

## Conflict of Interest Curriculum

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### 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.

### II. Competencies

The general goal of educating physicians about conflict of interest with the pharmaceutical and medical device industry is to help assure that physicians will always put the best interests of their patients first and be the best prescribers possible. Conflicts of interest are not simply a theoretical problem in ethics; they constitute a real and present danger to patients that has resulted in suboptimal care and even unnecessary deaths. This general goal can be broken down into more specific competencies, as follows:

- appreciate and accept the fact that marketing by the pharmaceutical and medical device manufacturers is designed to and does, in fact, influence physician behavior

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*“The idea of the fiduciary responsibility of the doctor to the patient is central to teaching and should be linked to the larger issue of professionalism.”*

*— Pedro Delgado, MD  
University of Texas Health  
Sciences Center at San Antonio  
School of Medicine*

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- recognize when marketing is occurring even in the guise of education
- realize that conflicts of interest can result in real harms to patients, even death
- take individual steps to remove oneself from marketing and conflict-of-interest situations
- acknowledge one's own conflicts of interest when they can't be avoided and work to manage those conflicts in an ethically appropriate manner
- advocate for and support actions to reduce, eliminate, or, if necessary, manage conflicts of interest in the workplace
- seek out, recognize and use the most reliable and unbiased sources of information to support optimal therapeutic recommendations

These general competencies can be taught in a number of specific domains including practices related to small gifts, pharmaceutical samples, continuing medical education, funds for physician travel, speakers bureaus, ghostwriting, purchasing and vendor relationships, and consulting and research contracts with pharmaceutical and medical device manufacturers (AMSA Scorecard; Brennan et al. 2006; Institute of Medicine 2009). Students can learn about the specific ethical issues that relate to each of these domains.

### III. Effective Teaching Methods

Each of the paragraphs below illustrate how social science theories about changing attitudes and behaviors can be applied using innovative teaching methods.

#### *“Hoodwinking” learners in order to reduce the “illusion of invulnerability”*

The mindset that “I can't be bought off by a sandwich” represents the major challenge to the educator. Physicians commonly believe that they are not susceptible to promotion, even though they're not so sure about their fellow physicians. One approach to reducing this “illusion of invulnerability” is to create a situation in which learners are “hoodwinked” into accepting biased information, followed by a revelation of the trick that was played on them. A good example of this was the use of university pharmacists who were presented to medical students as drug detailers. Students discussed the information presented to them by the “drug detailers,” unaware that the information was biased. The true identity of the pharmacists was then revealed to the students with the pharmacists telling the students how they had slanted the information (Wilkes and Hoffman 2001).

#### *Debunking*

Another approach forewarns the learners about the persuasive intent of drug company marketing, then “inoculates” the learners by giving them an opportunity to debunk a marketing attempt using a relatively easy target. Once learners become adept at recognizing marketing and

exposing biased or untruthful information, they will be more resistant to persuasion when they encounter it again in real situations (Sagarin et al. 2002). The Food and Drug Administration uses “bad ads” gleaned from its files that resulted in regulatory action to teach medical students how to recognize false claims, underreporting of adverse effects and risks, and overstatement of benefits of the drugs featured in the ads.

#### *Putting a face on the problem*

The most powerful driver of change will be to instill in learners the feeling that to ignore these issues is to put patients in harm’s way. The best way to do that is with true stories from patients who have suffered those consequences. Ideally, this can be done with live, in-person testimony from the patients themselves. Next best is to tell those stories either in a video by the patients or their families or through narrative story telling by a physician.

#### *Case-based approach*

Lecturing is probably one of the least effective teaching approaches, but it is the one most commonly used to teach medical and pharmacy students, accounting for 84% of the teaching activity reported in an international survey (Mintzes 2005). Small group discussions using case-based examples are more likely to be effective.

## **IV. Teaching Opportunities**

We found no literature pointing to the best time in the continuum of training when educational interventions are most effective. Nor did we find any evidence indicating how often curriculum interventions should occur. Recognizing this lack of empirical evidence, some suggestions can be offered to curriculum planners based on common sense.

