15th Annual Pharmaceutical Compliance Congress and Best Practices Forum

R&D and Medical Affairs Transparency

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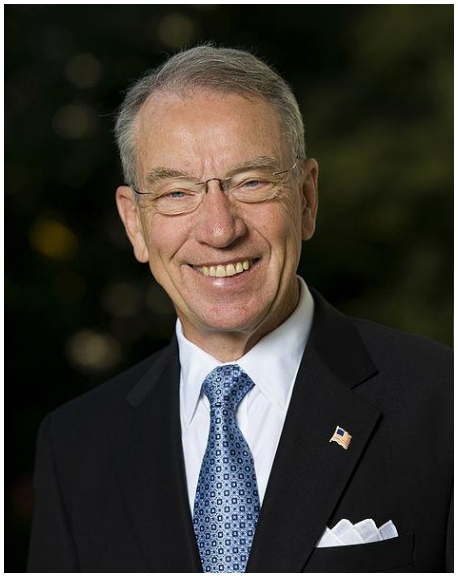
Pharmaceutical Compliance Forum Agenda

Why is this happening?

Disclosure of Financial Relationships



Senator Charles Grassley

(R-Iowa)

”I'm working to **shed light on financial relationships between drug companies and doctors**. I've conducted oversight, and I'm working for passage of **legislation that would require public reporting by drug companies** of the money they give to doctors for **consulting, travel, speeches, meals and other activities**. The public interest is clear. We all rely on the advice of doctors, and leading researchers influence the practice of medicine. Taxpayers spend billions of dollars each year on prescription drugs and devices through Medicare and Medicaid. The National Institutes of Health distributes $24 billion annually in federal research grants. So **the public has a right to know** about financial relationships between doctors and drug companies.”

Source: http://www.grassley.senate.gov/about/disclosure-drug-company-payments-doctors

Strong case for disclosure in research

INTEGRITY

"We want our doctors … to rely on evidence that is real and true and accurate and not partial or affected some way by a money interest behind it[1]"

TRANSPARENCY

"The case has clearly been made for requiring industry to report payments to physicians, especially those conducting highly influential research, often with taxpayer support. Operating with transparency sends a message that there's nothing to hide[2]."

PHYSICIAN SUPPORT

64% of surveyed physicians said that disclosure for doctors should be mandatory, while 83% supported mandatory disclosure for researchers[3].

1. Susan Winkler, AUSA (Boston), 13th Annual Pharmaceutical Regulatory and Compliance Congress (November 5, 2012)
2. Press Release by Senator Charles Grassley (October 29, 2009)
3. David Hodgson, Seth Whitelaw, Physician Payment Sunshine Act: Physicians and life sciences companies coming to terms with transparency?, Deloitte/ Forbes Insights (2012); https://www.deloitte.com/assets/Dcom-Global/Local%20Assets/Documents/LSHC/dttl_lshc_ForbesInsightsLSHCTransparencyReport.pdf

Practical Implementation and Challenging Areas

Research and Reportable Value Transfers

Research is a systematic investigation designed to develop or contribute to generalizable knowledge related broadly to public health, including behavioral and social-sciences research.

Reportable Value Transfers

- To be reportable, the research-related payment must also be made pursuant to a written agreement or contract between the applicable manufacturer, contract research organization (CRO) or site management organization (SMO) and the covered recipient
- Payments reportable even if the PI is not a physician regularly treating patients
- Material transfers to a researcher for discovery collaboration are not reportable if the material transfer is not part of a commercial/marketing plan preceding new product development.
- If research-related payment does not meet the statutory definition of research, it may still be reportable using other categories of payments or transfers of value defined in the Rules (i.e., consulting fees, education, food, or travel)

Company Sponsored Research
▪ Direct Payments ▪ Equipment and other in-kind ▪ Drug Supply ▪ OUS spend on U.S. HCPs ▪ Non-covered entities who employ US HCPs ▪ Editorial support for publications ▪ Physician recruiting expenses ▪ Physician employees of other manufacturers

Other Research-Related Areas
▪ Publications ▪ IIS ***1. Drug*** ***2. Money*** ***3. Medical Writing*** ▪ Business Development Activities

Some Challenging Areas

Equipment Loans

- **Reporting**
  - Product samples not intended for patient use
  - Equipment loans over 90 days

Scope of "Written Agreements"

- **Written Agreements**

Meals, Travel & Lodging Expenses

- **Tracking Expenses**
  - Break down by category
  - Itemizing payments
- **Payments and Transfers of Value**
  - Incidental expenses
  - Limiting expenses to business activities

"Pass Through" Costs to Research Sites

- **Pass Through costs**

Some Challenging Areas

Organizational

- **Understanding responsibilities**
  - Role of clinical contracting
  - Authority for the final decision
  - “Flagging” data
  - Interfacing with Compliance

Third Parties

- **Understanding the chain**
  - CROs
  - CROs using SMOs or other CROs
- **Receiving data**
  - CMS format
  - Company format

Process

- **Improving Existing**
  - Equipment loans
- **Creating New**
  - Delayed Payments
- **Communication**
  - Internal (among departments)
  - External (with physicians and institutions)

Systems and Data

- **Multiple Sources**
  - Clinical Trial Management System
  - Customer & Vendor Masters
  - CMS inputs (teaching hospital list)
- **Manual vs. automated systems**
  - Documentation
  - Business case for automation

Impact on Research

Research Professionals' Concerns

Many research professionals are concerned about the adverse impact of such disclosure requirements on medical innovation and clinical research

- **Research-Related Payments Misleading**
- **Compliance Costs divert Research Funds**
- **Harmful to Quality of Care**
- **Research Benefits could be Lost**
- **Lack of intended benefit for Patients**
- **Timing of Posting Relative to Activity**

Sources:
1. Shangold GA, Koren MJ. Impact of the Sunshine Law "Open Payment" Provision on Clinical Research, Bloomberg Law (December 20, 2013).

