



NAAMECC

North American Association of Medical Education and Communication Companies, Inc.

# Industry Funding of CME Under Attack:

## Enhancing Compliance and Mitigating Risk

*Proceedings of a Roundtable Discussion of  
Legal and Regulatory Experts*

## **NAAMECC Board of Directors 2006–2007**

Karen Overstreet, EdD, RPh, FACME  
President

Carolyn Darrow, MPH  
Director

Michael Lemon, MBA  
President-Elect

Stephen Lewis, MA  
Director

Mark Schaffer, EdM  
Secretary

Sondra Moylan, MS  
Director

Richard Tischler, Jr., PhD  
Treasurer

J. Brian O'Toole, PhD  
Director

Kurt Boyce, BA  
Past-President

Sandra Weaver, MS  
Director

## **Acknowledgements**

NAAMECC would like to thank the following companies who donated their time to support development of the roundtable and this monograph:

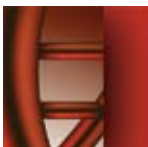
Indicia Medical Education, LLC, North Wales, PA, for project management, meeting planning, and editorial support

i3 CME, State College, PA, for design, layout, and production

This monograph was planned and produced as a service to the medical education, biopharmaceutical, and device industries by NAAMECC. For more information about NAAMECC, please visit <http://www.naamecc.org/>.

To request additional copies of this monograph, contact NAAMECC at:

3416 Primm Lane  
Birmingham, AL 35216  
Phone: (205) 824-7612  
Fax: (205) 823-2760  
E-mail: [info@naamecc.org](mailto:info@naamecc.org)



---

# **Industry Funding of Continuing Medical Education Under Attack: Enhancing Compliance and Mitigating Risk**

**Proceedings of a Roundtable Discussion  
of Legal and Regulatory Experts**

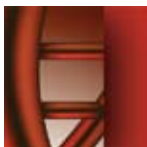
©2007 North American Association of Medical Education and Communication Companies, Inc.  
(NAAMECC)



**NAAMECC**

**North American Association of Medical Education and Communication Companies, Inc.**

---



Ensuring the integrity of continuing medical education (CME) funded by the biopharmaceutical industry is a critical matter to many professionals throughout the United States.

These issues are important to the officers and members of the North American Association of Medical Education and Communication Companies (NAAMECC), a nonprofit association dedicated to promoting best practices in CME and advocating for our members. Thus, NAAMECC provided support to fund a roundtable discussion of this important topic and the resulting monograph, which summarizes the meeting.

A panel of experts was convened Tuesday, May 22, 2007, at the Latham Hotel in Georgetown (Washington, DC). The participants—6 attorneys and 1 physician—have extensive experience as federal and state prosecutors and officials for government agencies including the FDA, OIG, and CMS.

The conversation among the panelists covered topics ranging from solicited versus unsolicited grants to the relative risk associated with various types of providers. This monograph summarizes activities that can mitigate risk and those that have not been shown to affect risk, as well as recommendations for handling investigations. The participants also make interesting and innovative recommendations for ensuring that aggressive enforcement of the fraud and abuse laws does not adversely affect public health.

Highlights of the discussion include:

- The type of provider should have little bearing on risk
- Firewalls should be established for all providers to ensure the independence of education
- Ongoing training is needed for both providers and supporters to create a culture of compliance

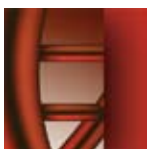
We hope this important project to clarify current legal and regulatory considerations related to commercial support of CME will be valuable for the biopharmaceutical industry and CME community. We look forward to continued dialogue, as all of us involved in educating health care professionals strive to enhance our effectiveness and ultimately patient care.

Karen M. Overstreet, EdD, RPh, FACME  
President, NAAMECC 2006–2007  
President, Indicia Medical Education, LLC  
karen.overstreet@indiciaed.com

*Note: The roundtable discussion and production of this monograph occurred in spring and summer 2007, before the Accreditation Council for CME published its revised policies.*

## Table of Contents

<b>Introductions</b>	<b>4</b>
<b>Commercially Supported CME</b>	<b>5</b>
<b>CME Providers and Educational Partners</b>	<b>6</b>
<i>Preferred Providers</i>	6
<i>Provider Type</i>	7
<b>Definition of “Commercial Interest”</b>	<b>8</b>
<i>Recent Proposal by ACCME</i>	8
<i>All Providers Should Have Firewalls</i>	9
<i>Separating Education from Promotion</i>	9
<i>Institutional Conflicts of Interest</i>	10
<b>Issues for Commercial Supporters</b>	<b>12</b>
<i>Solicited Grants</i>	12
<i>Recommendation of Faculty</i>	13
<i>Review of Content</i>	15
<i>Structure of Commercial Supporters</i>	17
<i>Medical Affairs</i>	17
<i>Grant-making Process and Participants</i>	18
<i>Marketing Documents</i>	19
<i>Multiple Supporters</i>	20
<i>Evaluations and Outcomes</i>	20
<b>Off-label Discussion</b>	<b>21</b>
<i>Off-label Dissemination Issues</i>	21
<b>Good Practices to Reduce Risk</b>	<b>22</b>
<b>Handling a Government Inquiry or Investigation</b>	<b>23</b>
<i>Questions the Government Will Ask Providers</i>	24
<b>Investigations Involving CME</b>	<b>24</b>
<i>Congressional Scrutiny of CME</i>	24
<i>State Enforcement Efforts</i>	25
<b>Aggressive Enforcement Undermines Public Health</b>	<b>26</b>
<i>Public Health Dangers Posed by Aggressive Enforcement</i>	27
<i>Company Perspective on Data</i>	28
<i>A Proposal for a Public Health Assessment Before Enforcement Decisions Are Made</i>	29
<b>Future Enforcement Trends Regarding CME Activities</b>	<b>30</b>
<b>Conclusions</b>	<b>32</b>
<i>Summary</i>	32
<b>Appendix—Biographies</b>	<b>33</b>



## Introductions

**Karen Overstreet (Overstreet):** On behalf of NAAMECC, the North American Association of Medical Education and Communication Companies, I would like to thank all the panelists for contributing their time, experience, and expertise in clarifying the legal and regulatory issues surrounding the funding of continuing medical education (CME) by the biopharmaceutical and device industries.

We are very pleased to have as the moderator of the discussion, Kenneth Berkowitz. Ken has a long history of involvement in regulatory issues affecting the marketing and promotion of prescription drugs and in providing guidance to the industry in its compliance efforts.

**Kenneth Berkowitz (Berkowitz):** We're very appreciative of the panelists taking the time to discuss this critical subject. Our purpose is pretty simple. Funding of CME by the industry is fraught, I'm afraid, with much confusion—confusion resulting from often broad and sometimes vague government and professional pronouncements, as well as differing industry interpretations of legal and regulatory requirements. It's rather interesting that this issue is not only facing government scrutiny, but is also a focus of the academic and professional communities. We will try to clarify the current legal and regulatory requirements and also take a look at a few trends.

We are pleased to have such a distinguished group of experts and commentators on this subject. Their experience and expertise reflects not only counseling on compliance for industry clients, and in some instances providers, but also representing the government in scrutinizing industry activities as former government prosecutors and officials. And that adds an extra dimension to our efforts to provide industry with this educational tool to ensure compliance with Food and Drug Administration (FDA) requirements, as well as the fraud and abuse statutes. With that as a brief overview, let's begin with introductions (see the biographical sketches in the Appendix for more information about the participants).

**Dara Corrigan (Corrigan):** I am an attorney at Arnold and Porter in Washington, DC, representing primarily pharmaceutical manufacturers, and lately I have been dealing with a number of off-label promotion issues in various contexts. I started out at the Justice Department, later as a prosecutor, and then spent about seven years at the Department of Health and Human Services (HHS), working with the Center for Medicare and Medicaid Services (CMS). My last position was as the acting Inspector General at the Office of the Inspector General (OIG) at HHS.

**Robert Malkin (Malkin):** I'm a partner at Hogan and Hartson in Washington, DC, primarily representing pharmaceutical and medical device manufacturers on fraud and abuse and compliance-related issues.

**Terry Coleman (Coleman):** I'm at the law firm Ropes and Gray in Washington, DC. I started at the FDA after I left law school. Later on, I was at the Health Care Financing Administration (HCFA), the predecessor to CMS, working on Medicaid and Medicare program issues. I currently do a lot of work in both the FDA and the fraud and abuse area with respect to pharmaceutical companies.

**Robert Sadowki (Sadowski):** I'm a partner at Olshan, Graundman, Frome, Rosenzweig, and Wolosky in New York City. Prior to joining that firm in September of 2005, I was in the United States Attorney's Office for the Southern District of NY, where I served the last four years as a healthcare fraud coordinator. In my practice now, I focus on fraud in both securities and the healthcare industry.

**Ray Bonner (Bonner):** I'm a partner in Sidley and Austin's Washington office, where I serve as Chair of the firm's FDA practice. I focus my practice on enforcement issues affecting the pharmaceutical and medical device industries. Prior to that, I was an Assistant U.S. Attorney in Maryland for about six years, where I prosecuted numerous FDA-regulated cases.

**Berkowitz:** Also joining us will be Scott Gottlieb, MD, former FDA Deputy Commissioner. While our focus will primarily be with pharmaceuticals, we would like the discussion to be a useful educational tool for the biotechnology and device industry as well.



## Commercially Supported CME

Let's begin our discussion by looking at a very general question: can industry provide an unrestricted educational grant for a CME activity to be developed to discuss medical issues such as disease states? The only involvement of the supporters is to provide a grant to an accredited provider. Any problems or risk to doing this?

**Malkin:** The answer is that they can, but you used the term “unrestricted educational grant,” and I think sometimes there is confusion around what that phrase means. Actually, I think these kinds of educational grants are usually restricted in important ways. For example, a manufacturer wants to get as much information about certain aspects of the program, such as how money is going to be used, what the topics are, what the agenda is, and what the budget is, but without influencing or controlling the content of the program. So the term “unrestricted educational grant” raises some issues. But I think the general answer to the question is, of course, pharmaceutical companies can fund educational programs.

**Berkowitz:** Do those types of restrictions, concerning where is the money going, raise any issues in terms of regulatory risk?

**Malkin:** Well, I think that when a manufacturer receives a request for educational grant funding, it should get a pretty detailed budget about what it is being asked to fund, such as honoraria for the faculty, so that it can evaluate whether it is in fact paying a reasonable amount, and reflecting fair market value for those services.

**Coleman:** To your original question about just providing a grant, of course industry can do it. The FDA encourages it. I'm sure that no one would take the position that it's improper. The issue is—the grant is never by itself. There are always other things going on with the pharmaceutical or the medical device company in addition to funding some particular CME activity. And that can be the potential problem. Are there other things going on that, when viewed in combination, the government sees as an off-label promotion scheme? While CME activities are indisputably permissible, and even encouraged by at least some of the government authorities like the FDA, you always have to look at them in the broader context to see whether there are compliance issues related to them. On the specific issue of the budget, I certainly agree with Rob that you should look at the budget to see that it's a reasonable amount that the company is funding.

**Berkowitz:** Has there ever been an enforcement action solely on the basis of a CME activity?

**Coleman:** I don't think there have been enforcement actions solely based on this. In enforcement actions, investigations and settlements, there's always much more going on. It's never CME in isolation that triggers a settlement or a thorough government investigation. In the real world, lots of things are going on at the same time and CME activities—funding of CME courses—is just part of what the supporter is doing.

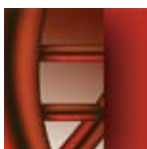
**Bonner:** That's an excellent point. When the Department of Justice is looking at a case where there's a whistleblower, generally speaking, there will be a range of activities that the prosecutor will be looking at. For example, whether it's an educational grant or unrestricted grant, however you want to call that grant, the prosecutor's going to start looking behind the scenes to determine whether the marketing or sales department was the initiator of the CME relationship. Second, how often is the marketing or sales department meeting with the CME provider? They're going to look to see if there is a business relationship that starts to develop whereby the CME provider becomes an arm of the company for purposes of some pattern or scheme that the government wants to investigate. So, I agree with Terry that this is an evolving process in which CME will be one component or practice the government looks at.

**Berkowitz:** These investigations are usually about the marketing practices of the pharma or device company. What would constitute an act on the part of that CME provider that might make it a target, other than of course, doing something like getting rid of documents?

*It's never CME in isolation that triggers a settlement or a thorough government investigation.*

*... the prosecutor's going to start looking behind the scenes to determine whether the marketing or sales department was the initiator of the CME relationship.*

*They're going to look to see if there is a business relationship that starts to develop whereby the CME provider becomes an arm of the company for purposes of some pattern or scheme that the government wants to investigate.*



*Any conspiracy or agreement or understanding between the CME provider and the commercial supporter that resulted in an off-label use being promoted and causing false claims to be submitted could provide a cause of action under the False Claims Act.*

**Bonner:** One scenario would be a situation where the government could prove that the CME provider was acting in concert with the supporter to do something that the company knew it could not do on its own. In other words, we do not have FDA approval for this off-label use. There is not very good clinical evidence, in fact the clinical evidence we have is either scant or contradictory. The use is certainly not listed in any compendium, but notwithstanding these facts, there is hatched between the company and the CME provider a plan to use CME to legitimize the use of this product off label to drive up profits. That is the complicity that the government would be looking for in that kind of scenario.

**Malkin:** In the Neurontin case involving Warner Lambert, the allegation was that the CME provider was in essence the right arm of the drug company. And I think Ray is right that this is exactly the type of scenario where one could envision the prosecution of a CME provider, where there is a possible conspiracy between the drug company and the CME provider to do things that the drug company could not do on its own. I think the government would actually find that to be quite an attractive case.

