The Relationship between Physicians and Industry Goes and Woes

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Declaration of Competing Interests


Steering Committees: multiple trials including antiarrhythmic drugs, implantable devices, ablation and novel anticoagulants.

Events Committees: multiple trials of miscellaneous agents with CV effects.

Editorial Role: Editor-in-Chief, EP-Europace and Clinical Cardiology; Editor, European Textbook of Cardiology, European Heart Journal, Electrophysiology of the Heart, and Evidence Based Cardiology.

Consultant/Advisor/Speaker: Astellas, Astra Zeneca, ChanRX, Gilead, Merck, Menarini, Otsuka, Sanofi, Servier, Xention, Bayer, Boehringer Ingelheim, Bristol-Myers Squibb, Daiichi Sankyo, Pfizer, Boston Scientific, Biotronik, Medtronic, LivaNova, St. Jude Medical, Actelion, GlaxoSmithKline, InfoBionic, Incarda, Johnson and Johnson, Milestone, Mitsubishi, Novartis, Takeda.
Partnership

Drugs and devices for evaluation
Development funding
Dissemination (educational funding) – product specific and general

Pharma Device

Clinical unmet need information
Clinical trial expertise
Clinical trial implementation (research sites and patients)
Clinical trial interpretation and guidance (including guidelines)
Clinical implementation (prescriptions, etc.)

Physician
Partnership (8P’s + 1)
The relationship between the doctor and the druggist or apothecary has been the subject of satire for hundreds of years. Moliere, in his play, *The Imaginary Invalid* (1673), skewers both professions who seek to exploit the hypochondriac, Argan, the imaginary invalid. In the play, both the physician and the apothecary fleece the patient for their own economic benefit.


The Ethics Arguments

- **Ethical physicians** are always motivated to do their best for their patients.

- Since any relationships between physicians and the drug industry might taint the objectivity of the physicians, the only correct behaviour for ethical physicians is to *ignore any and all pharma industry representatives, advertisements or incentives*.

- Physicians should prescribe drugs based **solely on their objective study of the scientific literature** and should not attend any lectures or obtain consultations from colleagues who have economic relationships with the pharma industry.

- The **ethical pharmaceutical industry**, on the other hand, should never seek to influence physicians or patients with advertising. No gifts or incentives should be offered to medical professionals.
Medical Research from Industry
Justification for Regulation

- Research misbehaviour
- Bias
- Secrecy
- Academic freedom
- Quality of research
-Appearances and public trust
Pharma Activity over Past Two Decades
Activity Up but New Molecules Down

1999–2001
86 FDA NME approvals (29 per year)

2009–2011
77 FDA NME approvals (26 per year)

Global R&D spending by world’s top 500 pharma companies (US$bn)

Number of companies performing pharma R&D

Note: FDA is the U.S. Food and Drug Administration. Percentages may not resolve due to rounding.
Sources: Parexel Sourcebook Biopharmaceutical R&D Statistical Sourcebook 2011/2012, Food and Drug Administration Center for Drug Evaluation and Research
(Potential) **Conflict** (Declaration of Competing Interest)

Framing a physician’s relationships with industry by using the term “Conflict of interest” insinuates that in order to receive commercial funding to do research, CME, or consulting, etc., the physician behaved (or appeared to behave) unprofessionally, putting patients at increased risk of harm.

“Conflict” carries an inherently **negative connotation**, insinuating that the physician has questionable motives based solely on an association with industry.

The COI framing bias dictates a conclusion by linguistic fiat – the only appropriate response to a “conflict” is to eliminate, manage, or reduce it. The framing bias cuts off from appreciation that **the complex relationships between industry and the medical profession are almost always positive and are perceived as such by most physicians.**
The Patient–Physician–Industry–Government Partnership
A Societal Good

While there have been cases of physician–researcher conflicts of interest “overall, however, the patient–physician–industry–government partnership has been a great success, and a union that has benefited many.”

What is important to consider is that with such significant breakthroughs in the past and present, who or what would replace the pharmaceutical industry if it had no incentive to make drugs, and stopped developing them?

Politicians are not likely to “nationalize the pharmaceutical industry as they did General Motors and Chrysler.”
Physicians and the Pharmaceutical Industry
Is a Gift Ever Just a Gift?

● 538 studies with any relevant data, 29 of could be included in the analysis

● Physician interactions with pharma representatives were generally endorsed, began in medical school, and continued on average 4 times/month.

● Meetings with pharma reps associated with requests by physicians for adding drugs to the hospital formulary and changes in prescribing practice.

