Teaching on conflicts of interest: a student-led model

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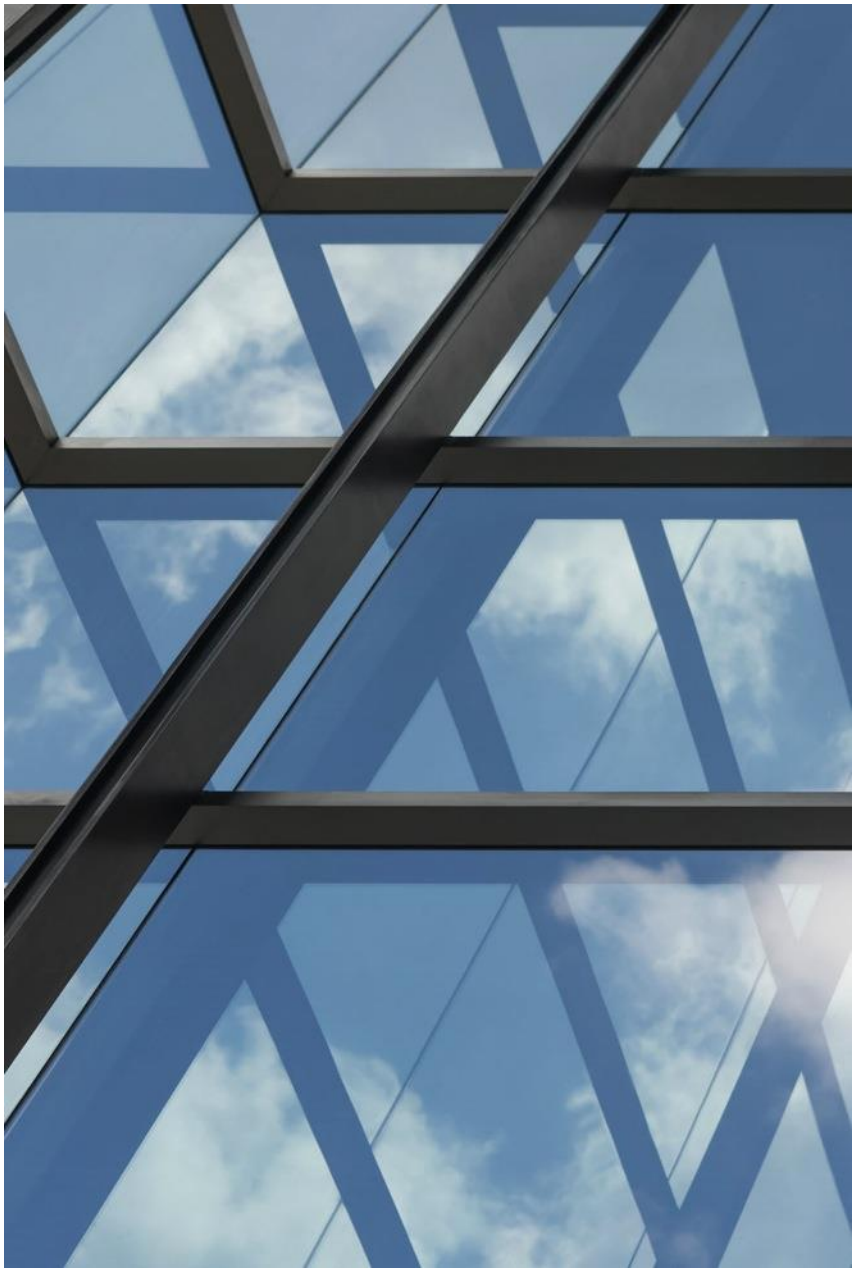
Workshop: Education on pharmaceutical promotion in medical training,
Amsterdam, VU, Sept 7, 2017

THE UNIVERSITY OF SYDNEY



Financial disclosure

- No pharmaceutical industry funding
- Expert witness on two Canadian class action suits against pharmaceutical companies

What I will cover

- Addressing the “hidden curriculum”
- American Medical Student Association (AMSA) model curriculum on conflicts of interest (COI)
- Has education been shown to be effective?

