Evidence and Recommendations for a Model PharmFree Curriculum

Executive Summary

Since 2002, AMSA's PharmFree Campaign has encouraged a relationship between physicians and the pharmaceutical and device industries that prioritizes patient care. In recent years, evidence has mounted demonstrating the negative influence that industry sometimes exerts on the medical practice, spurring calls for reform by the Institute of Medicine (IOM) and the American Association of Medical Colleges (AAMC). Both institutions issued reports that identified the need to change the way that physicians interact with industry, including the education that physicians in training receive.

Today, physicians interact with the pharmaceutical and device industries on a daily basis, yet they receive little education on how to appropriately manage these relationships. Building from the IOM and AAMC reports, **AMSA calls on medical schools to implement curricula that prepare students to interact with industry in a way that protects individual patients, promotes public health, and preserves the public trust in medicine**. AMSA's Model PharmFree Curriculum aims to provide students with the knowledge and analytical skills necessary to:

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.

"Evidence and Recommendations for a Model PharmFree Curriculum" is guide for students, faculty and administrators looking to incorporate a Model PharmFree Curriculum into existing curricula. This guide discusses:

- Five curricular competencies necessary for meeting the objectives of the Model PharmFree Curriculum described above (page 4).
- Strategies for teaching about conflict of interest, including an overview of literature on effective methods of teaching and instruction techniques that have been employed at medical schools throughout the world. AMSA recommends a variety of interactive methods of instruction to engage even skeptical students (page 8).
- Involvement of industry in education about conflict of interest. AMSA believes that the risks of involving industry in the education process outweigh the benefits, thus industry participation is strongly discouraged (page 14).
- Management of conflict of interest in education, including disclosure and prohibition of conflicts. AMSA recommends prohibiting conflict of interest in preclinical courses and disclosure for all physicians involved with instruction on the wards (page 15).

Introduction

The medical profession and pharmaceutical and the device industries have long enjoyed a close relationship. While some of these collaborations have undoubtedly led to significant advancements in medicine, this progress has come at a price that is now increasingly being recognized. Industry has influenced the practice of medicine through traditional advertising, manipulation of the evidence base for pharmaceuticals and devices, and by more subtle means of promotion such as showering gifts, money, and lucrative contracts on physicians, who have frequently come to accept these benefits as a well-deserved right. These practices have influenced patient care, from the drugs that physicians prescribe to the clinical research that provides the evidence base for prescription decisions.

Since its inception in 2002, the American Medical Student Association's (AMSA) PharmFree Campaign has shone a light on the impact of industry on the practice of medicine. Every year, AMSA evaluates the pharmaceutical policies at all US academic medical centers using an eleven-point scorecard.[1] One of these criteria measures how well medical schools provide their students with instruction on drug development and ethical physician-industry relationships.

In recent years, there has been increasing attention paid to the relationship between physicians and industry and several groups have examined how medical education should prepare future physicians for the practical and ethical challenges that accompany interactions with industry. In 2008, the American Association of Medical Colleges' (AAMC) Task Force on Industry Funding of Medical Education called on academic medical centers to limit many physician-industry relationships.[2] The Task Force recommended that medical schools incorporate topics into the undergraduate medical curriculum that provide students with the knowledge necessary to understand the drug development and approval process (see sidebar).

Less than a year later, the Institute of Medicine's report on "Conflict of Interest in Medical Research, Education, and Practice" came to a

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.

[1] Available at www.amsascorecard.org

[2] American Association of Medical Colleges. *Industry Funding of Medical Education: Report of an AAMC Task Force*. 2008. Available at www.aamc.org/research/coi

similar conclusion.[3] Echoing many of the sentiments of the AAMC report and in some cases going even further, the report called for a basic level of education on interactions between physicians and industry.

A global survey by the World Health Organization (WHO) and Health Action International (HAI) found that of 137 medical schools, 74% said that education on drug promotion was part of the curriculum. However, nearly one third of schools spent only one to two hours teaching about drug promotion.[4] Within the US, an even smaller proportion of medical schools are preparing their students- the 2009 PharmFree Scorecard found that less than 30% of schools included any instruction on conflict-of-interest (COI) and the impact of industry on medical practice. In many cases, this instruction consisted only of a review of the school's policies.[5] These surveys demonstrate the inadequacy of medical student education on interactions with industry, distinguishing evidence from promotion, and avoiding conflicts of interest.

AMSA calls on medical schools to implement curricula that prepare students to interact with industry in a way that protects individual patients, promotes public health, and preserves the public trust in medicine. The physician-industry relationship is complex and industry affects the medical practice in many direct and indirect ways. This document presents AMSA's recommendations on the core topics for understanding physician-industry interactions, describes examples of existing curricula, discusses a variety of teaching methods, reviews the controversial issues of industry involvement and conflict of interest in the classroom, and provides resources from which students, administrators and faculty can draw to implement a Model PharmFree Curriculum.

Recommended Curricular Competencies for a Model PharmFree Curriculum

> "*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.*"
> **AAMC Task Force on Industry Funding of Medical Education**

The objective of a Model PharmFree Curriculum is to provide students with the knowledge and analytical skills necessary to:

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.