Presenting the topic very early in the education of medical students during their first year of training emphasizes the importance of the topic by the faculty. The fact that medical students are out in the community with practicing physicians during the first year of medical school makes it likely that they will encounter pharmaceutical marketing. A true anecdote illustrates the point.

First-year medical students were recounting their 2-week experience with practicing physicians during their winter intersession when one student told his classmates about a wonderful experience he had. His preceptor invited the student to accompany him one evening to a well-known expensive restaurant to learn about a new therapy. The student excitedly told his envious classmates about the wonderful food and drink he and his preceptor enjoyed while learning about the new therapy. When the faculty member facilitating the session asked the student if he knew that a drug company was paying for the event and that the “expert” giving the talk was a paid spokesperson for the drug company, the student was thunderstruck. The disillusionment was followed by anger and indignation that he had been manipulated and that this sort of thing was allowed (Smith, personal communication).

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— Steven Craig, MD  
U. of Iowa Carver  
College of Medicine

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Courses on ethics and “Doctoring” courses in the first year of medical school offer an excellent opportunity to introduce students to conflict of interest.

The next point in the continuum of education where curriculum intervention would likely be most effective occurs just before students embark on their first third-year clerkships. This is particularly true for those schools that extensively use community-based clinical placements. Students are likely to find themselves in a situation that runs counter to the policies of the medical school vis a vis relationships with industry. Students can be presented with scenarios and asked to discuss how they should act in case they find themselves in similar circumstances.

The point in the fourth year of medical school when students have completed their residency interviews but have not yet received their match results may be a particularly good time for teaching about conflict of interest. This can be done most effectively within the context of a course to prepare them for what lies only a few months ahead when their orders will actually be carried out and their prescriptions filled. Students are keenly interested in learning how to get the information they will need to make clinical decisions and write prescriptions. They can learn about unbiased sources of information as well as when a healthy dose of skepticism needs to be employed.

Residency training is an appropriate time to teach about conflicts as they might arise in purchasing decisions by the pharmacy or the hospital in terms of medical equipment. Likewise, the problems with samples are appropriate for residents to grapple with (although this is also appropriate for students). Residents should be made aware of the influence of industry on education during residency and fellowships, as well as continuing medical education (CME) and ways to obtain CME free of industry bias.

## V. Case Studies

### *Albert Einstein College of Medicine*

An excellent example of how conflict-of-interest teaching was incorporated into a first-year medical school course comes from the Albert Einstein College of Medicine, taught by Elizabeth A. Kitsis, M.D., M.B.E. Dr. Kitsis feels it is important for students to recognize that COI is pervasive and not just limited to medicine. Students must be sensitive to the possibility that COI exists. The course uses real cases in which students need to reason their way through the situation. One case involved Dr. Jim Wilson, a gene scientist, and Jessie Gelsinger, a patient who died as part of a clinical trial in which Dr. Wilson and the university had equity ownership in a biotech company. Dr. Wilson actually came to Einstein to facilitate discussion of the case and point out the mistakes that he made.

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*“Students like real cases;  
they don’t like very abstract,  
theoretical, or scholarly  
approaches to the subject.”*  
— Elizabeth A. Kitsis, MD, MBE  
Albert Einstein School of Medicine

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### *The University of Iowa Carver College of Medicine*

Third-year medical students participate in a course called “Clinical Beginnings” just before they embark on their clinical clerkships in the community. Steven Craig, M.D., lets students know what they are likely to encounter in the community and how to handle themselves in those situations. Dr. Craig’s hope is that the students would be able to politely extricate themselves from situations that were ethically problematic if encountered in the clinical placement site, such as meals provided by pharmaceutical representatives.

### *Geisel School of Medicine at Dartmouth*

David Nierenberg, M.D., teaches a course in clinical pharmacology and therapeutics to fourth-year medical students at the Geisel School of Medicine at Dartmouth from late February to March. The focus is on what it takes to be a thoughtful and effective prescriber. Dr. Nierenberg heavily relies on telling true stories that illustrate how doctors can get in trouble and hurt their patients as a result of being influenced by pharmaceutical marketing.

## **VI. Evaluating impact**

Although we did not find articles in the medical education literature on efforts to evaluate the impact of teaching about conflict of interest, we can offer some suggestions on approaches to evaluation that might be taken.