● Attending sponsored CME events and accepting funding for travel etc. were associated with increased prescription rates of the sponsor’s medication.

● Conclusion: the extent of physician-industry interactions appears to affect prescribing and professional behaviour

# Frequency of Physician–Industry Relationships According to Benefit Received

Survey of 3167 physicians; 1651 responded

<table>
<thead>
<tr>
<th>Benefit</th>
<th>No. of Respondents (%)*</th>
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<tbody>
<tr>
<td>Drug samples</td>
<td>1255 (78)</td>
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<tr>
<td>Gifts</td>
<td>1391 (83)</td>
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<tr>
<td>Food or beverages in workplace</td>
<td>1386 (83)</td>
</tr>
<tr>
<td>Tickets to cultural or sporting events</td>
<td>122 (7)</td>
</tr>
<tr>
<td>Reimbursements</td>
<td>542 (35)</td>
</tr>
<tr>
<td>For admission to CME meetings (free or subsidized)</td>
<td>382 (26)</td>
</tr>
<tr>
<td>For meeting expenses (e.g., travel, food, lodging)</td>
<td>260 (15)</td>
</tr>
<tr>
<td>Payments</td>
<td>456 (28)</td>
</tr>
<tr>
<td>For consulting</td>
<td>282 (18)</td>
</tr>
<tr>
<td>For serving as a speaker or on a speakers’ bureau</td>
<td>278 (16)</td>
</tr>
<tr>
<td>For serving on an advisory board</td>
<td>139 (9)</td>
</tr>
<tr>
<td>For enrolling patients in clinical trials</td>
<td>55 (3)</td>
</tr>
<tr>
<td>Any of the above relationships</td>
<td>1554 (94)</td>
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**Specialty** | **Samples** | **Gifts** | **Re-imbursements** | **Payments** |
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<tbody>
<tr>
<td>Family practice</td>
<td>1.00‡</td>
<td>1.00</td>
<td>1.00‡</td>
<td>1.00‡§</td>
</tr>
<tr>
<td>Internal medicine</td>
<td>0.72 (0.42–1.25)‡</td>
<td>0.54 (0.32–0.90)†</td>
<td>1.26 (0.87–1.83)‡</td>
<td>1.35 (0.89–2.04)‡</td>
</tr>
<tr>
<td>Pediatrics</td>
<td>0.56 (0.33–0.94)‡</td>
<td>0.67 (0.40–1.12)</td>
<td>0.59 (0.41–0.86)†***</td>
<td>0.51 (0.33–0.78)†§**</td>
</tr>
<tr>
<td>Anesthesiology</td>
<td>0.05 (0.03–0.09)§, **††</td>
<td>0.89 (0.49–1.64)</td>
<td>0.31 (0.20–0.48)§, **††</td>
<td>0.21 (0.12–0.36)§, **††</td>
</tr>
<tr>
<td>Cardiology</td>
<td>1.64 (0.79–3.41)†</td>
<td>1.14 (0.61–2.13)</td>
<td>1.04 (0.69–1.55)†</td>
<td>2.20 (1.43–3.38)†‡,</td>
</tr>
<tr>
<td>Surgery</td>
<td>0.43 (0.24–0.77)†‡§</td>
<td>0.82 (0.47–1.43)</td>
<td>0.75 (0.51–1.11)†</td>
<td>0.43 (0.27–0.67)†§, **††</td>
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How Much Are Drug Companies Paying Your Doctor?

New data released today will promote transparency and help patients know when docs receive money from product makers.

Company U.S. Sales
- Novartis: $19B
- Pfizer: 17B
- Merck: 16.2B
- AstraZeneca: 16.2B
- Eli Lilly: 15.3B
- Amgen: 14.8B
- Johnson & Johnson: 13.9B
- GlaxoSmithKline: 12.8B
- Boehringer Ingelheim: 7.7B

Company Spending on Speaker Fees
- Boehringer Ingelheim: 12.5M
- Merck: 11.5M
- Amgen: 6M
- GlaxoSmithKline: 6.8M
- AstraZeneca: 24.1M
- Johnson & Johnson: 18.9M
- Eli Lilly: 14.3M
- Novartis: 12.7M
- Pfizer: 12.6M
- Forest: $32.3M