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[3] Institute of Medicine. *Conflict of Interest in Medical Research, Education and Practice.* 2009. Available at www.iom.edu/CMS/3740/47464/65721.aspx

[4] Mintzes Barbara. Educational initiatives for medical and pharmacy students about drug promotion: an international cross-sectional survey. October 2005. World Health Organization and Health Action International. WHO/PSM/PAR/2005.2 Available at http://www.haiweb.org/26012006/MRhaipromosurveyFINAL06.pdf

[5] American Medical Students Association. 2009 AMSA PharmFree Scorecard. Available at www.amsascorecard.org

AAMC Task Force on Industry Funding of Medical Education Report:

"Students often have limited understanding of subject areas important to interactions with industry, including:

- The processes of drug research and development;
- The statutes and regulations that govern these processes;
- The nature of the pharmaceutical and device industries;
- Product marketing and sales;
- The meaning and limitations of FDA marketing approval of a new therapeutic with respect to the safety and efficacy of that therapeutic; and
- The critical role of physicians in supporting the FDA's adverse event reporting system.

…Potential topics [for medical school modules] include pharmacology, safety, monitoring, adherence, pharmacogenomics, meta-analysis, clinical guidelines, performance measurement, and comparative effectiveness."

While IOM did not specify any teaching objectives, the AAMC Task Force report identified several topics that are important to understanding industry influence and recommended that these areas be addressed by medical school curricula (see box above). Previously, in 2006, AMSA joined the organizations Healthy Skepticism, No Free Lunch and PharmAware in calling for health provider education on drug and device promotion.[6] Building from these recommendations, AMSA has developed a detailed list of curricular competencies that outlines specific topics necessary to understand, interpret and navigate complex physician-industry interactions. In many cases, these topics build upon subjects already typically included in medical curriculum and can easily be integrated into existing educational modules. The five recommended competencies for medical students cover:

- Professionalism and Conflict of Interest
- Drug and Device Development
- Determining Drug and Device Safety and Efficacy
- Marketing and Physician Practice
- Continuing Medical Education

See below for details on these competencies.

[6] Mansfield PR, Lexchin J, Wen LS, Grandori L, et al. Educating Health Professionals about Drug and Device Promotion: Advocates' Recommendations. *PLoS*. 2006;3(11):1988-1991.

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.

Drug and Device Development

Competency: Describe the incentives for drug and device research and development, the stages of development and approval, and the clinical implications of FDA approval.

Rationale: An understanding of research and development (R&D) processes is fundamental to recognizing physician-industry conflict of interest, because the incentives, regulations and financing of pharmaceutical R&D determine the drugs that are developed and how they are promoted. Often overlooked, devices have a slightly different development pathway and a unique set of circumstances in the clinical setting that require special attention.

Students should understand:

- the stages of drug and device R&D;
- current incentives and financing of R&D, including a basic understanding of patents;
- how R&D incentives affect the kinds of drugs that are developed, their cost and their accessibility;
- the drug and device approval and regulatory processes (including generics), as well as the meaning and limitations of FDA approval;
- post-marketing surveillance and the physician's role in the FDA's adverse event reporting system; and
- regulations regarding off-label use of drugs.

Determining Drug and Device Safety and Efficacy

Competency: Critically evaluate clinical trial design and results, and describe the effects of publication bias and conflict of interest on available safety and efficacy data.

Rationale: Safety and efficacy data provided to regulatory agencies as well as research studies published in peer-reviewed journals are the foundation of evidence-based prescribing. Yet, these seemingly objective sources also subject to bias, both intentional and unintended, that alter perception of the safety and efficacy of drugs and devices.

Students should understand:

- the importance of skepticism about drug/device information, regardless of the source;
- "critical appraisal" skills for analyzing clinical trials, include analysis of study design, interpretation of data and basic statistical literacy;
- how conflict of interest and funding sources can and have impacted clinical trial findings;
- how publication bias and medical journal conflict of interest can influence the publicly accessible pool of evidence;
- the process of ghost-writing in the context of marketing campaigns (i.e. Vioxx);
- how bias influences decision-making; and
- the importance of and how to find independent sources of drug information and critical reviews.

Marketing and Physician Practice

Competency: Explain the relationship between influence and reciprocity and identify the ways by which marketing attempts to influence physician behavior.

Rationale: Marketing of drugs and devices is the most obvious yet under-taught topic. Recognition of the variety of marketing techniques employed by industry to influence practice and awareness of alternative sources of information enables future physicians to avoid biasing factors in prescription decisions.

Students should understand how and why marketing works in the following contexts:

- physician detailing;
- the influence of gifts (pens, food, trips, etc);
- drug samples and their effect on patient care as well as drug accessibility and cost;
- the use of "key opinion leaders" and speaker bureaus;
- direct-to-consumer advertising and handling patient requests for medication;
- advertising in medical journals, including critical analysis of ad content;
- promotional or "seeding" trials;
- "disease mongering," or the practice of creating or expanding disease markets;
- drug promotion on the internet;
- industry-initiated and/or supported patient groups; and
- industry-funded medical journals.

Continuing Medical Education (CME)

Competency: Describe the process of continuing medical education, identify sources of bias, and identify reliable sources of medical knowledge.