**Sadowski:** One of the provisions of the False Claims Act deals with conspiracy to submit false claims. Any conspiracy or agreement or understanding between the CME provider and the commercial supporter that resulted in an off-label use being promoted and causing false claims to be submitted could provide a cause of action under the False Claims Act.

**Corrigan:** I would add one point, which is that one huge risk for pharmaceutical companies is whistle-blowers. So many of these cases arise because of the whistle-blower, former employees. And I think the same is going to be true in this field where there is tremendous competition for huge CME dollars and so there is some likelihood that you might see a whistle-blower at a CME provider.

## CME Providers and Educational Partners

### Preferred Providers

**Berkowitz:** Suppose then, that a company has what is called a preferred provider, or you use one “vendor.” Is there anything wrong with having one source to do all your CME work—a preferred provider, for example?

**Bonner:** In terms of just one source, I would take the position that that alone shouldn't be a problem, particularly if the medical affairs or the medical education department makes that decision and is the group from the supporting company dealing with the CME organization. If it's the sales and marketing department, the question will be asked: if that's your one vendor or organization, why are you just using one? But, at some point, if that CME provider is so financially tied and its success is so financially tied to one grantor, you start to ask other questions. I'm not saying it's inherently wrong. I'm just saying it leads to other questions.

**Corrigan:** I think that raised a very important point about the way that law enforcement tends to investigate off-label promotion, which is that it isn't typically focused on one program or issue. Although, I would say that most of these cases arise out of two concerns of law enforcement: one is safety, and one is how much is the government paying for this particular drug. I think safety is why the government might look at CME programs—to see if somehow they're being used to compromise the science in any way that would benefit the pharmaceutical manufacturers. If, in fact, the CME process is being used by the company as part of a scheme for off-label promotion, and the science is somehow being misrepresented, and if company documents link CME to an off-label marketing strategy or a return on investment or some sort of tracking with the sales of the drugs, I think that's where a company faces the most risk.

**Berkowitz:** That's interesting, because other than this latest government action involving oxycodone and

*... most of these cases arise out of two concerns of law enforcement: one is safety, and one is how much is the government paying for this particular drug. I think safety is why the government might look at CME programs—to see if somehow they're being used to compromise the science in any way...*



Purdue Frederick, where safety was the critical issue, it usually seems to be utilization issues that are the government focus.

**Corrigan:** I agree. I would say that reimbursement drives most of the investigations, at least on the civil side, because they're pursuing cases under the False Claims Act. But I think as part of any law enforcement case, if you can bring in an element of a safety concern, that is going to be a much more compelling case for the government.

*... if you can bring in an element of a safety concern, that is going to be a much more compelling case for the government.*

## Provider Type

**Berkowitz:** But does it matter if the organization that will deliver the CME—the accredited provider—is a medical education or communication company (MECC) or an academic institution or professional medical society, when we look at the risks that may be raised and the need to comply? Are there different standards?

**Sadowski:** I don't think there should be different standards, but I think there has to be sensitivity when it's a for-profit provider. There's certainly a greater degree of scrutiny that could be looked at there. Academic institutions may get somewhat of a pass because of their credentials and the scientific aura and stature that they are perceived to have, whereas a MECC may be looked at with a little tougher scrutiny. So I think there has to be a sensitivity to maintain the independence, do something extra and dynamic, to provide the separation of marketing from education. That's extremely important for the private sector. But it's important to stress that CME activities can just as easily run afoul of the regulatory requirements if the accredited provider is an academic institution or other nonprofit.

*... it's important to stress that CME activities can just as easily run afoul of the regulatory requirements if the accredited provider is an academic institution or other nonprofit.*

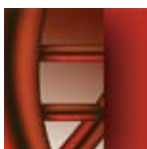
**Gottlieb:** As a physician and a consumer of medical education, I haven't been able to discern any difference myself, but I've certainly participated in CME from both for-profit and not-for-profit providers. I've never heard the FDA articulate a point of view with respect to whether they saw a difference between the for-profit companies versus the academic institutions. Intuitively, it seems to make sense that they might. The people in the agency see themselves coming out of academia for the most part, and they have more familiarity with that. So it might make sense that that sentiment would translate over to the CME context. I just haven't heard of it.

**Berkowitz:** In working with your clients, do you see any trend toward having only academic institutions or professional societies develop CME activities as opposed to MECCs? Some in the industry seem to be saying go academic and you'll be okay, but if you go with a medical education company, you'll have more problems and a much greater risk.

**Malkin:** I don't see a trend that pharmaceutical companies are only funding programs put on by academic institutions and not the MECCs, but I think there is a sense that they need to be more sensitive to the potential risks—as Rob Sadowski mentioned—because those may be more likely to be scrutinized. If you have a program put on by a corporation that some might argue really exists because of its relationships with pharma, there is likely to be more scrutiny on those types of arrangements. And I think pharmaceutical companies are understanding that and are insisting on things like firewalls and looking at them more closely. Yet, appropriate firewalls are important for any provider, be it for profit or nonprofit.

*... appropriate firewalls are important for any provider, be it for profit or nonprofit.*

**Bonner:** I don't see a trend either at this stage. It's interesting. You have to start with the premise that CME providers are there for the legitimate purpose of getting data and information exchanged. That's a good purpose. The government recognizes that. So you start with that assumption. If you become a CME provider that is viewed as being biased, or as promotional, I think the sophisticated audiences that attend those sessions won't sign up any further. These people are looking for real information, data being delivered in a professional manner, for example, the oncology sector, where there's a thirst for information on an ongoing basis. On the hospital or academic provider side, you would always ask, does this hospital have a particular agenda in terms of driving a disease state area? Are they significant purchasers of the company's product? There's going to be



*There's nothing inherently wrong with the provider being a medical education company...*

*Risk depends much more on what the underlying facts are than who is actually putting on the program.*

*The ACCME-proposed definition of commercial interest would be anyone who in any way profits from the manufacturer's sale or promotion of products. So anybody we've talked about today would potentially fall under that definition. It could be a hospital, a medical school, a publishing company, a MECC...*

*... it's worth thinking about whether this could be viewed as anticompetitive behavior, if it's in fact the case that the ACCME Board is going to exclude those who are not represented on the Board.*

a lot of factors that go into that process. So there's no perfect balance that will be achieved. Providers realize that if they don't develop responsible programs and maintain independence, people are not going to participate.

**Coleman:** I also am not aware of any trend. I view all these issues in the larger context of what is going on. And one of the problems—one of the potential issues—is who designed the activity? Who came up with the idea for the program? And was it essentially designed to disseminate information about some particular off-label use of the drug? And I think there may be a feeling that the private companies—MECCs—are more inclined to develop a program specific to an off-label issue, and then seek funding from the company whose drug is involved. And while by itself this is not a violation, it creates a situation that invites more scrutiny. Again, all of these CME situations, by themselves, probably don't create violations. But when viewed in the context of what else is going on in the company, if the government authorities can connect enough dots, they may see an overall plan. There's nothing inherently wrong with the provider being a medical education company, except that it's an additional dot to be connected. And perhaps some view academic institutions as an additional safeguard. But inherently, there's nothing wrong with it. Risk depends much more on what the underlying facts are than who is actually putting on the program.

## Definition of “Commercial Interest”

### Recent Proposal by ACCME

*Note: This discussion pertained to policy changes proposed by the ACCME in spring 2007. Final policies were published by ACCME in August 2007, but they are similar to the proposed policies.*

**Berkowitz:** I'd like to ask the panel's view with regard to some recently proposed actions by ACCME. Some background: ACCME is a nonprofit organization whose Board consists of representatives of ACCME's parents—professional medical associations (AMA and specialty groups), medical schools and hospitals, but not medical education companies. As you know, ACCME accredits organizations for the purposes of developing medical education activities that are certified for credit. The states impose licensing requirements, including the number of hours of CME credits that physicians must have in order to maintain their license. ACCME is not a governmental agency. From time to time, the ACCME will issue interpretations and revise their guidelines for accreditation. Several years ago they did that, in terms of defining what is a “commercial interest” in terms of restricting one's ability to be a provider. Very recently, the ACCME has proposed for comment another interpretation of “commercial interest.” That interpretation would appear to essentially eliminate the ability for many MECCs to be accredited as providers of CME. It would have that effect as they would be considered as a commercial interest if they or someone in their chain of parents or affiliated companies did advertising, speaker programs, or any type of marketing activity for a pharmaceutical or device company. Therefore, a provider would in essence be defined only as the medical schools, professional associations, hospitals, or other groups that are represented on the ACCME Board.

While this is a little bit far afield from fraud and abuse and FDA regulations, it's an interesting development that will affect the CME area, and I wondered if the panel has any views with regard to the ACCME proposal.

**Corrigan:** The ACCME-proposed definition of commercial interest would be anyone who in any way profits from the manufacturer's sale or promotion of products. So anybody we've talked about today would potentially fall under that definition. It could be a hospital, a medical school, a publishing company, a MECC; however, the ACCME exempts all providers from this new interpretation, except for MECCs.

**Malkin:** Well it would be a rather drastic step. It's clear that the ACCME has always had some concerns about MECCs. While I am not an antitrust expert, I think it's worth thinking about whether this could be viewed as anticompetitive behavior, if it's in fact the case that the ACCME Board is going to exclude those who are not represented on the Board.

**Gottlieb:** It will certainly have a practical effect of eliminating the amount and scope of medical education that can be in the marketplace, because, I don't think, the medical institutions themselves can dramatically expand the amount of medical education they provide. So without these companies being involved, you'll have less CME. My understanding is that the MECCs that engage in CME have significant firewalls set up internally to keep the various parts of their companies bifurcated. I would suspect that there might be ways to look at just auditing that and making sure those kinds of things are in place before you take such a drastic step.

## All Providers Should Have Firewalls

**Berkowitz:** The firewall concept has been applied by MECCs but may not be a concept that's been applied to other providers, like medical schools. If the firewall concept is important for independence, shouldn't it be applied across the board to any provider that performs CME?

**Gottlieb:** I think you're right. I think the point is valid that the rules should apply to everyone—including academic providers. Just by virtue of the fact that they work in academia or a specialty society or hospital, they aren't immune from the same kinds of potential influences and problems that may exist in a MECC, although, sometimes it's argued that they are. I don't think it's any different.

**Malkin:** And while there may have been subsequent statements from ACCME officials saying that what they meant was companies need to have adequate firewalls, clearly, that's not what the ACCME proposal says on its face. That would need to be spelled out very clearly.

**Corrigan:** It's troublesome that in other policy statements of the ACCME, they give a pass to hospitals, medical schools, specialty societies, insurance companies, government agencies; they basically give a pass to everyone but MECCs.

**Coleman:** It's one thing to be concerned about if, as in the past, pharmaceutical companies sometimes set up a subsidiary that was an accredited provider. But should the ACCME's new interpretation apply to a MECC with an appropriate firewall that insulates medical education activities? It seems to be a very extreme position that would not be reasonable.

**Malkin:** From a fraud and abuse standpoint, it seems like it's overkill. It looks like a fix that really is extreme.

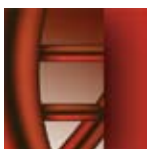
*... the rules should apply to everyone—including academic providers. Just by virtue of the fact that they work in academia or a specialty society or hospital, they aren't immune from the same kinds of potential influences and problems that may exist in a MECC...*

## Separating Education from Promotion

**Berkowitz:** What about firewalls for providers who develop medical education and non-CME activities? For example, such a provider may be part of another organization, or do things other than CME. They may do speaker programs or other types of promotional activities. Also, various pharmaceutical companies have different interpretations of the so-called "firewall" requirements. Some may require rigid physical separation—promotional and CME groups need to be in a separate facility or they need to have a separate computer system, they need to have a separate staff involved so they can't, in any way, be influenced by people who do ongoing marketing activities. In your experience with your clients, have you run into this issue of firewall separation of education from marketing or promotional activities?

**Coleman:** No, I have no experience with that, although it seems to resemble a lot of the same issues like separating marketing from medical affairs. My guess would be that there are no hard and fast rules about how to create a firewall, it's a question of assessing if the government were to look at this, do you have a strong case that you are in fact maintaining independence? People probably have various views about how strong

*... there are no hard and fast rules about how to create a firewall, it's a question of assessing if the government were to look at this, do you have a strong case that you are in fact maintaining independence?*



*Clearly, the key is a separation of personnel who are working on promotion versus those who are working on CME.*

that case should be, how conservative you ought to be, and I can certainly see how those kinds of criteria would develop among people who were worrying about the situation. In sum, however, like all these situations there are no hard and fast legal requirements to apply. What everyone is doing is simply looking at the possibility of government scrutiny and deciding what degree of a firewall, what degree of independence, is needed to make this look good in case the government inquires.

**Malkin:** Clearly, the key is a separation of personnel who are working on promotion versus those who are working on CME. But, as Terry says, there are no regulations that tell us how to separate those things, and so companies develop their own criteria. Certainly coming up with a checklist—maybe different e-mail systems, different telephone systems—is one way that a company can get comfort that there is actually an effective firewall in place.

**Berkowitz:** Let's explore further separating personnel who work on CME and non-CME. Does this just relate to those dealing with content and interaction with the faculty, or would that separation apply to personnel in the IT department, the HR department, meeting planning and logistics? Is it all personnel or just those who relate to content?

**Malkin:** Unfortunately, I do not think there is any clear answer. Without the benefit of some guidance from the government, it is all just going to be on a risk continuum. The more everybody is separated, the safer it is going to be. If you have the key content people separated that is certainly going to be the most helpful thing, but it is just one factor of many that could be examined.

**Berkowitz:** Do any of you recall seeing any CIAs discuss firewalls relating to providers? Do they ever get into that detail in terms of conducting CME programs or funding by the commercial supporter?