Most of Amgen's interactions with doctors last year came in the form of meals, but those accounted for a small share of its payments (excluding research). By contrast, promotional speakers accounted for far fewer interactions but at a much higher cost.
In 2014, Pfizer paid physicians about $287 million, but $234 million (over 80%) went to pay for research. Similarly, 78% of Merck’s $125.2 million in physician payments were also for research. The notion that doctors do research will likely come as a surprise to most. But the fact of the matter is that clinical trials for new drugs are run not by the sponsoring manufacturers, but by doctors at the leading teaching hospitals in the country and under the aegis of independent review boards. Much of the $6.5 billion being paid by companies to physicians is being used to pay doctors [and hospitals] for their work in conducting clinical trials.
Coronal Mass Ejection (CME)
Continuing Medical Education
A Challenge to Ensure Bona Fide Education

Elimination of Commercial Sponsorship of Accredited CME

First approach: surest way to eliminate commercial bias in CME, is to eliminate commercial sponsorship. Physicians would then have to pay for their own CME. Loss of the sponsored CME programs that do serve a true educational need. (approximately $1,500 currently funded by the pharmaceutical and device industry for each of the 633,000 physicians working in the USA).

Commercial Sponsorship of CME without Control of the Educational Agenda

Second approach: allow commercial organizations to sponsor accredited CME programs but not to control the agenda.

Pooled-Funding Mechanism

Independent CME grant organizations could amalgamate contributions from sponsors and award grants to support programs without allowing the donors to specify which programs.
Peer selling occurs when a pharmaceutical or medical device manufacturer or service provider engages a physician to conduct a seminar or similar event that focuses on its own products and is designed to enhance the sale of those products. This also applies to third party contracting on behalf of industry. This form of participation would reasonably be seen as being in contravention of the CMA’s Code of Ethics, which prohibits endorsement of a specific product. CMA= Canadian Medical Association

Reid L and Harper M, Open Medicine 2013;7(2)e32
“Speakers’ Bureaus”
Third Party CME Accreditation

Mechanisms for clarifying CME as credible alternative to speakers’ bureau events

➢ Requiring arms-length arrangements for industry funding of CME programs
➢ Limiting or prohibiting industry influence on CME content
➢ Limiting or prohibiting industry attendance or exhibition at educational events
➢ Applying educational rather than advertising standards to CME content
➢ Setting standards prohibiting ghost authorship of CME materials; requiring disclosure of co-authorship and forbidding (or requiring disclosure of) industry funding of or employees acting as co-authors

Mechanisms for controlling participants in speakers’ bureaus in terms of acting as CME faculty

➢ Forbidding direct industry payment to CME faculty for CME teaching
➢ Requiring disclosure from CME faculty and scientific committee members of their non-CME speakers’ bureau activities; preferentially recruiting non-speakers’ bureau participants to CME faculty and scientific committees; prohibiting speakers’ bureau participants from roles with CME faculty and scientific committees

Reid L and Harper M, Open Medicine 2013;7(2)e32
Relations between professional medical associations and the health-care industry, concerning scientific communication and continuing medical education: a Policy Statement from the European Society of Cardiology

