activities or the overall CME curriculum is an important question. But answering this empirical question cannot resolve the core ethical

challenge, no matter what the evidence should prove to be. Physicians are entrusted with the interests of patients. Where trust is central, the *appearance* of influence or bias can be as damaging as actual influence. Empirical evidence alone is not enough to overcome public skepticism. Even evidence that undesired consequences have not occurred cannot be expected by itself to restore confidence when trust has been compromised.

The available data neither support nor disprove that financial relationships influence CME. Standards have been established to address concerns about possible influence in CME, such as the ACCME Standards for Commercial Support.[SM] The efficacy of those standards or other processes to address the potential for industry influence on content or the overall range of CME topics is difficult to determine. Several recent studies have suggested that the great majority of physicians attending CME activities do not perceive bias in the content of those activities, based on their responses to questions about bias on standard evaluations of CME activities.[31,32,33] As the authors themselves note, these studies are subject to limitations, such as the "insensitivity of simple 'yes/no' questions to assess learners' perceptions of bias."[33, cf. 32, cp., 34]

Other research indicates that individual physicians, like everyone else, are subject to influence, even if they are not aware of how industry support of a CME activity could affect their clinical decisions.[35,36,37,38,39] Further, a recent review of the relevant literature found that although there is clear evidence that CME influences physicians' prescribing practices, the question of what effect changes in prescribing have on actual patient outcomes has not specifically been studied.[39]

To maintain productive relationships with industry that benefit patients and to sustain the trust on which the patient-physician relationship and public confidence in the profession depend, medicine must take steps to safeguard the independence and integrity of physician education.

ENSURING THE INDEPENDENCE & INTEGRITY OF CME

CEJA recognizes that competing interests are a fact of life for everyone, including but not limited to physicians. For physicians, however, even very modest potential or perceived competing interests can put trust at risk. As individuals and as a profession, physicians have a responsibility to protect the quality of professional education and the reputation of medicine. While competing interests cannot be eliminated entirely, prudent judgments can be made about how to minimize potential influence and prevent or reduce undesired consequences.

Minimizing the Opportunity for Influence

Physicians should aspire to avoid the potential for influence or the chance that confidence in the integrity and independence of their professional education could be diminished. Avoiding entirely situations in which there is potential for influence has the virtue of ethical clarity and practical simplicity. CME that is free of financial relationships with companies that have direct interests in physicians' recommendations strongly underscores medicine's defining professional commitment to independence and fidelity to patients. Avoiding such relationships also has the practical advantage of eliminating the administrative and resource costs that must otherwise be devoted to mitigating influence,[40] costs that may be particularly challenging for smaller CME providers.[25]

In their roles as CME providers, content developers, and faculty, physicians should strive to avoid financial relationships with industry. The Institute of Medicine has called for development of a new system of funding CME that is free of industry influence.[3] Medicine should cultivate alternative sources of support, should design and conduct educational activities so as to reduce costs, and should insist that content developers and faculty members not have problematic ties with

industry to ensure independent, unbiased, high quality educational programming that best meets physicians' needs and is accessible and affordable for all practitioners.

Changing the terms of financial relationships likewise can help minimize the potential for influence. For example, physicians who have decision-making authority in organizations that provide CME could set an upper limit on how great a proportion of the organization's income derives from industry support to ensure that the organization does not become overly reliant on commercial funding. Asking physicians who teach in or develop content for a CME activity to refrain from accepting compensation (honoraria, consulting fees, etc.) for a defined period before and after the activity from a commercial supporter that has an interest in the educational subject matter could similarly promote independence. Decisions to require that physicians involved in CME as faculty members or in other roles change the terms of their relationships with industry must, of course, be made fairly and consistently across individual cases.

That said, it is not always feasible, or necessarily desirable, for professional education to disengage from industry completely. In some situations financial relationships with industry can be ethically justifiable. When not accepting support from a commercial source or not permitting participation by individuals who have financial interests in the educational subject matter would significantly undermine medicine's capacity to ensure that physicians have access to appropriate, high-quality CME, it can be acceptable to permit such support or participation. In these situations, vigorous efforts must be made to mitigate the potential influence of financial relationships.

Mitigating Potential Influence

While there should be a presumption that physicians who organize, design, develop content, or teach in CME should not have concurrent financial ties to industry related to their CME responsibilities, it is important to recognize that not all relationships with industry are equally problematic. A relationship that is only indirectly related to an educational activity, modest in scope, or distant in time is not likely to adversely affect—or be perceived to affect—the activity in question. For example, having once conducted sponsored research or accepted a modest honorarium for speaking on behalf of a company would not necessarily create such clear potential for bias as to preclude an individual with the appropriate expertise from developing content or serving as a faculty member for a given CME activity.[41]

Financial relationships that are direct or substantial, however, have significant potential to undermine confidence in educational activities, even if they do not actually compromise those activities. Examples of a direct or substantial financial interest include ownership or equity interest in a company that has an interest in the educational subject matter of a CME activity or royalties or ongoing compensated relationships (e.g., consulting arrangements or service on scientific advisory bodies or speakers bureaus).[4] Relationships that involve fiduciary responsibilities on behalf of the funder (such as service on a corporate board of directors) or decision-making authority in financial matters can be similarly problematic.[42] In such situations, ethically strong practice requires that steps be taken to mitigate the possible influence of financial relationships on educational activities.

PRINCIPLES FOR SUSTAINING TRUST

The goal of mitigation is to promote–and enhance confidence in–the integrity of continuing professional education. Commitment to transparency, independence, and accountability enables physicians to achieve that goal, whatever role they may play in CME. Moreover, being transparent about financial relationships that have the potential to influence CME and forthcoming about what

steps have been taken to minimize possible influence supports physician-learners in exercising critical judgment individually as "consumers" of CME.

Transparency

As the ACCME Standards for Commercial Support[SM] recognize, transparency—i.e., disclosing the existence of a financial relationship—is a necessary first step in mitigating the potential of financial relationships to create bias (or the appearance of bias),[7] but it is not sufficient and may even have perverse effects. Disclosure places the burden on learners themselves to determine how skeptical they should be about possible bias in an educational activity.[43] To the extent that disclosure fosters the impression that the presenter is particularly honest and trustworthy, it can encourage false confidence in the activity. To the extent that the presenter believes disclosing a financial relationship is adequate to mitigate its potential influence, he or she may be less circumspect in ensuring content is free of such influence.

While transparency is essential, disclosing financial relationships is necessary but not sufficient to mitigate the potential for influence in CME.

Independence

Taking concrete steps to ensure that CME is independent and objective is equally important. Creating a "firewall" between funders and decisions about educational goals, content, faculty, pedagogical methods and materials, and other substantive dimensions of CME activities can help protect the independence of professional education. Both ACCME and the Inspector General of the Department of Health and Human Services have recommended clearly separating decisions about funding from substantive decisions about CME activities,[7,19] and many organizations are developing models, such as "blind trusts," to do so.[e.g.,44,45] Support of individual CME activities by multiple, competing funders may also help diffuse the potential influence of any one funder. Carrying out educational needs assessments prior to seeking or accepting commercial support or identifying faculty can similarly enhance the independence of the planning process and resulting CME programming. Likewise, having prospective peer review of a presentation (review of slides or other forms of communication in advance of the presentation by an objective and independent expert who has the power to require changes prior to the public showing) can help ensure that the presentation is free of commercial bias.

Accountability

Physician-learners, patients, the public, and the medical community as a whole should be able to be confident that physicians who organize, design, develop content, or teach in CME will uphold principles of transparency and independence. The expectation that physicians involved in CME will hold themselves accountable to address the potential that financial relationships with industry have to influence professional education is a cornerstone of self-regulation. That responsibility can be greatly enhanced by the efforts of accrediting and certifying bodies, but it cannot be supplanted by them. In particular, physician leaders in CME should be able and willing to discuss how the principles of transparency and independence have been applied in the educational activities with which they are involved or over which they have decision-making authority.

Exceptional Cases

At times it may be impossible to avoid a financial interest or extraordinarily difficult or even impossible to mitigate its potential impact on an educational activity. For the most part, accepting

support from a company or permitting participation by an individual when there is an irreducible financial interest would not be ethically acceptable. However, in certain circumstances, it may be justifiable.

Such circumstances include instances when accessible, high-quality CME cannot reasonably be carried out without support from sources that have a direct financial interest in physicians' clinical recommendations, such as activities that require cadavers or high-cost, sophisticated equipment to train physicians in new procedures or the use of new technologies. Similarly, in the earliest stage of adoption of a new medical device, technique, or technology the only individuals truly qualified to train physicians in its use are often those who developed the innovation. These individuals may have the most substantial and direct interests at stake, whether through employment, royalties, equity interests or other direct financial interests in the adoption and dissemination of the new technology. Physicians who organize CME should be transparent about what considerations led them to decide to permit an individual with a problematic financial interest to participate in a particular CME activity to ensure that such decisions are justifiable and persuasive to the professional community at large.

Putting Principles into Practice – The Exercise of Judgment

Inevitably, putting principles of transparency, independence, and accountability into practice calls for the exercise of judgment. It requires knowledge of the particular circumstances and thoughtful deliberation. Yet this is no different from the kinds of judgments physicians routinely make in the context of caring for patients and applying other portions of the *Code of Medical Ethics* to their daily practice.

One approach is to reflect on what "consumers" of CME (which arguably includes patients and the broader professional community, as well as individual physician-learners) would want to know to exercise their skills of critical judgment; that is, to make well-considered judgments for themselves about the objectivity and quality of a CME activity, its faculty, and its educational content. Such factors might include not only the existence of a financial interest(s), but equally the source of that interest, the type of interest (such as honoraria, consulting fees, equity, stock options, royalties), and the magnitude of the interest, e.g., dollar amount to the nearest $1,000, as currently required by the North American Spine Society.[46]

Similarly, consumers of CME could reasonably want to know how the potential influence of a financial interest has been addressed to protect the independence of the activity; or consumers may want to know on what grounds an individual who has a direct, substantial, and unavoidable financial interest has been permitted to participate in a CME activity. In the latter case, for example, reasonable decision-making criteria might include that the dissemination of the device, technique or technology will be of significant benefit to patients and to the public and the professional community; that the individual is uniquely qualified as an expert in the relevant body of knowledge or skills; that the individual discloses the source, nature, and magnitude of the specific financial interest at stake; that there is demonstrated, compelling need for the specific CME activity; that all feasible steps are taken to mitigate influence; and that this expert's participation in dissemination will, eventually, enable those without such financial interests to take on the educational role. An individual might be considered "uniquely qualified" when he or she is the only expert (or one of a few) who has significant knowledge about or experience in treating a rare disease or was involved in the early development or testing of a new treatment, device, or technology. A "compelling need" for a particular educational activity may be present when a new therapy becomes available to treat a disease present in the local community for which the new treatment represents a substantial improvement.

The need to rely on "conflicted expertise" can be affected by local conditions—CME in small or rural communities, for example, may not always have ready access to experts who are free of problematic ties to industry. In any event, when a substantial body of peer-reviewed evidence has evolved in a given subject area, or when a cohort of individuals without direct, substantial interests has become experienced in using a new medication, device, or technology and is available to teach, using a "uniquely qualified" expert becomes less justifiable.

As the professional community gains experience, it is to be expected that consensus will coalesce around core interpretations. As Harvard Medical School notes in its conflict of interest policy:

> These classifications are not intended to serve as a rigid or comprehensive code of conduct or to define "black letter" rules with respect to conflict of interest. It is expected that the guidelines will be applied in accordance with the spirit of the mission of Harvard Medical School in education, research and patient care. By this process, it is expected that a common institutional experience in the application of these guidelines will gradually evolve.[47]

We expect that a similar shared understanding of how principles of transparency, independence, and accountability should apply to financial relationships with industry in continuing medical education will evolve for the medical profession.

RECOMMENDATION

The Council on Ethical and Judicial Affairs recommends that the following be adopted and the remainder of this report be filed:

> In an environment of rapidly changing information and emerging technology, physicians must maintain the knowledge, skills, and values central to a healing profession. They must protect the independence and commitment to fidelity and service that define the medical profession.
>
> Financial or in-kind support from pharmaceutical, biotechnology or medical device companies that have a direct interest in physicians' recommendations creates conditions in which external interests could influence the availability and/or content of continuing medical education (CME). Financial relationships between such sources and individual physicians who organize CME, teach in CME, or have other roles in continuing professional education can carry similar potential to influence CME in undesired ways.
>
> CME that is independent of funding or in-kind support from sources that have financial interests in physicians' recommendations promotes confidence in the independence and integrity of professional education, as does CME in which organizers, teachers, and others involved in educating physicians do not have financial relationships with industry that could influence their participation. When possible, CME should be provided without such support or the participation of individuals who have financial interests in the educational subject matter.
>
> In some circumstances, support from industry or participation by individuals who have financial interests in the subject matter may be needed to enable access to appropriate, high-quality CME. In these circumstances, physician-learners should be confident that that vigorous efforts will be made to maintain the independence and integrity of educational activities.
>
> Individually and collectively physicians must ensure that the profession independently defines the goals of physician education, determines educational needs, and sets its own priorities for CME. Physicians who attend CME activities should expect that, in addition to complying with

all applicable professional standards for accreditation and certification, their colleagues who organize, teach, or have other roles in CME will:

(a) be transparent about financial relationships that could potentially influence educational activities.

(b) provide the information physician-learners need to make critical judgments about an educational activity, including:

(i) the source(s) and nature of commercial support for the activity; and/or

(ii) the source(s) and nature of any individual financial relationships with industry related to the subject matter of the activity; and

(iii) what steps have been taken to mitigate the potential influence of financial relationships.

(c) protect the independence of educational activities by:

(i) ensuring independent, prospective assessment of educational needs and priorities;

(ii) adhering to a transparent process for prospectively determining when industry support is needed;

(iii) giving preference in selecting faculty or content developers to similarly qualified experts who do not have financial interests in the educational subject matter;

(iv) ensuring a transparent process for making decisions about participation by physicians who may have a financial interest in the educational subject matter;

(v) permitting individuals who have a substantial financial interest in the educational subject matter to participate in CME only when their participation is central to the success of the educational activity; the activity meets a demonstrated need in the professional community; and the source, nature, and magnitude of the individual's specific financial interest is disclosed; and

(vi) taking steps to mitigate potential influence commensurate with the nature of the financial interest(s) at issue, such as prospective peer review.

(New HOD/CEJA Policy)

Fiscal Note: Staff cost estimated at less than $500 to implement.

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February 17, 2012

Marilyn B. Tavenner
Acting Administrator
Chief Operating Officer
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests

Dear Acting Administrator Tavenner:

On behalf of the undersigned organizations, we appreciate the opportunity to provide comments in response to the proposed regulation published on December 19, 2011, *Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests (CMS-5060-P)* (Proposed Rule). We are pleased that the majority of the Proposed Rule comports with the Affordable Care Act (ACA) statutory provisions and congressional intent; however, we are concerned that Centers for Medicare and Medicaid Service (CMS) has exceeded its statutory authority with regard to at least one significant provision and misconstrued Congress' overall intent and statutory requirements in other areas. While we support the underlying goal of enhancing transparency, we believe the proposed rule, if implemented without significant modifications, will result in the publication of misleading information and impose costly and burdensome paperwork requirements on physicians while shedding very little light on actual physician-industry interactions.

Background

The ACA mandates that beginning in 2012, manufacturers of specified drugs, medical devices, and biologicals participating in U.S. federal health care programs must begin tracking any transfers of value or payments of $10 or more (as indexed by Consumer Price Index) to physicians and teaching hospitals.[1] These reports must be submitted to the Secretary of Health and Human Services on an annual basis. The majority of the information contained in the reports will be available on a public, searchable website in 2013. In

[1] The statute and regulations exclude transfers of value less than $10, unless the aggregate amount transferred to a physician by a manufacturer exceeds $100. As a result, manufacturers must track all transfers (as physicians must as well to in order to challenge any inaccurate manufacturer reporting) in order to report transfers of value that are less than $10, but cumulatively exceed $100.

addition, the ACA mandates that manufacturers and group purchasing organizations (GPOs) must report ownership interests held by physicians and their close family members.

Implementation

We strongly support the proposal to delay reporting until a final rule has been issued by CMS to ensure that physicians have adequate notice of final transparency report requirements and to provide CMS and manufacturers/GPOs an adequate opportunity to establish a reporting process that is consistent with the statute and congressional intent. The proposed rule has generated many questions and there remains a great deal of confusion. We urge CMS to provide physicians and physician organizations adequate time to provide training and information about the final program prior to implementation.