Do Research Payments Affect Patient care?

There is currently no empirical basis for:

- **Tying researchers' financial interest in a study to negative outcomes for patients**
- **Estimating the frequency of such problems**
- **The likelihood that transparent reporting will reduce them**
- **The likely resulting effects on reducing the cost of medical care**

The potential implications of such disclosure requirements include:

- **Making physicians and researchers less likely to collaborate with industry**
- **Shifting of resources away from patient care and innovation toward compliance costs**

Sources:
1. Harmon K. Should Doctors Disclose Conflicts of Interest to Trial Patients. Scientific American (August 27, 2009)
2. Shangold GA, Koren MJ. Impact of the Sunshine Law "Open Payment" Provision on Clinical Research, Bloomberg Law (December 20, 2013).

The academic debate

Are industry-physician interactions beneficial?

Point:

Because of the **difficulty** in determining when financial interactions between life sciences companies and researchers interject an **inappropriate level of bias,** all financial interactions between companies and researchers should be banned.[1]

Counterpoint:

"Doctors paid by pharmaceutical companies are 'leaders in their fields,' and patients should want to see their physician among them.[2]"

"Physicians have to please sponsors to get funded…
that doesn't mean sponsors don't want them to aspire to truth.[3]"

1. Jerome Kassirer, Medicine's Obsession with Disclosure of Financial Conflicts: Fixing the Wrong Problem, in Science and the Media: Delgado's Brave Bulls and the Ethics of Scientific Disclosure, 79, 79 (Peter Snyder, et al., eds., Academic Press 2009)
2. Charles Ornstein and Tracy Weber, In Minnesota, Drug Company Reports of Payments to Doctors Arrive Riddled With Mistakes, ProPublica (Dec. 10, 2010, 9 a.m.), http://www.propublica.org/article/in-minnesota-drug-company-reports-of-payments-to-doctors-mistaken
3. Thomas Sullivan, David Korn: Financial Conflicts of Interest In Academic Medicine – Why is He So Vexed?, Policy and Med. (Dec. 29, 2010 at 06:17 a.m.); see also Norman Kachuck, Managing conflicts of interest and commitment: academic medicine and the physician's progress, 37 J. Med. Ethics 2 (2010)

The Future

What does the Future hold?

Transparency

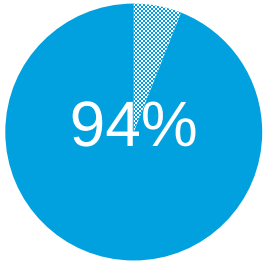
Patients will interrogate all information made available to them

Industry interactions with the medical profession have a profound positive influence on the quality of patient treatment but there is a growing expectation that industry interactions with healthcare providers should not only be conducted with integrity but also be transparent.

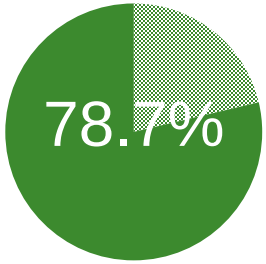
-- Anonymous Pharmaceutical Executive

Patients won't tolerate conflicts of interest

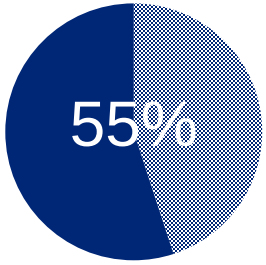
To bring about accountability, and accountability will strengthen the credibility of medical research, the marketing of ideas and, ultimately, the practice of medicine[1]



94% of U.S. physicians have had a relationship with a life sciences company[2]



Only 78.7% of U.S. physicians believe in putting a patient's interest above their own[3]



55% of patients believe their doctor receives industry gifts[4]

1. Press Release by Senator Charles Grassley (February 1, 2013)
2. Eric Campbell et al., A National Survey of Physician-Industry Relationships, 356 N Engl. J. Med. 1742, 1746-47 (2007)
3. Martin Roland, et al., Professional values and reported behaviors of doctors in the USA and UK: quantitative survey, Brit. Med. J. Quality & Safety at 3 (2011), http://qualitysafety.bmj.com/content/early/2011/02/07/bmjqs.2010.048173.full
4. David Grande, et al., Pharmaceutical Industry Gifts to Physicians: Patient Beliefs and Trust in Physicians and the Health Care System, J. Gen. Intern. Med. (Jun. 14, 2011), available at http://www.ncbi.nlm.nih.gov/pubmed/21671130

Patients use clinical study registers

The perception of burying study conclusions can be as harmful as doing so intentionally

Studies with **significant** or **positive** results were **more likely** to be published than those with non-significant or negative results[1]

Eliminating publication bias requires ensuring **public awareness** of studies and access to results. Clinical trial registries provide basic trial information, but access to unbiased trial results is **inadequate**[2]

Most trials subject to mandatory reporting [through the Food and Drug Administration Amendments Act (FDAAA) legislation] did **not report** results within a year of completion[4]

When full information about studies is inaccessible, **billions of dollars** in investment are wasted, bias is introduced, and research and **care of patients** are detrimentally **affected**[3]

1. Song, F et al. Health Technology Assessment 2010; Vol. 14: No. 8
2. Much, T et al. Pain 2014 Jul;155(7):1313-7
3. Chan, A et al. The Lancet 2014, Volume 383, Issue 9913, Pages 257 – 266
4. Prayle, A et al. BMJ 2012;344:d7373

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Professional Services means audit, tax, consulting and financial advisory services.