ESC Board*
Conflict of interest: Luigi Paolo Badano received speaker fees, honoraria, consultancy, advisory board fees, investigator, committee member, etc. from Malesci, Medtronic, GE Healthcare and also received speaker fees, honoraria, consultancy, advisory board fees, investigator, committee member, etc. from Actelion through institution. Jeroen Bax received speaker fees, honoraria, consultancy, advisory board fees, investigator; committee member, etc. HeartLog, Astra Zeneca, Servier, Philips, GE Healthcare, Lantheus Inc, Boston Scientific, Medtronic, St Jude Medical, Biotronik, Impulse Dynamics. Michael Boehm received speaker fees, honoraria, consultancy, advisory board fees, investigator, committee member, etc. from Astra Zeneca, Bayer AG, Boehringer-Ingelheim, Daiichi-Sankyo, MSD, Novartis, Pfizer, Sanofi-Aventis, Servier and also received speaker fees, honoraria, consultancy, advisory board fees, investigator, committee member, etc. from AstraZeneca, Bayer AG, Boehringer-Ingelheim, Novartis, Pfizer, Sanofi-Aventis, Servier through institution. Martin Borggreve received speaker fees, honoraria, consultancy, advisory board fees, investigator, committee member, etc. from St Jude Medical, Bard, Boehringer-Ingelheim, Sanofi Aventis, Bayer Healthcare, Medtronic, Impulse Dynamics, Boston Scientific, received speaker fees, honoraria, consultancy, advisory board fees, investigator, committee member, etc. from Boehringer-Ingelheim, Pfizer, Sanofi Aventis, Medtronic, St Jude Medical, Impulse Dynamics through institution and also received royalties for intellectual property from Thieme Verlag. Christi M. Deaton received speaker fees, honoraria, consultancy, advisory board fees, investigator, committee Member, etc. from St Jude Medical, Daiichi Sankyo, Eli-Lilly, Muzaffer M. Degertekin received speaker fees, honoraria, consultancy, through institution. Fausto Jose Pinto received speaker fees, honoraria, consultancy, advisory board fees, investigator, committee member, etc. from Boehringer-Ingelheim, Servier, GE Healthcare and also received speaker fees, honoraria, consultancy, advisory board fees, investigator, committee member, etc. from Servier through institution. Piotr Poniowskki received speaker fees, honoraria, consultancy, advisory board fees, investigator, committee member, etc. Schering-Plough, Amgen, Sanofi Aventis, Merck Sharp & Dohme, Sanofi Aventis, Novartis, Pfizer, Servier, Duke University, Johnson & Johnson, Bayer Healthcare, Merck Sharp & Dohme, Respiscardia, Vifor International, F. Hoffman La Roche Ltd. and also received speaker fees, honoraria, consultancy, advisory board fees, investigator, committee member, etc. from Schering-Plough, Amgen, Merck Sharp & Dohme, Novartis, Servier, Johnson & Johnson, Bayer Healthcare, Duke University, F. Hoffman La Roche Ltd. through institution. Adam Torbicki received speaker fees, honoraria, consultancy, advisory board fees, investigator, committee member, etc. from Boehringer-Ingelheim, Sanofi Aventis, Pfizer, Actelion, Lilly, Bayer Healthcare. Frans Van de Werf received speaker fees, honoraria, consultancy, advisory board fees, investigator, committee member, etc. from Eli Lilly, Merck Sharp & Dohme, Astra Zeneca, Boehringer-Ingelheim. Panagiotis Vardas received speaker fees, honoraria, consultancy, advisory board fees, investigator, committee member, etc. from Sanofi Aventis, Servier, Boehringer-Ingelheim. David Allan Wood received speaker fees, honoraria, consultancy, advisory board fees, investigator, committee member, etc. from Roche Pharma, Bayer Schering Pharma, AstraZeneca, Zentiva, Merck Sharp & Dohme, Chugai Pharma UK, Pfizer.
1. Every member of a programme committee must complete a DoI. No employee of a medical company can serve ...

2. Speakers should be selected for a session to provide a balanced view or a comparison between protagonists, with time for questions and discussion.

3. All chairpersons and speakers must complete a disclosure of interests.

4. All chairpersons and speakers must show a slide with their disclosure of interests, for long enough to ensure that the audience has time to read all of its contents. This should include a statement of possible academic conflicts of interest as well as any links with the health-care industry.

5. It is the responsibility of the chairpersons during any session to bring to the attention of the audience any clear conflicts of interest that have not been disclosed.
A clinical scientist gives a lecture on his own research, referring to an invention which he has patented but not yet commercialized, but without disclosing his interest or reviewing alternatives.
An interventional cardiologist presents the results of a non-randomized, open study of a new device that was developed in his institution in collaboration with a company, at a sponsored symposium during a congress. He does not declare that the results of the intervention were analysed by the clinical research organization of which he is the principal shareholder or that he will receive a fee for speaking. A fee is paid by the company to the congress organizers but this is not disclosed.
The Physician Payments Sunshine Act is a 2010 United States healthcare law to increase transparency of financial relationships between health care providers and pharmaceutical manufacturers.

The public registry would allow everyone to evaluate the level of financial gain and potential conflict of interest that a particular doctor, partner, or medical lecturer has with respect to a specific product or company.


Payments for the following must be reported:

- Research funding, such as grants
- Speakers’ honoraria
- Travel expenses
- Meals
- Entertainment
- Gifts
- Educational materials like textbooks or journal reprints
- Participating in a paid advisory board
- Writing manuscripts

Reports are only required for physicians licensed to practice in the United States. This excludes medical students, residents, support and office staff, nurses, advance practice nurses, physician assistants, and others.
Impact of the Massachusetts Pharmaceutical and Medical Device Manufacturer Code of Conduct on medical device physician-industry collaboration

July 2009: Pharma and Device companies should comply with a marketing code of conduct, obey specific compliance activities, and disclose payments to Massachusetts-licensed healthcare providers with a value of $50 or more.

- 75%: Gift Ban legislation had severely impaired their ability to interact with industry
- Nearly 75%: reported that the Gift Ban law had impaired physician education
- More than 50% reported that there would be a resultant negative long-term impact on patient care.
- Almost 50% reported that there had been a reduced exposure to therapeutic options
- 83% of respondents noted that there had been a resultant decrease in funding for fellowships, non-CME education, and research.