Exposure to marketing is widespread

OPEN ACCESS Freely available online

PLoS MEDICINE

Medical Students' Exposure to and Attitudes about the Pharmaceutical Industry: A Systematic Review

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Abstract

Background: The relationship between health professionals and the pharmaceutical industry has become a source of controversy. Physicians' attitudes towards the industry can form early in their careers, but little is known about this key stage of development.

Methods and Findings: We performed a systematic review reported according to PRISMA guidelines to determine the frequency and nature of medical students' exposure to the drug industry, as well as students' attitudes concerning pharmaceutical policy issues. We searched MEDLINE, EMBASE, Web of Science, and ERIC from the earliest available dates through May 2010, as well as bibliographies of selected studies. We sought original studies that reported quantitative or qualitative data about medical students' exposure to pharmaceutical marketing, their attitudes about marketing practices, relationships with industry, and related pharmaceutical policy issues. Studies were separated, where possible, into those that addressed preclinical versus clinical training, and were quality rated using a standard methodology. Thirty-two studies met inclusion criteria. We found that 40%–100% of medical students reported interacting with the pharmaceutical industry. A substantial proportion of students (13%–69%) were reported as believing that gifts from industry influence prescribing. Eight studies reported a correlation between frequency of contact and favorable attitudes toward industry interactions. Students were more approving of gifts to physicians or medical students than to government officials. Certain attitudes appeared to change during medical school, though a time trend was not performed; for example, clinical students (53%–71%) were more likely than preclinical students (29%–62%) to report that promotional information helps educate about new drugs.

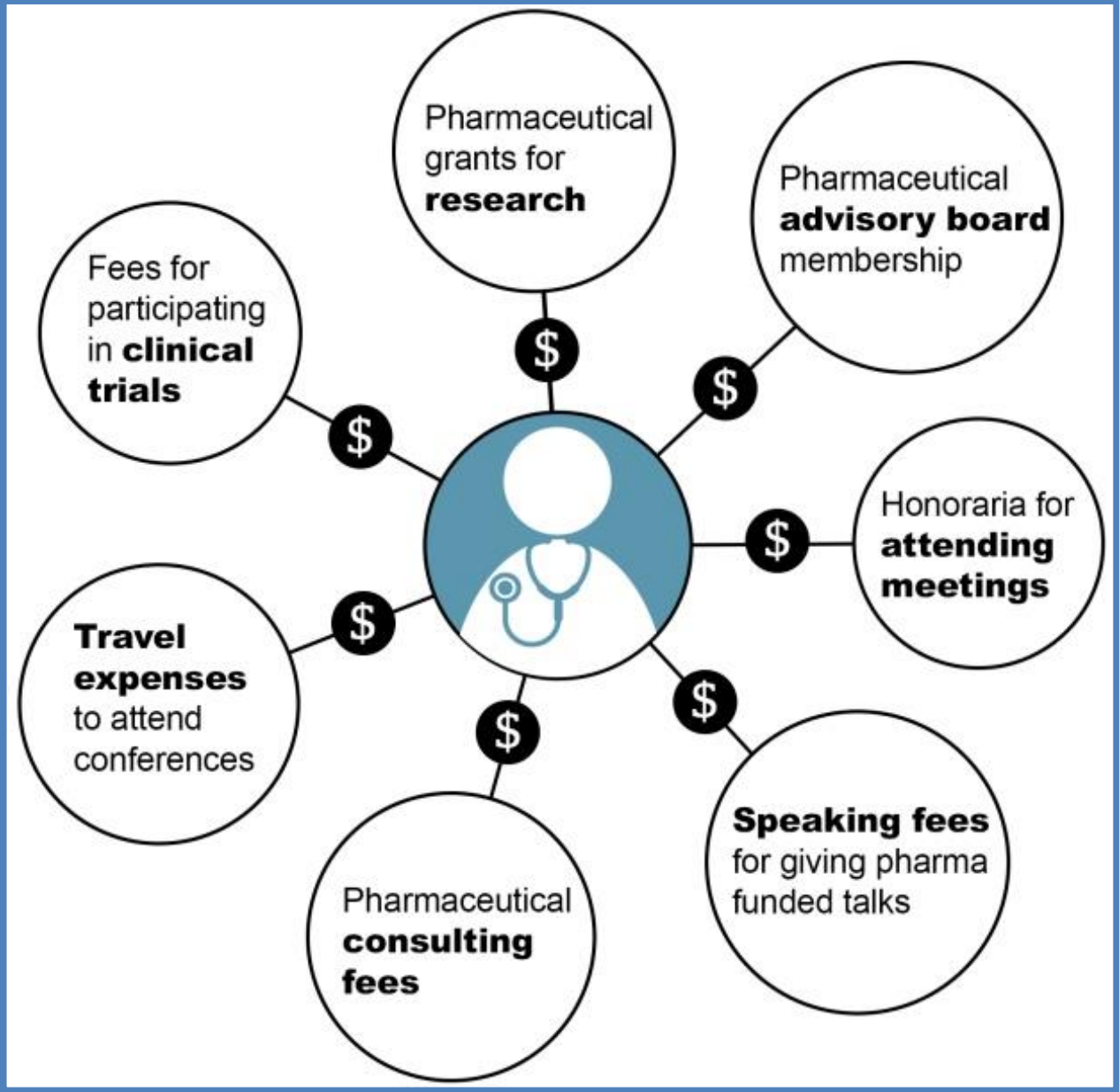
Austad et al. PLoS Med 2011; 8(5): e1001037