### *Knowledge assessment*

Assessing students’ knowledge about conflict of interest before and after a curriculum intervention is the easiest assessment to undertake, though also the least meaningful since it doesn’t tell anything about actual attitude change or behavior. Nevertheless, it can inform the teachers whether basic facts and concepts have been learned.

### *Attitude assessment*

Students can be asked to rate their agreement with statements that reflect their attitudes about conflict of interest before and after the curriculum intervention. Samples of attitudinal statements can be obtained from the literature (Sierles et al. 2005 and Wilkes and Hoffman 2001). Ideally, students can be followed longitudinally to track how attitudes change over time.

### *Behavioral assessment*

The most powerful and valid approach to evaluate impact is to measure how students behave. Objective structured clinical examinations (OSCEs) can be used to assessment how students behave when confronted with ethical problems such as conflict of interest (Smith et al. 1994). Student-initiated projects focused on conflict of interest offer another barometer of impact on learners.

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*“Telling true stories about  
how drug company  
marketing adversely  
affects patient care  
is the most powerful way  
to reach students.”*

*— David Nierenberg, MD  
Geisel School of Medicine  
at Dartmouth*

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## VII. Institutional Policies on Teaching Conflict of Interest

Some medical schools have policies that specify that the curriculum include instruction that will assure that students understand laws and policies related to conflict of interest. Such policies focus more on the “letter of the law” to assure that students are aware of and adhere to existing laws and policies. An example comes from the University of Florida College of Medicine:

The COM Curriculum Committee shall ensure that medical students at the University of Florida understand the importance of federal, state, and institutional conflict of interest laws, rules, policies and procedures. All University of Florida medical students shall receive specific instruction regarding this Conflict of Interest Policy.

Only a few medical schools have specific policies that require teaching about conflict of interest in a broader context of ethics and professionalism in the curriculum. One such school is New York University School of Medicine. Its policy states:

### **Training of Students, Trainees, Staff, and Faculty Regarding Potential Conflicts of Interest in Industry Interactions:**

The Undergraduate Curriculum shall contain a formal program aimed at providing medical students, at a minimum, these four elements:

- A. Recognition of the individual medical student and the individual medical practitioner’s responsibility to avoid promotional activities of the Pharmaceutical Industry because of its distorting effect.
- B. Understanding of concepts and techniques for distinguishing between what is valid medical evidence and what is, in reality, product promotion.
- C. Instruction in how to identify and access the most reliable sources of medical and pharmaceutical information.
- D. Recognition that there is ample evidence that pharmaceutical industry promotional activities distort prescribing practices, resulting in problematic repercussions from the level of the individual physician–patient relationship to the health care system as a whole.

The GME Curriculum Committee will assist all training programs in developing specific curricula to insure that all housestaff receive adequate training regarding interactions with industry.

The near universal inclusion of teaching about conflict of interest in the curriculum of medical schools indicates that the absence of formal policies prescribing that such teaching occur does not prevent teaching from taking place. Nevertheless, adoption of such policies could help assure that the curriculum continues to include teaching about conflict of interest in the future.

## VIII. Curriculum Resources

Curricula, policies and course syllabi referenced above are available for download on our companion website at:

[http://www.communitycatalyst.org/projects/prescription\\_access\\_and\\_quality/policy\\_guide](http://www.communitycatalyst.org/projects/prescription_access_and_quality/policy_guide)

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<http://tinyurl.com/AmcModelCoiPolicy>

The Toolkit is a publication of Community Catalyst, a national, nonprofit consumer advocacy organization dedicated to making quality affordable health care accessible to everyone. Among its prescription drug initiatives, Community Catalyst combats pharmaceutical marketing that creates conflicts-of-interest and threatens the safety and quality of patient care. We provide strategic assistance to medical schools and teaching hospitals seeking to improve their conflict-of-interest policies as part of the Partnership to Advance Conflict-Free Medical Education (PACME), a collaboration of Community Catalyst, The Pew Charitable Trusts, the American Medical Student Association and the National Physicians Alliance. PACME is supported by a grant from the Attorney General Consumer and Prescriber Grant Program, which was funded by the multi-state settlement of consumer fraud claims regarding the marketing of the prescription drug Neurontin.