CMS Is Required to Publish Accurate Transparency Reports

CMS has stated in the proposed rule that it does not believe that the federal government should "be actively involved in arbitrating disputes between" physicians and manufacturers/GPOs. CMS proposes (1) that manufacturers/GPOs voluntarily employ a pre-submission review/dispute process for physicians; and (2) a post-CMS submission process where physicians are provided aggregate reports by the agency, but must contact manufacturers/GPOs to resolve disputes. CMS indicates that to the extent disputes remain outstanding between a physician and manufacturer/GPO, the disputed information would be flagged by CMS in the public Web site and the agency would consider using the physician's disputed aggregated total. **At a minimum, we support the use of the aggregated total specified by the physician.**

Despite the foregoing, we are concerned that the proposed process does not provide an adequate means for physicians to challenge reports. False, misleading, and inaccurate information could be publicly posted on a government website while denying physicians basic due process rights to challenge such information. **It was reasonably expected that an objective arbiter and a standard, expedited process would be utilized to address disagreements concerning the contents of transparency reports.** We urge CMS to establish an independent process for resolving disputes between manufacturers/GPO and physicians about reports. This dispute resolution process could be conducted by CMS itself or by a separate entity. For example, CMS relies on accredited Independent Review Organizations (IRO), Independent Review Entities (IRE), and Qualified Independent Contractors (QIC) as part of the Medicare appeals procedures. These independent entities are contracted by Medicare to re-determine previous, lower level, decisions.

Even where an independent arbiter is utilized, if a physician continues to dispute a manufacturer's report, CMS should flag the disputed information on the public Web site and provide a comment section that allows a physician to include a rebuttal in narrative form. In addition, CMS should utilize the aggregated total specified by the physician. The consequences of a dispute between a manufacturer/GPO and a physician do not have the same impact on the standing and reputation of each party. A few disputes between a manufacturer and a handful of physicians are unlikely to ruin a

manufacturer/GPO's standing or even subject the manufacturer/GPO to civil money penalties (CMP). In contrast, physicians may have their careers and professional reputations damaged as a result of one disputed report, and physicians may incur significant expenses to resolve a dispute with a manufacturer/GPO.

The proposed rule outlines a process where the government would purport to bear no responsibility for ensuring the accuracy of publicly posted transparency reports (and that it is merely a conduit of reporting provided by manufacturers). Yet, as outlined in the proposed rule, there is little to no consequence for a manufacturer/GPO when they inaccurately report on transfers of value or ownership, whereas the consequences to an individual physician are potentially significant. In fact, manufacturers/GPOs have a strong incentive to report rapidly (as opposed to accurately) because failure to timely submit a complete report will be evident to the agency (and subject the manufacturer/GPO to CMPs). While CMS proposes to include an evaluation of the nature and amount of information reported in error and the degree of diligence exercised in correcting information reported in error when imposing a CMP, we are concerned that what a manufacturer/GPO and CMS may consider minor (when weighed against the totality of information reported) could actually have significant consequences for individual physicians. Furthermore, while it is straight-forward to determine whether a manufacturer missed a deadline, a dispute about the accuracy is likely to generate fewer sanctions for the manufacturer/GPO.

CMS has proposed that manufacturers/GPOs establish a voluntary process that allows physicians to review their applicable manufacturer/GPOs report prior to submission to CMS. The technology exists that would impose a minimal burden on manufacturers/GPOs to provide real-time as well as regular cumulative reports to physicians in multiple formats (e.g., mail, electronically, or web-based). **In order to meet the agency's obligation to ensure accurate reporting, manufacturers/GPOs should be required to establish a standardized process and procedures that provide ongoing notifications to physicians of all transfers of value/ownership interests with an opportunity to correct reports as well as a cumulative report before the manufacturer/GPO transmits a report to CMS.** If CMS bears the sole responsibility for providing such reports to physicians within a 45-day period, there will be an increased probability that false and misleading reports will be made public. We also support the secure Web site portal proposed by CMS, but we believe it is insufficient to ensure that reports are accurate and do not contain erroneous information that could be damaging to individual physicians.

The ACA provides physicians with a statutory right to challenge all reports even after publication. In the proposed rule, however, we believe this right would be diluted. **We oppose limiting a physician's ability to challenge the accuracy of reports to the "current" and prior reporting year within a compressed 45-day window each year.** There is no statutory support for this provision and it is inconsistent with the Congress' intent to ensure such reports are accurate. The ACA provides that before a report is made public, physicians are to have 45 days to review and submit corrections, ***at a minimum.*** This does not apply to corrections after the reports are made public.

Congress intended that disputes would not delay publication, but never provided that all disputes were to be compressed into a 45-day once a year period. Given the prescriptive nature of the statutory scheme, this would deny physicians substantive and procedural due process rights. In light of the current state of technology, CMS and manufacturers/GPOs have the capability to allow for real-time updates and modification of reports. Instead of compressing the challenge period into a short period of time that could require significant allocation of staff resources during this condensed period, it is reasonable to require manufacturers and CMS to allow modification and correction of reports on an ongoing basis as part of their normal workflow. **In sum, the statute does not establish a maximum 45-day window in which to challenge the accuracy of transparency reports and we do not support CMS imposing such an arbitrary limitation on the due process rights of physicians.**

We strongly urge CMS to re-structure the process the agency has outlined. The proposed rule opens the door to the real possibility that a large number of physicians could become the victims of false, inaccurate, or misleading reporting and suffer significant damages including investigation by government and private entities, potential disciplinary actions, public censure, ridicule, and destruction of professional reputation and livelihood. During congressional hearings, investigations, and legislative negotiations, the unambiguous intent of Congress was to provide a mechanism to ensure that the actual interactions between physicians and manufacturers were transparent. It was never contemplated that the information in the transparency reports would be false, misleading, or materially inaccurate.

Congress Did Not Authorize CMS to Expand Reporting to Indirect Transfers (Not Otherwise Specified in Statute)

When Congress passed ACA's Sec. 6002, it expressed an unambiguous intent to strike prior legislative language that would have required reporting on indirect transfers of value except when manufacturers make a payment or other transfer of value to an entity or individual at the request of or designated on behalf of a physician as specified in Section 6002(a)(1)(B). Earlier versions of what eventually became ACA Sec. 6002, H.R. 5605, *Physician Payments Sunshine Act of 2008*, and S. 2029, *Physician Payments Sunshine Act of 2007,* would have explicitly required that manufacturers report a payment or other transfers of value made, "directly, indirectly, or through an agent, subsidiary, or other third party." This language was not included in the ACA version of the Physician Payments Sunshine Act.

Sec. 6002 of the ACA provides for reporting on direct transfers except as outlined in Sec. 6002(a)(1)(B). This latter subsection was added in the ACA version of the Physician Payments Sunshine Act in order to capture when reporting on indirect payments and transfers would be required. As stated above, this would be where manufacturers are transferring payment or value to a third party at the request of the physician or designated on behalf of the physician. When Congress conferred the agency with the authority to add additional reportable categories, it did not confer the agency with the authority to expand reporting to indirect payments or transfers except in this carefully prescribed area.

Despite the foregoing, CMS's interpretation of "payment or other transfer of value," Sec. 6002(e)(10)(A), includes instances where the manufacturer learns of the identity of a physician before, during, or after the manufacturer makes a payment or transfers value to a third party or when made through an "agent." CMS proposes to require reporting where a manufacturer has actual knowledge of, or acts in deliberate ignorance or reckless disregard of, the identity of a physician. This interpretation is inconsistent with congressional intent, is unworkable, and could undermine the independence of certified CME and other activities where manufacturers make grants, but are barred from any control over how funds are used. This is amplified by the agency's overbroad proposal to make attribution of value even where there is little to no evidence that the physician receives any payment or value.

CMS proposes to expand the universe of detailed information manufacturers would demand to have about physicians where the manufacturer is reasonably expected to learn that a physician received a benefit from a transfer to a third party. This would add to the complexity of the reporting requirement since the third parties would have to report in detail back to all manufacturers the value attributed to each physician in their organization/company/conference after the indirect transfer is made.

For example, certified Continuing Medical Education (CME) activity faculty would have to be listed as receiving a payment from industry despite the fact that manufacturers are explicitly prohibited from having any control over the content, speakers, or attendees. While industry does not name the faculty, they could learn the identity of the faculty since this information is typically public. Many conferences that physicians attend in order to earn certified CME credit (either certified by the American Academy of Family Physicians, the American Osteopathic Association or the AMA) also publish a list of the participants so the manufacturer could "know" or "should know" who potentially received an indirect transfer of value after the transfer is made to the third party. However, the manufacturer cannot accurately report how to make proper attribution of value unless the CME provider or conference host provides a detailed attribution for all faculty and CME/conference attendees. The consequence of such an approach would be the transfer of an exhaustive amount of information to manufacturers about individual physicians participating in independent, certified CME. Congress never intended that transparency reports would become a gold mine of physician information for manufacturers.

All of the foregoing concerns were raised with congressional staff, and Congress elected to strike reporting on indirect transfers or transfers through an "an agent, subsidiary, or other third party." **At a minimum, CMS should replace the proposed standard with a regulation that provides that in all instances where a manufacturer would not necessarily know the identities of the specific recipients (who eventually receive a benefit) and the transfer is not made at the request of a covered recipient or designated on behalf of covered recipient, an indirect transfer is not reportable.** Further, we strongly oppose the effort to expand this provision to the agents of manufacturers since CMS fails to define the term agent and, more importantly, Congress specifically considered including agents, but rejected this approach as discussed fully above.

The Proposed Rule's overbroad interpretation of the statutory language is inconsistent with the Administration's stated goal of reducing regulatory burdens on physicians. As discussed more fully below, CMS has significantly understated the paperwork burden this imposes on all physicians since the wide swath of indirect reporting dictates that physicians track any activity that could conceivably have any indirect transfers of value (even where there isn't any transfer of value since most physicians will not know until they receive notice from a manufacturer or CMS whether or not they received anything of value from a manufacturer indirectly).

Congress Excluded Certified Continuing Medical Education (CME) from Reporting

We believe that CMS has exceeded its statutory authority to the extent it requires reporting on certified CME since Congress excluded certified CME from transparency reporting requirements. Though Congress contemplated including CME in transparency reports, it ultimately rejected this option. The American Medical Association (AMA) requires that accredited CME providers that certify CME activities for *AMA PRA Category 1 Credit*™ comply with the Standards for Commercial Support which include the Standards to Ensure the Independence of CME (SCS), promulgated by the Accreditation Council for Continuing Medical Education (ACCME), as well as the AMA's *Code of Medical Ethics.* In addition, all certified CME includes course content approved by the previously named certifying bodies.

Because certified CME is independent and manufacturers have no control or input into the content, the speakers, or the attendees, it is not covered by ACA Sec. 6002. The law includes a broad category of educational activities that are subject to reporting. These include promotional activities that are defined by the Food and Drug Administration (FDA) as education developed by or on behalf of a commercial entity and under the substantive influence of that entity to provide information on the therapeutic use of a product or service. Congress explicitly deleted reference to CME when the final version of the Physician Payments Sunshine Act was signed into law as part of the ACA.

We urge CMS to exclude from reporting certified CME as this is a reasonable interpretation of both congressional intent and the legislative history of this provision. As discussed above, earlier versions of the Physicians Payments Sunshine Act, S. 2029 and H.R. 5605, required reporting on a far larger universe of transfers/payments including all indirect transfers/payments and for "participation in a medical conference, continuing medical education, or other educational or informational program or seminar, provision of materials related to such a conference or educational or informational program or seminar, or remuneration for promoting or participating in such a conference or educational or informational program or seminar." Once Congress deleted CME and limited the universe of indirect transfers/payments that are reportable, it made clear its intent that certified and accredited CME were not to be included as part of the transparency reports.

CMS Is Required to Ensure Accurate Attribution and Not Estimates

The ACA mandates that manufacturers are required to specify and report the portion of the transfer of value/payment made directly to a physician or an indirect transfer made at their

request or designated on the physician's behalf. CMS's proposal to estimate or impute attribution even where there is no direct transfer or a qualifying indirect transfer is beyond its statutory authority, violates basic principles of due process, and is inconsistent with congressional intent. Congress did not direct CMS to develop reports that provide an approximation of the value transferred by manufacturers to physicians nor did Congress intend that transfers of value made by manufacturers to an organization or entity that employ physicians would be attributed to a physician without regard to whether they received the transfer, requested the transfer, or it was designated on their behalf. CMS has proposed that where an organization receives a payment or transfer of value, it will be apportioned among the physicians in the organization or institution. This, of course, 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, they do not receive directly (or even indirectly but in the most attenuated sense), and for which they have no knowledge so they are unable to effectively challenge it. We also strongly oppose CMS's 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. **CMS is required to direct manufacturers to document and report only those payments and transfers made directly to physicians or those specified indirect transfers/payments requested by the physician or designated on their behalf.**

Furthermore, we oppose efforts to attribute the total manufacturer payment/transfer of value for research when in many cases only a very small percentage could reasonably be attributed to a physician even were CMS to segregate these amounts into a separate reportable column on the public website as suggested in the Proposed Rule.

Notice

All individuals and entities that are the subject of public reporting have a basic due process right to notice of any report that implicates them as well as a right to correct false, misleading, and inaccurate reports. Where a payment or transfer of value is made at the request of a physician or designated as being made on behalf of the physician, the physician should receive notice as well as the entity/individual receiving the payment/transfer of value. Manufacturers will have the name and contact information for individuals/entities that receive the payment/transfer of value. Transmitting this information to CMS so that the agency is able to provide an aggregate report and an opportunity to review/correct the reporting is not anymore burdensome than doing so for physicians.

Personal Relationship Exemption & Reporting on Family Ownership Interest

CMS has proposed a personal relationship exemption where there are transfers of value/payment between individuals who have a personal relationship. We strongly support this proposal and recommend that CMS structure these exemptions for personal relationships to parallel those applicable to federal employees and those developed under the Lobbying Disclosure Act as amended.

CMS has also proposed that a physician's family member ownership interests should be reported in aggregate without identification of individual family members. We support this approach when manufacturers/GPOs transmit the reports to CMS. There are serious privacy concerns when detailed information about family relationships and ownership interests are introduced into the public arena (including the government) for no other reason than an individual is a family member of a physician. We urge CMS to mandate that manufacturers/GPOs report this information to the family member and the physician. There is no other way that a physician (or the family member) is able to dispute the report when it is false, misleading, or otherwise inaccurate.

Website Publication of Additional Helpful Information

We urge CMS to modify the language that it proposes to include as explanatory and background information generally concerning the transparency reports. The general public is inclined to conclude that these interactions constitute conflicts of interest or inappropriate relationships. CMS appears to take the view that the publication of these interactions will have the opposite impact since CMS proposes that it merely post on the Web site that the information in the database does not indicate that the payments/transfers of value are legitimate nor does it necessarily indicate a conflict of interest or any wrongdoing." The transparency reports and requirements do not establish ethical guidelines. We urge CMS to state unequivocally that the transparency reports and the Web site do not establish ethical guidelines that govern physician and industry interactions. We would urge CMS to include links to sites that do provide ethical guidelines for physician and industry interactions.

Exclusion of Educational Materials that Benefit Patients

We strongly support the exclusion from reporting educational materials that directly benefit patients. We urge CMS to adopt such an exclusion as well as offer clear guidance providing that this exclusion would also apply to items that are not necessarily given to patients, but includes educational materials that increase a physician's medical knowledge.

Information Collection Requirement Burden on Physicians is Significant

CMS has provided a very limited estimate and analysis of the burden associated with the information collection requirements for physicians of the Proposed Rule. While we strongly believe this estimate would be alleviated by requiring manufacturers/GPOs to provide ongoing updates and cumulative reports to physicians in their preferred mode, the current Proposed Rule would require all physicians to maintain ongoing records of every activity that they engage in so that they are able to ensure accurate reporting. This is not an overstatement given the large universe of indirect reporting requirements contained in the Proposed Rule. We believe that CMS has greatly underestimated the amount of time physicians would need to review cumulative reports and to challenge them before they were posted given the resources that physicians would likely need to dispute inaccurate, false, and misleading reports. The 45-day review time proposed in the rule is far too short and would dictate that all physicians maintain detailed reports of all professional activities. Realistically, we would

anticipate that the paperwork requirements of documenting all of a physician's activities could easily exceed 80 hours a year.

We disagree that this would impact only a subset of the universe of physicians. All physicians would have to document their activities since they cannot know in advance when an indirect transfer/payment becomes a reportable event. The foregoing is contrary to congressional intent that physicians would not bear this paperwork burden. CMS would need to revise this assessment and the underlying assumptions to the extent the Proposed Rule remains unchanged. The overall paperwork burden for physicians would be substantially diminished if manufacturers/GPOs were required to provide ongoing notification and a cumulative report before submitting a report to CMS, proper attribution was required, and only those indirect transfers/payments specified in statute were included.

We appreciate the opportunity to provide our comments and look forward to working with you to ensure that the transparency reports contain meaningful and accurate information.