Medical students' exposures and attitudes
n=32 studies in 14 countries

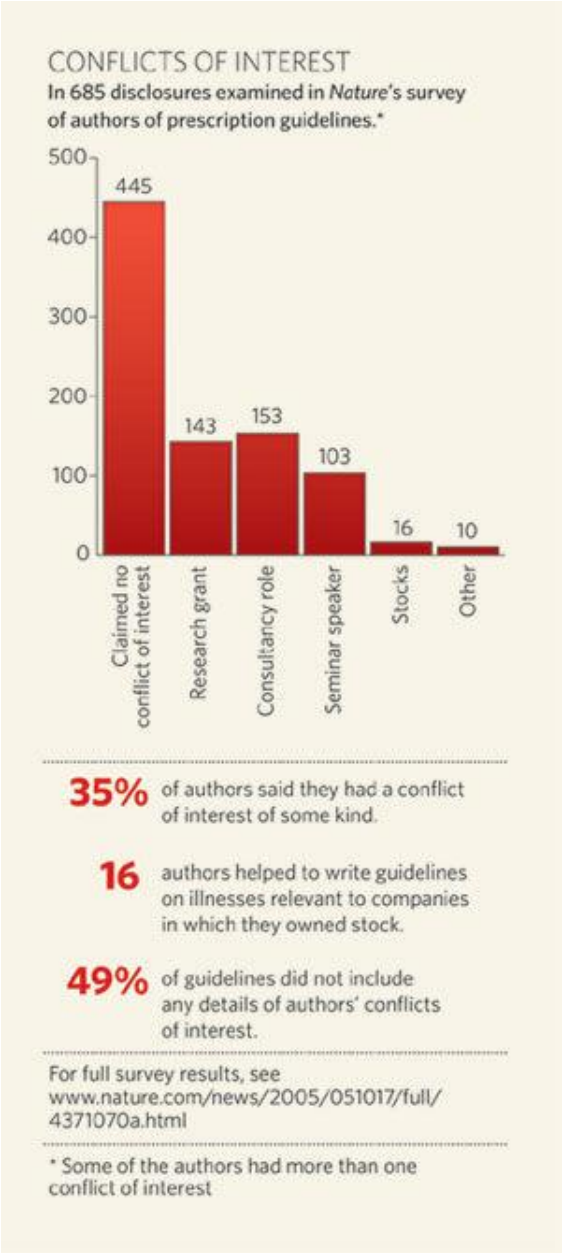
- Frequent exposure to marketing throughout training
- More contact in clinical than pre-clinical years
- More restrictive policies, more skepticism
- 62 to 86% felt inadequately educated on interactions