- 70% of industry-stakeholder respondents noted an impaired ability to collaborate with physicians
- 83% reported a decreased interest in collaborating with Massachusetts physicians

The hypothesis was confirmed that 105 CMR 970.000 has impaired medical device physician-industry collaboration related to technology development and physician education in Massachusetts.

Wolf, Daniel W. 2010 http://hdl.handle.net/1721.1/58093
Physician Disclosure of Payments from Pharmaceutical Companies

ProPublica, compiled the **Dollars for Docs** database of payments to individuals from publically available data from seven US pharmaceutical companies during the period 2009 to 2010.

- Cohort of 373 physicians in this database who each received USD $100,000 or more in the reporting period 2009 to 2010.
- These physicians received a total of $52,600,624 during this period (mean payment per physician $141,020).
- 147 of these physicians authored a total of 134 publications in the first quarter of 2011 and 77% (103) of these publications provided a COI disclosure.
- 69% of the 103 publications did not contain disclosures of the payment listed in the **Dollars for Docs** database.

Norris et al. BMC Medical Ethics 2012, 13:24
Failure of commercial organisations to prevent bribery

(1) A relevant commercial organisation ("C") is guilty of an offence under this section if a person ("A") associated with C bribes another person intending—
   (a) to obtain or retain business for C, or
   (b) to obtain or retain an advantage in the conduct of business for C.

(2) But it is a defence for C to prove that C had in place adequate procedures designed to prevent persons associated with C from undertaking such conduct.

(3) For the purposes of this section, A bribes another person if, and only if, A—
   (a) is, or would be, guilty of an offence under section 1 or 6 (whether or not A has been prosecuted for such an offence), or
   (b) would be guilty of such an offence if section 12(2)(c) and (4) were omitted.

(4) See section 8 for the meaning of a person associated with C and see section 9 for a duty on the Secretary of State to publish guidance.
Brussels, 15 October 2014 – The Executive Committee of the European Diagnostics Manufacturers Association (EDMA) and the Board of the European Medical Technology Industry Association (Eucomed), both members of MedTech Europe, in a continuous effort to reinforce their respective Codes of Ethical Business Practice today announce their recommendation to members to phase out by 1 January 2018 direct industry sponsorship of healthcare professionals (HCPs) to third-party organised conferences. Both associations are also recommending the introduction of stricter rules for indirect sponsorship. The MedTech industry remains committed to supporting the continuing medical education of HCPs and will continue its ongoing consultation with HCP organisations and other stakeholders to ensure that HCPs have access to the education they need.
Principles of the Code

The Principle of Image and Perception
Member Companies should, at all times, consider the image and perception of the medical technology industry.

The Principle of Separation
Interaction between industry and HCPs must not be misused to influence through undue or improper advantages, purchasing decisions.

The Principle of Transparency
Interaction between industry and HCPs must be transparent and comply with national and local laws, regulations or professional codes of conduct.

The Principle of Equivalence
Where Healthcare Professionals are engaged by a Company to perform a service, the remuneration paid must be commensurate with a fair market value.

The Principle of Documentation
For interactions between a Company and a HCP, there must be a written agreement setting out, the purpose of the interaction, the services to be performed, the method for reimbursement.
Event Location and Venue

Location/venue should not be main attraction

- Adverse public perceptions of the location
- Perceived image of the location/venue must not be luxury, or holiday-oriented
- The location/venue should be centrally located
- The need for ease of access for attendees
- The location/venue should be in/near a city/town which is conducive to the exchange of ideas and knowledge.
- Must take into account the season – not tourist
1. General Principles

Member Companies *may invite Healthcare Professionals to Company Events*. Such events include, as defined in the

- Product and Procedure Training and Education Events
- Sales, Promotional and Other Business Meetings

2. Product/Procedure Training

In order to facilitate the safe and effective use of medical technologies, therapies and/or services, Member Companies *should make product and procedure training and education available to relevant Healthcare*
c. The payment (or provision of other support) by way of any Grant or Charitable Donation shall always be made out in the name of the recipient organisation and shall be paid directly to the organisation. A Member Company shall not provide Grants or Charitable Donations in the name of any Healthcare Professional. In addition, all Grants and Charitable Donations shall identify the Member Company as the provider of the Grant or Charitable Donation.
Physician Pharma Partnership
Ensuring Progress

“Cur’d yesterday of my disease, I died last night of my physician.”

The Remedy Worse than the Disease

Matthew Prior (1664-1721)
Thank you for your attention