Rationale: With advancements in medicine quickly outpacing a physician's undergraduate medical training, the skills of being an effective "lifelong learner" are crucial. Understanding how industry interacts with the education process reinforces the importance of independent sources of knowledge and enables physicians to continue their education after medical school with the best evidence available, rather than the best marketing.

Students should understand:

- how CME courses are developed and accredited, as well as what accreditation means;
- how industry influences topics and speakers in CME activities;
- how to critically evaluate speakers selected for CME; and
- how to find independently sponsored CME courses.

Recommended Strategies for Teaching about Conflict of Interest and Physician-Industry Relationships

Doctors often think of themselves as less susceptible to marketing than their peers. For example, 1% of internal medicine residents felt that sales representatives influenced their prescribing a great deal, while 51% felt that reps influenced their peers to the same extent.[7] Medical students have similarly resisted suggestions that they are susceptible to marketing, making the teaching strategy all the more important.[8] Surveys and published literature provide some guidance about the instructional methods employed at different institutions and their effectiveness.

Current teaching methods and supporting evidence. Ideally, medical schools could draw from a wealth of faculty experience teaching on these topics and data regarding which are the most effective teaching strategies. Unfortunately, the medical literature contains very little experimental evidence on the efficacy of teaching methods on pharmaceutical promotion or physician-industry relations. A 2007 review found only 12 studies that contained empiric data on educational initiatives to educate "trainees," and only four of these pertained to medical students specifically.[9] While limited in scope, these four studies provide some examples about how some schools have approached teaching these issues, with varying degrees of success (see Table 1).

Though experimental evidence supporting specific teaching methods is slim, many schools have employed different mechanisms to teach about pharmaceutical issues. In 2005, the World Health Organization and Health Action International conducted a survey of educational practices on pharmaceutical promotion in medical and pharmacy schools.[10] They reported that the most common teaching techniques employed by medical schools were lectures, mentioned by 80% of medical schools that taught about pharmaceutical promotion, followed by small group discussions or workshops (65%), critical analysis of sample advertisements (42%), response to case scenarios (26%), and role playing (10%). Other techniques mentioned included: debates on drug promotion and clinical research ethics/bias, case studies of scandals such as Vioxx, videos on sales representatives, and problem-based learning coupled with small group discussion.

[7] Steinman MA, Shlipak MG, McPhee SJ. Of principles and pens: attitudes and practices of medicine house staff toward pharmaceutical industry promotions. *American Journal of Medicine.* 2001; 110(7): 551-7.
[8] Sierles FS, Brodkey AC, Cleary LM, McCurdy FA, et al. Medical Students' Exposure to and Attitudes About Drug Company Interactions: A National Survey. *JAMA.* 2005; 294(9):1034-1042.
[9] Carroll AE, Vreeman RC, Buddenbaum J, Inui TS. To What Extent Do Educational Interventions Impact Medical Trainees' Attitudes and Behaviors Regarding Industry-Trainee and Industry-Physician Relationships? *Pediatrics.* 2007;120:e1528-e1535.
[10] Mintzes B. Educational initiatives for medical and pharmacy students about drug promotion: an international cross-sectional survey. World Health Organization / Health Action International. 2005. WHO/PSM/PAR/2005.2

Table 1: Evidence on educational interventions abo ut the physician-industry relationship

Study	Demographic	Explanation of Intervention	Summary of Results
Stanley et al[11]	3rd year medical students in the UK	12 week, 70 hr course designed in conjunction with industry: lectures, classroom activities, practicals, case study, site visit, 2000-word dissertation, 1000-word advertisement critique, The Pharm Game	*Post-module evaluation:* - Participants had a more positive perception of industry compared to pre-test - The most popular sessions were interactive (i.e. the advertisement critique, The Pharm Game)
Wilkes et al[12]	3rd year	3hr session w/ 20 min talk by pharmacists posing as sales representatives, followed by Q&A and discussion on detailing, gifts and accessing unbiased information	*12 weeks later, students:* - were more likely to think that resort trips, pens, calendars, and noneducational materials influence physician behavior - were less likely to view information in drug advertisements as reliable for education - recognized the effects of many techniques used by pharmaceutical companies, but they were not more likely to view any of them as unethical - already had substantial exposure to industry by 3rd year (95% received gifts, 43% received samples, 35% received dinners, 68% books or other learning tools)
Wofford et al[13]	3rd year , during internal medicine clerkship	90 minute lecture developed w/ a sales rep; interactive discussion and role-playing led by two faculty and a manager of industry representatives	*Immediately after workshop:* - Perceived educational value of industry rep interactions increased significantly for both students (22.1% pre vs. 40.5% post) and physicians (17.7% pre vs. 43.2% post) - Perceived degree of influence on prescribing increased (44.2% to 62.1%) - Only 5% had no personal experience with an industry rep
Vinson et al[14]	2nd year	50 minute lecture on pharmaceutical marketing practices	*7 weeks after intervention:* Students were less likely to approve of books, pens, CME dinners, paid travel and expensive gifts compared to a control group