Austad et al. PLoS Med 2011; 8(5): e1001037

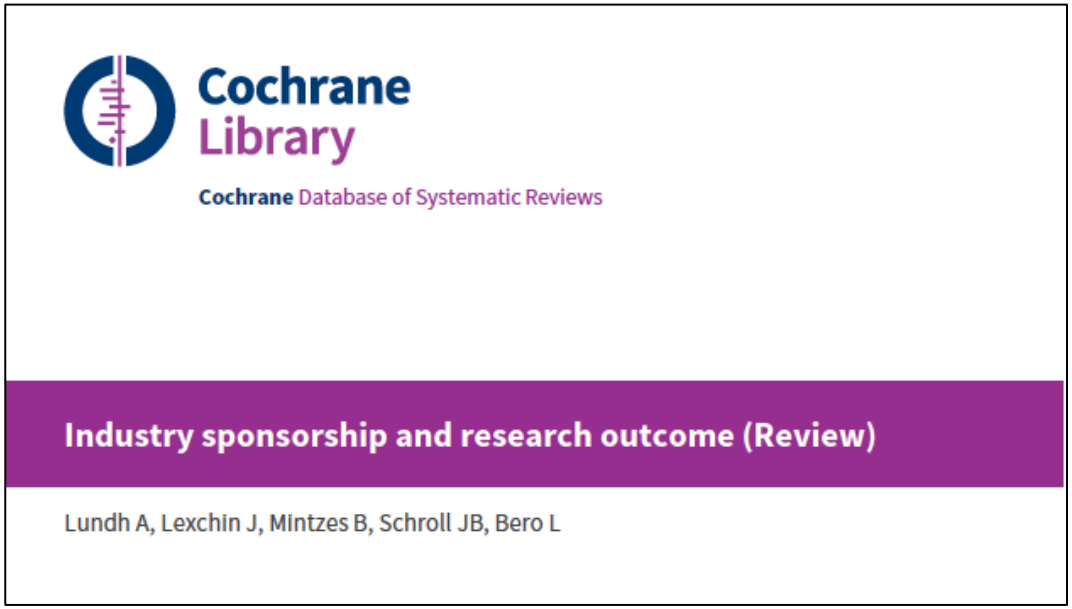
Funding of faculty members

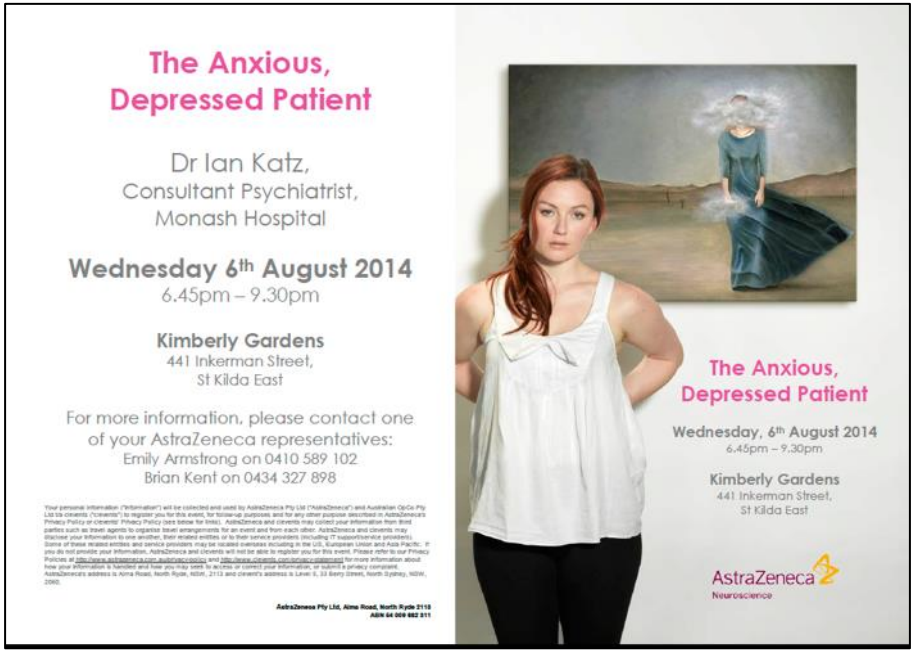


http://www.cbc.ca/news/health/doctors-pharmaceutical-funding-1.4164625



Taylor R, Giles J. Cash Interests Taint Drug Advice. Nature 2005; **437**: 1070-1





Questionable content of an industry-supported medical school lecture series: a case study

Table 1 Analgesics listed in the WHO pain ladder and lecture version

		WHO pain relief ladder[13]	'Modified WHO analgesic ladder'
Step 1	Non-opioids±adjuvants	Aspirin, paracetamol	Acetaminophen, aspirin, NSAIDs
Step 2	Mild or weak opioids±non-opioids±adjuvants	Codeine	Tramadol, codeine, oxycodone
Step 3	Strong opioids±non-opioids±adjuvants	Morphine	Hydromorphone, morphine, oxycodone, fentanyl, methadone, buprenorphine

NSAIDs, non-steroidal anti-inflammatory drugs.

