

Is the Sunshine Act the twilight of pharma-sponsored medical writing support?

John P. Gonzalez

Director of Publications Policy

AstraZeneca



Conflict of interest disclosure

- I am a full time employee of AstraZeneca
- I hold shares in AstraZeneca
- I am a member of the Board of Trustees of ISMPP and the MPIP Steering Committee
- The views expressed in this presentation are mine and NOT those of AstraZeneca



Physician Payment Sunshine Act

is part of the
“Patient Protection and Affordable Care
Act” (PPACA)

“Requires manufacturers and group purchasing organizations to report on a wide range of payments to physicians and physician-owned entities”



Physician Payment Sunshine Act

Items required to be reported:

- Consulting fees
- Compensation for services other than consulting
- Honoraria
- Gifts
- Entertainment
- Food
- Travel
- Education
- Research
- Charitable contributions
- Royalties or licenses

- Current or prospective ownership or investment interests
- Compensation for serving as faculty member or as speaker for CME program
- Grant
- *Any other nature of the payment or other transfer of value defined by the Secretary of Health & Human Services (sic)*



Physician Payment Sunshine Act

Excluded from reporting:

- Payments in the aggregate of less than \$100
- Product samples
- Patient education materials
- The loan of a device for less than 90 days
- Warranty replacements (devices)
- Items for use as a patient
- Discounts and rebates
- In-kind items used in charity care
- Dividends or distributions from a publicly-traded company



Physician Payment Sunshine Act

“Payment or other transfer of value”



What value does medical writing have?

- **\$ value**
- **Scientific reputation**
- **Opportunity; funding, promotion, etc**



Physician Payment Sunshine Act

Indirect payments: What is the value being calculated?

- \$20K paid to an agency for a medical writing project,
- Manuscript has 2 company authors 3 external authors, lead author does more work than co-authors.
- What about the agency costs in the 20K not directly associated with the medical writing?
- How much is the transfer of value in \$ for each author?
- What if the medical writer is a freelancer and charges \$10k for same job?
- What if the medical writer is a staff member at the pharmaceutical company?
- How will “fair market value” be applied?



Physician Payment Sunshine Act & Medical Writing

Lawyers are still working on this & the jury deliberating



What's next?





CODE OF PRACTICE
for the
PHARMACEUTICAL
INDUSTRY
2011

PMCPA | Prescription Medicines
Code of Practice Authority

- **Disclosure of the total amount of fees paid to consultants for certain services**
- **Total amounts paid to sponsor attendance at meetings organised by third parties.**
- **Monetary value of certain support to patient organisations**
- **Companies are encouraged to make publicly available information about benefits in kind provided by them**





Helping doctors make better decisions

Home

Research

Education

News

Co

Search all BMJ comment articles



From

1840



Jan

OPEN ACCESS: All **research articles** are freely available online, with no word limit

EDITOR'S CHOICE

Editor's choice

A sunshine act for Europe

BMJ 2011; 343 doi: 10.1136/bmj.d6593 (Published 13 October 2011)

Cite this as: *BMJ* 2011;343:bmj.d6593



The Law of Unintended Consequences!



No distinction between types of payments

Expert • Independent • Nonprofit

ConsumerReports.org®

Cars ▾ Appliances ▾ Electronics ▾ Home & Garden ▾ Babies & Kids ▾ Me

Home > News > Health > Drug safety

Top Product Ratings: [Ellipticals](#) | [Hospitals](#) | [Tooth whiteners](#) | [Blood-glucose meters](#) | [Insurance plans](#) | [Blood-pressure m](#)

Consumer News

Subscribe to Consumer News Feed

Twitter Facebook Email RSS Print More

DRUG SAFETY

Report identifies doctors on pharma's payroll

Oct 19, 2010 12:01 AM

"Tens of thousands of U.S. physicians are paid to spread the word about pharma's favored pills and to advise the companies about research and marketing," reports a [new investigation from ProPublica](#), an independent, nonprofit newsroom for investigative journalism. Consumer Reports, along with NPR, PBS Nightly Business Report, Boston Globe, and the Chicago Tribune, have joined with ProPublica to help inform the public about its report on these financial arrangements.



Research collaborations could be reduced

Health: Drug firms' relationships with doctors are cooling

Story

Comments

Share Print Font Size: - +

Share

Tweet

0

Recommend

Posted: Monday, November 7, 2011 12:01 am

By CYNTHIA BILLHARTZ GREGORIAN, St. Louis Post-Dispatch |

ST. LOUIS - Last year, pharmaceutical companies paid Dr. David Weinstein, an obstetrician and gynecologist with Consultants in Women's Healthcare in West County, Mo., \$43,000 less than they did in 2009. His speaker fees dropped from \$106,000 to \$66,293.

Dr. Kathryn Diemer, assistant dean at Washington University School of Medicine, collected about \$23,000 less from drug firms with her speaker fees falling from \$78,000 in 2009 to \$55,000.



Damage to the doctor-patient relationship

Expert • Independent • Nonprofit
ConsumerReports.org[®]

Cars ▾

Appliances ▾

Electronics ▾

Home & Garden ▾

Babies & Kids ▾

Mo

Home > News > Health > Drug safety

Top Product Ratings: [Ellipticals](#) | [Hospitals](#) | [Tooth whiteners](#) | [Blood-glucose meters](#) | [Insurance plans](#) | [Blood-pressure m](#)

Consumer News

Subscribe to
Consumer News Feed



DRUG SAFETY

Consumers wary of doctors who take drug-company dollars

Oct 19, 2010 12:02 AM

Would you trust a doctor who moonlights for a drug company? Most Americans are skeptical of such financial arrangements, according to a new, nationally representative poll of 1,250 U.S. adults from Consumer Reports National Research Center.

Most respondents, 74 percent, disapprove of doctors taking payments from drug companies in exchange for promoting specific drugs to other doctors. And 77 percent would be concerned—some “very concerned” (37 percent) and others



Implications?

- Will public disclosure of medical writing support received from industry discourage authors from accepting this assistance?
- More negative publicity around influence of industry on medical literature
- Will this “value” have to be disclosed in the journal
- What other models of medical writing provision could emerge, i.e. detailed in Clinical Trial Agreement, investigator contracts with 3rd party?
....and others?



Thank you!

Any questions?

Confidentiality Notice

This file is private and may contain confidential and proprietary information. If you have received this file in error, please notify us and remove it from your system and note that you must not copy, distribute or take any action in reliance on it. Any unauthorized use or disclosure of the contents of this file is not permitted and may be unlawful. AstraZeneca PLC, 2 Kingdom Street, London, W2 6BD, UK, T: +44(0)20 7604 8000, F: +44 (0)20 7604 8151, www.astrazeneca.com