**Sadowski:** I am not aware of that, but a firewall is one of those things the government may look at just as it might look at whether there is a CIA in place and whether the terms are being respected. If it is not, it is an indication that the firewall or the CIA is just window dressing and that is very troubling to the government. It is going to raise a specter that the company is not concerned about compliance issues even though they have a firewall, even though they have a CIA. That raises the hackles of a prosecutor that there may be a culture there that fosters illegal activity.

*I do not think that any of the corporate integrity agreements have gotten to that level of specificity about CME providers' firewalls.*

**Malkin:** I do not think that any of the corporate integrity agreements have gotten to that level of specificity about CME providers' firewalls. Maybe they would if there were ever a case against a CME provider, but I do not think that issue is addressed in the pharmaceutical company CIAs. They simply say that your CME funding should be independent and there may be some specifics in terms of what the independent review organization (IRO), the outside organization that has been retained by the company to check on its compliance, is supposed to look at when it is auditing those types of arrangements, but I do not think they have ever stated specifically what an effective firewall would be.

## ***Institutional Conflicts of Interest***

**Berkowitz:** What about firewalls and separation issues for academic institutions and specialty societies? For example, an academic institution could be doing clinical trials related to an investigational use of a product. What are the risks if they are doing that clinical research for a pharma company and also receiving funding from the company for CME in that same area?

**Bonner:** Let me start with the investigator's approach. Whether it is a medical education company, an academic institution, or a hospital, what they are going to look at is what the financial relationship between the supporting company and the CME provider is. You probably already have some built-in relationship if the institution is

a purchaser of the supporter's product. So right away, my instinct is to say that purchasers are going to get more scrutiny. Also, if a pharma company is trying to arrange for CME with a hospital that is a purchaser of its products, the hospital or institution better make sure that it has a firewall between the purchasing department and its CME department. You certainly do not want simultaneous discussions going on in terms of purchasing and price and other things of value being given to the entity. I think inherently there are some issues that you have to focus on immediately in the hospital purchaser context.

**Malkin:** Those are good points in that there are absolutely issues to be addressed with CME grants to academic institutions and hospitals. It is a slightly different issue, though, because academic institutions and hospitals are usually not doing the same type of promotional, or what we think of as traditional promotional work, as some medical education companies or related companies might be engaged in. But the bottom line is that all of these relationships raise potential issues under the antikickback law. An example is the TAP Pharmaceuticals case, where one of the circumstances was a grant, an educational grant of \$65,000 to a health system. It was alleged by the government that the grant was offered in lieu of a lower price on the product. So with regard to an antikickback problem, it can occur regardless of what type of entity you are, whether you are an academic institution or a medical education company.

**Sadowski:** I think the fundamental things that the company needs to look at are whether there is a fair market value to the grant and what the researcher-physician is going to be doing to earn that grant. I do not think academic institutions by any means have a pass. They have an imprimatur that their work is going to be peer reviewed, but again that is just window dressing. The investigator is going to look behind it to see if the grant recipient is actually doing work that earns the kind of dollars that are being offered to the institution. For example, the chair of the psychiatry department may receive a huge grant, and the question will be whether the work of the department really supports the kind of money that is being given to the institution.

**Coleman:** Let me suggest to you why some pharmaceutical and/or medical device companies may feel that an academic institution provides less risk. Take as a scenario, but not a totally unrealistic one, where the pharma company has a potential off-label use of its drug—a very widespread off-label use. While they see that as a potential source of increased sales, they know they cannot promote it. And so they want to have a marketing plan that takes advantage of legal methods of getting out information about the off-label use, but avoids promotion. The marketing plan may identify supporting CME as the vehicle for increasing sales of the drugs. People in the company would understand that having CME activities in this therapeutic area is likely to, even if it is not funded explicitly for disseminating information about the off-label use, inevitably get around to discussing this important off-label use.

The question then is how to make sure that it is not promotional because promotion is illegal. And so we want this CME to be as pure as possible about this off-label use. We want to stay on the legal side and not do anything that is promotional. We want to maintain complete independence from that provider so that none of this can be attributed back to us as having been our effort. We do not want the CME provider to be seen as our agent. Based on such a scenario, if you are concerned about not crossing that promotional line, if you are concerned that you want to support CME, but you want it to be seen as not promotional, you may well take the position that we have to build in various safeguards against the perception that the grantor is doing something promotional. On one hand we could have Johns Hopkins do these programs. On the other hand we could have a medical education company be the provider. Which looks safer to us? One can see a company reaching the conclusion that they would be better off having the University of Chicago or Johns Hopkins do these programs because the prosecutor might see them as less likely to be an agent of the pharmaceutical company than some for-profit provider that appears to make its business by serving pharmaceutical companies. So from that perspective, I can see the supporter's perception that it is less risk, but as my colleagues have discussed, it may not be.

**Berkowitz:** Is that situation changed at all when Johns Hopkins or the University of Chicago uses a medical education company to essentially develop the activity under their guidance?

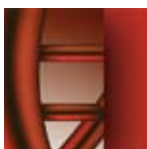
*Also, if a pharma company is trying to arrange for CME with a hospital that is a purchaser of its products, the hospital or institution better make sure that it has a firewall between the purchasing department and its CME department.*

*Those are good points in that there are absolutely issues to be addressed with CME grants to academic institutions and hospitals.*

*So with regard to an antikickback problem, it can occur regardless of what type of entity you are, whether you are an academic institution or a medical education company.*

*They have an imprimatur that their work is going to be peer reviewed, but again that is just window dressing.*





*... prosecutors have been increasingly pursuing cases against academic institutions. When they are going after the Mayo Clinic and Yale, I do not think there is any reason in a prosecutor's mind why academic institutions are not subject to scrutiny.*

*... traditionally academic providers have not had the controls that often are in place with MECCs.*

*I think the time is ripe for institutions to really examine themselves to make sure that they are not going to be subject to an investigation, and by the same token manufacturers have to be aware of the potential risks facing academic institutions and factor that into their risk analysis.*

**Coleman:** If I were in the company, I would say at least we have this intermediary and that was the University's decision, not ours, to use this provider. So, when the Government shows up on the doorstep, we will say we hired the Department of Medicine at the University of Chicago to do this. What they did was up to them, that was their decision, not ours. The company may feel more protected in that situation.

**Corrigan:** I have two thoughts here. One is that prosecutors have been increasingly pursuing cases against academic institutions. When they are going after the Mayo Clinic and Yale, I do not think there is any reason in a prosecutor's mind why academic institutions are not subject to scrutiny. And the reason I think that is particularly risky, not only for the academic institution but also pharmaceutical manufacturers, is because traditionally academic providers have not had the controls that often are in place with MECCs. If there is an investigation, whether it is in the off-label promotion world, or grant funding for example, which has been the subject of numerous cases recently, the academic institution's reaction to that is, "for goodness sake, we are doing the most important research in the world and we are above reproach and why are you imposing all of these expensive requirements upon us?" There has been that level of almost disbelief that law enforcement could go after an academic institution. I do not think you can take any comfort anymore just because you are an academic institution. I think the time is ripe for institutions to really examine themselves to make sure that they are not going to be subject to an investigation, and by the same token manufacturers have to be aware of the potential risks facing academic institutions and factor that into their risk analysis.

## Issues for Commercial Supporters

### Solicited Grants

**Berkowitz:** Having explored the issue of "accredited provider," let's now look at some scenarios and potential levels of risk. A healthcare company sends out an invitation to bid to various providers. The correspondence notes that the company is seeking to fund a certified activity on new developments in the diagnosis and treatment of cancer. The company receives several responses, and they choose a provider to put on a continuing education program. Is that action by the company to solicit grants concerning a specific therapeutic area appropriate?

**Coleman:** I think that's a low-risk situation. The mere fact of that solicitation is not a problem. The fact that they have expressed the topic in such broad terms, and assuming that they then don't scrutinize the precise agenda of the meeting, I think that's quite a low-risk situation that you have positioned there.

**Berkowitz:** Is there any difference in risk if, instead of soliciting, they just sit back, and the same thing comes in through the mail? A provider says we're interested in putting on a meeting on the same subject—diagnosis and treatment of cancer—would you be interested in funding it? Is there any difference in the level of risk?

**Coleman:** Well there you get into a situation of what the company knows about the providers. I would say the ultimate answer is no: there's no difference in the risk. But if a provider is known to the company as someone who will tailor a program to the supporter's satisfaction, then potentially it's a greater risk factor when looked at after the fact. But, from the scenario you described, no, I don't think it matters where the solicitation started as you positioned the original scenario with a very broad therapeutic area as a topic. Of course, the real question is, what goes on below the surface? Is there some sort of an understanding there on more specific issues that will be covered?

**Malkin:** I think there may be at least a slightly decreased risk when the company just passively receives grant requests as opposed to actively soliciting them. I agree with Terry that it really depends on the underlying facts and what the intentions and motivations of the company are, but if the company is soliciting grant requests specifically, there could be an inference drawn that it's attempting to somehow control the content. Certainly, we haven't heard any indication of that actually going on in your hypothetical scenario, but if somebody were to scrutinize it, they could look at that.



**Corrigan:** The questions in this area remind me of similar issues that are being raised with patient assistance programs that used to be sponsored by the manufacturers. The reason I draw the analogy is that the Inspector General's (IG) office has looked at CME programs—they've looked at patient assistance programs—and their preferred model for patient assistance programs is to have a 501(c)(3) (nonprofit) foundation. Similarly, I think if you ask the IG's office, their model for CME would be no participation by pharmaceutical manufacturers. But I think in both areas they're willing to accept the idea of an independent, or intermediary, between the pharmaceutical manufacturer and the ultimate goal, whether it be patient assistance, or CME. But it does get down to what we've been talking about already, which is, what actually happens? For patient assistance programs, a lot of it comes down to how you're defining the disease state. And I think there's a parallel to CME where you look at the content and you see whether it is oncology or whether the content is designed, really, to focus on a specific cancer diagnosis or drug. In the patient assistance program context, you are looking at any interaction between foundations and pharmaceutical companies that might be inappropriate in some way where there's a commercial link. And there's a similar concern on the CME side, where you're going to look at the monies paid, what they're for. I think that those are the questions that will play into the amount of risk a company is undertaking, whether it's accepting a grant request or putting a bid out there.

*I think there may be at least a slightly decreased risk when the company just passively receives grant requests as opposed to actively soliciting them. I agree with Terry that it really depends on the underlying facts and what the intentions and motivations of the company are...*

**Bonner:** I think at a very practical level, you can look at either scenario. A pharma company or a medical device company is going to look at a situation and say, who is this provider? How long have they been in the business? What's their track record in terms of how many activities have they developed? Who participates? How many physicians attend? They're also going to ask, what types of faculty participate? Are you getting the thought leaders of great eminence, or is this the third or fourth team that shows up at your conferences? That's the kind of information I think companies look for because they want that legitimacy around the activities they're going to fund. What it comes down to is, is it a real scientific and data exchange? In the oncology sector, that's crucial for many reasons, because I think the presentation of that information is critical in terms of the possible use of that product in different areas, often a life or death decision.

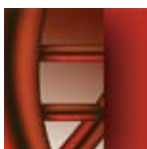
## Recommendation of Faculty

**Berkowitz:** Can we better define the line in terms of what a company perhaps can and cannot do, with regard to CME? Putting aside the grant-making process for the moment, although we will return to that in terms of where it should be located, let's look at the role a pharmaceutical company can have in responding to inquiries from the provider about the faculty. What type of flexibility is there? The company is not saying we want you to do this and here are the people that you must have as the speakers. I think we'll all accept that that's something that should not be done. But let's assume the grant request looks pretty good, a qualified provider is selected, and now the provider is developing an activity on oncology. The provider now comes to the supporter and asks do you have any recommendations or do you have any contacts with regard to faculty who we might choose to participate in the CME program? Is this appropriate?

**Corrigan:** I don't think asking for recommendations about faculty, by itself, is inherently problematic. I think what happens though, is the pharmaceutical manufacturer has to examine its existing ties with the speakers that it's recommending because if in fact it has a preexisting financial relationship, where they've been providing financial support through consulting or speaker fees, then it's going to be more suspect. But as you described it, I don't think that recommending speakers is necessarily inherently of huge risk. But the supporter is going down the risk continuum as it starts getting involved in the program.

*I don't think that recommending speakers is necessarily inherently of huge risk. But the supporter is going down the risk continuum as it starts getting involved in the program.*

**Berkowitz:** Very interesting. Let's explore that a little bit. Suppose now I'm your law firm's client. I call and say we made a grant for CME at this terrific, major oncology society annual meeting, and the provider has asked us to recommend speakers. And the top person in the field is Dr. Jones and we pay Dr. Jones \$150,000 a year as a clinical consultant. Our compliance people are telling us, as much as he'd do the job and he's terrific, he's a recognized key opinion leader, so stay away from him for this program. And they're asking you for your advice.



Medical affairs people are saying he's the best, but yet we know the environment and we're very concerned. What type of advice would you give your client in that situation?

**Corrigan:** It's important to me that the question is coming from medical affairs. And my assumption is that medical affairs, on the clinical side of a pharmaceutical manufacturer, is the right spot at the company; they are in a position to know who the thought leaders are. In my risk assessment, it would matter how much they were actually paying that physician on an annual basis. In my experience, \$150,000 is not a huge amount in comparison to other real examples that I've faced. I would say that the manufacturer is assuming a risk, but if it is outweighed by the scientific credentials of that particular speaker, I think that risk can be managed by the manufacturer.

**Sadowski:** I think that's absolutely right. The risk can be managed. And one of the ways of doing that, for example, is making sure there's a strong showing of fair market value to the payment that's being made to the faculty. Obviously, if you have known speakers or authors who are highly regarded in the industry, that gives a certain degree of comfort. So I think there are plenty of ways to manage the risk. What the government looks to in these kinds of cases is, is there an underlying current? Can the evidence be put together that there is something that we haven't really talked about yet—is there an attempt by the marketing department to utilize CME in a way that the government finds objectionable?