[11] Stanley AG, Jackson D, Barnett DB. The teaching of drug development to medical students: collaboration between the pharmaceutical industry and medical school. *British Journal of Clinical Pharmacology*. 2005;59:464-74
[12] Wilkes MS, Hoffman JR. An Innovative Approach to Educating Medical Students about Pharmaceutical Promotion. *Academic Medicine*. 2001; 76(12). 1271-1277.
[13] Wofford JL, Ohl CA. Teaching appropriate interactions with pharmaceutical company representatives: the impact of an innovative workshop on student attitudes. *BMC Medical Education*. 2005;5:5
[14] Vinson DC, McCandless B, Hosokawa MC. Medical students' attitudes toward pharmaceutical marketing: possibilities for change. *Family Medicine*. 1993;25:31–33

Teaching strategies. The issues covered by the PharmFree Curriculum can be contentious. In a traditional lecture format, students who do not share the professor's viewpoint may be defensive and be less open-minded to existing evidence. At the end of the day, the object is not to convince students that the pharmaceutical industry is "evil," but to educate students of the risks of physician interactions with industry by providing the theoretical framework for conflict of interest and the factual foundation for evaluating current practices. Therefore, instructional techniques that engage students and engender two-way discussion or application of the principles taught are more likely to be effective than those that rely on passive absorption.

Students learn many of their future habits from observing doctors throughout their training. While the below teaching strategies are helpful to address students' knowledge gap, the most effective strategy is to teach by example. House staff and faculty should emulate appropriate prescribing behaviors and institutions can create an appropriate learning environment by implementing a Model PharmFree Policy.[15]

The table below lists a number of teaching approaches that have been culled from existing programs, surveys, published articles and student suggestions. Each method of instruction has its advantages, and the strongest programs apply a variety of techniques to ensure all students are reached through at least one channel. The instruction methods are illustrated with a few examples of topics that could be effectively explored through that particular medium.

Table 2: Educational techniques for teaching conflict-of-interest and industry influence on medicine

Mode of Instruction	Example
Case studies of high profile scandals	Students use a prominent case study to analyze the factors contributing to the scandal, the impact on clinical care, the role of physicians in the event, and how various stakeholders responded to prevent reoccurrence. Possible topics include: • off-label marketing of gabapentin (Neurontin) • marketing, data suppression and subsequent withdrawal of Vioxx • anti-depressants and suicide risk in clinical studies
Critical appraisal of advertisements	Students analyze print, television or internet advertisements for: • the accuracy and representation of claims • the quality and applicability of references • how the imagery and/or sounds furthered the marketing message • how the ad complies with national regulatory codes or voluntary industry codes on marketing Drug Ad Bingo- Combines the classic game with analysis of advertisements[16]

[15] See the PharmFree Scorecard for more information- http://www.amsascorecard.org/
[16] Pharmed Out. Drug Ad Bingo. http://pharmedout.org/bingofunwithpharmads.pdf

Mode of Instruction	Example
Lectures	The old mainstay of a medical education. Lecturers should engage students in discussion and encourage voicing alternative viewpoints, using discussion to illustrate key principles. While lectures are not the optimal instruction technique, Vinson et al showed that even a 50 minute lecture can influence perspectives on conflict of interest.[17]
Pharmacology problem sets	Students critically appraise a controversial study (i.e. the JUPITER trial), evaluating the study design, appropriateness of comparison, interpretation of results, abstract as a accurate representation of the paper, and potential conflicts of interest and the direction of bias expected.
Role-playing	• Students learn how to respond to a standardized patient asking for an advertised medicine (i.e. Nexium) • Pharmacists or physicians posing as sales representatives presenting sales pitches to students, with subsequent debrief and critique session
Research essays	Students research the evidence supporting and contesting adverse effects of pharmaceutical marketing on prescribing practices. Students are assigned a side of the issue to support in their essay, then must critique a peer's essay taking the opposing viewpoint.
Small group discussions in tutorial/workshop	Students discuss the meaning of conflict of interest and how it applies to physician-industry interactions. A facilitator uses an article or video as a prompt (see www.pharmfree.org/resources for suggestions) and guides discussion to make sure pertinent issues are discussed and to inject relevant evidence or teaching points.
Student debates	Student teams are assigned for/against positions, then research and debate the impact of small gifts (i.e. pens, pizza) on clinical practice. The teams are then asked to research the opposing viewpoint and defend it against their own arguments in a subsequent debate.

For other sources of ideas about the introduction of these topics into the curriculum, schools are encouraged to look at the AMSA PharmFree Scorecard (www.amsascorecard.org). Updated annually, the Scorecard provides a summary of the conflict of interest curriculum at each school and, when schools permit, links summaries to source materials. While the ratings criteria for curricula may evolve, the Scorecard helps to identify medical programs that have successfully incorporated these topics and can serve as valuable references.

In addition, the World Health Organization (WHO) and Health Action International (HAI) are piloting a curricular component to medical and pharmacy schools called *Understanding and Responding to Pharmaceutical Promotion: A Practical Guide* that would serve as a valuable resource.[18] This guide has emerged from research conducted by WHO and HAI on the impact of pharmaceutical promotion on the medical practice and ways that medical schools are teaching about the issue. The pilot is being

[17] Vinson DC, McCandless B, Hosokawa MC. Medical students' attitudes toward pharmaceutical marketing: possibilities for change. *Family Medicine*. 1993;25:31–33

[18] For further information, see World Health Organization / Health Action International. *Understanding and Responding to Pharmaceutical Promotion: A Practical Guide*. First Edition: A Working Draft for Pilot Field Testing. 2009.

conducted over the course of the 2009-2010 academic year, with wider dissemination expected thereafter. A draft version of the curriculum is currently available from HAI.

