The Conflict of Interest Policy and Curriculum Task Force was charged in April 2010 jointly by the Essential Core Steering and Clinical Studies Steering Committees to:

1. Define COI principles and guidelines for the curricular setting across all four years, by reviewing and abstracting from those already described in UCOP, UCSF, SOM, UCSFGME, and UCSFCME documents; and by creating additional ones as necessary. Principles and guidelines are not limited to COI disclosure.
2. Provide recommendations for implementation practices of these principles and guidelines at the course/clerkship/rotation level.
3. Provide recommendations for components of core curriculum (including assessments) on COI for our students across the years (e.g. a developmental roadmap approach).
4. Provide recommendations for a mechanism for curricular stewardship of this set of topics.

The Task Force created the acronym “CONSUME” for CONflict of IntereSt in Undergraduate Medical Education. Membership is as noted below and consisted of representatives from both ECSC and CSSC along with content and curriculum experts and medical students. The Task Force was ably supported by David Rachleff, MSW from Undergraduate Medical Education.

<table>
<thead>
<tr>
<th>Task Force Member</th>
<th>Role</th>
<th>Department</th>
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<tbody>
<tr>
<td>Steven Polevoi, MD*</td>
<td>Co-Chair</td>
<td>Emergency Medicine</td>
</tr>
<tr>
<td>Gordon Fung, MD, PhD†</td>
<td>Co-Chair</td>
<td>Medicine, Cardiology</td>
</tr>
<tr>
<td>Cindy Lai, MD†</td>
<td>Course Director, Intersessions</td>
<td>Medicine</td>
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<tr>
<td>Maxine Papadakis, MD</td>
<td>Assoc. Dean, Student Affairs</td>
<td>Medicine</td>
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<tr>
<td>Dana Rohde, PhD*</td>
<td>Course Director, Organs Block</td>
<td>Anatomy &amp; Physio</td>
</tr>
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<td>Michael Steinman, MD</td>
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<td>Medicine, Geriatrics</td>
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<tr>
<td>Beth Apsel†</td>
<td>4th year Medical Student</td>
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<tr>
<td>Anuj Aggarwal*</td>
<td>2nd year Medical Student</td>
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</tr>
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</table>

1 * = ESSC Member
2 † = CSSC Member
Background and Importance:

The missions of Academic Medical Centers and the pharmaceutical, biotechnology, or medical device industry can be divergent:

This divergence can lead to the students' perception of or actual conflict of interest. The importance of this issue has been emphasized by the publication of several reports from national organizations. The Institute of Medicine recently published a report entitled “Conflict of Interest in Medical Research, Education, and Practice” which proposed many recommendations that impact Academic Medical Centers. Additionally, the Association of American Medical Colleges has recently produced documents on the issue of Conflict of Interest in Medical Education and Clinical Practice.

The University of California and UCSF in particular have a long history of productive relationships with the pharmaceutical, biotechnology, and medical device industry. Dr. Susan Desmond-Hellmann, Chancellor of UCSF and former Genentech executive was asked by the co-chair of CONSUME (S. Polevoi) how best to teach students about pharmaceutical industry-academia relationships. Dr. Desmond-Hellmann pointed out that UCSF needs industry to bring discoveries to patients, and that industry-academia relationships shouldn't be considered a "scarlet letter".
Policies and guidelines have been developed to help govern these relationships (see below) but direct attention to the needs of UCSF Medical Students and Medical School faculty has been perceived as deficient. This deficiency prompted the class of 2012 to request faculty to disclose their financial relationships with industry and begin a discussion of conflicts of interest as CONSUME was being developed. In order to focus our efforts, a member of the Task Force (A. Aggarwal) created a medical student needs assessment in Spring, 2010. Over the course of two weeks, 115 medical students across the four classes submitted complete surveys from which the results were compiled. Response rates ranged from 43% for the class of 2013 to 15% for the class of 2010. In general, respondents felt the existing curriculum does not address issues of conflict of interest adequately and that they lack the skills in addressing and resolving such issues (see table below).