Sincerely,

American Medical Association
Aerospace Medical Association
American Academy of Dermatology Association
American Academy of Family Physicians
American Academy of Neurology
American Academy of Ophthalmology
American Academy of Physical Medicine and Rehabilitation
American Association of Clinical Endocrinologists
American Association of Clinical Urologists
American Association of Neurological Surgeons
American Association of Neuromuscular and Electrodiagnostic Medicine
American Association of Orthopaedic Surgeons
American College of Cardiology
American College of Chest Physicians
American College of Emergency Physicians
American College of Mohs Surgery
American College of Osteopathic Family Physicians
American College of Osteopathic
American College of Osteopathic Surgeons
American College of Phlebology
American College Radiology
American College of Surgeons
American Congress of Obstetricians and Gynecologists
American Gastroenterological Association
American Medical Group Association
American Osteopathic Academy of Orthopedics
American Osteopathic Association

American Society for Clinical Pathology
American Society for Gastrointestinal Endoscopy
American Society for Pediatric Nephrology
American Society for Radiation Oncology
American Society of Cataract and Refractive Surgery
American Society of Echocardiography
American Society of Hematology
American Society of Nuclear Cardiology
American Society of Plastic Surgeons
American Thoracic Society
American Urogynecologic Socity
American Urological Association
College of American Pathologists
Congress of Neurological Surgeons
Heart Rhythm Society
Joint Council of Allergy, Asthma and Immunology
Medical Group Management Association
Renal Physicians Association
Society for Cardiovascular Angiography and Interventions
Society for Vascular Surgery
Society of Gynecologic Oncology
The Endocrine Society
The Society of Thoracic Surgeons

Medical Association of the State of Alabama
Alaska State Medical Association
Arkansas Medical Society
California Medical Association
Connecticut State Medical Society
Medical Society of Delaware
Medical Society of the District of Columbia
Florida Medical Association Inc
Hawaii Medical Association
Idaho Medical Association
Illinois State Medical Society
Iowa Medical Society
Kansas Medical Society
Kentucky Medical Association
Louisiana State Medical Society
Maine Medical Association
MedChi, The Maryland State Medical Society
Massachusetts Medical Society
Michigan State Medical Society
Minnesota Medical Association
Mississippi State Medical Association
Missouri State Medical Association

Montana Medical Association
Nebraska Medical Association
Nevada State Medical Association
New Hampshire Medical Society
Medical Society of New Jersey
New Mexico Medical Society
Medical Society of the State of New York
North Carolina Medical Society
North Dakota Medical Association
Ohio State Medical Association
Oregon Medical Association
Pennsylvania Medical Society
Rhode Island Medical Society
South Dakota State Medical Association
Tennessee Medical Association
Texas Medical Association
Utah Medical Association
Vermont Medical Society
Medical Society of Virginia
West Virginia State Medical Association
Wyoming Medical Society

February 16, 2012

Marilyn Tavenner, Acting Administrator
Center for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-5060-P
P.O. Box 8013
Baltimore, MD 21244-8013

Dear Acting Administrator Tavenner,

The undersigned represent the national organizations involved in Continuing Medical Education (CME) in the United States, including Accreditation of CME Providers, granting of CME Credit for CME activities, and fulfillment of the responsibility of the Profession of Medicine to self-regulate in the arena of Continuing Medical Education. We are pleased to comment on the proposed rule "Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests", 42 CFR Parts 402 and 403 [CMS-5060-P] RIN 0938-AR33.

The CME community in the United States is supportive of the Physician Payments Sunshine Act (PPSA), as adopted by Congress as Section 6002 of the Patient Protection and Affordable Care Act of 2010. Indeed, during the crafting of the PPSA we had the opportunity to describe to legislative staff the complexities of relationships in Accredited and Certified CME offered by CME Providers in the US, in contrast to promotional educational programs offered to physicians directly by pharmaceutical and device manufacturers. For example, we were able to provide information on definitions and nuances of relationships, such as the distinction between grants to providers of certified CME, who in turn select faculty, in contrast to direct payments to physicians by companies for purposes related to drug development, marketing and promotion.

Language of the PPSA as adopted appropriately addressed a few specific issues, which appear in the proposed rule to need clarification and modification, to avoid unintended consequences. These issues include:

1. Distinguishing between Accredited and Certified CME offered by CME providers, and promotional education offered by pharmaceutical and medical device manufacturers;
2. Recognizing the roles and relationships that faculty in Accredited and Certified CME programs have with CME Providers and not with companies which may provide grants to CME Providers; and
3. Recognizing that attendees at or participants in Accredited and Certified CME programs have no relationships with companies which may provide grants to CME Providers.

We will address our comments to the two sections of the proposed rule, including first:

- Page 78748, Column 1, bullet 13, Direct compensation for serving as faculty or as a speaker for a medical education program, and
  Page 78750, column 1, (4) Direct Compensation for Serving as a Faculty or as a Speaker for a Medical Education Program;
  - In the federal register, it states "We propose that this category be interpreted broadly to encompass all instances where applicable manufacturers pay physicians to serve as speakers, not just those situations involving 'medical education programs.'" It goes on to state "We realize that this interpretation does not allow for differentiation between continuing medical education (CME) accredited speaking engagements, and all other speaking engagements. We are considering, and welcome comments on, whether to limit this category to CME-accredited speaking engagements and report other speaking engagements in another category, such as compensation for services other than consulting, or additional category."

And second:

- Page 78750, Column 2, h. Exclusions, bullet 13, Transfers of value made indirectly to a covered recipient through a third party in cases when the applicable manufacturer is unaware of the identity of the covered recipient, and Page 78751, Column 2, (5) Indirect Payments Through a Third Party;
  - In the federal register it states "However, any payment or other transfer of value provided to a covered recipient through a third party, whether or not the third party is under common ownership with an

applicable manufacturer or operating in the US, must be reported, if the applicable manufacturer is aware of the covered recipient's identity."

First, let us provide some applicable background. For example, the Federal Register references accredited CME, but does not reference extant firewalls in place in the Professional Self-regulation of relationships between CME Providers and industry.

Accredited and Certified CME:

"**Accredited CME**" refers to those activities in Continuing Medical Education that have been deemed to meet the requirements and standards of a CME accrediting body (ex., the Accreditation Council for Continuing Medical Education (ACCME); the America Osteopathic Association, the American Academy of Family Physicians). **"Certified CME"** refers to those activities in Continuing Medical Education that carry CME credit offered by one of the three grantors of CME credit in the US: the American Academy of Family Physicians (since 1948), the American Medical Association (since 1968), and the American Osteopathic Association (since 1972).

Professional Self-regulatory Firewalls in Accredited and Certified CME:

All organizations involved in Accredited and Certified CME in the US have adopted and operate under the strict firewalls which are promulgated, monitored and enforced through the "Standards for Commercial Support (SCS): Standards to Ensure the Independence of CME Activities" of the Accreditation Council for Continuing Medical Education (ACCME), to which the entire profession of medicine adheres. The SCS (most recently revised in 2004) set standards for relationships between Accredited and Certified CME Providers and the companies which may provide grants to CME Providers. Faculty of certified Continuing Medical Education (CME) programs are selected, directed, reviewed, evaluated and paid by the Accredited CME providers, and have no relationship with the manufacturers. Indeed, not only is this a requirement of SCS, but also of the "Code on Interactions with Health Professionals" of the Pharmaceutical Research and Manufacturers of America (PhRMA Code).

Faculty who have no relationships with companies supporting certified CME programs will not be pleased to be put in a position of being assumed and reported to have a relationship with a manufacturer, by virtue of their accepting an invitation to present at the CME program. Indeed, many if not most speakers who have no relationships with manufacturers will refuse to serve as faculty, in order to avoid being assumed and reported to have such relationships.

In the context of Accredited and Certified CME, direct payments to physicians (either in the role of faculty or attendees) by companies are prohibited, cannot occur, and therefore would be irrelevant when it comes to disclosure under the PPSA. Manufacturers will not be in a position to comply with this provision of the Act, as they have no relationships with CME faculty, either directly or indirectly.

Required Disclosure of Relationships Between Physicians and Industry:

When a faculty member at a CME program has a relationship with a manufacturer, pre-dating and outside of the CME program, such as serving on a corporate speakers' bureau, stock ownership, or other relationship, those relationships must be disclosed as part of the CME activity. Such relationships are reportable under PPACA Section 6002 and must be disclosed under transparency reports. However, in the context of Accredited and Certified CME, a speaker's participation in the CME activity does not qualify as a reportable activity under Sec. 6002, as the manufacturers cannot have any role in speaker selection for the Accredited and certified CME activity. Furthermore, manufacturers cannot, and do not, under all rules governing faculty of CME programs, provide *"direct compensation for serving as faculty or as a speaker for a continuing medical education program."*

Company Relationships with Speakers in Promotional Education:

In the proposed rule, there may be confusion of the roles and relationships of faculty in Accredited and Certified CME programs as contrasted with the roles of speakers in promotional education offered directly by pharmaceutical and medical device companies, as reflected on page 78748 of the proposed rule, column one, bullet thirteen, where one of the categories listed for reporting is "Direct compensation for serving as faculty or as a speaker for a medical education

program", and which are instead overseen by the Food and Drug Administration (FDA). This is the critical distinction we successfully made with congressional staff during the period of crafting the PPSA.

We agree with disclosure of relationships between manufacturers and speakers at a promotional educational program sponsored by the manufacturers, as these relationships should be transparent and are appropriately included under other categories, such as consulting fees, compensation for services other than consulting, or honoraria. However, these speakers should not described as "faculty or speakers in a CME program" since promotional educational programs, offered directly by manufacturers, are not Accredited and Certified CME programs.

Absence of Relationships of Participants in Accredited and Certified CME Programs:

There could be unintended consequences inherent in the communication of the names of physician participants to funding companies. CMSS Member Organizations are concerned that publishing the names of participants who attend independent CME events funded by commercial support, and identifying those participants as having a relationship with the funding company, may discourage physicians from attending. Moreover, communication of such a list of names could be used by funding companies for marketing purposes, which would seem to defeat the ultimate intent of these bills, to control expenditures in the Medicare and Medicaid programs.

Summary:

Direct compensation by an applicable manufacturer to a physician serving as a speaker in a promotional educational program should be reportable. Payments made by a CME Provider to faculty of Accredited and Certified CME activities are not reportable under Sec. 6002 of the PPACA. Grants from applicable manufacturers to CME Providers are governed by the ACCME Standards for Commercial Support, which prohibit direct payments from manufacturers to faculty, and prohibit manufacturers from having any influence on the CME program, including selection of faculty.

The proposed rule needs to be clarified and modified to avoid unintended consequences in two areas that relate to Accredited and Certified CME:

1. Page 78750, column 1, (4) Direct Compensation for Serving as a Faculty or as a Speaker for a Medical Education Program

   The final rule needs to distinguish between direct compensation for serving as a speaker in a promotional educational program offered by an applicable manufacturer, which should be reportable under the Act; in contrast to faculty serving as speakers in Accredited and Certified CME programs, in which the faculty are selected and paid by the CME Provider and have no relationship with any applicable manufacturer which might be supporting the CME activity through an educational grant to the CME Provider.

2. Page 78751, Column 2, (5) Indirect Payments Through a Third Party

   The final rule needs to clarify that grants from applicable manufacturers to CME Providers for Accredited and Certified CME activities do not constitute an indirect transfer of value, either to faculty independently selected and paid by the CME Provider, or to participants in the Accredited and Certified CME activity, nor are there in such cases payments made at the request of or on behalf of the faculty.

Thank you for the opportunity to comment on the proposed rule to implement the Physician Payments Sunshine Act, of which we are supportive. Should you have any questions, or should our comments require clarification, please do not hesitate to contact us.

Signers:

Murray Kopelow, MD, MS(Comm), FRCPC
ACCME Chief Executive and Secretary
Accreditation Council for Continuing Medical Education (ACCME)

Andrew T. Filak, Jr., MD
President
Association for Hospital Medical Education (AHME)

Martin S. Levine, DO
President
American Osteopathic Association (AOA)

Executive Vice President and CEO
Council of Medical Specialty Societies (CMSS)

Humayun J. Chaudhry, DO, FACP
President and Chief Executive Officer
Federation of State Medical Boards (FSMB)

Gabrielle Kane, MB, EdD, FRCPC
President
Society for Academic Continuing Medical Education (SACME)

James L. Madara, MD
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American Medical Association (AMA)

Roland A. Goertz, MD
Chair, Board of Directors
American Academy of Family Physicians (AAFP)

Damon K. Marquis, MA, MS, FACME
President, Alliance for Continuing Education in the Health Professions (ACEHP)

Lilly
Answers That Matter.

Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana 46285
U.S.A.

September 7, 2012

Submitted electronically via Patricia_hameister@aging.senate.gov

Patricia Hameister, Chief Clerk
United States Senate Special Committee on Aging

Dear Ms. Hameister,

Eli Lilly and Company ("Lilly") is pleased to submit this statement for a public round table discussion to be held by the United States Senate Special Committee on Aging regarding the implementation of the final regulations of section 6002 (the "Sunshine Act") of the Patient Protection and Affordable Care Act.

Lilly has been an industry leader with respect to disclosing payments to health care providers and other recipients and has long supported increased transparency. In 2004, Lilly became the first company to voluntarily make public its U.S. clinical trial data in the Lilly Clinical Trial Registry. In 2007, Lilly became the first biopharmaceutical company to publicly report the funding it provides in the U.S. to institutions in the form of educational grants and charitable contributions to support medical education, patient education and other activities that it believes increase health care knowledge and improve patient care.

Currently, Lilly is tracking and reporting a wide range of financial interactions with U.S.-based physicians pursuant to its Corporate Integrity Agreement (CIA) as well as State reporting obligations. Over the past several years, Lilly has gained extensive experience in defining new internal and external processes, creating training and modifying IT systems to enable data tracking and reporting. We have used this knowledge to provide comments that underscore practical implementation insights and suggestions regarding the proposed rule and the statutory interpretations that CMS has shared. In addition, we have proposed clarifications we know will be necessary to ensure consistency, reduce confusion, minimize unintended readings of the law, and substantially improve implementation of the final regulations.

In the spirit of facilitating quality implementation of the Sunshine Act, Lilly would like to highlight the following six points which should be addressed in the final regulations. The first two points focus on implementation timing and a step-wise approach that will help facilitate the most complete and accurate data collection and data reporting to CMS and consequently to the public. The last four points focus on clarification of key issues that have been highlighted in comments submitted by Lilly, PhRMA and the Transparency and Disclosure Coalition[1].

[1] The Coalition is a small working group of five pharmaceutical companies (AstraZeneca, Eli Lilly, Johnson & Johnson, Merck, and Pfizer), each of which has been on the leading edge of efforts to disclose accurate financial information about interactions with physicians and has been reporting detailed information about expenditures and

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

The final rule should provide applicable manufacturers with at least 180 days to implement the final rule. For the majority of applicable manufacturers, the process of implementing a comprehensive system for tracking and reporting will be new, complicated and necessarily imprecise and iterative. When implementing the requirements of its CIA, Lilly learned first-hand, over the span of 23 months leading up to its first full quarterly registry publication, that no reporting scheme can contemplate or anticipate every possible implementation question.

Based on review of the proposed rule, notwithstanding the substantial efforts already undertaken to enable current reporting, Lilly itself would need to revise many of its existing processes and systems to address several areas where the proposed rule differs from the manner in which Lilly is capturing and reporting data today (e.g. meal methodology, patient education materials, knowledge trigger for third party payments). There are simply 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.

2. **The final rule could be implemented more effectively using a phased approach.**

Lilly urges CMS to look at the phased implementation of Lilly's CIA requirements and consider a phased 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. Phasing will yield better results for all interested parties, especially patients and physicians who expect and deserve these reports to be clear, meaningful and accurate.

Lilly suggests Sunshine data collection and reporting be divided into three phases.

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 is recommended that Phase 1 direct payments not include payments for research made to Clinical Research Organizations (CROs) or payments to reimburse expenses as the processes needed enable detailed reporting of these payments do not usually exist. For Lilly, a Phase I report of payments would disclose over 70% of the total dollars currently being reported by Lilly in our CIA registry. If we were to assume a similar distribution for most manufacturers, focusing a Phase I implementation

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other items of economic value they provide to physicians substantially in advance of the requirements of Section 6002. Each company has devoted significant resources to such efforts and has developed considerable experience and expertise in addressing the complex issues involving such disclosures.

on direct payments only (versus other transfers of value) would enable the public to have visibility to over 70% of what is targeted for disclosure under the Sunshine Act while providing applicable manufacturers additional time to investigate and implement data collection processes and systems that would be necessary to enable the next phases.