Additional resources and a list of organizations that are actively engaged on these issues can be found at the end of this document. These resources may be beneficial to medical schools or faculty looking to build or improve their curricula.

Timing of education. The timing of education modules is also an important consideration. In some cases, students will benefit more by learning about topics after they have some clinical experience and understanding. For other topics, interventions may be more effective if conducted prior to potential interaction with industry. For instance, Wilkes *et al* documented that of their third year medical students, 95% of the students had already received a gift from industry, wherein 68% had received a book or other learning tool, 43% had received samples, and 35% had received dinners.[19] In Wofford's study, only 5% of students taking their third year module had no personal experience with pharmaceutical representatives by their third year.[20] Clearly, there is a risk that delaying education on these issues may result in students who have already started to buy in to outdated models of physician-industry relationships.

A balanced approach can introduce various topics at different points throughout medical student training, building upon existing related topics and accenting the type of learning for that stage. For instance, critical appraisal of clinical trials could be taught during preclinical years as students learn pharmacology, and techniques for handling patient requests of advertised medications could be addressed in practice of medicine courses. Similarly, students can learn about marketing in the context of the gabapentin scandal in their psychiatry rotation and about risks of industry sponsored continuing medical education in their fourth year capstone courses. In each instance, topics specific to that level of training can be discussed in the context of the larger conflict of interest narrative, connecting students to the bigger picture of physician-industry relations.

AMSA has identified several thematic areas that are common across most medical school curricula in which PharmFree curricular topics could be implemented (see Table 3).

[19] Wilkes MS, Hoffman JR. An Innovative Approach to Educating Medical Students about Pharmaceutical Promotion. *Academic Medicine*. 2001; 76(12). 1271-1277.
[20] Wofford JL, Ohl CA. Teaching appropriate interactions with pharmaceutical company representatives: the impact of an innovative workshop on student attitudes. *BMC Medical Education*. 2005;5:5

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
Overview of various marketing mechanisms:	
Physician detailing	4th Yr Capstone, Ethics / Professionalism
Gifts (pens, food, trips, etc)	4th Yr Capstone, Ethics / Professionalism
Drug samples	4th Yr Capstone, Ethics / Professionalism, Prescription Writing
"Key Opinion Leaders" and speaker bureaus	4th Yr Capstone, Ethics / Professionalism
Direct-to-Consumer advertising	Practice of Medicine, Prescription Writing
Print advertising (medical journals and popular magazines)	4th Yr Capstone, Pharmacology, Prescription Writing
Promotional trials	4th Yr Capstone, Pharmacology
Disease marketing	4th Yr Capstone, Pharmacology, Practice of Medicine

Topic	Point of Curricular Integration
Marketing and Physician Practice (continued)	
Promotion on the internet	Pharmacology
Industry-funded patient groups	4th Yr Capstone, Practice of Medicine
Industry-funded medical journals	4th Yr Capstone, Pharmacology
Resources to reduce or eliminate inappropriate marketing influences	4th Yr Capstone, Clerkships, Ethics / Professionalism, Practice of Medicine, Prescription Writing
Continuing Medical Education	
Development and accreditation of CME	4th Yr Capstone
Industry influences on CME	4th Yr Capstone, Ethics / Professionalism
Critical evaluation of CME course	4th Yr Capstone
Finding independent CME courses	4th Yr Capstone

Description of courses:

- 4th year Capstone- A course near the end of medical school that transitions students from medical students to their internship year.
- Clerkships- Clinical rotations, typically during 3rd and 4th years.
- Ethics / Professionalism- A course that describes the historical context of ethics and professionalism in medicine and instructs students on the difficult ethical and professional dilemmas they will face as physicians.
- Pharmacology- A course that describes the basics of how drugs, drug selection and dosing works. Often includes biostatistics, critical analysis of clinical literature and factors affecting drug selection.
- Practice of Medicine- The "how-to-be-a-doctor" class. This course usually teaches on how to interact with patients and factors that may influence patient care.
- Prescription Writing- Usually a short class on drug selection (generic vs. brand name, cost, formulary) and how to actually write a prescription.

Industry participation in the education process. Presentation of opposing viewpoints may serve to engage students better than a one-sided curriculum, preventing students from becoming defensive or feeling like they are being proselytized. Providing an objective portrayal of both sides of these issues can be accomplished without the involvement of industry representatives. However, schools must determine whether it is in the best interest of students' future patients to include industry representatives in the education process. Doing so carries potential benefits and as well as potential risks.