*Disclosure cures a lot of issues when it comes to potential fraud.*

**Bonner:** Ken, I think you've essentially described. Dr. Jones as kind of the Tiger Woods of this specialty. I agree with Dara. I think the analysis has to be if this person is in fact the best person who can talk about these issues, even if there's an underlying financial relationship, you can still make sure that when he speaks—or she speaks—there's disclosure. Disclosure cures a lot of issues when it comes to potential fraud. If you're upfront, and this is truly Tiger Woods, and everybody realizes that this is a person who needs to be at this conference, and you disclose that financial relationship, I think you're in much better shape. Is there always risk? Sure, there's always risk, but I think the disclosure will cure a lot.

**Berkowitz:** And then the opposite of that is, if there is no disclosure, it really would raise the level of risk?

**Bonner:** Yes, a lot of the various guidelines and standards are predicated on disclosure. If you had a significant relationship of a million or two million dollars a year, in terms of this doctor consulting with the company, then questions are going to be asked. Is there something else going on here? That's why, in most typical scenarios in terms of advising clients, this question comes up. The approach is, why don't you provide a list of top-flight people, rather than just one name?

**Berkowitz:** On the issue of choosing experts, does it matter if the expert you recommend is your employee? Suppose he's in your clinical department, and let's assume disclosure. Are we notching the risk up a little bit if the person is an employee of the pharmaceutical company, even though that will be disclosed, that Dr. Jones is, for example, the head of clinical affairs?

It's an approved product, but let's discuss two scenarios. One, Dr. Jones will stick strictly to on-label uses. Secondly, he'll discuss in some detail that the company is doing various studies that are exploring the potential uses of this product in other, unapproved disease states. He won't make representations that it is safe or effective, and will say these are not approved uses. Let's accept that if he starts promoting off-label use of the product, saying it has been shown to be safe and effective in the various trials we've done, we're going to increase the risk significantly.

**Coleman:** Well, if he sticks to the approved labeling, I don't see a problem at all. Even a sales rep could do that and it would be fine. To the extent that he's talking about investigational work you're in the gray area. You obviously cannot be promotional, yet the FDA rules allow for scientific exchange. And in your scenario where he wasn't describing safety and efficacy conclusions—he was simply describing the ongoing studies—that can possibly be done. It makes a lot more sense if they are his own studies. If he was the investigator and he

simply is at a scientific conference, reporting the results of his own work in an objective way, that seems to me that's scientific exchange, assuming it's a scientific conference. But if it's not his own work, then you certainly ask the question why is he doing this? Isn't there someone else that could be doing this, rather than to have the employee of the company discussing someone else's work? It's not a course of action that I would see as the best possible course.

**Bonner:** In a follow-up on Terry's point, I don't think that's a typical scenario, unless you authored a study. I think companies would be fairly reluctant to do that. I think the more common situation would be that you're at a scientific or medical gathering, and the purpose is to discuss, in a scientific context, recent results or data. Then there's going to be a peer exchange of information from a science or data standpoint, and I think it has legitimacy. There's no sales, there's no promotion—you're not there for that purpose. The only situation I would get concerned about is if the employee of the company is not at just one conference, or two conferences, but is there as a regular speaker. Then you're wondering, what's really going on here? Is there an agenda behind the scene? Is he really just promoting new uses? I think that's the concern.

**Malkin:** So the bottom line is, I think we probably all agree that it does move things along the risk continuum a little bit, and I think some companies believe it moves it enough that they, in their policies, do not permit their own employees to speak at CME events.

**Berkowitz:** I think you all summarized it well, that unless there is some documented reason why this employee must be there, or can add significant value, the better direction would be to have an outside speaker.

## Review of Content

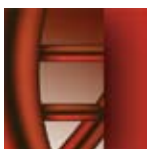
**Berkowitz:** Let's move on to a more difficult or grayer area, and that is content—any possible role that commercial companies—device or pharmaceutical companies—can have concerning content. Suppose the accredited provider says that this is what's going to be presented. We would like your scientific input to ensure medical accuracy. How do we feel about that if the provider is now approaching the commercial supporter?

**Coleman:** I think that's a relatively common practice, but it's the kind of practice that makes me nervous. If the supporting company looks at the slides and doesn't make any comments or makes the most trivial comments, then there should be no problem. But suppose they suggest some significant changes, all in the theory of technical accuracy, and those changes are made? If the changes elevated the way that an off-label indication was discussed, for example, it's a real risk. It carries a potential risk if there are significant changes that result from that interaction.

**Corrigan:** I agree with Terry, that this is slipping much farther down the risk continuum. In theory, if a manufacturer's clinical or scientific staff reviews the content, it would be viewed as ensuring the scientific accuracy of the information being presented. However, I think there's an inherent skepticism on the part of law enforcement and the FDA that you're venturing into areas where the manufacturer's dictating content. And I don't know where that line is, which makes it harder for me to advise clients that there's no risk. I mean, is it okay if they have a red line markup of the slides? Is it okay if they simply comment on the slides? I think the more you're going down the line of red line changes and back and forth with the provider, you're going into very risky territory.

**Sadowski:** I think that's absolutely right. You can manage the risk, but you're moving into an area where you're creating a record that the government could scrutinize. If you have red line versions of a critique of presentations or input and comments by individuals that are not well thought out, there is a record there that the government will scrutinize. And it's very easy with enough of that kind of input and comment for the government to start to make a case that something inappropriate is happening.

*In theory, if a manufacturer's clinical or scientific staff reviews the content, it would be viewed as ensuring the scientific accuracy of the information being presented. However, I think there's an inherent skepticism on the part of law enforcement and the FDA that you're venturing into areas where the manufacturer's dictating content.*



*The more the supporter gets involved in terms of the content of the program, the more risk there is.*

*... are companies being put in a catch-22 situation? If they review the content, there are issues relating to independence and possibly fraud and abuse. If they don't, there could be product liability implications.*

*It would seem to me that if a company took the position that it never reviewed content, it's hard to see how they would have significant risk in the product liability area.*

*I've seen some SOPs that go as far as saying when the commercial supporter can review material, who at the company can review, and in what circumstances. Usually, it is only for its own products, for medical accuracy, only to be reviewed by medical affairs people.*

**Bonner:** I think everybody that's spoken is focused on the key issue here, and that is this is supposed to be independent CME. The more the supporter gets involved in terms of the content of the program, the more risk there is. The other thing you have to consider is the safety aspect. Let's say, for example, you're reviewing a slide deck. You red line that slide deck, and at the same time, there's discussion about toxicity or some other adverse event report that's out there, and you, as the company, know more—or should know more—and you have not included that information as part of your markup. You not only raise issues on independence, but also in terms of disclosure of safety-related information. And those are the cases I think the government focuses on, where there's a lot going on in terms of the product presentation. There may be other problems as well.

Let me give you one other example. Let's say a slide deck is sent to the supporter for review—and it indicates that there's an impeccable safety record. Yet the company knows that there's a trend in terms of adverse event reports, let's say, from one area in Europe. Maybe the label's slightly different in Europe than it is in the U.S., but you're starting to see a trend and there's some epidemiologic data that suggests some issues. In that situation, if you looked at that slide deck, wouldn't you have an obligation to correct that in terms of at least presenting to the CME provider that information? That would be one situation from a product liability standpoint, where I think if you didn't reference that information, you would be criticized.

**Berkowitz:** From what has been said, are companies being put in a catch-22 situation? If they review the content, there are issues relating to independence and possibly fraud and abuse. If they don't, there could be product liability implications.

**Coleman:** It would seem to me that if a company took the position that it never reviewed content, it's hard to see how they would have significant risk in the product liability area. Maybe there is an issue if a company has a practice of customarily reviewing slide decks, and they don't want to create an exception, that could be held against them. Suppose they reviewed 50 slide decks, but one particular provider didn't want it to be reviewed by the commercial supporter. So it would be the 51<sup>st</sup> they would not have reviewed. And if there's a problem with the content, then they could be seen as having deviated from their customary practice.

**Berkowitz:** These areas that we've been discussing—selection of faculty or experts and content—are guidelines established in company SOPs. A companion question is, based on your experience with Corporate Integrity Agreements (CIAs), is the government requiring specific limitations on content or speaker input for CME programs?

**Malkin:** In terms of the SOPs, I think yes and no. Larger companies are certainly addressing these issues. It's a question of the degree of detail that they get into and about what the company can do in terms of reviewing the material. I've seen some SOPs that go as far as saying when the commercial supporter can review material, who at the company can review, and in what circumstances. Usually, it is only for its own products, for medical accuracy, only to be reviewed by medical affairs people. We see some smaller companies that simply have a statement that sales and marketing is going to be removed from the grant-making process. So it really runs the gamut. But yes, I think these issues are being addressed in SOPs, but the question is, to what degree?

**Bonner:** Picking up on the earlier question, would anybody here have a problem in terms of the medical affairs or scientific affairs department reviewing content? I think the issue is influence. But if you have somebody from medical or scientific affairs, under the FDA's Guidance, where that's compartmentalized separately, does anybody have any issues with regard to those groups reviewing slides before the presentation?

**Coleman:** I believe it is the same potential risk. The mere fact that it's someone in medical affairs as opposed to marketing that beefs up the section on off-label use, assuming the worst case scenario, I don't see how that would salvage the situation. On the other hand, it certainly looks better if it's someone from medical affairs doing it, as opposed to someone from marketing, even if they both have the same knowledge level. From

just an appearance standpoint, it looks much better. So to your question, Ray [Bonner], I guess I still see a potential risk regardless of who does it, but it's obviously much better for it to be done by medical affairs.

**Sadowski:** Yes, I think cosmetically, it will look much better if it's medical affairs, but I think any prosecutor would look behind that to see what is really the content that's being influenced—what goes behind that—and whether medical affairs has taken on a role of marketing. Then you have a serious problem; you ratchet up the risk, even though there's some window dressing on it that looks good. If the compliance program that's in place, or the SOP that's in place, is dynamic, and there's a real effort to have medical affairs really engage in only medical affairs activities, you're in a much better position, but again, it's a matter of content and substance. I don't think the window dressing will change anything.

## ***Structure of Commercial Supporters***

### **Medical Affairs**

**Berkowitz:** Does it matter to whom medical affairs reports? Suppose medical affairs reports into the business, as does marketing? Does that in any way change things?

**Bonner:** I'll use the analogy of good manufacturing practices, or quality control systems. The FDA likes to see the quality assurance department reporting into somebody else other than the manufacturing head. There is perceived tension where manufacturing may try to control the decision-making process. If you want to create real independence and get away from the promotional side, I think the smart thing to do is to have medical affairs reporting to somebody other than marketing. What that also means is that marketing doesn't control the budget, which is critical in terms of the division of responsibility within a company.

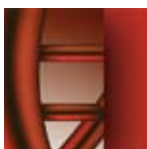
**Berkowitz:** Is it a better scenario for medical affairs to report into Research and Development (R&D), as opposed to marketing, or reporting directly into the business?

**Coleman:** Not all companies have an R&D unit in the United States. These organizational issues only become critical after the fact, if something went wrong. So when you talk about organizational issues, I think you're talking about prophylactic issues, and if it's not convenient to put them over in the R&D group—it's not something that I would view as being a high priority.

**Corrigan:** Terry is exactly right that the examination is going to occur after the fact. For example, it isn't really necessary to have a compliance officer at a company if you're complying with the law. It's recommended and it is the best way to conduct business, but you don't have to do it. There's not an absolute requirement unless you're under a CIA. The preferred method is to have the compliance officer report directly to the CEO. All companies don't do it that way. There are a wide variety of ways that companies, and in particular device companies and smaller pharmaceutical companies, are able to manage their medical affairs department. It could be one person in medical affairs and one person in the marketing department. And it's much harder in that sense to segregate in any way that would absolutely protect the company. As you get into a larger organization, it is easier to put medical affairs in R&D, and that probably is safer. But I would agree with Terry that imposing some rigid structure doesn't necessarily protect the manufacturer.

*... the smart thing to do is to have medical affairs reporting to somebody other than marketing. What that also means is that marketing doesn't control the budget, which is critical in terms of the division of responsibility within a company.*





*In the last several years, it [grant making] has moved from the marketing group over to something like medical affairs, clinical affairs or the educational department. It's been a little bit of a slower move for some of the smaller drug manufacturers and also for the device companies. They're catching up now...*

## Grant-making Process and Participants

**Berkowitz:** In your experience, where do you find the grant-making and budget responsibility for CME?

**Malkin:** In the last several years, it has moved from the marketing group over to something like medical affairs, clinical affairs or the educational department. It's been a little bit of a slower move for some of the smaller drug manufacturers and also for the device companies. They're catching up now, moving a little bit more slowly. As far as the funding, same thing, for some companies, moving from marketing to medical affairs.

**Bonner:** What I see in terms of trends is that companies are now very concerned about grant money, and so what they've now done is to establish a real grant committee, with a legal and compliance person on that committee. In other words, everybody has a seat at the table. There's a real review process; controls are in place. Companies are centralizing it largely because of compliance concerns. One of the views held by some in the Department of Justice is that unrestricted grant money that was given out with regularity was the equivalent of cash payments. And so companies have moved to establish real controls on the process.

**Berkowitz:** Does marketing have a seat at that table?

**Bonner:** Typically, yes. But it's more of a democracy than one group having the dominant voice.

**Corrigan:** That is my experience as well, although I think there is a difference between companies about how much influence marketing actually has at the table. Sometimes marketing still has a significant say because of the evolution over time when grants came out of the marketing department. There still is an evolutionary process going on in really trying to extricate the influence of marketing—not that it doesn't have a place at the table, but equalizing the influence across the board.