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. Payments made to CROs for research should be included in this category for such reporting requires alignment of systems, training and new processes for data collection by the CROs that are currently not in place. For Lilly, in 2011, of all the value reported on Lilly's payment registry, 21% represented payments to CROs for research done by CROs. 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. These types of processes do not typically pre-exist in companies because such information and data is not needed for any other business purpose. These processes are distinct from the processes that companies would normally have in place to know about and record payments (the proposed focus of Phases I and II).

A phased approach would balance the goal of timely, quality and reliable public reporting with the very real challenges faced by manufacturers in implementing comprehensive and complex process and systems changes within the practical limitations of existing and unique organizational structures, systems, and practices of individual companies. It would also provide wide visibility into over 90% of manufacturers' spend in the first phase, thereby substantially and meaningfully delivering on the goal of the Sunshine Act in providing greater transparency regarding financial relationships with health care providers.

3. The standard of knowledge for reporting third party payments should be based on influence or control.

The proposed rule would require manufacturers to report payments and transfers of value made to a covered recipient by a third party (i.e. indirect payments) even when the applicable manufacturer has no influence or control over the selection or engagement of the covered recipient.

For example, Lilly may contract with a vendor to develop medical information software and not be aware that the vendor will contract with a licensed physician to provide advice related to the software. In this case, Lilly would have no transparency in the down-stream compensation to any sub-contractors because such contracting was neither required nor influenced by Lilly.

Under the proposed rule, Lilly would have an obligation to proactively identify the relationship between the vendor and the physician at any point during the contract period and report the payment (or some portion thereof) as an indirect payment by the manufacturer. This is an approach that is different than what Lilly and other reporting companies employ today and 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.

Lilly urges that indirect payments be reportable only when the applicable manufacturer controls or influences the selection of the covered recipients engaged by the third party.

4. The meal allocation methodology must be factual and workable.

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 broadening the statutory definition of "covered recipient."

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.

5. The patient materials exclusion should be more broadly interpreted.

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 is concerned 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.

For example, Lilly provides reimbursement support services that help patients understand their insurance coverage prior to initiation of a particular drug therapy. Lilly also makes available pa-

tient items such as starter kits and disease state resources (e.g., blood sugar logs; anatomical models; nutrition books). Lilly strongly believes that provision of these programs, services, and items do not constitute a "transfer of value" because they do not benefit physicians personally or professionally. The physician is not the ultimate intended recipient of these materials; they are provided to the physician as a "pass through," so that the physician can make them available to his or her patients.

Lilly therefore urges 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.

6. The definition of 'applicable manufacturer' should align with the statutory definition.

The proposed rule definition of "applicable manufacturer" would require companies to track and report payments and transfers of value even if they are not operating in the United States. This definition sweeps in many foreign affiliates that do not operate in the United States but that do produce a covered product or a product component. These foreign affiliates are not preparing to report under the statute. Lilly urges that the final rule align with the statutory definition of "applicable manufacturer," which expressly includes a requirement for the manufacturer to be operating in the United States.

Finally, Lilly encourages CMS to recognize the need for ongoing communication with industry throughout implementation of the final rule to help ensure clarity and consistency and to address the implementation challenges or questions that will inevitably arise.

Lilly appreciates the consideration of these comments on CMS-5060-P by the Senate Special Committee on Aging. We encourage CMS to continue to engage stakeholders as it evaluates the proposed rule and its implementation. Lilly welcomes the opportunity to further share its experiences and to provide any additional information that would be helpful. If you have questions, please feel free to contact me at 317.655.1965 or ofarrell_elizabeth_g@lilly.com.

Sincerely,

Elizabeth G. O'Farrell
Senior Vice President, Policy & Finance

Statement for the Record
Special Committee on Aging
United States Senate
Roundtable on Implementation of the Physician Payments Sunshine Act
September 12, 2012

Chairman Kohl, Ranking Member Corker, members of the Committee, thank you for extending an invitation to the Association of Clinical Research Organizations (ACRO) and providing us an opportunity to share our concerns regarding Section 6002 of the Patient Protection and Affordable Care Act (PPACA), otherwise known as the Physician Payment Sunshine Act.

My name is Doug Peddicord and I serve as Executive Director of the Association of Clinical Research Organizations (ACRO) which represents the world's leading clinical research organizations (CROs). Our member companies provide a wide range of specialized services across the entire spectrum of development for new drugs, biologics and medical devices, from pre-clinical, proof of concept and first-in-man studies through post-approval and pharmacovigilance research. With more than 75,000 employees engaged in research activities around the world, ACRO advances clinical outsourcing to improve the quality, efficiency and safety of biomedical research. Each year, ACRO member companies conduct more than 11,000 clinical trials involving nearly two million research participants in 115 countries.

For 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, each of our member companies works with more than 500 research sponsors – applicable manufacturers – annually, so we have a broad and unique understanding of how research payments are made.

For today's Roundtable, I will focus my comments on research and the payments 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.

Let me begin by saying that ACRO has argued and continues to believe that fair-market payments made for legitimate research activities should have been excluded from the provisions of Section 6002. Quite unlike payments or other transfers of value that might support activities that benefit (and potentially influence) physicians and teaching hospitals without requiring an actual exchange of value between the payor and the payee, payments made to support or purchase clinical research activities from physicians and teaching hospitals are, simply, fair-market payments for goods (e.g., laboratory tests) and services (e.g., physical examinations). Several state statutes regulating "sunshine" already exclude reporting requirements for payments for bona fide research activities and we believe that the inclusion of such payments in sunshine reporting will, inadvertently, create a disincentive for physicians and

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ACRO
ASSOCIATION OF CLINICAL RESEARCH ORGANIZATIONS

teaching hospitals to participate in the clinical research that produces new drugs and new treatments for the patients who need them. We are not opposed to "sunshine" and greater transparency in how dollars flow from the biopharmaceutical industry to physicians and teaching hospitals – but we are very much concerned that failing to exempt payments for legitimate research activities from the requirements of CMS's proposed rule will have deleterious effects on the research enterprise in the United States.

In fact, survey research conducted in 2010 showed 24 percent of the 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. We believe the reason for this is because the data has great potential to be misrepresented. And if that is the case, the U.S. faces the potential loss of one-quarter of its clinical investigators, which will slow innovation and delay the delivery of needed treatments for patients.

With our concern for the research enterprise in mind, ACRO looks forward to working with Senators Kohl and Grassley, other stakeholders and, most importantly at this point, CMS to ensure implementation of a rule that achieves the goal of producing a "sunshine" that will illuminate the landscape for patients and other consumers, be fair to physicians and teaching hospitals, AND facilitate desperately needed clinical research.

Direct and Indirect Research Payments

Having reviewed with CMS staff in May 2011 the complexity of the flow of research payments from manufacturers and CROs through a wide variety of vendors and intermediaries to a terminus, typically, at the teaching hospital or physician practice group, (see the attached chart,) ACRO recognizes the December 2011 proposed rule's attempt to capture that complexity by introducing the notion of *direct* and *indirect* research payments. **Regrettably, however, we are entirely confused by the methods the proposed rule suggests for reporting research payments**. Acknowledging that such reporting is likely to be complicated, the rule variously indicates that:

- *direct* research payments would reflect total payments made by manufacturers or CROs to covered recipients, including all items and activities associated with the research project, not only the physician's time and services;
- payments that include both *direct* and *indirect* research payments would report (the same?) total costs paid to teaching hospitals and ultimately to physician covered recipients, regardless of whether a salaried physician actually receives any actual income for the conduct of the research;
- payments made to clinics, hospitals (except for teaching hospitals) and other organizations that facilitate the conduct of research, such as site management organizations (SMOs), that are reported under the rubric of *indirect* research "should also include the name of the entity or individual that received the payment", which presumably means that HHS will have in its data a multitude of non-covered recipients, from physician practice groups to non-teaching hospitals to SMOs; and

- "end users would understand" that total payments made to teaching hospitals would include a wide range of goods and services, but that attributing full research payments to individual physicians "could be misleading" and that HHS will figure out a way to not include such total payments into the aggregated payment amount attributed to an individual physician.

Not only are the requirements for the reporting of *direct* and *indirect* research payments inconsistent, misleading and sometimes frankly contradictory, ACRO believes that requiring the reporting of many *indirect* payments would exceed the specific legislative language of the Act relating to payment or other transfers of value. Under the Act, manufacturers are required to report indirect payments and transfers that are made to a third party *at the request of the physician or designated on behalf of the physician.* But 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, we believe, not reportable under the Act. For instance, if physicians participating in a multi-site clinical trial program travel to an investigator meeting to review and train on the research protocol, as is typical and necessary, any travel or food or other related costs of the meeting occur incidentally to the physician's participation in the research project, and are neither "requested by" nor "designated on behalf of" the physician – typically such costs are not even attributed to individual covered recipients (i.e., to Dr. Jones as opposed to Dr. Johnson, at a meeting that includes 20 physicians) for accounting purposes. Similarly, the proposed rule's intention to capture payment data relating to non-covered recipients, such as non-teaching hospitals and SMOs, exceeds the legislative authority conveyed by Sec. 6002.

Related to the issue of *direct* and *indirect* payments for research, the proposed rule presumes a level of visibility by manufacturers and CROs into medical practices and hospitals involved in the conduct of clinical research programs that simply does not exist today. We believe that CMS should replace the proposed standard for research payments or transfers of value with a regulation 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.

In brief, ACRO believes that CMS would do best to 'go back to the drawing board' in its proposals for the tracking of research-related payments and transfers of value – and that it do so by starting with the principle that payments and transfers of value pertaining to research should be tracked and reported to the level of visibility that exists today. Because of the

confusing and highly complex reporting requirements proposed, and resulting inability for us to comment constructively on an understandable and tangible proposal, we strongly urge CMS to issue a second proposed rule for comment before moving to finalize a regulation to implement the Act.

CMS's misunderstanding regarding manufacturer visibility into the details of payments and transfers of value for research services displayed in the proposed rule would create an enormous compliance burden, 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. Related to this point, we note that in its estimate of compliance costs CMS projects only minimal costs for physicians and hospitals relative to their 'review' of payment amounts reported by manufacturers, a paradigm that we believe misses entirely the very substantial costs that will be incurred by covered recipients in order to put in place new financial tracking systems and to create a level of detail ('transparency') that is considered unnecessary today. In practical terms, 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.

The proposed rule takes the approach that what the Act calls "natures of payment" should be considered and reported in segregable categories. We disagree. ACRO believes that 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. Simply, if a payment or transfer of value occurs incidentally to a research project – again, if physicians participating in a multi-site clinical trial program travel to an investigator meeting to review and train on the research protocol – 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, we believe the travel, food and other costs should be reported as *research* payments. By contrast, the Agency's proposal to allocate such costs across multiple physicians would be arbitrary and expensive, and provide minimal value to an individual trying to understand payments for research from manufacturers to physicians and teaching hospitals.

One specific impact of the proposed rule's contrary approach of segregable categories is that manufacturers would report *research* payments that could be delayed from publication for up to four years, even as the arbitrarily associated payments made for research-related food and travel would be separated and made publicly available in the normal reporting cycle; a distinction that would be misleading and inconsistent with the intent of the law to protect competitive information.

As an alternative, CMS might consider narrowly defining *research* to exclude products which have not yet been approved for any use by the FDA. Likewise, *research* that is mandated by the FDA or another regulatory authority, such as REMS (risk evaluation and mitigation strategies) studies or the maintenance of a registry to which physicians contribute data might also be

exempted. A narrow definition of *research* would significantly reduce the regulatory burden, protect highly-sensitive competitive information and still address the Act's intent to limit a perception of undue influence on physicians.

Finally, ACRO is very much concerned that under the proposed rule the payment and transfer of value data related to *research* to be reported to the Department, and ultimately to the public, is likely to be incomplete at best, terribly inaccurate at worst. We are specifically concerned about the potential for double and even triple counting of research payments that flow "directly" to teaching hospitals and "indirectly" to intermediary organizations such as SMOs and then "indirectly" again down to physician investigators. We agree with the AMA and other physician societies that "CMS's proposal to estimate or impute attribution even when there is no direct transfer or a qualifying indirect transfer is beyond its statutory authority, violates basic principles of due process, and is inconsistent with congressional intent... "

Selected other concerns:

In the proposed rule, *covered recipient* means—"(1) Any physician, except for a physician who is an employee... of an applicable manufacturer...." But CMS makes clear that in regard to *research* CROs make payments on behalf of manufacturers and can be treated interchangeably with manufacturers; for example, payments are made to an institution conducting research "either by an applicable manufacturer or a CRO entity." Just as physicians who are employees of applicable manufacturers are excluded from the definition of "covered recipient," so also physicians who are employees of a CRO or who provide research services on a contract basis to a CRO should be similarly excluded.

For example, CROs employ and contract with physicians as medical directors and medical monitors, and as investigators in Phase I clinical trial units, but none of these physicians are receiving "payments or other transfers of value" consistent with the intended meaning of the Act. CRO physician employees and contractors are certainly not receiving either *direct* or *indirect* payments or transfers of value from manufacturers for research services, but instead are working for the CRO, just as a physician working for a manufacturer is. Thus, we believe that (1) above should read, "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**; or".

Reporting and the Costs of Reporting

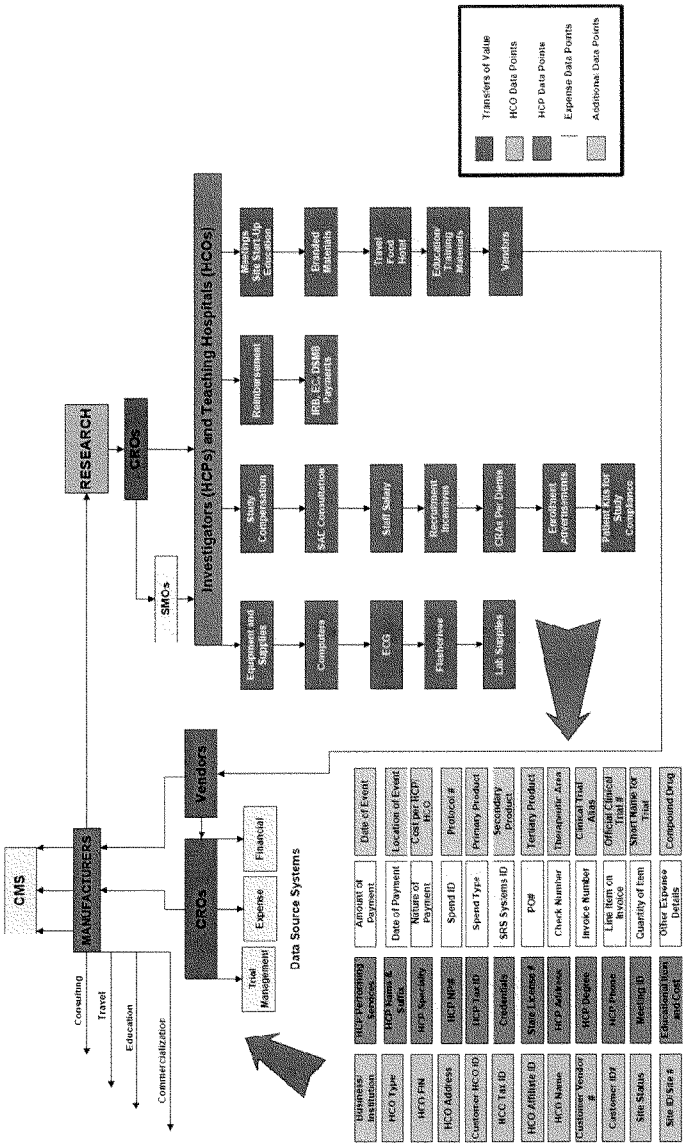
While the proposed rule contains 'templates' for the reporting of payments/transfers of value and ownership/investment interests, ACRO continues to believe that a template that clearly encourages standardized reporting by manufacturers is required at this point. Today, every applicable manufacturer has its own specific format for how it wants to see payment information. As a result, there is an enormous lack of consistency within the industry, and a great deal of cost being incurred by all, including manufacturers, CROs, hospitals, and

physicians. Consistency in format would not only reduce costs incurred by the affected parties but, as importantly, would likely produce more complete and more accurate data to be made available publicly by the Department.

Timing of Implementation

Finally, the proposed rule appears to presume that the reporting of payments and transfers of value can be easily implemented within 90 days of a final rule being issued. We submit this is not the case and there should be a lag of at least 15 months, as envisioned in the legislation, before reporting is required. Because the financial systems of research and healthcare organizations are designed for calendar year reporting, ACRO strongly believes that reporting of payments and transfers of value related to research should begin at the beginning of a calendar year, with the first reports due in March of the following year. Initiating the system with partial year reporting would not only be impractical and costly, but likely to lead to non-representative, potentially misleading data.

ACRO appreciates this opportunity to participate in today's Roundtable and we look forward to working with CMS and the affected industry toward developing a reporting system that supports transparency without creating undue compliance burdens for those involved in the development of new biomedical products.