Industry participation provides the their perspective and can give students the opportunity to critically engage industry. On the other hand, too much or inappropriately-designed industry representation may expose students to well-honed marketing and may dilute the effectiveness of the teaching objectives. In the review of educational interventions described previously, the two interventions targeting medical students that were developed in conjunction with pharmaceutical representatives resulted in more favorable opinions of the pharmaceutical industry and an increase in the perceived educational value of detailing.[21,22] This suggests that involvement of industry in educational initiatives may actually be

[21] Stanley AG, Jackson D, Barnett DB. The teaching of drug development to medical students: collaboration between the pharmaceutical industry and medical school. *British Journal of Clinical Pharmacology*. 2005;59:464–474

counterproductive and may counteract the clinical evidence of pharmaceutical influence. Perhaps reflecting these concerns, the WHO/HAI survey found that only 12% of medical schools who taught about drug promotion chose to include a sales representative in the education process.

AMSA believes that the risks of involving industry in the education process outweigh the benefits, thus industry participation is strongly discouraged. If schools decide to include industry, industry should not be involved in the planning of the curriculum, and any industry participation should be proceeded by instruction on marketing techniques and moderated by faculty who understand the risks of industry interaction.

Conflict of Interest and Implementation of the PharmFree Curriculum. It is important for medical schools to determine an appropriate policy to minimize conflict of interest within the education process itself. The issue of disclosure versus prohibition of conflict of interest has been the point of contention for many aspects of the physician-industry relationship, especially in the education setting. The relative inexperience of medical students makes them more susceptible to bias, rendering this issue all the more important.

The argument for disclosure is that it makes students aware of potential bias and allows them to critically analyze the provided information and neutralize any bias. However, bias is difficult to detect and students are left with the responsibility of sorting out biased and unbiased content. This task is difficult even for fully trained physicians and experts in marketing, and is a heavy requirement to ask of medical students in the early stages of their training. Further, some evidence suggests that disclosure causes individuals to underestimate the risks posed by the conflict, rendering them more susceptible to biased instruction.[23]

A learning environment that avoids conflicts allows students to focus on learning the material without undue distractions. To limit preventable bias in education, this approach prohibits lecturers from speaking on topics for which they have a conflict. The oft-expressed downside of this approach is that it would prohibit experts with conflicts of interest from teaching students on their areas of expertise, depriving students of valuable education experiences. Alternatively, it could be argued that medical students at the beginning of their training do not need expert teachers to explain basic concepts of medicine, and the costs of bias outweigh the potential benefits.

Regardless of approach, regulation of conflict of interest in the classroom and on the wards should pertain not only to instruction on topics described in the Model PharmFree Curriculum, but to the entire curriculum. If a lecturer has a conflict of interest with the subject being taught, it must be prohibited or disclosed. Disclosure of conflict of interest is the minimum standard for the American Academy of

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[22] Wofford JL, Ohl CA. Teaching appropriate interactions with pharmaceutical company representatives: the impact of an innovative workshop on student attitudes. *BMC Medical Education*. 2005;5:5

[23] Kassirer JP. Science and the Media: Delgado's Brave Bulls and the Ethics of Scientific Disclosure: Chapter 7-Medicine's Obsession with Disclosure of Conflicts of Interest. Edited by Snyder PJ, Mayes LC, Spencer D. 2008.

Continuing Medical Education accreditation, and the standards for educating physicians in training should be at least as strong as the standards for physicians who have completed their training.

AMSA makes the following recommendations for conflict of interest in undergraduate medical education:

Preclinical- Preclinical classes frequently take the form of didactic lectures, so management of conflict of interest is fairly straight forward:

- Lecturers should be prohibited from teaching subjects for which they have conflicts of interest whenever suitable alternatives are available.
- When non-conflicted lecturers are unavailable, lecturers should disclose any relevant conflicts, the nature of the conflict (i.e. consulting arrangement, research funding, patent ownership) and the monetary amount.

Clinical- Instruction on the wards is much less structured than preclinical education. While prohibition of conflict of interest among attending physicians is not practical, some policies can mitigate the influence of conflict of interest:

- As part of hospital policy and in keeping with a PharmFree Policy, all physicians should publicly disclose conflicts of interest, the nature of the conflict, and the monetary amount. Prior to the clerkship experience, schools teach students how to access this information.
- Attending physicians should verbally disclose to students conflict of interest when it is relevant to controversial teaching points.

Instruction of PharmFree curricular competencies. Physicians often feel strongly about conflict of interest and the medical practice, regardless of industry affiliation, and the tendency may be for medical schools to search within their own ranks for instructors on these topics. However, an inter-disciplinary approach may help bring a fresh perspective from non-physicians. Schools may find that patients and public health advocates, as well as non-physician health experts in areas such as economics, ethics or law may be able to provide unique viewpoints on conflict of interest that shed light on how these matters are viewed from outside of the medical profession. Still, it is important to screen for conflict of interest in these potential instructors as well, as industry sponsors patient groups, advocacy organizations, and academic researchers of all varieties.

Model PharmFree Curriculum Checklist

This following checklist can be used by schools to evaluate their curricular needs, as well as to facilitate communication between medical schools and evaluators for the PharmFree Scorecard (see Table 4). It may contribute to a clearer understanding of what topics each school teaches, though medical schools should not feel constrained by this format and should structure courses that best complement each school's unique curricular structure.