Persaud N, Journal of Medical Ethics 2013; 0: 1-5

Jarvinen et al. JGIM 2015; 277: 662-673

A need for institutional change

AAMC Task Force on Industry Funding of Medical Education

Recommendation: Medical schools and teaching hospitals should design curriculum standards and teaching materials for all phases of medical education—from medical school to residency to continuing medical education—that provide tools to educate students, residents, and faculty about the processes and disciplines of drug discovery, development, clinical testing, safety, therapeutics, and regulation.

Institute of Medicine "Conflict of Interest in Medical Research, Education, and Practice"

Recommendation 5.2: Academic medical centers and teaching hospitals should education faculty, medical students and residents on how to avoid or manage conflicts of interest and relationships with pharmaceutical and medical device industry representatives. Accrediting organizations should develop standards that require formal education on these topics.

American Medical Students Association

amsa
American Medical Student Association

http://amsascorecard.org/

AMSA Scorecard 2016

Scorecard | About | Methodology | Executive Summary | Policy Updates

Conflict of Interest Policies at Medical Schools

● MODEL ◑ GOOD ○ POOR/ABSENT

Institution	Grade	Gifts	Meals	Speaking relationships	CME	Promotional events	Scholarships and awards	Ghostwriting	Consulting	Sales reps	Device reps	Disclosure	COI curriculum	COI policy extension	Enforcement
Indiana University School of Medicine Indianapolis, IN	A	●	●	●	◑	●	◑	●	●	●	●	●	●	●	●
Florida International University Herbert Wertheim College of Medicine Miami, FL	A	●	●	●	●	●	●	●	●	◑	●	●	●	◑	●
Jacobs School of Medicine and Biomedical Sciences at the University at Buffalo Buffalo, NY	A	◑	◑	●	●	●	●	●	●	●	●	●	●	●	●
University of Chicago Division of the Biological Sciences The Pritzker School of Medicine Chicago, IL	A	●	●	◑	●	●	◑	●	●	●	●	●	●	●	●
Edward Via College of Osteopathic Medicine (Alabama, South Carolina, and Virginia	A	●	◑	●	●	●	●	●	●	○	●	●	●	COI Policy Extension: 3	

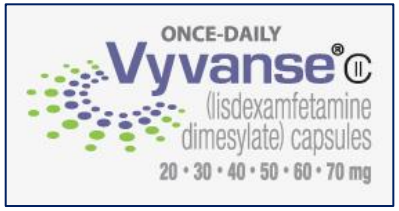
AMSA PharmFree ScoreCard
"Just Medicine" campaign

- 2007 – first public reporting of medical faculty COI policies
- 2008 collaborated with Pew Prescription Project to develop a systematic "scorecard" with 11 domains; 4-point scale
- Annual assessments 2008 to 2013
- Influence on policy: by 2013, 26% had an A vs 5% in 2008
- In 2014, ScoreCard revised:
  - Increased from 11 to 14 domains
  - Curriculum criteria strengthened:

    "comprehensive curriculum mirroring AMSA best practices"

BMJ

BMJ 2013;346:f264 doi: 10.1136/bmj.f264 (Published 31 January 2013)



RESEARCH

Medical school gift restriction policies and physician prescribing of newly marketed psychotropic medications: difference-in-differences analysis

Marissa King *assistant professor of organizational behavior*[1], Connor Essick *research assistant*[1], Peter Bearman *Jonathan Cole professor of the social sciences*[2], Joseph S Ross *assistant professor of medicine*[3]

[1]Yale University School of Management, New Haven, CT, USA; [2]Interdisciplinary Center for Innovative Theories and Empirics, Columbia University, New York, NY 10027, USA ; [3]Section of General Internal Medicine, Department of Medicine, Yale University School of Medicine, New Haven, CT, USA

AMSA ScoreCard

- In 2016(n=173): medical faculty grade A (24%); B (44%), C (16%). incomplete 16%
  - Curriculum on conflicts of interest: 25%
  - No gifts : 54%