Written Statement for the Record

Roundtable on Implementation of the Physician Payments Sunshine Act
U.S. Senate Special Committee on Aging
September 12, 2012

Dr. Daniel J. Carlat
Director, Pew Prescription Project
Pew Health Group, The Pew Charitable Trusts

Chairman Kohl, Ranking Member Corker and members of the Special Committee on Aging, thank you for the opportunity to testify about the importance of implementing the Physician Payments Sunshine Act (the "Sunshine Act") as quickly as possible.

The Sunshine Act will bring critical and much needed transparency to the financial relationships between physicians and pharmaceutical manufacturers and medical device companies, and it has the broad support of diverse stakeholders, including consumer groups, industry groups and leaders within the medical profession. Industry trade organizations have publicly weighed in on the need to move forward with transparency measures contained within the Sunshine Act. Congress recognized the importance of making these relationships transparent when it included the Physician Payments Sunshine Act in the Patient Protection and Affordable Care Act (2010). Yet, despite an October 1, 2011 statutory deadline, the final regulation implementing the Sunshine Act has not been released.

The Pew Charitable Trusts is driven by the power of knowledge to solve today's most challenging problems. Pew applies a rigorous, analytical approach to improve public policy, inform the public and stimulate civic life. Based on research and critical analysis, the Pew Health Group seeks to improve the health and well-being of all Americans.

The Sunshine Act requires pharmaceutical and medical device companies to publicly report their gifts and payments to physicians and teaching hospitals. Medical products are central to modern health care, and academic-industry collaboration is vital for their development. At the same time, it is essential that the use of these products be guided by sound evidence and good science. Every patient deserves the safest, most effective treatment.

The drug and medical device industries spend heavily to influence a physician's choice of

products. Estimates of the exact amount vary, but pharmaceutical companies alone spend tens of billions of dollars per year on marketing.[1] According to a study published in 2010 in the Archives of Internal Medicine, 84 percent of U.S. physicians have some kind of financial relationship with industry, including receiving payments, drug samples or, most often, free meals or gifts.[2] About 14 percent of physicians reported being paid by one or more companies for services such as serving on speaker bureaus, consulting or enrolling patients in clinical trials.

The influence of pharmaceutical marketing is well established.[3,4] Leaders within the medical profession have recognized these impacts and called for transparency. A major Institute of Medicine (IOM) report in 2009, entitled "Conflict of Interest in Medical Research, Education and Practice,"[5] emphasized that some financial relationships between physicians and industry raise concerns about the risk of bias in clinical decisions. For example, companies have paid some physicians large but generally undisclosed amounts to give talks to other physicians, whose prescribing practices were then tracked by company sales representatives. Drug samples and other gifts to physicians by company sales representatives are major marketing tools that evidence suggests influence prescribing choices. The IOM concluded that conflicts of interest "present the risk of undue influence on professional judgments and thereby may jeopardize the integrity of scientific investigations, the objectivity of medical education, the quality of patient care, and the public's trust in medicine."

An optimal reporting system will ensure that all payments are reported clearly enough for consumers to understand what the numbers mean. For example, companies fund research in a variety of ways, sometimes by paying doctors directly, and other times by paying hospitals which then pass the funds on to doctors in charge of the research. It is important that in both cases, whether the payment to doctors is direct or indirect, that consumers be informed when doctors are receiving research payments from industry. This is not to suggest that research payments are undesirable. Indeed, these collaborations are vital, but the financial relationships should be

[1] Gagnon MA, Lexchin J. The cost of pushing pills: A new estimate of pharmaceutical promotion expenditures in the united states. PLoS Med. 2008;5:el

[2] Campbell EG, Rao SR, DesRoches CM, et al. Physician Professionalism and Changes in Physician-Industry Relationships from 2004 to 2009. Archives of Internal Medicine. 2010; 170 (20)

[3] Wazana A. Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift? JAMA. 2000; 283(3)

[4] Dana J, Loewenstein G. JAMA. 2003; 290

[5] Institute of Medicine. Conflict of Interest in Medical Research, Education and Practice. IOM Report Brief. April 2009

transparent.

A related issue is that some stakeholders have suggested that only IRS-reportable payments should be reported. However, this 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. The intent of the law is to ensure that the financial relationship between companies and physicians is reported, and there should be no third party structures that might serve to obscure the reporting of such payments. Without language clarifying that all payments to physicians should be captured, whether IRS-reportable or not, there is the potential for undermining comprehensive reporting of payments.

Pew is committed to working with industry, CMS, Congress, and other stakeholders to ensure the system is as strong as it can be. The issues we discuss above should not be a reason to delay the final regulations. Failure to fully implement this law as quickly as possible runs counter to the clear intent of Congress in passing the law, which was to start tracking payments as of January 1, 2012. The Sunshine Act was passed 2 ½ years ago after years of discussion, which provided ample time for companies to set up tracking and compliance systems. Similar state transparency laws have been in place since the early 1990s. Many companies are already disclosing payments, either voluntarily or as a condition of legal settlements with the Department of Justice. In fact, most companies are already substantially prepared for the disclosure requirements. A recent Deloitte survey of pharmaceutical executives found that 88 percent of companies reported being at least 50% prepared for Sunshine Act compliance requirements, with 33% of companies being 100% prepared.[6] Companies will be able to begin reporting payment data by January of 2013 if the final regulations are released soon. Stakeholders agree that it is important to begin the data collection process soon so that CMS can test the new system and can address any technical issues that will arise as quickly as possible.

The intent of the Sunshine Act is to protect patients and restore trust in the medical profession. The Pew Health Group urges the Administration to avoid further delay and act quickly to implement this important consumer protection legislation.

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[6] Deloitte. Physician Payment Sunshine Act: Physicians and life sciences companies coming to terms with transparency? 2012

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UNITED STATES SENATE SPECIAL COMMITTEE ON AGING
ROUNDTABLE

"LET THE SUNSHINE IN: IMPLEMENTING THE PHYSICIAN PAYMENTS SUNSHINE ACT"

SEPTEMBER 12, 2012

STATEMENT FOR THE RECORD:

THE ADVANCED MEDICAL TECHNOLOGY ASSOCIATION (AdvaMed)

701 PENNSYLVANIA AVENUE NW, SUITE 800

WASHINGTON, DC 20004

The Advanced Medical Technology Association (AdvaMed)

The Advanced Medical Technology Association (AdvaMed) appreciates the opportunity to provide written testimony for today's Roundtable. AdvaMed is the world's largest trade association of medical device manufacturers who produce the medical technologies that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. AdvaMed represents approximately 370 manufacturers of medical devices, diagnostics and health information systems, ranging from the largest to the smallest medical technology innovators and companies. AdvaMed members manufacture roughly 60 percent of U.S. sales of medical technology.

AdvaMed Supports Physician Payments Sunshine

AdvaMed endorses and proactively embraces appropriate disclosure of relationships between medical technology companies and physicians. AdvaMed is a longtime supporter of Physician Payments Sunshine and encouraged the legislative efforts of Chairman Kohl and Senator Grassley, which culminated in the passage of Section 6002 (the Physician Payments Sunshine Act, referred to below as the "Sunshine Provisions") of the Patient Protection and Affordable Care Act (PPACA). *Throughout the regulatory process, we have urged CMS to provide sufficient time for device and diagnostics manufacturers to fully comply with the final implementing procedures HHS issues by providing at least 180 days to implement the final rule.*

AdvaMed's member companies recognize that strong ethical standards are critical to ensuring appropriate collaboration between the medical device industry and health care professionals to produce the world's most advanced medical technologies. We take seriously our responsibility to ensure ethical interactions with our physician partners. We recognize that adherence to ethical standards is essential to the industry's ability to continue its collaboration with health care professionals. That is why AdvaMed developed a Code of Ethics[1] ("AdvaMed Code" or "Code") to distinguish interactions that result in bona fide contributions to the advancement of medical technology from interactions that may inappropriately influence medical decision-making.

Medical Device Innovation

The medical technology industry is fueled by intense competition and the innovative energy of our member companies – firms that drive rapid innovation cycles among products, in many cases leading to new product iterations every 18 months. Our constant innovation leads to the introduction of new technologies that prevent illness, allow earlier detection of diseases, and treat patients as effectively and efficiently as possible.

Physicians and teaching hospitals are partners in many aspects of innovation. They are often the inventors of new devices, and it is critical that our industry continue to work closely with them to transform their innovative ideas from concept to reality. Physicians make valuable recommendations on improving existing devices and consult with companies to provide expert technical assistance and feedback in the development and refinement of those improvements. In

[1] *Available at:* http://www.advamed.org/MemberPortal/About/code/

short, physician expertise, feedback, and experience are critical to ongoing advances and innovations in medical technology, and the Sunshine Provisions must be implemented in a manner that does not discourage physicians from participating in bona fide collaborations that fuel medical device innovation.

In addition, device companies forge important training arrangements with physicians and teaching hospitals, essential for the safe and effective use of medical devices. How well a medical device works depends, in large part, on the skill and training of the physician using the technology. In fact, the FDA often requires device manufacturers to provide product-specific education and training to physicians as a *condition* of FDA clearance. The technical prowess necessary to use medical devices makes physician involvement crucial to the training and education required after market approval, as specific techniques often need to be taught, and physician operators are best suited to provide this training to fellow physicians. Some training on medical technologies requires travel to central facilities that can accommodate large medical technologies or to specialized training facilities, such as simulated operating rooms.

Physician and teaching hospital innovation and collaboration with the device industry have led to groundbreaking advances in patient care that benefit millions of American patients. These innovations have helped fuel a robust, competitive medical technology industry that is the global leader. *The Sunshine Provisions should be implemented in a manner that serves the legislative intent to provide patients with clear, meaningful information concerning industry relationships, but implementation should not discourage beneficial interactions critical to the development and safe and effective use of innovative medical technologies.* For this reason, we believe CMS should provide clear rules and definitions to facilitate a common reporting approach by manufacturers and to ensure the reported data is meaningful.

Implementation of Physician Payments Sunshine

Following the passage of PPACA, AdvaMed met and shared detailed comments and recommendations with the Centers for Medicare & Medicaid Services (CMS) on implementation of the Sunshine Provisions. We strongly urged CMS to expeditiously publish implementation guidance to enable industry to develop the systems necessary to comply with the law.

We also urged CMS to take seriously 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. 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."

In December 2011, CMS released a Proposed Rule and AdvaMed submitted detailed comments on the proposed rule to CMS on February 17, 2012.

Consequences of the Delayed Regulation

The Physician Payments Sunshine Act will provide transparency in requiring reporting of payments to teaching hospitals, physicians, and physician ownership and investment interests. In response to the proposed rule, CMS received over 300 comments from a wide range of

stakeholders. In May 2012, CMS reiterated its commitment to addressing the valuable input received during the comment period, and to ensuring the accuracy of the data collected. CMS also announced that it will not require data collection before January 1, 2013. AdvaMed and its member companies appreciate the efforts and attention to reporting details that CMS has thus far exhibited in working to implement the Sunshine Provisions.

As we approach 2013, we ask that when CMS completes its thorough review of all stakeholder comments and releases a final regulation, CMS grant medical device and diagnostics manufacturers sufficient preparation time to implement the final rule. In our February 17 comment letter on the Proposed Rule (Attached), we asked that CMS provide applicable manufacturers 180 days after publication of the final rule before requiring data collection. Our comments included an example implementation work plan and timeframe to clearly illustrate implementation steps necessary to ensure successful and compliant tracking and reporting. The work plan identifies each stage critical to successful and accurate data collection and tracking—including for example, system development, implementation, testing, and training.

The Proposed Regulation leaves important threshold questions unanswered, and where procedures and terms are vague, undefined, unknown or unclear, companies are unable to build the systems necessary to comply,. The law requires the Secretary of HHS to define the contours of key aspects of the PPACA, including what constitutes an applicable manufacturer, covered recipient, payment or transfer of value (including what is exempt from reporting) and what kinds of payments or transfers manufacturers are required to report.

CMS sought comments on almost every aspect of the Proposed Rule and the Proposed Rule includes several divergent approaches that must be resolved before companies can make threshold systems implementation decisions. Further, CMS is proposing to expand the definition of "applicable manufacturer," potentially implicating additional entities and divisions that did not previously anticipate tracking or reporting data pursuant to the Sunshine Provisions. Without a final rule from CMS clarifying these threshold issues, manufacturers cannot adequately prepare to meets their legal obligations under the Sunshine Provisions. We will object to any effort to impose penalties or otherwise enforce reporting requirements during a timeframe in which manufacturers lack the finalized relevant reporting procedures. *We believe it is unreasonable to begin active implementation of the Sunshine Provisions until at least 180 days after HHS issues final implementing regulations, and we therefore reiterate our request for waiver of the statutory obligations until 180 days following issuance of final implementation guidance.*

Summary of AdvaMed Recommendations Submitted to CMS

AdvaMed appreciates the enormous technical and other complexities associated with implementation of the Sunshine Provisions. Our broad industry includes companies of all sizes—from multi nationals to small pre revenue emerging growth companies----and all medical and diagnostic fields. As you may know, the device and diagnostics industry is confronting major regulatory, tax and Medicare related implementation challenges, in addition to implementing new systems to enable tracking and reporting under the Sunshine Provisions. As a result, our industry, while committed to successful implementation, includes companies at various stages of readiness in the absence of final regulatory guidance. Given these complexities, AdvaMed has met with CMS to discuss implementation and followed up with

recommendations to the agency since the passage of the Sunshine Provisions. A copy of our comments to the proposed rule, which includes our July 2011 letter to CMS is attached to this testimony.

Among our many recommendations, we offered the following:

Topic	AdvaMed Recommendation
Definition of Applicable Manufacturer	• Payments or other transfers of value made by foreign affiliates at the direction or request of a manufacturer should be reported by the manufacturer. • CMS should further consider the potential unintended consequences and inequities that may arise as a result of the proposed definition of applicable manufacturer, particularly with respect to foreign affiliates, affiliates who manufacturer non-covered products, and affiliates whose business relates to non-healthcare products and services. • The definition of "common ownership" should be limited to circumstances where the same individual, individuals, entity, or entities own at least 50% of total ownership in two or more entities. • Manufacturers should have flexibility to report either at the holding company level or by division.
Background Information on Industry-Physician Relationships	• CMS should publish proposed background text related to industry-covered recipient relationships for public review and comment in advance of final promulgation. • The background information should not be limited to industry-physician relationships, because context of transfers of value to teaching hospital covered recipients is equally important.
Associated Products	CMS should allow manufacturers to report the product category or therapeutic area in lieu of a market name or scientific name of an associated product, if any.
Identification of Covered Recipients	• CMS should create a list that specifically identifies each corporate entity that qualifies as a teaching hospital covered recipient and provide that entity's TIN. • CMS should create a single list of national identifiers for all physician covered recipients, with each physician assigned a unique identifier. • Both lists of covered recipients should be published at least ninety days prior to the beginning of each reporting year. • Manufacturers should be required to report only with respect to the specific covered recipients identified on CMS' lists.
Delayed Implementation	CMS should provide manufacturers at least 180 days after publication of the final rule to begin implementing the Sunshine Provisions.

Research Payments	• Only research payments made to covered recipients should be reported. • Where the research payment is not made directly to a physician covered recipient, but instead to a covered recipient entity (*e.g.*, teaching hospital), manufacturers should also disclose the name of the covered recipient principal investigator(s), if known at the earlier of the contract execution date or the date of payment. However, the value of the research payment to the covered recipient entity should not be separately attributed to the identified principal investigator(s), if any. • "Product research or development agreements" and "clinical investigations" should not require a written research protocol for delayed publication, as written research protocols are not required under the express language of the Sunshine Provisions. Alternatively, CMS should clarify that "product research or development agreements" and "clinical investigations" include arrangements involving written research protocols that may take a variety of forms. • Delayed publication should be available for payments related to clinical investigations of new applications of existing medical technology.
Educational Materials	Educational materials that serve a genuine educational function for covered recipients should be deemed to "directly benefit patients," and thus excluded from reporting, and the educational materials exclusion should align with Section IX of the AdvaMed Code.
Food and Beverage Allocation	The cost of meals should be allocated among all individuals who partook of the meal, regardless of whether the individual is a covered recipient, and the manufacturer should then report only the value of the meal associated with each covered recipient, to the extent required under the Sunshine Provisions.
Third Party Payments	• Manufacturers should be required to identify third party entity recipients, but not third party individual recipients. • Determinations as to what, if any, entity to report as a third party recipient should be guided by federal income tax policy and treatment.
Awareness Standard	A manufacturer's awareness or knowledge of the identity of a covered recipient should be measured at the earlier of (1) the time a contract is executed or (2) the date the manufacturer makes a payment or other transfer of value to the third party.
Review Period	• The required review and correction period should extend for a period of 90 days during the first year of implementation, and 60 days each year thereafter. • The review period should be segregated into distinct phases,

	each to be assigned a specific time frame, to occur sequentially. • Manufacturers should not be required to collect and report how the covered recipient would like to be notified of the start of the review period. • Notifications to CMS regarding disputes, if any, should be made by the manufacturer only.
Medical Education Programs	Manufacturers should not be required to report payments to any program sponsors that utilize an independent selection process for speakers, including ACCME and other applicable continuing education and continuing education recognition programs, when the manufacturer is not selecting and directly compensating the covered recipient faculty/speaker.
Physician Owned Distributors, Physician Owned GPOs and Physician Owned Manufacturers	• CMS should revise the definition of applicable GPO to be: "An entity that (1) operates in the United States, or in a territory, and (2) purchases, arranges for or negotiates the purchase of a covered drug, device, biological, or medical supply for individuals or entities, and (a) is not a physician-owned provider, such as a hospital, ambulatory surgery center or group practice, (b) is the end-user of the device with patients and (c) bills for the device or the implant procedure." • The definition of ownership or investment interest should not exclude stock options and convertible securities received as compensation until they are exercised. All stock options, whether received as an ownership interest or compensation, should be disclosed when granted. • If an ownership or investment interest in an applicable GPO is held by a family member of a physician, the applicable GPO should report the interest in the name of the physician as well as the family member's name and relationship to the physician.