Table 4: Model PharmFree Curriculum checklist

Topic	Title of Course (including year of training)	Method of Instruction	Materials Provided	Materials Can Be Shared
Professionalism and Conflict of Interest- *Explain what constitutes a conflict of interest and describe how conflicts of interest influence clinical practice and professional standards.*				
What is conflict-of-interest			Y / N	Y / N
COI, clinical care and clinical research			Y / N	Y / N
COI, disclosure and transparency			Y / N	Y / N
COI, clinical practice guidelines and formularies			Y / N	Y / N
Industry sponsorship of conferences, education and organizations			Y / N	Y / N
Managing COI in industry relationships			Y / N	Y / N
Drug and Device Development- *Describe the incentives for drug and device research and development, the stages of development and approval, and the clinical implications of FDA approval.*				
Stages of drug and device R&D			Y / N	Y / N
Incentives and financing of R&D			Y / N	Y / N
Drug R&D priorities, drug cost and accessibility			Y / N	Y / N
Drug/device approval processes			Y / N	Y / N
Regulations on off-label use			Y / N	Y / N
Post-marketing surveillance and the physician's role in the FDA adverse event reporting system			Y / N	Y / N
Determining Drug and Device Safety and Efficacy- *Critically evaluate clinical trial design and results, and describe the effects of publication bias and conflict of interest on available safety and efficacy data.*				
Critical appraisal of scientific information			Y / N	Y / N
Conflict-of-Interest and clinical evidence in medicine			Y / N	Y / N
Independent sources of drug information and reviews			Y / N	Y / N
How bias influences decision making			Y / N	Y / N
Marketing and Physician Practice- *Explain the relationship between influence and reciprocity and identify the ways by which marketing attempts to influence physician behavior.*				
How marketing influences physicians			Y / N	Y / N
Overview of various marketing mechanisms:			Y / N	Y / N
Physician detailing			Y / N	Y / N
Gifts (pens, food, trips, etc)			Y / N	Y / N
Drug samples			Y / N	Y / N
"Key Opinion Leaders" and speaker bureaus			Y / N	Y / N
Direct-to-Consumer advertising			Y / N	Y / N
Print advertising (medical journals and popular magazines)			Y / N	Y / N
Promotional trials			Y / N	Y / N
Disease marketing			Y / N	Y / N
Promotion on the internet			Y / N	Y / N
Industry-funded patient groups			Y / N	Y / N

Industry-funded medical journals			Y / N	Y / N
Resources to reduce or eliminate inappropriate marketing influences			Y / N	Y / N
Continuing Medical Education- *Describe the process of continuing medical education, identify sources of bias, and identify reliable sources of medical knowledge.*				
Development and accreditation of CME			Y / N	Y / N
Industry influences on CME			Y / N	Y / N
Critical evaluation of CME course			Y / N	Y / N
Finding independent CME courses			Y / N	Y / N
Other related topics (please describe):				
			Y / N	Y / N
			Y / N	Y / N
			Y / N	Y / N
Total Time spent teaching these topics (hours)**:**				

Please attach a description of the institution's policies on disclosure or prohibition of conflict of interest in undergraduate medical education and any involvement of the pharmaceutical or device industry in the development or implementation of the curriculum.

Conclusion

The need for education on conflicts of interest and industry interactions exists at multiple levels of the medical profession. Research suggests that these topics are consistently underrepresented throughout the spectrum of medical education, with attendant risks to patient health. Though the scope of this document is restricted to undergraduate physician training programs, AMSA encourages institutions to explore educational opportunities on these topics for all clinical medical professions (i.e. nursing, pharmacy, physician assistants) and at all levels of training and practice, including undergraduates, residents, and fellows . Industry-funded and industry-influenced continuing medical education for fully certified physicians is an area of particular concern that has received attention from the AAMC and IOM reports and that deserves additional scrutiny by medical schools.

The physician-industry relationship is constantly changing. AMSA believes that a strong curriculum that incorporates these recommendations will effectively prepare students to maximize patient well-being in their interactions with industry. However, evidence about industry techniques for influencing medicine continues to emerge, suggesting the need for continued attention regarding methods for preparing students, especially as new models of marketing and influence are developed. Medical schools should revisit these issues on an annual basis and ensure that education keeps up with the latest evidence and policy developments.

Additional Resources

The following resources may be useful for designing and determining the content of a Model PharmFree Curriculum. Of course, schools are encouraged to visit PharmFree.org for the latest information on pharmaceutical influence and the medical practice.