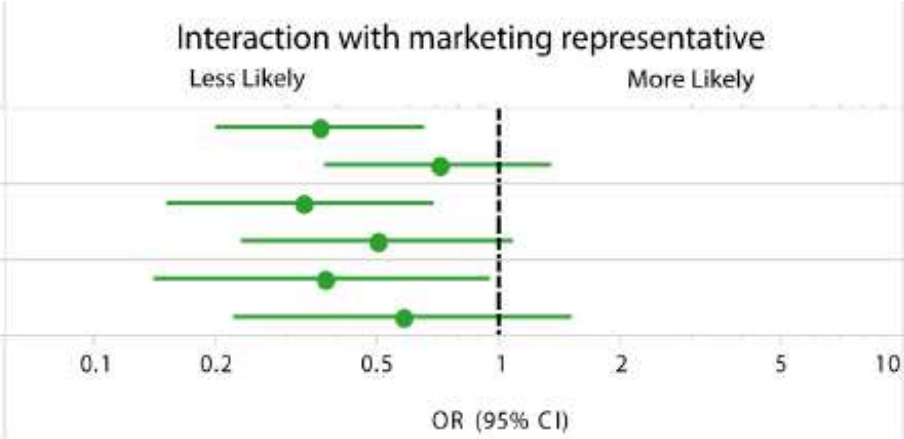
  - No industry-funded meals: 24%

  - No Faculty on company speakers' bureaus: 49%

Student reports versus faculty policies

Yeh et al. PLoS Med 2014; 11 (10): e1001743

Scoring System	Model	OR (95% CI)
AMSA Grade	Unadjusted	0.36 (0.20 , 0.65)
	Adjusted	0.71 (0.37 , 1.35)
AMSA Score	Unadjusted	0.33 (0.15 , 0.69)
	Adjusted	0.50 (0.23 , 1.08)
IMAP Score	Unadjusted	0.37 (0.14 , 0.95)
	Adjusted	0.58 (0.22 , 1.51)



Scoring System	Model	OR (95% CI)
AMSA Grade	Unadjusted	1.43 (0.62 , 3.29)
	Adjusted	2.69 (0.96 , 7.53)
AMSA Score	Unadjusted	2.53 (0.93 , 6.94)
	Adjusted	4.63 (1.41 , 15.24)
IMAP Score	Unadjusted	8.15 (2.43 , 27.30)
	Adjusted	10.95 (2.81 , 42.65)

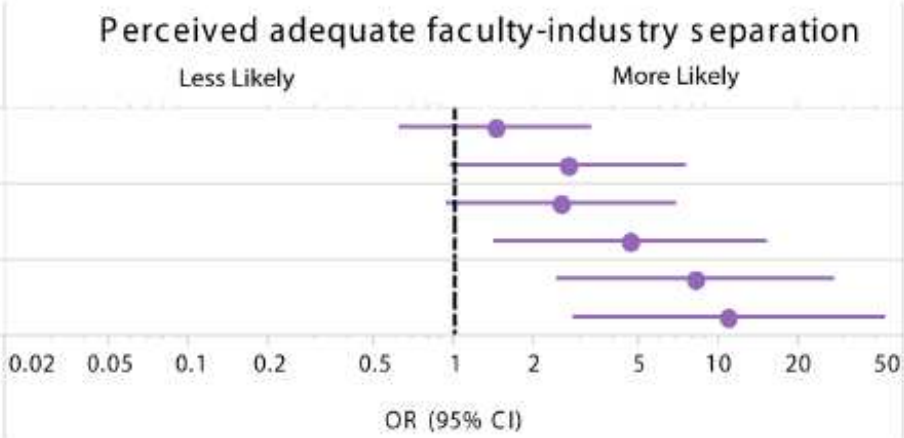


Figure 1. Association between strength of medical school industry interaction policies and survey responses. Outcome comparing

Model curriculum

Smith SR, Hams M, Wilkinson W. 2013

Conflict of Interest Policy Guide for Academic Medical Centers and Medical Schools

COMMUNITY CATALYST

Conflict of Interest Curriculum

I. Introduction

Teaching about conflict of interest affords medical schools and residency programs an opportunity to focus on the broader issue of professionalism (AAMC 2008). Conflict of interest is not merely about relationships with the pharmaceutical and medical device industry, but rather about the broader social compact between the profession of medicine and the public good as well as the special fiduciary relationship between doctor and patient. Focusing on conflict of interest with the pharmaceutical and medical device industry can act as a catalyst to kindle broader considerations of the proper role of physicians in putting the interests of patients above self-interest and achieving a just health care system. Faculty who teach about conflict of interest can serve as role models, eschewing inappropriate relationships with the pharmaceutical and medical device industry.