Conclusion

In closing, we would like to reiterate our appreciation to Chairman Kohl, Senator Grassley, and the Special Committee on Aging for their work on this issue, and to also emphasize AdvaMed's support for appropriate disclosure of relationships between medical technology companies and physicians. We believe a uniform, comprehensive federal disclosure system can provide important information to patients in a manner that preserves important collaborations between industry and physicians and leads to advances in patient care. We were pleased to support legislation introduced by Chairman Kohl and Senator Grassley, the Physician Payments Sunshine Act, and we appreciate the sponsors' continued leadership and willingness to work with our industry as it is implemented.

Submission to the Senate Special Committee on Aging
Roundtable on Sunshine Act Implementation
Senate Dirksen Office Building 562

September 12, 2012

Dear Chairman Kohl and Senator Corker:

It is our pleasure to submit these comments on behalf of the CME Coalition (www.cmecoalition.org), an advocacy organization comprised of and representing continuing medical education (CME) providers, supporters and beneficiaries, regarding the implementation of Section 6002 of the Patient Protection and Affordable Care Act (PPACA)—also known as the Physician Payment Sunshine Act (Sunshine Act). We appreciate the opportunity to express our views concerning our opinion that, unless CME-related support payments are exempted from the Sunshine Act's reporting rules, the Act will bring about a devastating, albeit unintended, effect on the professional training and education of medical professionals, and ultimately, patient care.

I. Introduction

The CME Coalition both appreciates and endorses the manifest goals of the Physician Sunshine Act; namely, the public reporting of direct payments from manufacturers of medical products to the medical professionals who use them. For a host of reasons, we recognize the public interest in knowing whether physicians are financially benefiting from the same companies that produce the medicines they prescribe and the devices that they use.

We firmly believe, however, that it was never the intent of Congress to expand the public reporting requirements to include transactions related to the provision of continuing medical education when such payments are made from commercial interests to CME providers without allowing for the supporting entity to enjoy any control regarding either the presenters, the curriculum, or the attendees of a given educational program.

If interpreted to include coverage of these CME support payments, the Sunshine Act reporting requirements will create the erroneous impression that CME instructors have an inappropriate relationship with the commercial organizations that support the programs that include them through grants and other means. It will also foster the impression that attendees of commercially supported CME programs are inappropriately benefiting from

these commercial companies. These misimpressions, and the stigma that attaches to them, will severely chill participation in educational programming among leading practitioners and academics, and will undermine the credibility and integrity of all accredited CME. Additionally, as our comments will attest, it will be virtually impossible to effectively meet the reporting requirements of the Sunshine Act in the CME context without making it practicably unworkable for the private sector supporters of CME to continue to participate.

As health care and educational professionals who value the importance of enhancing the continuing education of the country's physicians, we are troubled by the notion that the Federal Government would not be seeking ways to encourage, rather than impede, this important practice. As our comments will indicate, we believe that the multitude of current accrediting standards and regulations that govern the medical community are more than adequate to ensure that CME is provided without supporter bias of any kind.

II. Background on CME Coalition

The CME Coalition represents a collection of continuing medical education provider companies, in addition to other supporters of CME and the vital role it plays in our health care system. Our member organizations manage and support development of healthcare continuing education programs that impact more than 500,000 physicians, nurses and pharmacists annually.

Graduation from medical school and completion of residency training are the first steps in a career-long educational process for physicians. To take advantage of the growing array of diagnostic and treatment options, physicians must continually update their technical knowledge and practice skills. CME is a mainstay for such learning. Most State licensing authorities require physicians to complete a certain number of hours of accredited CME within prescribed timeframes to maintain their medical licenses. Hospitals and other institutions may impose additional CME requirements upon physicians who practice at their facilities.

The Accreditation Council for Continuing Medical Education (ACCME) is the principal CME accrediting authority in the United States and "plays a pivotal role in ensuring the integrity of CME by determining whether providers qualify to offer accredited CME programs and by providing ongoing oversight of the CME industry."[1] Once a CME provider gains ACCME accreditation, the provider may offer programs as accredited CME activities without seeking ACCME review or approval of the topic, content, faculty, or format of the individual activity. Generally, physicians can use only accredited CME to satisfy licensure and hospital privileging requirements. According to the most recent report, ACCME has 694 nationally accredited CME providers.

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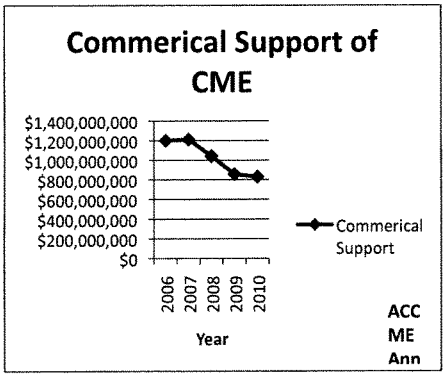
[1] Lew Morris Testimony Senate Finance Committee

Current State of CME

For a variety of reasons, commercial support of CME funding has declined $297 million or 31.4 percent since 2007.[2]



It now accounts for approximately one-third of CME spending annually. Without a reversal of this trend, or an infusion of government funding, health professionals will soon face significant challenges accessing the appropriate, high quality CME necessary to stay current with innovations in the practice of medicine. In fact, a recent survey revealed that 52.2% of physician respondents said they have lately had to spend more time and effort locating appropriate CME and 64.1% said they have had to pay more for the cost of CME for themselves or staff. [3]

In 2010, accredited providers produced more than 81,000 activities, a 14.2% decrease of activities from 2009, and a 27.8% decrease in activities since 2007. Also in 2010 there were over 660,000 hours of instruction, which is 29,000 (4.2%) fewer hours than in 2009. In 2010, 1.5 million physicians participated in live courses this is down from 1.6 million in 2009 (representing an 8% reduction).[4]

The number of ACCME-accredited providers grew steadily until 2007. The ACCME lost 42 national providers (6%) since 2007, including 13 providers (2%) between 2009 and 2010. The number of accredited providers now is at its lowest level since 2002. Most of the loss has been from the following provider types:

[2] ACCME Annual Report Data 2010 (Published August 2011)
[3] Medlinx Survey 2011
[4] ACCME Annual Report Data 2010 (Publishes August 2011)

- Nonprofit physician membership organizations,
- Publishing/education companies, and
- Hospital/health care delivery systems.

A Biannual survey conducted by the Society for Academic CME (SACME) Research Committee and the Association of American Medical Colleges (AAMC) also found decreased access to high quality or appropriate CME.[5] The Biennial Survey of CME units at medical schools in the U.S. and Canada showed a drop in CME units over the past three years. Specifically:

- In 2010, over 130 courses on a yearly basis vs. 147 in 2008
- In 2010, approximately 1,363 credits vs. over 3,000 credits in 2008
- In 2010, attendance of 7,500 physicians vs. 9,000 physicians in 2008
- In 2010, attendance of 4,000 non-physicians vs. 4,600 non-physician participants in 2008

There was also a drop in CME units who provide credit for regularly scheduled conferences, series or rounds (RSS):

- Specifically, in 2010, there were 58 regularly scheduled series with 1,600 credits vs. 83 in 2008 2,274 credits in 2008.

In addition, the numbers of asynchronous audio, video, and online courses also decreased.

- Specifically, in 2010, there were 52 courses used video with over 230 credits, audio vs. 170 courses and 266 credits in 2008.
- In 2010, these attracted 4,000 documented physician users vs. 6,895 in 2008.

More concerning is that over 25% of doctors found CME quality decreasing.[6]

Moreover, health professionals will also face challenges accessing appropriate, high quality CME because the economic climate, coupled with decreased commercial support, has affected state-accredited CME providers, universities, and even the federal government. For example, at least one medical school[7] and the Department of Defense (DOD) closed their continuing education offices last year, and the number of CE providers accredited by state medical societies fell by 18.7% to 1,450 between 2003 and 2010.[8] AMA's Council on Medical Education noted that unabated, this trend could

[5] SACME-AAMC Harrison Survey 2010 (Published June 2011)
[6] Medlinx Survey 2011
[7] http://www.policymed.com/2011/10/cme-and-the-health-care-economy-hospitals-and-universities-cutting-back.html
[8] ACCME Annual Report Data 2010 Ammendum

"impede the delivery of cost-effective, quality, accessible certified CME" dealing with local health issues.

III. CME and its Role in Improving Patient Outcomes

According to a recent study, physicians who attended an industry-supported educational activity were 50% more likely to provide evidence-based care for COPD than nonparticipants were.[9] Another program showed that the patients of physicians who attended an industry supported educational activity were 52% more likely to receive evidence-based hypertension care than those seen by health care providers than nonparticipants were.[10] In addition, the results of a recent study showed that "heart disease patients whose general practitioners participated in an interactive, case-based CME program had a significantly reduced risk of death over 10 years compared with those whose doctors didn't receive the education."[11]

Moreover, when industry is unable to support CME providers, academic institutions, physicians will lose a valuable source of information and scientific evidence about new treatments and therapies. CME is necessary because new drugs are complex chemical products that require a close understanding, and because research and development often involve the creation of new products. However, the creation of new products will produce enduring social gains only if physicians are properly trained and educated about them.

Pharmaceutical and device manufactures provide grants to CME providers, CME providers to offer objective and independent CME programs, which follow the ACCME SCS. Producers of pharmaceutical products and medical devices ought to have an ability to support education that is unbiased, such as CME, to continue supporting the education of health care providers. Further, CME also provides the function of making sure doctors are aware that new therapies, indications or treatments are actually on the market.

Today's CME providers have the experience, expertise, and long-term commitment to manage the challenges posed by an increasingly complex healthcare environment. Additionally, many stakeholders that comprise the CME enterprise have taken significant steps toward quality improvement. CME programs with commercial support are no different from non-supported CME programs because the content has to be vetted to ensure lack of any commercial bias. CME programs are not provided to "naïve audiences." Commercially supported CME programs speak to physicians who face their own reputational and liability risks when they prescribe drugs or devices and consonant of risk and cautious before changing the way they practice medicine In most of these

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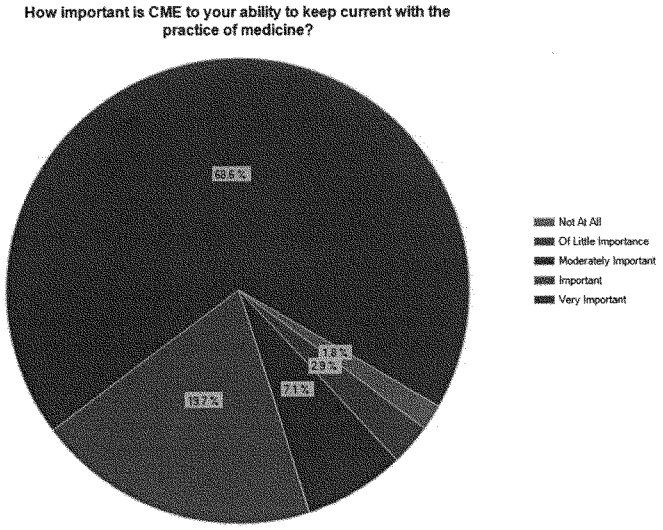
[9] *Improving COPD Patient Outcomes: Breaking Down the Barriers to Optimal Care.* American College of Chest Physicians annual meeting Chest 2010 in Vancouver, British Columbia.
[10] Drexel, C. et al. *J Clin Hypertens* (Greenwich). 2011 Feb;13(2):97-105
[11] Kiessling, A. et al. *Annals of Family Medicine* 9:211-218 (2011).

sessions, physician questioning plays a prominent role, and there is little reason or incentive to think that a commercially supported CME program would push improper risk-making claims given the risk the provider could have of losing its accreditation or other legal sanctions from the FDA, ACCME, HHS OIG, or DOJ.

Physicians overwhelmingly value industry-supported CME and attendees overwhelmingly assert that industry-supported CME programs provide up-to-date, timely, useful, and reliable information about medications to treat particular conditions, and knowledge or skills helpful in their practice.

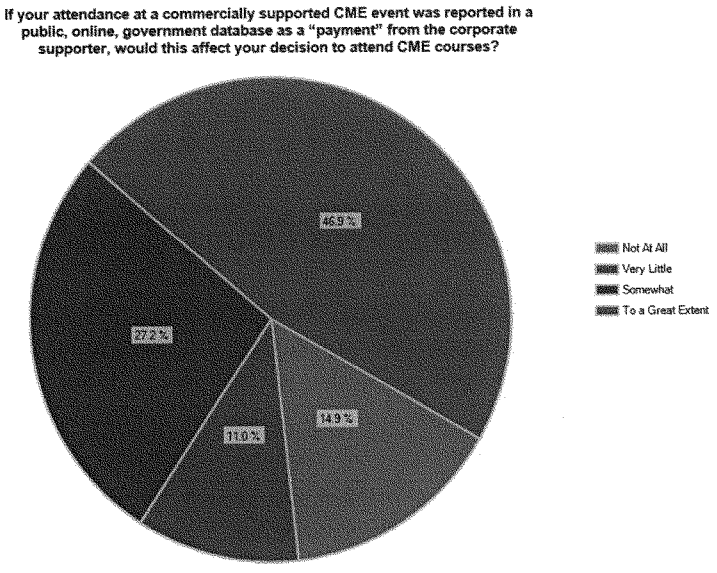
IV. CME Coalition Survey of Physicians

In a recent survey of 467 physicians conducted by the CME Coalition, respondents testified overwhelmingly to both their reliance on CME to improve patient outcomes, and to the importance of commercial support in making these programs financially viable. According to the report, 94 percent of doctors have attended accredited CME events in the last year, and over half of those polled had attended four or more events. Further, physicians clearly recognize the positive impact that accredited CME can have on their ability to improve health care outcomes for their patients. When it comes to both '[keeping] current with the practice of medicine' and '[improving] patient outcomes,' over 95 percent of those polled said that CME was *at least* 'moderately important' – with over two-thirds reporting that CME is 'very important' in keeping up with the latest innovations in their industry.



But despite their recognition that continued medical education increases their capacity to improve the quality of care that they provide, many health care professionals indicate that the reporting requirements mandated by the proposed rule implementing the Sunshine Act will chill their participation in such courses. A significant majority of physicians fear that having their information cataloged in a publicly available database as having received 'payment' from corporate supporters of CME programs will create the stigma that there is bias in these courses, and that their participation is somehow inappropriate. When asked if "attendance at a commercially supported CME event was reported in a public, online, government database as a 'payment' from the corporate supporter, would this affect [the] decision to attend CME courses," 75 percent of doctors responded that it would *at least* affect their decision 'somewhat,' and 47 percent said that their decision would be affected 'to a great extent.'

Moreover, results seem to similarly indicate that significantly fewer physicians would be willing to take leadership at CME events under CMS' proposed rule for the Sunshine Act, as 47 percent responded that their decision to participate as a panelist or presenter would be affected 'to a great extent' under the proposed rule. Additionally, health care providers recognize the important role of companies in providing the financial support – which would not be otherwise available – that is necessary to put on CME events. Among those surveyed, 89 percent of physicians agreed that health care companies should be *at least* 'somewhat' encouraged to provide financial support to underwrite accredited continuing medical education programming and online resources, two-thirds of which thought their financial support should be encouraged 'to a great extent.'