**Berkowitz:** Do sales people still have a role?

**Sadowski:** There's certainly no blanket approval nor inherent prohibition on sales people offering information, given what they know about the industry and the physicians that are out there who make good candidates for a CME program. As has been said, there needs to be a democratic process so that there's a vetting of the objective, scientific criteria to ensure that faculty recommendations from sales, for example, have a seal of approval from the entire panel including medical affairs, not just the sales people.

**Berkowitz:** Does the involvement of the sales person increase the level of risk?

**Sadowski:** Of course, there's a level of risk, because you don't know what's going on between that sales person and the particular individual (possible faculty) or program that they're proposing. That's where the company has to, again, look behind what the sales people are doing, and assess the risk and potential problems that might be behind a sales person suggesting a particular activity or faculty person. That's what the democratic process is there for in the grant-making process.

**Berkowitz:** That is interesting because it seems that if there's one group government dislikes more than marketing, it's the sales force.

**Bonner:** I think sales people are going to have a lot of important information. They're going to be learning on the ground, what's happening in the real world. Do they have an interest in terms of the sales component? Yes, and you can't ignore that. I think the key component is that they can have input, but not be the final authority.



**Coleman:** In the usual situation, the marketing group already knows what the sales people know. And if sales people identify key opinion leaders, that's already known to marketing, for reasons unrelated to CME. So I would think it's not necessary to involve the sales people. And if it reduces the risk not to involve sales personnel—which it might—why involve them?

*... if it reduces the risk not to involve sales personnel—which it might—why involve them?*

**Corrigan:** I think Terry is right, though some companies try and make what I believe is an artificial distinction between sales and marketing. I have been asked if some sales functions are moved to marketing, will that protect the company? In my view, in general, law enforcement lumps them together. It's sales and marketing. It isn't simply sales. That said, I have had the experience where if the sales force wants to have some input into the process, they have to report whatever they want to marketing, which is what Terry is talking about. Sales and marketing work so closely together that an independent role for sales may not be that important to the company overall.

**Bonner:** Let me use a practical example. Let's say a CME event takes place in the Philadelphia region, and the event is well received. Afterwards, a sales rep who is going to a number of practices in the area hears from a couple of physicians that, yes, it was a good event, I got a lot out of it, but on the other hand, I was surprised that Dr. Jones, from down in Wilmington, was not invited. Well, if you hear that one or two or three times, you might want to communicate to your marketing people that Dr. Jones from Wilmington is highly regarded and people were wondering where he was. There's nothing wrong with that kind of process, and I think that's what happens in some of these practical situations.

**Malkin:** There are also opportunities for sales reps, who are the ones on the front line, to be identifying what may be the educational needs of the doctors they're calling on. So there's certainly a role for them to identify those types of things on a macro level, in which case they're not really identifying specific doctors. They're just helping out generally in this whole process.

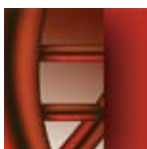
## Marketing Documents

**Berkowitz:** We have spent a good deal of time talking about the government investigator's approach. It seems that in an investigation the government is always very interested in looking at marketing documents to see what the manufacturer did and why.

**Bonner:** Marketing plans get a lot of attention. The reason is that the government focuses on the fact that upper management authors those plans to show the goals for a particular product. One of the things that companies are spending more time on doing, both compliance and legal, is reviewing those marketing plans. Both compliance and the legal departments of companies are trying to make sure from the start that activities are handled appropriately. It is where providers will be sought out by the government through subpoena or testimony to determine whether or not that plan was executed. It is where the interplay between the pharma and medical device companies and the CME providers kick in.

*... providers want to be careful about how they describe their own intentions and marketing objectives the same way that pharma companies have to be careful about how they articulate their objectives and goals.*

**Coleman:** While damaging things show up in the documents at the pharma companies under investigation, the same thing could be theoretically said about a CME provider. For example, suppose providers had all kinds of internal documents including marketing plans about putting on CME related to a particular off-label use. I would think providers want to be careful about how they describe their own intentions and marketing objectives the same way that pharma companies have to be careful about how they articulate their objectives and goals.



## ***Multiple Supporters***

**Berkowitz:** Have you seen instances of your clients moving more towards multiple supporters for CME? In other words, do they think that there is safety in numbers and that if they can get two or more companies to fund CME programs that the risk would be less?

**Malkin:** I actually have seen some companies look to ensure that they are not the sole funder of a particular program, and they ask the CME provider who else is participating. Presumably, it is so that they are not viewed as somehow “highjacking” the program and controlling the content. They view that as a decrease in risk as you move along the risk continuum.

**Coleman:** I agree with what Rob [Malkin] said. I think a proposal from a provider is regarded as less risky if there are multiple supporters. I have not seen the situation where the supporter seeks out another company to develop a joint program. It is more the situation where the provider is seeking funding from multiple sources and companies do feel comfortable, at least slightly more comfortable, in that situation.

## ***Evaluations and Outcomes***

**Berkowitz:** What about any activities the commercial supporter might be interested in pursuing to be sure that the program met the educational goals and objectives? Have you had any experience where the commercial supporter asks to see evaluations or any outcome information or looks for access to participant lists of who attended the meeting that they might want to use down the road? Do you think that that is a factor that the government would be interested in when they are looking at some of the issues we talked about for CME programs?

**Bonner:** The real issue that we encounter, and this often happens early on in investigations, is that someone who is working with the government will say that after these sessions conclude there is a follow-up by sales and marketing, the so-called ROI. “Let’s go visit doctors that showed up at the conference. Let’s ask ‘probing’ questions to develop off-label discussions.” It is those kinds of considerations that I think the government focuses on in terms of follow-up.

**Malkin:** It partly depends on what information the company is asking for. I think they clearly have a right to look at certain information like the evaluations, what the attendees thought of the logistics of the event, how it was handled, and the quality of the speakers. If the company is funding the activity, they have an interest in knowing how the money was spent. On the other hand, there are a lot of other things that they should not be looking at, and Ray alluded to things related to ROI, following up with sales and marketing visits. But purely evaluations by the attendees, I think would be appropriate.

**Corrigan:** I agree. What Ray was saying is critical, which is if they do get the list of physicians, what are they doing with those lists? Are they then put on the call plan to go out and visit? Nothing inherently wrong with that, but it is something the government is going to look at to see how much the company is evaluating whether or not the CME program was a good return on investment.

**Sadowski:** I agree. In a government investigation, this gives the investigator a roadmap of evaluations and a set of documents that the investigator would be very interested in. Fine, let’s look at the evaluations. Okay, what was the follow-up on these evaluations, which physicians were visited, what are the prescribing patterns of those physicians following this meeting? It just creates a roadmap for an investigator.

## Off-label Discussion

**Coleman:** The financial relationship between the faculty and the company can be important in certain circumstances, but it's usually not the most important issue. The critical issue in CME is off-label discussion. If your expert here provided no information except what was in the approved label, the government usually wouldn't have a concern there even if there was a financial relationship. The problem comes—or the potential problems come—if the speaker provides off-label information and that speaker was the one who was identified and pushed by the company. And then the government can put together a case that this is one element of a larger scheme to promote that particular off-label use. It's one of the things that will be viewed after the fact. Did the speaker turn out to be one who presented important off-label information? Can it be said that that was part of a larger scheme by the company to promote off-label use? Is the fact that the company recommended that particular speaker, who spoke on that particular topic, something that can be viewed as part of the overall company effort? So it seems to me that it is an important area for the company to be careful about their involvement in. It certainly is permissible to provide a list of speakers. The FDA has said that explicitly. And so I can't imagine that providing lists of speakers would get anyone into trouble by itself.

**Bonner:** The on-label situation, I agree, is much, much less of a problem. You could get a situation in which faculty are talking about a product that is viewed as therapeutically equivalent, but the product they're talking about is more expensive, which creates the utilization and pricing issue. But the most important factor to keep in mind when you look at the FDA Guidance in this area is, if it is non-promotional, the FDA basically states that it doesn't want to put a stop to the legitimate exchange of scientific information. And that's important in a number of disease states.

**Gottlieb:** As a physician, I have a lot of public health concerns about some of the restrictions on information—particularly when you're talking about therapeutic areas in which a lot of the prescribing is being driven by off-label use of drugs where advances come along very rapidly, and there's a time lag in terms of getting indications on the label.

I think the recent issue with Herceptin (trastuzumab) provides a good example. There were recent data that Herceptin cut breast cancer recurrence by 50%. That's a dramatic result that is going to save lives. It took the FDA approximately 18 months to get that indication on the label. While there is extensive off-label use in cancer, the reality is, especially when you're talking about cancer treatment, often doctors aren't using it until they have the ability to get good information, get some familiarity with how to prescribe it, and understand its side effect profile better because these drugs are not always easy to prescribe. And in fact, if you look at the utilization rate of Herceptin, there wasn't the dramatic uptake you would expect, based on the results of that study. You would expect that once these study results came out, the next day every patient with the type of breast cancer that would respond to Herceptin would be on the drug. That wasn't the case. The trend in sales was very slow, and there were still payers not paying for it. And I think the inability of the manufacturer to speak at all to those results had a very detrimental public health impact. I am afraid that we're going to see that more and more in the future as we learn more rapidly about the utilization of drugs. That's why I'm deeply concerned about the reported investigation into Genentech's drug Rituxan (rituximab). I think that's a very similar scenario—there is a new use for it which is now, in some respects, the standard of care and the company is alleged to have engaged in inappropriate CME activity. And that kind of activity, I think, is extremely important with a lot of these off-label uses of drugs, that are, in fact, the standard of care.

## Off-label Dissemination Issues

**Berkowitz:** In the area of off-label dissemination, are these cases that are being brought based on actions that were taken years ago in pharmaceutical or device companies, or do they concern more current activities of companies?

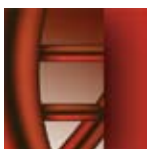
*The financial relationship between the faculty and the company can be important in certain circumstances, but it's usually not the most important issue.*

*... the potential problems come... if the speaker provides off-label information and that speaker was the one who was identified and pushed by the company. And then the government can put together a case that this is one element of a larger scheme to promote that particular off-label use.*

*... so I can't imagine that providing lists of speakers would get anyone into trouble by itself.*

*... the most important factor to keep in mind when you look at the FDA Guidance in this area is, if it is non-promotional, the FDA basically states that it doesn't want to put a stop to the legitimate exchange of scientific information.*

*As a physician, I have a lot of public health concerns about some of the restrictions on information—particularly when you're talking about therapeutic areas in which a lot of the prescribing is being driven by off-label use of drugs...*



*Currently in our office, we are handling at least three off-label promotion cases, and one of them is a criminal case. In my experience, the allegations with respect to CME continue to the present day. It is not simply historic conduct now.*

**Corrigan:** Currently in our office, we are handling at least three off-label promotion cases, and one of them is a criminal case. In my experience, the allegations with respect to CME continue to the present day. It is not simply historic conduct now.

**Malkin:** I agree with that. Some of the cases do tend to focus on relatively old practices, but certainly the government is asking for documents going right up to the present. One thing you hope to find as defense counsel, is that practices have changed for the better over time, after the enforcement actions and the guidance from OIG, FDA, and ACCME.

**Coleman:** Over the last few years, there has been a gradual attempt to eliminate the practices that raise the most concern, but has off-label promotion gone away? I think the answer is no. There are still lots of practices out there, and of course I am not talking about some egregious practices, but, for example, the use of consultants and advisory boards, the funding of CME, the sponsoring of speakers bureaus. Some of those practices have elements that can raise off-label promotion concerns.

**Sadowski:** As time goes on, most of the prosecutions that come to light are aged. In 2007 enforcement actions, for example, activities that come to light were engaged in 2001–2002, but that is not to say that there still are not rogue individuals out there who are going to cause the company problems going forward. It is going to be a constant battle to make sure that compliance is such that the companies continue to minimize their risk.

**Bonner:** Off-label cases will continue to be a major source of government enforcement efforts. They're going to continue to look hard at these cases, and if a company has products that are used off-label, all that it takes is one whistleblower to go to the government, and you have an investigation. And what will that mean? That all your marketing practices, including relationships with CME providers, will be looked at under a microscope.

**Coleman:** The underlying issue is that there is so much money potentially recoverable by the government. If you're in the area of off-label uses, and the off-label use is significant, then it is potentially a huge amount of money that can be attributed to federal purchases for off-label uses. And that's why it's so attractive. Ultimately, these recoveries can amount to hundreds of millions of dollars; off-label sales are one of the few areas in which recoveries are of that magnitude.

## **Good Practices to Reduce Risk**

*... just like you audit your financial practices or numbers every quarter, companies are starting to audit themselves at least from a compliance perspective in a much more robust way. With that hopefully will come earlier identification of problems starting to develop.*

**Berkowitz:** Let's talk about some ways to reduce risk. Do you see a difference in terms of the larger companies versus the smaller companies, the pharmaceutical companies versus the device companies in their efforts to reduce risk?

**Bonner:** I think the big difference today versus five years ago is that there is a significant emphasis by companies on not having general policies, but specific policies and procedures. If you have a good compliance or audit department and you are out there auditing, you have a much better process to monitor best practices so that you learn about issues at an earlier stage. A good analogy, although I do not think it has gotten to this point yet, is that just like you audit your financial practices or numbers every quarter, companies are starting to audit themselves at least from a compliance perspective in a much more robust way. With that hopefully will come earlier identification of problems starting to develop.

Also, my experience has been that companies will do some third-party auditing. I am not sure they have the same access, although it may be in the contractual provisions. At the end of the day, unless you can interview people and review documents, you are not going to get at the real information. And that is the most important part of audits.

**Malkin:** I do see differences between the bigger and the smaller companies in terms of these issues. In a recent report issued by the Senate Finance Committee on funding of CME, they found that the big drug companies had policies and statements which reflected all the right things. I do not know that you would find that with some of the smaller companies. They are just catching up, and they often do not have the level of detail in their policies and procedures and their auditing and monitoring as the bigger companies.