This toolkit provides a succinct overview of the competencies that learners should achieve, the educational theory supporting various pedagogical approaches, particularly appropriate points along the continuum of education for teaching, examples of actual curricula being taught, and ideas on how to evaluate the impact of the teaching. It also discusses possible institutional policies that would require medical students and residents to complete such courses.

Conflict of Interest Curriculum

"The idea of the fiduciary responsibility of the doctor to

https://www.communitycatalyst.org/resources/publications/document/CC-Toolkit-1-Curriculum-FINAL.pdf

Collaboration Pew Charitable Trust, AMSA, and National Physicians' Alliance

AMSA model curriculum

Three main learning objectives:

1) Understand the nature of conflicts of interest and how they pertain to the practice of medicine;
2) Recognize how industry can impact clinical care and develop strategies to mitigate the negative influences; and
3) Properly manage industry relations to maximize patient and societal benefit.

"Arming physicians with a healthy dose of skepticism about whatever they hear is probably one of the most powerful lessons that medical education can instill."

- *American Association of Medical Colleges (AAMC) Task Force on Industry Funding of Medical Education, 2008*

https://www.amsa.org/wp-content/uploads/2015/03/ModelPharmFreeCurriculum.pdf

AMSA model curriculum

Five recommended competencies:

1. Professionalism and conflict of interest
2. Drug and device development
3. Determining drug and device safety and efficacy
4. Marking and physician practice
5. Continuing Medical Education

https://www.amsa.org/wp-content/uploads/2015/03/ModelPharmFreeCurriculum.pdf

Professionalism and Conflict of Interest (COI)

Competency: Explain what constitutes a conflict of interest and describe how conflicts of interest influence clinical practice and professional standards.

Rationale: COI helps explain how industry relationships overlap or conflict with a physician's primary obligation to the patient and industry's legal obligation to maximize shareholder value through the development and sale of pharmaceuticals or medical devices. When judging the appropriateness of interactions with industry, physicians must avoid COI whenever possible and mitigate the negative effects of unavoidable COI.

Students should understand:

- what constitutes a conflict of interest;
- how COI influences clinical care and clinical research;
- the role and effectiveness of disclosure and transparency in COI;
- the impact of COI on clinical practice guidelines and formulary development;
- how industry sponsorship influences conferences, continued medical education, and standard-setting organizations such as professional and state medical societies; and
- how to avoid, manage or minimize COI in physician-industry relationships such as speaking and consulting agreements and research contracts.

https://www.amsa.org/wp-content/uploads/2015/03/ModelPharmFreeCurriculum.pdf

Effective Teaching Methods

- “debunking” – get students to evaluate false claims
- “putting a face on the problem” – in-person testimony from patients who were harmed
- “case-based approach” with small groups.

Table 3: PharmFree topics and areas for curricular integration

Topic	Point of Curricular Integration
Professionalism and Conflict of Interest	
What is conflict-of-interest	Ethics / Professionalism, Practice of Medicine
COI, clinical care and clinical research	Ethics / Professionalism
COI, disclosure and transparency	Ethics / Professionalism, Pharmacology
COI, clinical practice guidelines and formularies	4th Yr Capstone, Ethics / Professionalism, Pharmacology, Prescription Writing
Industry sponsorship of conferences, education and organizations	4th Yr Capstone, CME, Ethics / Professionalism
Managing COI in industry relationships	Ethics / Professionalism, MD/PhD program
Drug and Device Development	
Stages of drug and device R&D	Pharmacology
Incentives and financing of R&D	Pharmacology
Drug R&D priorities, drug cost and accessibility	4th Yr Capstone, Clerkships, Pharmacology, Practice of Medicine, Prescription Writing
Drug/device approval processes	Pharmacology
Regulations on off-label use	4th Yr Capstone, Pharmacology, Practice of Medicine, Prescription Writing
Post-marketing surveillance and the physician's role in the FDA adverse event reporting system	4th Yr Capstone, Pharmacology
Determining Drug and Device Safety and Efficacy	
Critical appraisal of scientific information	4th Yr Capstone, Clerkships
Conflict-of-Interest and clinical evidence in medicine	4th Yr Capstone, Clerkships, Pharmacology, Prescription Writing
Independent sources of drug information and reviews	4th Yr Capstone, Clerkships, Ethics / Professionalism, Pharmacology, Practice of Medicine, Prescription Writing
How bias influences decision making	Ethics / Professionalism, Pharmacology, Practice of Medicine
Marketing and Physician Practice	
How marketing influences physicians	4th Yr Capstone, Ethics / Professionalism, Practice of Medicine, Prescription Writing