### Summary of Ranking Questions

<table>
<thead>
<tr>
<th>Question?</th>
<th>Class of 2010</th>
<th>Class of 2011</th>
<th>Class of 2012</th>
<th>Class of 2013</th>
<th>Mean</th>
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<tr>
<td>Your understanding of what constitutes COI (n=115)</td>
<td>4.00</td>
<td>3.44</td>
<td>3.23</td>
<td>3.58</td>
<td>3.55 (+/- .86)</td>
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<tr>
<td>Ability to address and resolve COI (n=115)</td>
<td>3.06</td>
<td>2.78</td>
<td>2.62</td>
<td>2.60</td>
<td>2.64 (+/- .94)</td>
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<td>How well do the essential core (Years 1-2) prepare you regarding COI (n=115)</td>
<td>2.29</td>
<td>2.11</td>
<td>2.24</td>
<td>1.92</td>
<td>1.9 (+/- .89)</td>
</tr>
<tr>
<td>How well do clerkships (Years 3-4) prepare you regarding COI (n=86)</td>
<td>2.06</td>
<td>2.52</td>
<td>2.6 (n=5)</td>
<td>2.13 (n=15)</td>
<td>2.14 (+/- .71)</td>
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**Charge #1: Define COI principles and guidelines for the curricular setting:**

A number of relevant UC and UCSF policy documents and guidelines already exist at the GME and CME levels. These were obtained with the assistance of Neal Cohen, Vice Dean School of Medicine and Robert Baron, Associate Dean of GME and CME. Each of these documents was reviewed with an eye toward relevance for medical students and the faculty that are in contact with them. The Task Force reviewed the following documents:

1. Guidelines for Interactions Among UCSF Faculty, Students and Staff and Industry; Effective Date: July 15, 2007 (Revised July 1, 2007). Office of Origin: Office of the Dean, UCSF School of Medicine
2. UCSF Industry Relations Policy; Effective Date: 7/1/08; Implemented May 2010. Office of Origin: Executive Vice Chancellor and Provost
4. Guidelines for Interaction Among UCSF Faculty, Residents, Fellows, and Staff and Industry. Approved by: Graduate Medical Education Committee (GMEC). Effective Date: September 22, 2008.
5. UCSF CME Faculty Disclosure and Resolution of Conflict of Interest Policy. Adoption Date: March 22, 2005.
A summary of these documents’ most relevant points pertaining to the charge of CONSUME is as follows:

1. All gifts regardless of monetary value from pharmaceutical, biotechnology, and device manufacturer directly to students, residents, and faculty are prohibited.
2. Faculty participation in industry-sponsored speaker’s bureaus has been prohibited, effective January 1, 2010.
3. “Ghostwriting”, the practice of manuscript production by industry representatives with faculty authorship is prohibited.
4. All education programs within the School of Medicine must abide by the Standards for Commercial Support established by ACCME (Accreditation Council for Continuing Medical Education) regardless of whether CME credit is offered.
5. Faculty and staff must disclose and resolve all financial interests with industry; the disclosure method is dependent on the activity (e.g research, publication, and teaching).

**Charge #2: Recommendations for implementation:**

Upon review of these policies and guidelines, the Task Force focused primarily on disclosure and resolution as it relates to teaching in the School of Medicine. This was driven by the realization that there was no existing mechanism to ensure disclosure by classroom, clinical or student advising faculty in the School of Medicine across the four years and by the desire of students for transparency (as reflected by student comments in the needs assessment noted above). Additionally, beginning last year, a number of 1st year students requested disclosure from faculty in Brain, Mind, and Behavior. This was met with little resistance and compliance was good, suggesting that faculty in the School of Medicine understand the importance of transparency and disclosure.