**Berkowitz:** And what about biotech and device companies?

**Malkin:** In my experience, they're still trailing big pharma a little bit, but also catching up.

**Corrigan:** One problem that big pharmaceutical companies have is that they have a huge sales force. It becomes more difficult to go out and figure out what is happening with your sales force in California versus New York. With smaller pharmaceutical companies, it is easier to monitor what your sales force is doing in their interactions with physicians or even with CME providers. A company's control over its sales force is going to be the key to any later investigation.

## Handling a Government Inquiry or Investigation

**Berkowitz:** Turning to providing some guidance and advice for providers who all of a sudden see a subpoena or hear a knock at the door and there are a couple of investigators who want to talk to them, to look at their records. Since this is an area that a lot of the companies have no experience with, can we give them some guidance on how to handle these types of inquiries? For example, any problem with them picking up the phone and calling the pharmaceutical/device company and telling them that they have just been contacted by, or visited by, a government representative—OIG or FBI?

**Bonner:** The first thing I would do is find out from the agent which government prosecutor or lawyer is working the case. Then I would get in touch with a lawyer who works in this field, and I would have that lawyer call the prosecutor or government lawyer and figure out what is this investigation about and what is my status? If you ever hear the word "target," that is not good news. What you want to hopefully find out is that you are a potential witness or you are a document provider as part of some larger investigation.

The other thing that you have to do right away, and this should be on the top of the list of any lawyer that the company hires, is to be sure you and the company preserve documents immediately. Generally speaking, if you hear that you are in a witness or fact-finding role, the one way you can find yourself in trouble is if you do not get the word to your employees that you need to preserve all documents, and documents disappear—even inadvertently.

**Corrigan:** I would actually suggest a preliminary step. Someone within the company, an in-house lawyer or a compliance person, whose role it is to explain the current environment, should let employees know that there have been cases recently where the FBI, the OIG, and an FDA official show up at the doors of employees late at night and question them. In my experience, most people will invite the person in and talk to them for an hour or two. In general, you can let people know that they have the right to say no and talk to other people at the company first. A lot of people are unaware of that right, even though you see it on television all the time, but it is scary to have the FBI show up at your door. I think Ray is exactly on track for what should happen after that.

**Bonner:** Dara brings up a good point. If you are in the healthcare world, you are going to get a visit or subpoena at some point. The one thing you can never tell people is not to talk. It has to be an advice of rights that it is fairly balanced so they know what their rights are, but you can never tell somebody do not talk to the agency.

*... the big drug companies had policies and statements which reflected all the right things. I do not know that you would find that with some of the smaller companies. They are just catching up, and they often do not have the level of detail in their policies and procedures and their auditing and monitoring as the bigger companies.*

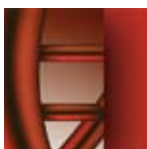
*A company's control over its sales force is going to be the key to any later investigation.*

*If you ever hear the word "target," that is not good news. What you want to hopefully find out is that you are a potential witness or you are a document provider as part of some larger investigation.*

*The other thing that you have to do right away, and this should be on the top of the list of any lawyer that the company hires, is to be sure you and the company preserve documents immediately.*

*If you are in the healthcare world, you are going to get a visit or subpoena at some point.*





**Corrigan:** Employees have the absolute right to talk to counsel. Or you can tell them, you can talk to the government representative, that is your right as well. Or you can talk to someone else in the company.

**Sadowski:** Agents from OIG or FBI tend to come at unusual hours—7:00 in the morning or 6:00 in the evening—that is just the way they operate. The more your colleagues are comfortable with how the investigators operate and what they are going to do, the more at ease they will be to be able to express their rights that they would like to have counsel present.

**Berkowitz:** Any problem with notifying the pharmaceutical company or the device company that you have been visited?

**Bonner:** No problem. That is your choice also. By the way, performance evaluations could create problems and lead to an investigation. When you let people know they are underperforming, they are not happy. The relationship is starting to get strained. What happens next? Well, they may start raising either legitimate or phantom issues with regard to your compliance. In such situations you may get those complaints at the end of the year in terms of “I was being pressured to share our CME content and get input from the client.” That kind of scenario can unfold, and if you see that scenario unfolding that is something that you have to internally investigate, whether you think it is right or wrong. You want to make sure that if there is something wrong, you cure it, as you are in a much better position as a company when you face the government after a complaint is filed.

## **Questions the Government Will Ask Providers**

**Bonner:** It may also be helpful to know that in this area the government will focus on content. Looking at CME, they are going to go to a CME provider and start asking a series of questions: Who do you contract with at the company? Is it marketing or is it med ed? Who pays you, who writes the check? When you go to meet with them, who is at those meetings? Is there discussion about content? Who from your company is there in terms of content? What is the back and forth? That is how government investigations work. I would be more likely to go to the provider to learn how that supporter worked. This is how it unfolds—the key focus area for the providers is content. Is there some “scheme” between the company and the provider to do something the company cannot do on its own?

**Berkowitz:** In summing up, it would seem that while providers are not the first-line target of the government in investigations, they would be well advised to have compliance procedures, training, and education on an ongoing basis to ensure that employees are aware of what the current requirements are as they deal with medical education activities.

## **Investigations Involving CME**

### **Congressional Scrutiny of CME**

**Berkowitz:** Let's move on to the recent investigation and report on CME funding by the pharmaceutical industry by Senators Grassley and Baucus of the Senate Finance Committee (SFC). Two questions here. First, your view on the report and what effect, if any, it might have on the US Attorneys and the OIG in looking at medical education. Secondly, will we continue to see legislative activity in the area of CME as a result of this inquiry and report?

**Corrigan:** One of the things that I found most interesting about the SFC report was the general sense that

*... while providers are not the first-line target of the government in investigations, they would be well advised to have compliance procedures, training, and education on an ongoing basis to ensure that employees are aware of what the current requirements are as they deal with medical education activities.*



someone should be reviewing the content of CME, that FDA is not doing it and someone out there needs to be doing it, like an after-the-fact analysis of content. I think where it is going is more scrutiny and more control of the content. What you may begin to see in future CIAs is law enforcement trying to insert itself into this process. And I think that is a very dangerous precedent to set. Another development to watch is Congressman Waxman's recent inquiries—he has issued subpoenas to various companies investigating their off-label promotion and off-label use of certain drugs. In each of those subpoenas, requests from Waxman's committee were related to speaker programs, CME, and any grant to non-profits. It looks like Waxman is on the same path as Grassley and Baucus.

**Coleman:** The general tone of these Congressional inquiries is similar to the US Attorney's approach of great suspicion that the pharmaceutical companies in particular are doing something improper and they are trying to find out what it is. Actually, I thought that the Senate Finance Committee Staff Report was pretty favorable. It showed that the bulk of companies were following best practices. But they are still looking. I think they want to find something wrong and that they will continue to look. I believe it would be very difficult to legislate in the CME area, except maybe to codify some of the existing principles about the independence and so forth. I do not think Congress would want to shut down industry funding of CME. There would be too many legitimate objections to that. So it may be an issue that percolates for a long time as people continue to be concerned about it in Congress and in the US Attorney's offices. But, in my opinion, there would not be any sort of imminent action against CME.

**Sadowski:** I think it is clear in the Senate report that there is a significant concern about cost, and that is really driving this issue. I expect that Senator Grassley will continue his scrutiny as will US Attorney's offices.

**Malkin:** I agree with Terry that the report was relatively favorable at least with respect to pharmaceutical company policies. Interestingly, they did not address specific practices very much. They did criticize ACCME somewhat, but I did not think overly so. I agree with Terry. I do not see legislation coming in this area any time soon.

## State Enforcement Efforts

**Berkowitz:** We have talked throughout the morning about OIG, Department of Justice, and the Congress. Are state enforcement agencies also beginning to scrutinize CME?

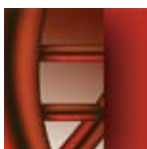
**Sadowski:** With Jim Sheehan moving over from the US Attorney's office in the Eastern District of Pennsylvania to take on the new role of Inspector General for Medicaid fraud in New York State, there is going to be a greater emphasis on marketing and pricing activities. This is particularly true in New York State, which has one of the largest expenditures of Medicaid dollars in the country. There is also a new Deputy Attorney General for Medicaid fraud in New York, Heidi Wendel, who is formerly from the US Attorney's office. She is very attuned to using the False Claims Act and the new New York State False Claims Act that was enacted in the end of April. So, definitely, I think we are going to see a lot of action by the states, although it may not be focused on CME at the present time.

**Bonner:** It is interesting because I think the state AGs not only have the Medicaid units, they also have consumer protection units. So you are dealing with a number of different groups within the AG's office. And one of the approaches in terms of a consumer protection perspective is that if you are promoting your product in certain ways without disclosing other material information, then you could be defrauding the consumers of this state. And you could imagine creative theories being worked out by those consumer divisions that would include how one company uses CME for purposes of educating or in their view maybe promoting the product. The AGs are getting much more organized, and they are involved in a lot more cases from the start, so industry needs to be alert to this.

*One of the things that I found most interesting about the SFC report was the general sense that someone should be reviewing the content of CME, that FDA is not doing it and someone out there needs to be doing it, like an after-the-fact analysis of content.*

*I do not think Congress would want to shut down industry funding of CME. There would be too many legitimate objections to that.*

*I think we are going to see a lot of action by the states, although it may not be focused on CME at the present time.*



## Aggressive Enforcement Undermines Public Health

**Berkowitz:** A couple of questions to explore this issue more deeply. Isn't this parade of million dollar fines concerning off-label usage an area that has developed without any court decisions—except maybe one preliminary decision up in Boston in the Neurontin case? Companies sign extremely restrictive CIAs, sometimes inhibiting perfectly legitimate communication activities, fearful of the risk of litigating, losing, and being excluded from federal healthcare programs. I can't remember dealing with an area of law or regulation that has been so one-sided, without the opportunity to litigate any of the critical issues. I'm not trying to legitimize promoting off-label, but from a public policy standpoint, are we moving into areas that could potentially undermine the public health?

**Bonner:** Well, the first thing that you'll hear from the government in off-label cases is that the company has made a fundamental choice to promote the product off-label and generate more sales. It is a company-wide conspiracy the government will claim. My view is, generally speaking, you have to understand how the usage actually develops. Number one, the science does make great strides, particularly in the oncology area. You have significant advances, new data, developments being reported from medical conferences; patient advocacy groups are spreading information over the Internet. All of this drives a lot of this off-label usage, putting aside anything that the company does. So, what is really generating the off-label usage? Is it really being orchestrated by a company effort to promote off-label? Putting aside the various legal defenses, including the First Amendment argument, there is a major public policy issue here: should the Department of Justice be making these decisions, without rule making, without FDA's full vetting of the issues, without the full vetting by the pharmaceutical and medical device industries, in terms of process?

**Malkin:** Unfortunately, these potential legal defenses usually don't get fully developed, in part because companies simply can't take the risk of going to court, losing, and being excluded from participating in federal healthcare programs. So the government has tremendous leverage over companies. What happens, therefore, is they enter into settlement and CIAs to avoid exclusion, which have exactly the types of very onerous requirements that you referred to, Ken.

*This situation of off-label promotion is a highly anomalous legal situation, and I don't think there's a parallel anywhere else in the legal universe.*

*But because the FDA has not fleshed out these rules and because the Justice Department proceeds on a case-by-case basis in extracting settlements rather than going to court, except in the case of individuals who seem to be acquitted universally, there is a major problem here.*

**Sadowski:** What is particularly troubling is what has recently occurred in the Purdue Frederick case, where executives were basically forced to plead guilty to a misbranding violation even though the government admitted there was no knowledge on the part of the individuals that statements were made that constituted the misbranding. And I think that climate in that particular case creates a deep concern about the potential abuse by prosecutors of that particular statute.

**Coleman:** This situation of off-label promotion is a highly anomalous legal situation, and I don't think there's a parallel anywhere else in the legal universe. Just look at the situation. The dissemination of information about off-label scientific use is affirmatively desired by society. There are all kinds of publications and CME activities that advance that; the FDA favors it; everyone supports the dissemination of information about new uses of drugs. The one rule is that the company who manufactures the drugs cannot itself disseminate the information, even though as a public policy matter, it is desirable for that information to be out there. And so the result of this strange situation is that the rules are really quite highly technical.

Since the dissemination of information by itself is favored by public policy, and only the issue of the disseminator is a potential problem, there are all these technical rules about whether the request was unsolicited, whether it was scientific exchange versus promotion. But these technical rules are not fleshed out. There are general concepts of promotion versus scientific exchange, and unsolicited requests versus solicited requests, for example, or whether it's independent CME versus medical education that is not fully independent. It's the kind of situation that would greatly benefit from much more explicit rules about where the lines are, because you can't apply public policy and decide whether something was good or bad. But because the FDA has not fleshed out these rules and because the Justice Department proceeds on a case-by-case basis in extracting settlements rather than going to court, except in the case of individuals who seem to be acquitted universally,

there is a major problem here. If there were much more explicit rules, then people would follow them. But there aren't explicit rules and people are in the dark, and that's why we are having this discussion today, because people are trying to understand where the lines are—where the risks are.

**Berkowitz:** With companies not litigating the issues because of the risks we have discussed and with the Justice Department taking a case-by-case approach, does it leave it to the FDA to provide some clarification?

**Gottlieb:** I think what the agency could do is provide some clarity around what its point of view is with relation to the dissemination of journal articles—peer-reviewed journal articles. The agency could simply put out a guidance document that says it's not going to regulate the dissemination of these articles because, as a matter of public health, there is importance in enabling the dissemination of this kind of information. That would have a practical effect of reminding the US attorneys, who are really driving much of this debate, that there is public health value in a good portion of this information.

