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

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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”

How does this apply to medical writing support to a 3rd party? i.e. is this an indirect payment?

How would that “value” be calculated & reported?

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?
• 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
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!
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.
Health: Drug firms' relationships with doctors are cooling

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.
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?