V. CME and FDA's Risk Evaluation Management Strategies (REMS)

As you are aware, the Food and Drug Administration Amendments Act of 2007 (FDAAA) created new section 505-1 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), which authorizes FDA to require a risk evaluation and mitigation strategy (REMS) when necessary to ensure that the benefits of a drug outweigh the risks. FDA may now require REMS for any New Drug Application (NDA), Abbreviated New Drug Application (ANDA), or Biologic License Application (BLA) at any stage of the product lifecycle when the FDA determines that such a strategy is necessary to ensure that the benefits of the drug outweigh the risks.

Section 505-1 also authorizes FDA to require holders of covered applications approved without a REMS to submit a proposed REMS if the FDA becomes aware of new safety information as defined in 505-1(b)(3) and determines that such a strategy is necessary to ensure that the benefits of the drug outweigh the risks of the drug. Once the holder of an approved covered application is notified by FDA that a REMS is necessary, the holder must submit a proposed REMS within 120 days, or within such other reasonable time as FDA requires to protect the public health (section 505-1(a)(2)(B)). Once approved, the REMS create an enforceable obligation for the manufacturer and the FDA. Proposed REMS may contain any of the following elements:

- **Medication Guide** – Document written for patients highlighting important safety information about the drug; this document must be distributed by the pharmacist to every patient receiving the drug.
- **Communication Plan** – Plan to educate healthcare professionals on the safe and appropriate use of the drug and consists of tools and materials that will be disseminated to the appropriate stakeholders.
- **Elements to Assure Safe Use (EASU)** – These are strictly controlled systems or requirements put into place to enforce the appropriate use of a drug. Examples of EASUs include physician certification requirements in order to prescribe the drug, patient enrollment in a central registry, distribution of the drug restricted to certain specialty pharmacies, etc.
- **Implementation Plan** – A description of how certain EASUs will be implemented.
- **Timetable for Submission of Assessments** – The frequency of assessment of the REMS performance with regard to meeting the goal(s) and objective(s). FDA requires that assessments be conducted at 18 months, 3 years, and 7 years post-launch, at a minimum. Results of these evaluations must be reported to the FDA and will determine whether additional actions or modifications to the REMS program are required.

A drug's REMS program may not require the provision of all the components above, as the specific components a REMS program employs will vary based on the severity of the

risks, the population likely to be exposed, and other factors. Most common REMS only require the provision of a medication guide. While REMS components are not uniform, some do and will contain new provisions and requirements for physicians and other certified health care providers.

The strong connection between FDA, manufacturers and CME providers is clearly demonstrated by REMS. In fact, recently, FDA began requiring companies to fund CME for REMS education in long acting opioids. The central component of the Opioid REMS program is an education program for prescribers (*e.g.,* physicians, nurse practitioners, physician assistants) and patients. The REMS notification letter expressed FDA's expectation that the training would be conducted by accredited, independent continuing education providers. FDA later elaborated its vision for prescriber education stating that it expected the CE training to be provided without cost to the healthcare professionals and that supporters would offer unrestricted grants to accredited CE providers to develop CE for the appropriate prescriber groups. FDA Commissioner Margaret A. Hamburg, M.D. asserted that, "the prescriber education component of this opioid REMS balances the need for continued access to these medications with stronger measures to reduce their risks."

In the final Opioid REMS Blueprint, FDA provided an outline of the required prescriber education. The outline specified that the education must include information on weighing the risks and benefits of opioid therapy, choosing patients appropriately, managing and monitoring patients, and counseling patients on the safe use of these drugs. In addition, the education must include information on how to recognize evidence of, and the potential for, opioid misuse, abuse, and addiction. FDA's expectation is that the initial or basic REMS related CE that should be offered to all prescribers of long-acting and extended-release opioids should consist of a "core" content of about 2 to 3 hours.

Under the Sunshine Act rules as proposed, however, funds given to CME providers to produce REMS-mandated CME would constitute a transfer of value and would have to be reported. This could be a huge disincentive to participate in a REMS program because many physicians would not want to appear on lists for attending such programs. Moreover, the publication of payments made by manufacturers to CME providers who are providing the FDA mandated REMS would suggest impropriety and brings into question the objectivity of the program, despite the fact that FDA has mandated the specific educational components. However, concerns about improper influence or conflicts of interest in REMS programs should be misplaced, given the safeguards in place and the significant penalties companies can face. Failure to comply with FDA REMS can render the company's drug misbranded. Penalties can range from $250,000 to $1 million cap per violation; $1 million to $10 million cap per proceeding.

VI. Accredited CME Already Abides by Strict Standards to Avoid Potential Conflicts

CME today is vastly different from CME of the past. New standards of commercial support create a principled firewall that prevents undue industry influence. CME providers that accept commercial support are committed to transparency, accountability, and independence in producing CME programs and strictly follow all of the rules, standards and regulations cited above to eliminate any kind of potential bias or "conflict of interest." Even more recently, the Coalition published a CME Code of Conduct to bring clarity to the rules governing CME.

The combined efforts of these organizations have worked. In fact, studies demonstrate concerns about commercial support of CE are misplaced. In 2010, three large studies conducted independently by the Cleveland Clinic,[12] Medscape,[13] and the University of California, San Francisco,[14] were published in peer-reviewed journals. These studies produced substantial data that provide evidence there is a complete lack of commercial bias in industry-supported CME. Given the large amount of well-established CME regulations and guidance already in place, coupled with the results from these very large studies, additional regulations are unnecessary, duplicative, and burdensome.

ACCME Standards for Commercial Support

In 2004, the ACCME adopted its first set of Standards for Commercial Support (SCS) to provide guidelines and rules for CME providers who receive commercial support. The Standards were updated in 2006 and again in 2007. Under the SCS, CME providers must ensure that the following decisions are made free of any control of a commercial supporter: (a) Identification of CME needs; (b) Determination of educational objectives; (c) Selection and presentation of content; (d) Selection of all persons and organizations that will be in a position to control the content of the CME; (e) Selection of educational methods; (f) Evaluation of the activity.[15]

Providers must also show that everyone who is in a position to control the content of an education activity has disclosed all relevant financial relationships with any commercial interest to the provider. The ACCME defines "relevant" financial relationships" as financial relationships in any amount occurring within the past 12 months that creates the

[12] Kawczak S, Carey W, Lopez R, Jackman D. The effect of industry support on participants' perceptions of bias in continuing medical education. *Acad Med.* 2010;85(1):80-84.
[13] Ellison JA, Hennekens CH, Wang J, etal. Low rates of reporting commercial bias by physicians in online continuing medical education activities. *Am J Med.* 2009;122:875-878.
[14] Steinman MA, Boscardin CK, Aguayo L, Baron RB. Commercial influence and learner-perceived bias in continuing medical education. *Acad Med.* 2010;85(1):74-79.
[15] SCS Standard 1

perception of a conflict of interest.[16] An individual who refuses to disclose relevant financial relationships must be disqualified from being a planning committee member, a teacher, or an author of CME, and cannot have control of, or responsibility for, the development, management, presentation or evaluation of the CME activity.[17] CME providers must implement a mechanism to identify and resolve all conflicts of interest prior to the education activity being developed and delivered to learners.[18]

Providers must make all decisions regarding the disposition and disbursement of commercial support[19] and cannot be required by a commercial interest to accept advice or services concerning teachers, authors, or participants or other education matters, including content, from a commercial interest as a condition of contributing funds or services.[20] CME providers must have a written agreement that documents the terms, conditions, and purposes of the commercial support that binds the provider and its educational partner(s).

CME providers must also have written policies and procedures governing honoraria and reimbursement of out-of-pocket expenses for planners, teachers and authors.[21] Moreover, CME providers, the joint sponsors, or designated educational partners must pay directly any teacher or author honoraria or reimbursement of out-of–pocket expenses in compliance with the provider's written policies and procedures.[22] This means that an applicable manufacturer can never pay a faculty member directly nor can they make any other payment to the director of the activity, planning committee members, teachers or authors, joint sponsor, or any others involved with the supported activity.[23] Additionally, CME providers are prohibited from using commercial support to pay for travel, lodging, honoraria, or personal expenses for non-teacher or non-author participants of a CME activity.[24] The provider may use commercial support to pay for travel, lodging, honoraria, or personal expenses for bona fide employees and volunteers of the provider, joint sponsor or educational partner. CME providers must produce accurate documentation detailing the receipt and expenditure of the commercial support.[25]

Arrangements for commercial exhibits or advertisements cannot influence planning or interfere with the presentation, nor can they be a condition of the provision of commercial support for CME activities.[26] Product-promotion material or product-specific advertisement of any type is prohibited in or during CME activities. The

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[16] Standard 2.1
[17] Standard 2.2
[18] Standard 2.3
[19] Standard 3.1
[20] Standard 3.2
[21] Standard 3.7
[22] Standard 3.8
[23] Standard 3.9
[24] Standard 3.12
[25] Standard 3.13
[26] ACCME Standard 4.1

juxtaposition of editorial and advertising material on the same products or subjects must be avoided. Live (staffed exhibits, presentations) or enduring (printed or electronic advertisements) promotional activities must be kept separate from CME.[27] Educational materials that are part of a CME activity, such as slides, abstracts and handouts, cannot contain any advertising, trade name or a product-group message:[28]

- For *print*, advertisements and promotional materials may not be interleafed within the pages of the CME content. Advertisements and promotional materials may face the first or last pages of printed CME content as long as these materials are not related to the CME content they face and are not paid for by the commercial supporters of the CME activity.

- For *computer based*, advertisements and promotional materials may not be visible on the screen at the same time as the CME content and not interleafed between computer 'windows' or screens of the CME content.

- For *audio and video recording*, advertisements and promotional materials may not be included within the CME. There will be no 'commercial breaks.'

- For *live, face-to-face CME*, advertisements and promotional materials cannot be displayed or distributed in the educational space immediately before, during, or after a CME activity. Providers cannot allow representatives of commercial interests to engage in sales or promotional activities while in the space or place of the CME activity.

The content or format of a CME activity or its related materials must promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial interest.[29] Presentations must give a balanced view of therapeutic options, and the use of generic names is encouraged in order to contribute to this impartiality. If the CME educational material or content includes trade names, where available, trade names from several companies should be used, not just trade names from a single company.[30]

Individual faculty or CME presenters must disclose to learners any relevant financial relationship(s). This disclosure must include (1) the name of the individual; (2) the name of the commercial interest(s); (3) The nature of the relationship the person has with each commercial interest.[31] For an individual with no relevant financial relationship(s) the learners must be informed that no relevant financial relationship(s) exist.[32] Moreover, the

[27] ACCME Standard 4.2
[28] ACCME Standard 4.3
[29] ACCME Standard 5.1
[30] ACCME Standard 5.2
[31] ACCME Standard 6.1
[32] ACCME Standard 6.2

source of all support from commercial interests must be disclosed to learners. When commercial support is "in-kind" the nature of the support must be disclosed to learners.[33] Provider must disclose the above information to learners prior to the beginning of the educational activity.[34]

VII. Including Payments to Support CME under the Sunshine Act is Unworkable for Many Reasons

Definition of "Awareness" is Problematic

We believe that requiring applicable manufacturers to report payments to third parties, such as CME providers, when they are "aware" of the identity of a covered recipient who will receive payment indirectly from the third party is impossible to implement in any practical sense.

Section 1128G(e)(10)(A) of the Act excludes the reporting of payments or other transfers of value that an applicable manufacturer makes indirectly to a covered recipient through a third party when the applicable manufacturer is *unaware* of the identity of the covered recipient. The Coalition believes that the vague meaning of this provision will create significant uncertainty for CME supporters, providers and participants. Under the proposed interpretation, for example, if a CME provider (who is not a covered recipient) receives an educational grant from an applicable manufacturer, and either 1.) the CME provider included the names of faculty in a CME proposal or 2.) the applicable manufacturer subsequently learned of the faculty's participation at some point, the applicable manufacturer would have to report the payment as if it were made directly to the faculty.

In its Proposed Rule, CMS provided no explicit guidance as to what point during the process a CME grant is awarded, an applicable manufacturer to be considered "aware" of the covered recipient's identity. For example, a typical scenario is where a CME provider applies for a CME grant without designating faculty, no faculty have been hired or reached out to, and only the CME scientific staff have worked on the proposal. In this case, if the CME provider is awarded a grant at this stage, the applicable manufacturer has awarded an educational grant in which they were "unaware" of the identity of a covered recipient.

The Coalition believes that if a grant is awarded under such circumstances, and the manufacturer somehow later becomes "aware" of the identity of a covered recipient, this payment should be exempt because the manufacturer had no involvement in choosing the faculty (even though such is banned by ACCME, FDA, PhRMA, OIG) and the recipient's

[33] ACCME Standard 6.3
[34] ACCME Standard 6.5

identity played no role in the manufacturer's grant awarding decision. Essentially, if an applicable manufacturer is unaware of a covered recipient's identity at the time they are awarding a grant, there is no need to publish these payments because the grant was awarded based on the educational and practice gaps and the scientific evidence contained in the proposal.

We are concerned as to what happens in the case in which a supporter's final payment for services to a provider does not occur until after the program has been completed and the identities of the presenters have been disclosed? Does this now become a reportable transaction?

Furthermore, we are also uncertain as to what the impact will be on CME program attendees whose identity becomes known to a program supporter. Will their subsidized attendance qualify as a payment that must be reported? If so, is it not misleading to the public to create the impression that these attendees are receiving payment from health care manufacturers?

In the case of accredited CME, however, the above circumstances are moot. Manufacturers can never have any say in choosing faculty for any CME program, which is why we believe the concern for publishing payments made to faculty through CME providers is unnecessary. There are significant rules and regulations in place that CME providers follow to choose faculty, which we discussed in detail above. While the Coalition supports the goal of the Sunshine Act for promoting transparency and reducing potential conflicts of interests, the CME industry and CME providers already have sufficient mechanisms and regulations in place to mitigate and manage such risks.

Moreover, we believe that requiring the public reporting of payments made from manufacturers indirectly to CME faculty is improper and misleading. CME faculty, who are typically physicians and thus "covered recipients," are never paid directly from an applicable manufacturer for an accredited CME program; they are paid through the accredited CME provider. CMS cannot, thus, directly attribute a manufacturer's payment to CME faculty when the accredited provider receives the payment, and the faculty never receives payment from the company/grantor. Publishing payments as if the faculty received the payment directly from the applicable manufacturer calls into question the independence of an accredited CME program, which FDA, OIG, ACCME, PhRMA and AdvaMed standards and rules were designed to preserve.

Furthermore, because applicable manufacturers must report any product or service associated with the payment, publishing a payment to a CME faculty member would create an association between the CME program and promotion of a particular company's product. Juxtaposing a CME faculty member's name and payment for a CME program, with a manufacturer's product manifests a direct violation of the ACCME SCS and puts

the accredited CME provider into non-compliance with the ACCME's mandates. It is also improper to link CME faculty to an applicable manufacturer in the context of accredited CME programs because many of these individuals will have no contact or association with the company, other than knowing the names of companies that are supporting the program with an educational grant.

ACCME SCS's prohibit inappropriate relationships between faculty and a manufacturer and therefore, publishing such payments would again put a CME provider in non-compliance with ACCME requirements. In addition, imposition of these requirements will also enable the breach of independence of CME providers from applicable manufacturers by suggesting that these manufactures may dictate the amount and the nature of payment by the CME provider to a faculty who is also a covered recipient.

Additionally, the disclosure of CME faculty members to applicable manufacturers could reduce the independence accredited CME provides have in producing independent programs. Under FDA and OIG Guidance, ACCME SCS, and PhRMA/AdvaMed Codes, an applicable manufacturer can only provide educational grant funding to an accredited provider. Applicable manufacturers have no say in what faculty is utilized or how much honoraria and related payments the accredited provider gives to the faculty. The accredited provider is not obligated to disclose any specific information to the supporting applicable manufacturer on payments made to individual faculty.

Accurately Dividing the Payments Among Presenters Would be Close to Impossible

Many CME programs involve numerous presenters as well as a multitude of official supporters. Many more companies help to underwrite the cost of educational programming by purchasing booths and displays.

We worry that each supporter or booth purchaser that becomes aware of a program's presenters' identities might have to find a way to calculate what amount of their payment was attributable to a given presenter and report it as such. Additionally, once a CME supporter became aware of the identity of an attendee, it might have to report some portion of its payment as though it were made to that individual as well.

Such an outcome creates an impossible tracking and attribution role for the CME provider companies that are tasked with coordinating these events. Further, the absence of any certainty in this regard, coupled with the sizable fines for corporations that fail to make accurate reports, will have the added impact of dissuading many commercial supporters from even taking the risk of supporting CME activity going forward. If commercial support were to further erode from CME, it would put tremendous strain on our current means of providing our medical practitioners with the continuing education they desperately need.

Creates Unfair Misimpression and Stigma, Leading to Reduction in CME Participation

As strong advocates for CME, we see the education of medical practitioners as an indispensible ingredient in the expansion of health care innovations and improvements in patient outcomes. A robust commitment to CME requires adequate resources from across the health care system. It also requires the participation from expert practitioners and academics who will take the time to share their knowledge with other medical professionals. We harbor great concern that the requirement that such indirect payments be reported will cause many leaders in their field to forego participation in CME rather than have to answer questions related to the so-called commercial payments they were reported to have received.