*I think the public policy issue goes back to how much control do you want law enforcement to have over scientific exchange of information and what is really in the patient's interest.*

## Public Health Dangers Posed by Aggressive Enforcement

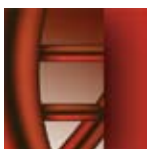
**Corrigan:** I think the public policy issue goes back to how much control do you want law enforcement to have over scientific exchange of information and what is really in the patient's interest. There is a real question about what information should be available to doctors, because, ultimately, these decisions should be made by the scientists. Having the most information—truthful, fair-balanced information—seems to me to be in the interest of the public. Scott [Gottlieb] was just talking about treatment in the oncology area. I've seen these issues debated in the treatment of adolescents for various different conditions. You can't simply say, in any broad way, that there can't be treatment of adolescents with off-label uses. It would not help doctors, it would not help the public. The really tough question is, what information—what truthful, balanced information—should be given to physicians, and how quickly should it be given? Those are very difficult scientific decisions. If there are going to be regulations, they should take place within the FDA where the scientists are located. I'd hate to see that body of law develop through CIAs and settlement agreements.

*The really tough question is, what information—what truthful, balanced information—should be given to physicians, and how quickly should it be given? Those are very difficult scientific decisions. If there are going to be regulations, they should take place within the FDA where the scientists are located. I'd hate to see that body of law develop through CIAs and settlement agreements.*

**Gottlieb:** I go back to the Herceptin example, where you have a drug that's sometimes difficult to prescribe, and clinicians should be using it—and in many cases are using it—and the manufacturer is completely prohibited from discussing the appropriate utilization of the drug and its application. Certainly, if there were a problem with the utilization of the drug and patients experienced some adverse effect, the manufacturer would be on the hook to some degree for the adverse event, yet they would be unable to educate physicians about the appropriate use. I also believe this is going to be a much more significant problem going forward, as you see more and more people engaging in retrospective analysis of clinical data and putting out conclusions from studies that might be poorly conceived. We've seen that very recently, where the companies were inhibited or prevented from responding to the studies because they might address certain off-label aspects of the use of the drug. So you have these studies going out, and they reverberate in the marketplace, and companies are basically prohibited from responding to certain aspects of even their own studies because they address off-label uses. That's a significant problem, and it creates public health issues—public health concerns.

*I think the restrictions placed on companies that are sponsors of clinical trials is creating an information gap that ultimately is going to harm patients, because you're not going to have the most informed party able to speak to some of the issues on a timely basis.*

As we have been discussing, I think the information issues have become much more complicated. More people are putting information out in the marketplace, and sometimes their motivations aren't entirely transparent. You have patients themselves putting information out, you have motivated third parties who have a political interest, and you have trial lawyers putting information out into the marketplace. Yet, the industry is restricted in what they can say. I think the restrictions placed on companies that are sponsors of clinical trials is creating an information gap that ultimately is going to harm patients, because you're not going to have the most informed party able to speak to some of the issues on a timely basis.



## Company Perspective on Data

**Berkowitz:** How do you deal with that issue, then? Let's assume there's information out there that is not supported by scientific evidence, and the company, either pharmaceutical or device, wants to provide balance or provide the data with regard to that. At the same time, they're concerned that the OIG or Department of Justice is going to look at it very closely—the states are going to jump in. How do you deal with that? I guess you could—although it would take time—try to provide a grant to some medical group or some provider to hold a scientific meeting. But it's going to take time to respond to these issues or put them in perspective. From a product liability standpoint, you may have an obligation to respond as well. Suppose tomorrow morning you get up, and your client is on the phone saying, hey, there's this retrospective study—that says this thing, and all our data shows it's inconsistent, and we're very concerned that physicians will stop prescribing the drug. Even worse, patients will read about it and stop using the drug without even talking to their physician. What can we do?

*The one thing FDA suggests, through guidance, is that you get your medical department to respond. Your sales people, according to the FDA and the Justice Department, can't talk about this. It's not on the label. You can also go the CME route. Those are the two regular routes, that at least the government views as kind of cleansed approaches, separate from marketing and promotion, that allow you to at least disseminate information from a clinical standpoint.*

**Bonner:** Well, let me take a flip side. If you have the scenario that Scott described, where you're going to get significant positive information, a lot of things are going to start working. Advocacy groups, the Internet, publications, newspaper articles, CBS reports—you're going to get a lot of information. So the first question is how does a company deal with that, given the OIG and the government? The one thing FDA suggests, through guidance, is that you get your medical department to respond. Your sales people, according to the FDA and the Justice Department, can't talk about this. It's not on the label. You can also go the CME route. Those are the two regular routes, that at least the government views as kind of cleansed approaches, separate from marketing and promotion, that allow you to at least disseminate information from a clinical standpoint.

**Berkowitz:** Could the company offer a letter to the relevant specialists, trying to clarify the issues, even if it's going to get into an off-label discussion?

**Bonner:** Yes, one bit of advice is to partner with FDA. The FDA is going to get calls as well—they're going to get inquiries. What does this information mean? Shouldn't I be on this drug? If there's really significant evidence, at some point the government and the companies need to figure out a way for communication. We do that in the recall context. When there's a problem, there's a way companies and the FDA can work out issues, so that you're balancing the recall, but at the same time, not frightening people, from a public health perspective. There may be a need to do the same thing when there are significant events that are not technically covered by the label.

**Gottlieb:** Oftentimes with these studies, you're blindsided and manufacturers have the best ability to respond quickly, a lot of times, to those studies and put them in appropriate context. The agency sometimes is not even in a position to do that. In some instances, this is making the companies more and more dependent on surrogates who are directly affiliated with the company—the key opinion leaders and the medical communities step in and speak up—but you don't always have that. Sometimes, you basically don't have a strong leader; you don't have someone who's willing to weigh in because of political concerns about putting themselves out in front of these issues. So, that's the kind of environment we're operating in where the company really is unable to respond in some cases. And that's creating public health concerns.

**Coleman:** If it requires getting into the off-label area, it may not be capable of a solution. It's possible that maybe you can do something scientific that will not be viewed as promotional or have an outside expert make a statement. But these are poor solutions, given the current legal situation and it's the kind of situation that the FDA should address.

**Bonner:** And I guess it's disappointing on one level, if you get this major kind of news, a significant development in terms of treatment. Believe it or not, I think the securities market is more able to absorb that information and adjust accordingly than the pharmaceutical industry.



**Berkowitz:** So should we let the securities markets handle the dissemination of information?

**Bonner:** I'm not saying that, but if it's a public company, besides touching base with your FDA lawyers and your healthcare lawyers, you're going to have to touch base with your securities lawyers soon, because this is going to have an impact on your stock price, and you may be obligated to issue some kind of a release that makes sense for the securities markets.

**Berkowitz:** In summary, you certainly need to develop, at the very least, a way to respond to inquiries from the news media. The idea of reaching out to experts is important. The third bit of advice is to try to get to the FDA and work with them very quickly to see what you can do. And none of this may be satisfactory. You can also see if you could quickly work to put together some independently prepared educational initiative. It sounds like, from all of your input, that these are certain things you could explore—none of which may be totally satisfactory in the type of examples that Scott has given.

## ***A Proposal for a Public Health Assessment Before Enforcement Decisions Are Made***

**Berkowitz:** The other issue to consider is that in a number of the off-label actions the government has taken, the uses may be covered in a recognized compendium. That becomes even stronger since under Medicare and Medicaid, if it's in one of the recognized compendia, the government will reimburse for it. Yet, that doesn't seem to play into an enforcement decision, or does it?

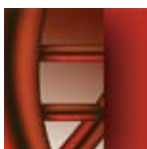
**Bonner:** Years ago when I brought cases on behalf of FDA, when I was at the US Attorneys Office in Maryland, I would try to select the most egregious conduct and bring a felony case—not a strict liability case—a felony case. You're looking for that fraud, a pattern of fraud. In the off-label context, that's a fair point, because if recognized compendia have done their independent analysis, and there's clinical support for uses of certain drugs in off-label areas, is that the egregious conduct that the government should be criminalizing with felony charges? That's a fair question. Or is there another way to handle these, in terms of looking at it just from a civil perspective? Because the civil perspective allows you to avoid the exclusion remedy.

**Gottlieb:** That's exactly right. A lot of these uses are listed in compendia. And the one example I gave, that cancer indication, was in fact listed in the compendia and is being reimbursed by Medicare. So it does create an interesting dichotomy within the government. You have one arm, recognizing its legitimate use, and the other arm preventing you from disseminating information about it. I think the US Attorneys—and they'll probably cringe at this—ought to, as part of their analysis of which cases they're going to bring, first consider the public health implications of the cases. Maybe they should be required to check with a public health authority like the FDA or NIH before they bring cases. They consider the legal parameters of their actions, they consider how much money they can recoup, and how easy it is to win a case. And what consideration is there as to whether it is a legitimate use of the drug? Was the company acting consistently with the current state of the science? Was Medicare paying for it? Those things don't get considered at all, at least in my view.

*I think the US Attorneys—and they'll probably cringe at this—ought to, as part of their analysis of which cases they're going to bring, first consider the public health implications of the cases.*

**Berkowitz:** So we ought to require a public health assessment.

**Gottlieb:** Put something in the staff manual of the US Attorneys, saying that they have to check with the public health authority. They may not have to heed what the public health authority says, but at least to remind them that this ought to be a component they consider before they bring a case. From a policy standpoint, it would make a lot of sense. How could you argue with that?



*... the US Attorneys Office does not have the expertise of the FDA, and I think that the FDA should have a greater role in these prosecutions.*

*... public health determinations should not be made by lawyers alone.*

**Corrigan:** Well the interesting thing is, when I was a prosecutor I would have said that I disagreed. But having worked at CMS, my views changed completely because the US Attorneys Office does not have the expertise of the FDA, and I think that the FDA should have a greater role in these prosecutions. Going back to my prosecution days—prosecutors view themselves as representing the United States versus representing a client, like FDA or CMS, in many situations. I think that distorts the best decision making, and there should be a public health assessment in these cases. And frankly, public health determinations should not be made by lawyers alone. So I agree with much of what Scott said.

**Berkowitz:** On these investigations and these actions, do FDA and/or CMS currently have any role at all?

**Gottlieb:** I think they check with FDA, but they check with lawyers at FDA. They check with people on the enforcement side of FDA, and that's not, in my view, necessarily checking with the totality of FDA. You should be talking to the people who work in the therapeutic divisions in getting public health assessments.

**Sadowski:** I think, having prosecuted some cases in this area, that, as a reasonable prosecutor, you should work closely with the program people in the agency. You should want to bring it to their attention not only because maybe this is not the case I want to prosecute, but you should also make them aware that this is happening, and they should consider doing something about it in their agency's discretion. So as a prosecutor, the last thing I want to do is build a case and bring it forward, and not have the agency behind me. It's just irrational and it's irresponsible; it's the wrong thing for a prosecutor to do. I would hope that in these instances there is, if not a formal policy of contacting the agency (FDA or CMS), it's done on a regular basis. My first question to everyone I supervised in my office when they came to me to review whether this was a case we should pursue was, have you contacted the agency and what's their view on it?

**Berkowitz:** Would you agree though that there are two issues? One may be contacting the agency, which makes a lot of sense, but the second thing is contacting people who give you a public health assessment at the agency, as opposed to contacting the general counsel or chief counsel's office, who will say, yes, you're right, legally it's impermissible. That's the thing we're focusing on and it may be unique to the situation dealing with the anti-kickback law as it's applied to healthcare issues. I believe the panel seems to agree with it.

**Sadowski:** I think that that's absolutely right, and I think a prosecutor has to push, and not rely on just agency counsel saying, yes, technically under the rules, that's a violation without being armed with a public health assessment.

## Future Enforcement Trends Regarding CME Activities

*I think that one of the things to watch is the possibility of a whistle-blower suit against a provider of CME. That would change the landscape considerably and put providers in a similar defensive posture as the industry as a result of any type of settlement or CIA.*

**Corrigan:** I think that one of the things to watch is the possibility of a whistle-blower suit against a provider of CME. That would change the landscape considerably and put providers in a similar defensive posture as the industry as a result of any type of settlement or CIA. That's one trend that I think there is a real potential for happening.

**Malkin:** I wonder whether—and maybe we're already seeing it to some extent—funding for CME will just decrease as responsibility for the grant-making moves from marketing to medical.

**Gottlieb:** When you look at the types of cases that have been brought by US Attorneys, you can make a reasonable argument that the cases they're choosing to bring are less egregious from a public health standpoint,



or in some cases, situations where the alleged promotion of an off-label use of the drug provided a lot of public health utility. Originally, the cases pertained to really egregious actions on the part of the companies promoting drugs for uses when there was very limited or no information. That's an obvious concern.

**Coleman:** I don't see any major trends. I anticipate the next few years will look like the past few years, with one exception being that, as Scott alluded to, the cases will not be so egregious, probably because the companies are gradually tightening up their policies. But there's so much money involved, so much opportunity for the government authorities to make major settlements, that I think there will still be a lot of intensive investigation. The one thing that may happen, though, is the FDA coming under more pressure to issue guidance on what's permissible in the off-label area. My understanding is maybe they're moving in that direction, and that would be very useful. That may be the one thing that could change the course of the recent trend.

**Sadowski:** At any one point in time, there are over one hundred false claims that are pending in the Department of Justice. I have no doubt that if CME providers are not targets, they are definitely going to be witnesses. So there's no avoiding involvement in these kinds of investigations. Mindful of that, I think the CME providers have to look at areas of reducing their risk and protecting themselves, because they will be confronted with investigators looking at their involvement with the pharmaceutical and device industries funding of CME. It's unavoidable.