How successful is the educational programme on drug promotion at your institution in meeting its goals? (n=262)

	Half a day or less n=69	Four to nine hours n=66	10 or more hours n=89
Very successful	2 (3%)	2 (3%)	12 (14%)
Somewhat successful	26 (38%)	41 (62%)	53 (60%)
Somewhat unsuccessful	16 (23%)	8 (12%)	10 (11%)
Not at all successful	4 (6%)	0	1 (1%)
Unknown/no comment	*17 (25%)*	*12 (18%)*	*8 (9%)*

Mintzes. WHO/HAI survey, 2005
http://apps.who.int/medicinedocs/pdf/s8110e/s8110e.pdf

To What Extent Do Educational Interventions Impact Medical Trainees' Attitudes and Behaviors Regarding Industry-Trainee and Industry-Physician Relationships?

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[a]Children's Health Services Research and [c]Department of Medicine, Indiana University School of Medicine, Indianapolis, Indiana; [b]Regenstrief Institute, Inc, Indianapolis, Indiana

Financial Disclosure: The authors have indicated that they have no financial relationships relevant to this article to disclose.

- 10 studies of educational interventions, 1995 to 2006
- Mainly pre-post intervention (3/10 controlled)
- Small-scale interventions, short-term outcomes
- Attitudes and knowledge

Carroll et al. Pediatrics 2007; 120: e1528

ORIGINAL RESEARCH

Medical Schools' Industry Interaction Policies Not Associated With Trainees' Self-Reported Behavior as Residents: Results of a National Survey

James S. Yeh, MD, MPH
Kirsten E. Austad, MD
Jessica M. Franklin, PhD
Susan Chimonas, PhD
Eric G. Campbell, PhD
Jerry Avorn, MD
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ABSTRACT

Background Medical students attending schools with policies limiting industry/student interactions report fewer relationships with pharmaceutical representatives.

Objective To investigate whether associations between students' medical school policies and their more limited industry interaction behaviors persist into residency.

Methods We randomly sampled 1800 third-year residents who graduated from 120 allopathic US-based medical schools, using the American Medical Association Physician Masterfile. We surveyed them in 2011 to determine self-reported behavior and preferences for brand-name prescriptions, and we calculated the strength of their medical schools' industry interaction policies using the 2008 American Medical Student Association and Institute on Medicine as a Profession databases. We used logistic regression to estimate the association between strength of school policies and residents' behaviors with adjustments for class size, postresidency career plan, and concern about medical school debt.

Results We achieved a 44% survey response rate (n = 739). Residents who graduated from schools with restrictive policies were no more or less likely to accept industry gifts or industry-sponsored meals, speak with marketing representative about drug products, attend industry-sponsored lectures, or prefer brand-name medications than residents who graduated from schools with less restrictive policies. Residents who correctly answered evidence-based prescription questions were about 30% less likely to have attended industry-sponsored lectures (OR = 0.72, 95% CI 0.56–0.98).

Conclusions Any effect that medical school industry interaction policies had on insulating students from pharmaceutical marketing did not persist in the behavior of residents in our sample. This suggests that residency training environments are important in influencing behavior.

Yeh et al. Journal of Graduate Medical Education 2015; 7(4): 595-602

In conclusion

- AMSA ScoreCard: a student-led initiative for change
- Extensive influence on institutional policy
- Education on COI embedded in broader policy shifts
- Can education change practice?

Questions or comments?

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