Additionally, while all agree that we should be encouraging physicians to take on as much education as they can, we fear that Sunshine Act reporting requirements will cause many medical professionals to forego CME.

VIII. Conclusion

Since the first academic-industry-physician alliances helped produce insulin over eighty years ago, American's have enjoyed a high standard of living, including their state of health and the medical discoveries and treatments that have steadily improved it. This active partnership between science and commerce has created a wide-ranging and productive exchange of knowledge and information. For the last century, physicians have worked hand-in-hand with industry to create some of the most revolutionary advances in medicine and healthcare. Today, it would seem impossible for a physician to be competent in medicine without the information, tools, treatments, data, and other resources industry provides. As a practical matter, commercially-supported CME, both online and in person, serves an irreplaceable role in disseminating this information to doctors.

More than 400,000 medical journal articles are published each year, making the practice of medicine very dynamic. The sheer volume of new scientific data and changes in medicine requires as many appropriate avenues for funding certified CME as possible. In addition, the changes to practice in medicine occur rapidly. The nature of medicine involves constant advancement, testing, and application. Medicine features landmark breakthroughs, such as the discovery and testing of a new therapeutic agent. Changes in medicine often are revolutionary. Patients and society demand that our physicians receive information instantaneously, and that updates in treatment, diagnosis, and prevention are disseminated to physicians as soon as practically possible. Without CME, health care practitioners cannot get the most recent and up to date advances. Such advances are pivotal in allowing physicians to begin implementing new breakthroughs sooner and improve patient outcomes before it is too late.

If it is extended to CME support payments, we believe that the Sunshine Act could adversely affect CME providers and deny society the benefits of the knowledge that highly regarded and well-motivated professionals possess. Since 1945, we have had the benefit of these collaborations without having seen any sign of the systematic abuse that could justify their reporting.

Ultimately, payments made to CME providers for education fall outside of the Sunshine Act's intentions because CME providers are not covered recipients. If CMS believes that CME providers should be treated as covered third parties, then we would suggest that payments to CME providers should be exempted from reporting because of the ACCME's Standards of Commercial Support or the safeguards, firewalls, and transparency protections already required for certified CME. Otherwise, publication of such grants and payments would be detrimental to CME providers in many ways, such as finding sufficient subject-matter expert faculty, planning and budgeting high cost and high quality CME, and soliciting funding. We urge you to consider our position that the negative impact on CME providers and those who depend upon CME outweigh any potential gain publishing such payments will accomplish.

We thank you very much for this opportunity to share our comments.

Chris Lamond
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September 11, 2012

Delivered via E-mail

United States Senate Special Committee on Aging
Honorable Herb Kohl, Chairman
G31 Dirksen Senate Office Building
Washington, DC 20510

Re: Implementing the Physician Payment Sunshine Act

On behalf of MMIS, Inc. and the Regulatory Law Group, PLLC, we formally submit these written comments to the Senate Special Committee on Aging relative to the implementation of the Physician Payment Sunshine Act. Over the last 3 years, the Regulatory Law Group, PLLC and MMIS, Inc. have conducted multiple surveys to understand the attitudes, awareness and concerns of physicians as they relate to the Physician Payment Sunshine Act. Based upon the results of the surveys as outlined below, as well as research conducted by 3rd parties, there is a significant need for physician education, prior to the implementation of the Physician Payment Sunshine Act, and a platform to encourage industry to share disclosure data with physicians prior submission to CMS.

In January, 2011, the Regulatory Law Group, PLLC conducted a cross-specialty survey of physicians designed to gather information on physicians' attitudes, opinions and awareness as they relate to various issues surrounding physician/industry relationships. The survey announcement was distributed to 3,300 physicians via e-mail that contained a link to the online survey. The survey was completed by 250 physicians, the majority of which (52%) have been in practice for greater than 15 years. According to the survey results:

- 47% of the respondents were not aware that pharmaceutical and medical device manufacturers will be required to track and report to the federal government certain expenditures made to or on behalf of physicians greater than $10.00.
- 53% of the respondents were not aware that the information disclosed to the federal government will be made available to the public in a searchable database.
- 63% of the respondents expressed a desire to review and correct, if necessary, all disclosures prior to industry submission to the federal government.

Approximately one year later in December 2011, MMIS, Inc., in conjunction with the American Medical Association, replicated the survey previously conducted by the Regulatory Law Group, PLLC. Survey invitations were distributed to 50,000 physicians contained within the AMA Masterfile. The survey was completed by 1,057 physicians, the majority of which were specialists (64%) with greater than 20 years of experience (58%).

Similar to the results obtained in the Regulatory Law Group, PLLC survey, the results to the AMA/MMIS, Inc. survey showed a continued lack of awareness on the part of physicians.

- 47% of the respondents were not aware of the requirements of the Physician Payment Sunshine Act.
- 67% of the respondents were not aware that the information collected would be reported to HHS and made available in the public domain.
- 56% of the respondents are concerned about the implications of the Physician Payment Sunshine Act.

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- 54% of respondents are "somewhat" or "very" concerned about the public availability of the information disclosed in the public domain.

As the survey results demonstrate, there is a significant lack of awareness on the party of physicians with regard to the Physician Payment Sunshine Act. When made aware of the requirements, physicians have expressed concern over the implications on their relationships with both patients and industry alike. According to a survey recently conducted by Kyruus, Inc., 87% of physician respondents would be "concerned" or "very concerned" if the information publicly disclosed was false or incorrect. Moreover, respondents indicated that the disclosure of false information would negatively impact their relationships with industry (66% would reduce interactions and 45% would reduce utilization).

As the Special Committee on Aging monitors the implementation of the Physician Payment Sunshine Act, it is important to recognize the need for significant physician education with regard to the requirements of the Act. In addition, considering the implications as they relate to the erroneous disclosure of information in the public domain, it is recommended that industry be encouraged to share disclosure data with physicians prior submission to CMS.

The successful implementation of the Physicians Payment Sunshine Act requires participation from all stakeholders. In order to achieve the objectives of the Act, it is necessary for physicians and consumers alike to be educated and to fully understand the benefits achieved through physician/industry relationships and interactions.

Thank you for providing us with the opportunity to submit our comments. Please do not hesitate to contact us should you have any questions about the information contained herein.

Warm Regards,

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NATIONAL DIALOGUE FOR
Healthcare Innovation

UNITED STATES SENATE SPECIAL COMMITTEE ON AGING ROUNDTABLE
"LET THE SUNSHINE IN: IMPLEMENTING THE PHYSICIAN PAYMENTS SUNSHINE ACT"
SEPTEMBER 12, 2012
2:30 pm

STATEMENT FOR THE RECORD:
NATIONAL DIALOGUE FOR HEALTHCARE INNOVATION
AN INITIATIVE OF THE HEALTHCARE LEADERSHIP COUNCIL
750 9th Street, NW, Suite 500
Washington, D.C. 20001

The *National Dialogue for Healthcare Innovation* (NDHI) appreciates the opportunity to provide a statement for the record to the Special Committee on Aging roundtable on the implementation of the Physician Payments Sunshine Act. We were pleased to have an NDHI working group member – Dr. Douglas Peddicord, Executive Director, Association of Clinical Research Organizations (ACRO), Washington, D.C. – participate in the roundtable discussion. Principled collaboration between doctors and manufacturers continues to benefit patients and advance medical innovation. We agree with Senators Grassley and Kohl that information provided to the public about this collaboration must be transparent and informative. As the Special Committee on Aging monitors the implementation of the Physician Payments Sunshine Act, it is important to consider the value of exchanges between industry, physicians, and researchers, and more specifically, the medical advances and patient benefits that have been derived from physician-industry collaboration.

The *National Dialogue for Healthcare Innovation*
The Healthcare Leadership Council (HLC), a coalition of chief executives representing all sectors of American healthcare, formed the NDHI as an interactive forum where leaders from across the healthcare industry – government, academia, industry, payers, providers, societies, and patient and consumer organizations – work toward consensus on the most important issues affecting healthcare innovation, and ultimately, patient care.

NDHI recognizes the value of the Patient Protection and Affordable Care Act "sunshine" provisions to ensure transparency and public disclosure regarding financial relationships between physicians and industry, and knows these provisions are both necessary and important to protecting patients. NDHI also recognizes physician-industry collaboration as vital to preserving innovation. Accordingly, NDHI has advanced the discussion on the importance of principled physician-industry collaboration, and how to ensure its continuation. NDHI's 2010 inaugural event – the NDHI Summit on Physician-Industry Collaboration – represented one of the first cross-disciplinary cooperative dialogues among leaders from stakeholder groups across the U.S. healthcare system. An NDHI congressional briefing held earlier this year focused on how to ensure principled physician-industry collaboration that serves the public interest and furthers the discovery of new cures, treatments, and medical technologies.

The Importance of Principled Physician-Industry Collaboration

Collaboration between healthcare professionals, scientists, and non-health industry experts has been at the heart of most of the advances in U.S. healthcare over the past several decades. Appropriate collaboration – guided by clear principles and conducted for the benefit of patients – drives medical innovation, meaningful health outcome improvements, and national economic growth. In an effort to broaden public understanding of how physician-industry collaboration has been critical to medical innovation, NDHI has compiled examples of collaborative efforts that have advanced patient care. Physician-industry collaboration has resulted in:

- Longer and healthier patient lives through improved health outcomes and the safe and effective use of technology;
- Important training and education initiatives, many related to new therapies, which have enhanced patient safety; and
- Significant economic benefits in the form of increased jobs, more cost-effective healthcare, and greater workforce productivity.

Patient and economic benefits of principled physician-industry collaboration and resulting innovation include:

- 40% decline in mortality resulting from coronary heart disease (1980-2000)
- 30% decline in the overall hospitalization rate for heart failure (1998-2008)
- 50% reduction in U.S. AIDS deaths (1995-1996)
- 55% reduction in hospital mortality from acute myocardial infarction (1975-1995)
- 90% reduction in Haemophilus influenzae type b (Hib)-related meningitis and other diseases in the U.S. (1975-1995)
- 30-year gain in life expectancy (age 46 versus age 76) over the 20th century representing more than $1.2 million per person in the current population
- $3.2 trillion per year to national wealth as a result of gains in life expectancy (1970-2000)
- 10% reduction in all-cause mortality over 30 years, valued at over $18.5 trillion

NDHI Consensus Statement on Principled Collaboration

In recent years, concerns about undue influence of industry on healthcare research and clinical practice have presented an increasingly complex challenge to medical research, education, communication, and innovation efforts. After its first summit, NDHI gathered individuals representing varying perspectives to discuss the importance of avoiding undue influence by industry in research and patient care with the value to the patient of collaboration between industry and providers. The group identified many areas of agreement in how to balance these interests. The group developed a consensus statement of principles on collaboration that continues to garner new signatories.

The *NDHI Principles Statement on Collaboration for Healthcare Advancement* – developed by stakeholder perspectives from across American healthcare – provides a basic framework to help guide principled collaboration and maintain the confidence and trust of all participants in our healthcare system, including patients, providers, payers, industry, researchers, academia, and government. NDHI has identified four principles to guide collaborations designed to advance medical technology and patient care. These principles focus on patient benefit and putting patients' interests first, the autonomy of healthcare professionals to treat each patient in a manner consistent with the patient's needs and best medical practice, transparency and reasonable access to relevant and meaningful information, and accountability and internal self-regulation with recurrent training and communication.

The organizations and healthcare professionals agreeing to this statement and participating in the *National Dialogue for Healthcare Innovation* comprise a diversity of voices, but share a common goal – to promote the American innovative spirit so that new advances in medicine and medical technology can continue to make the journey from concept to the practice of medicine for the benefit of patients. In order to do this, NDHI seeks to preserve and enhance an environment that fosters the innovation of new products, practices, and ideas.

As the Physician Payments Sunshine Act is implemented, it is critical that information is presented in a complete, easily understood format in context to its relevance. It is also important that the process for collecting this information be as simple and burdensome-free as possible so as not to add significant costs to the healthcare system. It is also critical that the healthcare industry have ample time to implement the sunshine regulations so that the process is seamless and provides meaningful information to the consumer. We urge the Senate Special Committee on Aging to draw from the NDHI consensus principles when considering the important balance that is needed in implementation of the Physician Payments Sunshine Act.

Thank you for providing us with the opportunity to submit our comments. We look forward to working with the Senate Special Committee on Aging as it continues to monitor the implementation of the Physician Payments Sunshine Act. Please do not hesitate to contact us should you have any questions, or would like additional information about NDHI.

Statement of Gregory E. Demske
Chief Counsel
Office of Inspector General
Department of Health and Human Services

PHYSICIAN PAYMENT REPORTING PROVISIONS IN CORPORATE INTEGRITY AGREEMENTS

This statement summarizes the history and evolution of corporate integrity agreement (CIA) provisions that require drug and device manufacturers to report information about payments that they make to physicians.

The Department of Health and Human Services Office of Inspector General (OIG) has long recognized the importance of transparency about financial relationships between physicians and health care companies, including manufacturers of drugs and medical devices. OIG has emphasized the benefits of transparency in testimony before Congress. *See, e.g.*, Testimony of Lewis Morris to House Committee on Ways and Means, Subcommittees on Health and Oversight, June 15, 2010, and Testimony of Gregory E. Demske to Senate Special Committee on Aging, February 27, 2008.

OIG has required transparency about the payments of drug and device manufacturers to physicians through CIAs entered as part of fraud settlements with specific manufacturers. As OIG has stated in prior testimony, the requirement of public disclosure of these payments will help the Government, as well as the health care industry and the public, to monitor relationships and should have a sentinel effect to deter kickbacks and other inappropriate payment relationships.

In recent years, the U.S. Government (working through the Department of Justice and OIG) has entered numerous settlements with drug and device manufacturers to resolve allegations that the companies defrauded Medicare, Medicaid, and other Federal health care programs. OIG routinely requires drug and device manufacturers to enter CIAs with OIG as a condition for permitting the manufacturers to continue to do business with the Federal Government. Although CIAs contain many standard terms, they are negotiated documents that vary according to the particular entity, the alleged fraud, and relevant risk areas. Among other things, CIAs require the manufacturers to establish or maintain comprehensive compliance programs that include designating a compliance officer, establishing policies and procedures, training, and auditing. The CIAs also require the manufacturers to report certain information to OIG, and OIG monitors the manufacturers' compliance with the terms of the CIAs.

OIG understands that drug and device manufacturers routinely have financial relationships with physicians. There are legitimate reasons that such relationships may exist, but many such relationships may be suspect under existing fraud and abuse laws or may otherwise create conflicts of interest. OIG has concerns about any relationship that raises the inference that the manufacturer is paying the physician, in part, to influence the physician to use, recommend, or prescribe the manufacturer's products. In 2008, OIG began to require more transparency about the relationships between manufacturers and physicians through its CIAs with such entities. These CIAs require the manufacturers to post on their company Web sites information about payments they make to physicians. Manufacturers must post the information on both a quarterly and an annual basis. The specifics of the requirement have

changed over time in different CIAs, but OIG has continued to include a public disclosure requirement, where appropriate, in CIAs with drug and device manufacturers. To date, the payment-posting provisions have been included in 15 CIAs with drug and device manufacturers.[1]

The early CIAs containing the payment-posting provisions predated the passage of section 6002 of the Patient Protection and Affordable Care Act (ACA) (also known as the Sunshine requirements). Accordingly, the definition of the term "payments" used in the early CIAs was not based on a statutory standard. Following the passage of ACA, OIG aligned the definition of "payments" in CIAs with the definition of "payments" in section 6002 of ACA to minimize confusion and inconsistency that could be caused by different definitions. Current CIAs explicitly define "payments" for CIA purposes to include all "payments or other transfers of value" as those terms are defined in section 6002 of ACA and any regulations promulgated thereunder.

OIG has occasionally received questions from the manufacturers under CIAs about the payment-posting requirements. To the extent that OIG received specific questions about how manufacturers should interpret the definition of "payment" for purposes of the CIAs, OIG has generally answered such questions with the caveat that manufacturers must follow the definition of payments as set forth in section 6002 of ACA and any implementing regulations.

Section 6002 of ACA requires that the Centers for Medicare & Medicaid Services (CMS) consult with OIG on implementing its provisions. CMS has consulted with OIG in developing its regulations, as required by the statute.

OIG remains committed to preventing and detecting fraud and abuse, to using CIAs effectively to promote compliance, and to working with internal and external stakeholders to ensure the integrity of the Federal health care programs.

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[1] The testimony and CIAs referenced in this statement may be found on the OIG Web site at: http://www.oig.hhs.gov.

September 10, 2012

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