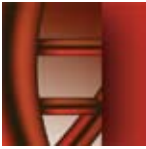
**Bonner:** I think there are going to be many, many more cases driven by whistle-blowers. And remember the State Attorneys General. They have different angles they can approach, including the consumer protection side. Just think about the variety of creative ways in which the government can frame, from a Medicaid or a consumer protection standpoint, its cases. Also, I think the government's going to be very discerning going forward, given its recent acquittal record against individuals. Companies are in a very different situation. The risk is very different for a company, given the exclusion sanction. So, I still think there will be a fair amount of activity. The only thing you need is a whistle-blower to bring a case. The government has to do something with it in terms of the merits. The one area to watch for is drug safety.

**Berkowitz:** In light of the Purdue Frederick case, and even the recent publicity with the Epo-type drugs, what we may be seeing is more of a focus on the safety issues, as opposed to just off-label prescribing issues. In summary, the best thing providers and supporters can do is to be sure they have in place good compliance policies and procedures, that they conduct training and education, not only of what the statutory or regulatory requirements are, but of trends and changing focuses of the government. Doing this in advance could at least put you in the best situation that you might possibly be in should the government come calling. Would you agree?

**Bonner:** I think you have to do it. I think the benefit should be apparent though—you don't hear enough about this from the government—for the cases that do go forward, there are a large number that get declined. If you have a good compliance program in effect, you often catch the problems and you deal with them, you ought to get some credit for it. The other interesting thing to consider is there are more and more companies that are agreeing to CIAs. Those companies have all kinds of disclosure obligations under the CIAs. Disclosure takes away, as far as the whistleblower component, the government going forward with a case. So in some ways, I think those agreements that some manufacturers are living under may actually provide some additional protection.

*At any one point in time, there are over one hundred false claims that are pending in the Department of Justice. I have no doubt that if CME providers are not targets, they are definitely going to be witnesses. So there's no avoiding involvement in these kinds of investigations.*

*In summary, the best thing providers and supporters can do is to be sure they have in place good compliance policies and procedures, that they conduct training and education, not only of what the statutory or regulatory requirements are, but of trends and changing focuses of the government.*



## Conclusions

**Overstreet:** That was a most enlightening discussion of the evolving issues regarding commercial support of CME and the value of off-label information (see the summary below). Everyone who contributed to the discussion sincerely hopes that these proceedings will help ensure that CME fulfills its promise of improving clinical practice—and ultimately patient outcomes—in the United States and around the world.

## Summary

- CME activities have not been singled out as a target for enforcement actions. When there have been issues, they concerned CME being part of an overall marketing effort by the supporting company.
  - As long as CME is independent, it should not pose regulatory problems.
- The type of provider—academic or MECC—should have little bearing on risk.
- There is no difference in risk between solicited and unsolicited grants for activities relating to disease states.
- Supporters can recommend speakers so long as the ultimate decision is made by the provider.
- There is risk in supporter review of content for medical accuracy regardless of who might do the review.
- Firewall requirements should be established for all providers to ensure independence.
- CIAs do not generally address requirements for firewalls.
- Tips on handling a government inquiry or investigation include:
  - Be sure to immediately contact counsel familiar with fraud and abuse issues.
  - If you so choose, you can speak to counsel before you speak to the government.
  - Be sure to preserve all documents once you are contacted by an investigator.
- The dissemination of off-label information has public health consequences, and enforcement actions should not be undertaken unless the public health implications of such actions are first evaluated by government medical or scientific personnel.
- Recent proposals to treat only MECCs as “commercial interests” may be viewed as anticompetitive and an extreme overreaction to current issues.
- Ongoing training is needed for providers and supporters to create a culture of compliance.

## Appendix—Biographies



### **Kenneth P. Berkowitz** **Moderator**

Kenneth P. Berkowitz is a healthcare industry consultant specializing in FDA regulation, prescription drug policy issues, and other matters relating to the approval and marketing of prescription drugs. He has played a major role in issues such as the Hatch-Waxman patent restoration, health care reform, FDA regulatory reform, and product utilization.

Formerly Assistant General Counsel at Hoffmann-La Roche, Ken was also Vice President, Public Affairs, Drug Safety and Drug Regulatory Affairs, and a member of the Pharmaceuticals Business Leadership Board.

In 1992 he chaired the joint PhRMA/ BIO Staff Task Force on User Fees that worked with FDA to develop the Prescription Drug User Fees Act (PDUFA). In 1993, Ken was a recipient of the FDA Commissioner's Special Citation for providing invaluable assistance to the Food and Drug Administration.

Ken has long been an advocate of the importance of advertising and other marketing communications and of their protection under the First Amendment. He has spoken before major trade and education associations and business schools and has created educational and training programs for individual companies and the industry. He was the Executive Editor of the pharmaceutical industry resource *Understanding Promotional and Educational Regulations/Guidelines for Prescription Drugs: A Training Program*.

Ken has served as Vice President, Treasurer, Director, Counsel, and Special Advisor to the HealthCare Marketing & Communications Council (HMC), of which he became President in 2005. He also served as Adjunct Assistant Professor at Fairleigh Dickinson University, lecturer at the Amos Tuck School of Business, Dartmouth College, and Rutgers University Graduate School of Management. He is on the editorial Advisory Board of *RX Compliance*, an industry newsletter for compliance issues.

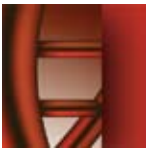
### **Raymond A. Bonner**

Raymond A. Bonner served as an Assistant U.S. Attorney in the District of Maryland for 6 years, where he prosecuted major pharmaceutical fraud and GMP cases and litigated other FDA-related cases. He concentrates his practice on FDA and healthcare-related enforcement matters. Throughout his tenure as a prosecutor, Ray counseled FDA and its Special Prosecution Staff investigating the healthcare industry and developed extensive FDCA expertise. He has substantial experience with regulatory reporting and submission requirements, good manufacturing and laboratory practices, and marketing and labeling requirements. Ray also counsels industry manufacturers on industrial espionage matters.

Ray is the recipient of FDA's Harvey W. Wiley Medal and Commissioner's Special Citation. He received his JD from New York University School of Law and a BA, *summa cum laude*, from the University of Maryland. He clerked for the Honorable Paul H. Roney of the Eleventh Circuit Court of Appeals.

#### **Admissions and Certifications**

- U.S. Court of Appeals, 4th Circuit, 1990
- U.S. District Court, District of Columbia, 1990
- U.S. District Court, District of Maryland, 1990
- District of Columbia, 1989
- Maryland, 1987
- Pennsylvania, 1987



## **Terry Coleman**

Terry Coleman is a partner in Ropes & Gray's Washington, DC, office, where his practice focuses on healthcare financing law, food, drug, and device law.

Experience at both the FDA and the Health Care Financing Administration (now the Centers for Medicare & Medicaid Services) enables Terry to address issues in both areas and provides a rare capacity to deal with issues that cut across the 2 agencies' authorities. Problems that he regularly advises on include Medicare coverage of products and technologies, the risks of various practices under the fraud and abuse laws, Medicaid rebates, Medicare payment policies affecting physicians and other providers, and issues of FDA law.

Terry began his legal career at the FDA, where he rose to serve as Associate Chief Counsel for Food. Subsequently, he worked at the U.S. Department of Health and Human Services, where he served for a year as Acting General Counsel. During his time at HHS he also worked for the Health Care Financing Administration as both Chief Counsel and Deputy Administrator.

### **Bar Admissions**

- Washington, DC, 1976
- Minnesota, 1973

### **Courts**

- Supreme Court of the United States, 1980
- U.S. Court of Appeals for the District of Columbia Circuit, 1978
- U.S. Court of Appeals for the 1st Circuit, 1980
- U.S. Court of Appeals for the 3rd Circuit, 1981



## **Dara Corrigan**

Dara Corrigan is a partner in the healthcare practice at Arnold & Porter, where she has counseled pharmaceutical and device manufacturers, universities, and healthcare providers about all aspects of government regulation, including reimbursement, coverage, fraud and abuse, conflicts of interest, and ethics. As an integral part of her practice, she defends clients in criminal, civil, and administrative litigation related to all federal healthcare programs.

As the former Acting Inspector General at the Department of Health and Human Services (HHS), Dara managed a staff of approximately 1,600 auditors, investigators, policy analysts, and attorneys; testified before Congress on issues related to healthcare fraud; and supervised all investigations, audits, and litigation involving the department's healthcare programs. She made recommendations about fraud and abuse issues to the Secretary's office at HHS, the Administrator for the Centers for Medicare and Medicaid Services (CMS), and the Senate Finance Committee.

Prior to serving as Acting Inspector General, she was the Director for Program Integrity at CMS, where she served as the point of contact for all Medicare program integrity issues and oversaw the accuracy of all payment benefits. As Deputy Chief Counsel for CMS (1999–2003), Dara provided counsel on program integrity issues, including nursing home quality of care, provider enrollment, and fraud and abuse matters.

In addition to her positions at HHS, Dara was an Assistant United States Attorney for the District of Columbia (1995–1999), where she defended the United States in civil actions and worked on healthcare fraud and abuse issues, and a trial attorney in the civil fraud section at the Department of Justice (1991–1995).

Dara's 14 years in the federal government—both as a litigator and as a high-level healthcare policymaker—have given her a unique insight into the federal government's approach to healthcare enforcement and policy issues. She has handled numerous high-profile fraud and abuse matters, both from a governmental perspective and since joining Arnold & Porter on behalf of clients, including matters involving off-label promotion, product pricing, and grant fraud.



## Scott Gottlieb, MD

A practicing physician, Scott Gottlieb has served in various capacities at the Food and Drug Administration. He has been a Senior Adviser for Medical Technology, Director of Medical Policy Development, and most recently, Deputy Commissioner for Medical and Scientific Affairs. Scott has also served as a senior policy advisor at the Centers for Medicare and Medicaid Services.

Scott received his MD degree from Mount Sinai School of Medicine and a BA in economics from Wesleyan University.

### Professional Experience

- Deputy Commissioner for Medical and Scientific Affairs, FDA, 2005–2007
- Medical Internist, Stamford Hospital, 2003–2007
- Resident Fellow, American Enterprise Institute, 2004–2005
- Senior Adviser to the Administrator, CMS, 2004
- Director of Medical Policy Development, FDA, 2004
- Senior Adviser for Medical Technology to the FDA Commissioner, 2003–2004
- Columnist, *Forbes.com*, 2007–present
- Author, *Forbes-Gottlieb Medical Technology Report*, 2004–2005
- Staff Writer, *British Medical Journal*, 1997–2005
- Author, *Gilder Biotech Report*, 2000–2002
- Senior Editor, *Pulse*, *Journal of the American Medical Association*, 1996–2001
- Health Care Analyst, Alex Brown & Sons (investment bank), 1994–1995



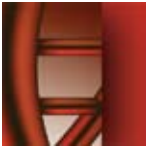
## Robert G. Malkin

Robert G. Malkin is a partner in the Washington, DC, office of Hogan & Hartson LLP, and a member of the firm's Health Practice Group. In his practice, Robert represents a wide variety of clients in the health field, including manufacturers of pharmaceuticals and medical devices, hospitals, academic medical centers, and professional/industry associations. He devotes much of his time to handling healthcare fraud and abuse and compliance-related matters, including anti-kickback, false claims, and physician self-referral issues.

Robert has assisted clients on a wide range of reimbursement, regulatory, and enforcement matters. He provides advice on issues that raise potential fraud and abuse or other regulatory concerns, and he frequently assists with the implementation or review of corporate compliance programs. In addition, he often works with clients involved in civil and criminal government investigations, as well as internal investigations. Robert speaks frequently on healthcare fraud and abuse and compliance issues.

Robert received his BA in 1992 from Princeton University and his JD and MHA degrees in 1997 from Washington University in St. Louis. He is a member of the American Health Lawyers Association and the American Bar Association's Health Law Section, and is admitted to the bars of the District of Columbia and Missouri.





## **Robert W. Sadowski**

Robert Sadowski is engaged in commercial litigation practice for Olshan, Grundman, Frome, Rosenzweig, and Wolosky, LLP, with emphasis on fraud, healthcare, tax, accounting, civil rights, insurance, administrative law, and environmental matters.

Prior to joining the firm, Robert was an Assistant United States Attorney in the Southern District of New York for 14 years, where he supervised civil healthcare fraud prosecutions. He has litigated numerous healthcare fraud prosecutions under the federal False Claims Act involving physician practice groups, hospitals, laboratories, billing companies, and nursing homes for defrauding Medicare and Medicaid in connection with cost reports, false billings, quality of care, kickbacks, drug diversions, and misbranding and adulteration of pharmaceuticals. He also handled matters involving federal grant fraud and federal housing fraud. He handled property insurance litigation arising from the terrorist attacks of September 11, particularly addressing liability and insurance coverage issues stemming from environmental contamination and remediation. Robert also handled the litigation and mediation involving the insurance coverage for property damage resulting from the volcanic eruption of Mount Pinatubo in the Philippines that destroyed the United States Naval base for which he was awarded the 2005 Attorney General's John Marshall Award for Outstanding Achievement in Alternative Dispute Resolution. He has handled numerous civil rights prosecutions and is an expert in the Americans with Disabilities Act, having litigated accessibility issues involving stadiums, major sports franchises, and several Broadway theaters, for which he was awarded the 2004 Attorney General's John Marshall Award for Outstanding Achievement in Litigation.

### **Professional Experience**

- *Gillespie v. United States*, litigated the valuation of a block of Washington Post stock establishing the method used to determine the blockage discount for estate tax purposes.
- New York Federal Bar Council
- New York State Bar Association (Health Law Section, Committees on Fraud and Abuse and Health Care Providers)





NAAMECC

North American Association of Medical Education and Communication Companies, Inc.

3416 Primm Lane  
Birmingham, AL 35216