Educational resources

- **AMSA PharmFree Scorecard-** Every year, AMSA and the Pew Prescription Project (see Organizations below) collaborate to evaluate the conflict of interest policies at every medical school in the United States. In addition to looking at how medical schools teach conflict of interest and how industry promotion affects clinical practice, the Scorecard assesses policies on purchasing, samples, CME, rep access to staff, and other topics. Where schools permit, the Scorecard also provides links to information on a school's curriculum. www.amsascorecard.org
- **AMSA PharmFree Website: Literature**- A brief bibliography of journal articles on influencing physician behavior, the risks of pharmaceutical samples, and ghost-writing. http://www.pharmfree.org/resources?id=0002
- **Consumer Prescriber Grant Program**- Part of the settlement from the illegal marketing of Neurontin established the CPGP, which provided resources for 28 awards "to fund the development, dissemination and evaluation of curricula to provide practicing health professionals, and those in training, with the critical skills necessary to evaluate prescription drug information and industry marketing techniques, and to apply this knowledge to their own prescribing practices." Several of these awards have gone towards projects that educate medical students. http://www.consumerprescribergrantprogram.org/
- **Healthy Skepticism Library-** A digital library of more than 16,000 articles on drug promotion that is updated continuously. http://www.healthyscepticism.org/global/library
- **No Free Lunch: Required Reading**- This non-profit's website provides links to slide presentations, independent drug information resources, and a news archive. The recommended reading includes a bibliography of journal articles on many of the topics covered by the Model PharmFree Curriculum, including education interventions. http://www.nofreelunch.org/reqreading.htm
- **World Health Organization / Health Action International's *Understanding and Responding to Pharmaceutical Promotion: A Practical Guide***. A manual for teaching about pharmaceutical promotion in medical and pharmacy schools across the world. WHO and HAI are piloting the manual during the 2009-2010 academic year with wider distribution expected after revisions. www.haiweb.org/
- **World Health Organization / Health Action International's Drug Promotion Database**- A searchable database of all journal articles on pharmaceutical promotion until 2002, around 2200 articles total. Includes bibliographies and abstracts. The website also has several research and review articles based on findings from the database. www.drugpromo.info

Independent sources of drug information

- **Consumer Report's Best Buy Drugs**- Funded partially by the Consumer Prescriber Grant Program, CR's Best Buy Drugs evaluates the drugs available to treat specific diseases and the differences

between treatments, with the intent of educating consumers and improving dialogue between patients and physicians. The information comes from the Drug Effectiveness Review Project (see below). http://www.consumerreports.org/health/best-buy-drugs/index.htm

- **Drug Effectiveness Review Project (DERP)**- "DERP is a collaboration of public entities, the Center for Evidence-based Policy and the Oregon Evidence-based Practice Center, who have joined together to produce systematic, evidence-based reviews of the comparative effectiveness and safety of drugs in many widely used drug classes, and to apply the findings to inform public policy and related activities in local settings." http://www.ohsu.edu/ohsuedu/research/policycenter/DERP
- **Independent Drug Information Service**- A website developed by physicians and drug researchers at Harvard Medical School that creates clinical summaries of commonly used medications without funding from the pharmaceutical industry. www.rxfacts.org
- **The Medical Letter-** A non-profit, independent organization that publishes critical appraisals of new drugs and comparative reviews of old drugs in regular newsletters. It reaches 200,000 readers in 100 countries. www.medletter.com
- **Therapeutics Initiative: Evidence Based Drug Therapy-** A British Columbia-based organization that provides independent assessments of drug information, Cochrane meta-analyses and industry presentations. TI produces newsletters on clinical evidence and drug assessment reports, as well as podcasts and other educational events, which are available for free on its website. www.ti.ubc.ca

Organizations

- **AMSA's PharmFree Campaign-** A campaign of medical students and alumni that promotes evidence-based prescribing, the innovation of safe and effective drugs and access to medicines. AMSA has a chapter at nearly every medical school in the country that would be supportive of a PharmFree Curriculum, and national leadership that can provide support for schools lacking a local chapter. www.pharmfree.org
- **Health Action International-** "HAI is a non-profit, independent, worldwide network of over 200 members including consumer groups, public interest NGOs, health care providers, academics, media and individuals in more than 70 countries." Among other issues, HAI advocates for greater transparency of pharmaceutical decision-making, rational use of medicine and provision of independent information for prescribers and consumers. HAI has worked in conjunction with the WHO on the Drug Promotion Database and a manual on teaching about pharmaceutical promotion in medical and pharmacy schools (see above). www.haiweb.org
- **Healthy Skepticism**- "Healthy Skepticism is an international non-profit organisation for health professionals and everyone with an interest in improving health. Our main aim is to improve health by reducing harm from misleading drug promotion." The organization's focus is on investigation into drug promotion, development of initiatives to reduce the impact of harmful marketing practices and the development of educational strategies that improve health care decision making.
- **No Free Lunch-** A New York City-based non-profit organization of health care providers that promotes prescribing practices on the basis of scientific evidence rather than pharmaceutical promotion. http://www.nofreelunch.org/reqreading.htm

- **Pew Prescription Project- "**The Pew Prescription Project is an initiative of The Pew Charitable Trusts to promote consumer safety through reforms in the approval, manufacture and marketing of prescription drugs, as well as through initiatives to encourage evidence-based prescribing. The Pew Prescription Project conducts rigorous nonpartisan research related to federal oversight of drug safety to better illuminate problems and potential solutions." www.prescriptionproject.org
- **PharmedOut-** An independent, publicly funded organization that documents and disseminates information on industry influence of prescribing. Pharmed Out provides independent educational resources that can contribute to develop of modules, as well as over 200 industry-independent CME courses. www.pharmedout.org
- **Public Citizen Health Research Group-** Public Citizen is a nonprofit consumer advocacy organization**. "**The Health Research Group promotes research-based, system-wide changes in health care policy and provides oversight concerning drugs, medical devices, doctors and hospitals and occupational health." www.citizen.org/hrg