Amplifying the importance of this is passage of the Physician Payment Sunshine provisions as part of the Federal Patient Protection and Affordable Care Act of 2009. These provisions require all drug and medical device manufacturers begin reporting all gifts and payment to physicians and teaching hospitals annually to the Department of Health and Human Services, which will post this information on a publicly accessible website. Thus, failure of UCSF faculty to disclose could lead to discrepancies between publicly available and internal sources.

In view of this, it is the recommendation of the Task Force that:

1. All faculty (Essential Core, Clinical Core, and Advanced Studies) in contact with medical students must disclose financial relationships with industry.
2. This requirement shall be phased in beginning with large group teaching sessions. Eventually small group leaders, facilitators, and preceptors will be included in this process.

3. A central clearinghouse (e.g. Academic Affairs, UME, or Medical Staff Office) should be able to collect disclosures on behalf of courses and clerkships, some of which are already being collected annually in accordance with the Health Sciences Compensation Plan.

4. A standardized reporting form, preferably modeled after that already in use by CME, should be employed for this purpose. This form will be familiar to many faculty.

5. The directors of the courses and clerkships will be responsible for the process of resolution utilizing procedures already in use by GME and CME. Possible mechanisms for resolution include: recommend an alternative speaker for a topic, submit a presentation in advance to allow for adequate peer review, or divest oneself of the financial relationship. Students should be encouraged to participate in peer review activities.

6. The directors of the courses and clerkships will ensure that students have access to disclosure and resolution information before the teaching activity commences.

7. It is recognized that some faculty (e.g. volunteer, non-UCSF sites) that have contact with medical students may be difficult to capture by the methods described above, but courses and clerkships directors should nevertheless make attempts to do so. Those volunteer faculty that maintain a non-salaried appointment at UCSF must submit teaching hours annually, so this may be an opportunity to request information on financial relationships as well.

**Charge #3: Provide recommendations for components of core curriculum**

Based on the needs assessment mentioned above and the realization that disclosure and resolution of faculty financial relationships is inadequate by itself, it is apparent that students need focused teaching on the issue of academia-industry relations. The Task Force identified curricular components already in existence in Prologue and Intersessions, but while considered valuable by students, they were insufficient by themselves. Additionally, given the fluid nature of the curriculum these components were given variable emphasis and in fact, were considered optional.

The Task Force identified and reviewed several existing curricula by query of the AAMC’s CurrMIT database, MedEd Portal, and by Google search. The most promising identified were the American Medical Student Association’s model curriculum and the Institute on Medicine as a Profession’s web-based curriculum. The Task Force
reviewed these in some detail and attempted to include elements of each in a proposed curriculum for our medical students.

It is noteworthy that “defining and appropriately managing conflicts of interest” and defining the role of “PHARMA” in the healthcare system have been identified as milestones in our Medical School’s new competency-based assessment and advancement system. These milestones are imbedded in sub-domains of the core competencies Professionalism and Systems-Based Practice.

A challenge recognized by the Task Force is to determine the best places to insert these elements into an already crowded curriculum and what instructional methods to employ. A natural progression from basic principles to more complex and divisive issues through the 4-year curriculum is desired.

The following were felt to be the minimum curricular elements required. Students should have an understanding of:

1. Basic principles, definitions, terminology
2. Altruism and patient primacy
3. Influence and reciprocity
4. Role of funding sources and potential bias in reporting
5. Interactions with pharmaceutical and device company representatives
6. Marketing
7. Methods of resolution

Task Force members then attempted to deconstruct each of these into discrete learning objectives. The goal was to provide course and clerkship leadership with moderately specific elements that could be inserted into the existing curricula. This does not necessarily represent either an exclusive or comprehensive list of learning objectives, but is meant as a starting point that will undoubtedly be revised and modified based on logistics and feedback.

1. Basic principles, definitions, terminology
   a. Discuss the importance of academic-industry relations in medicine and at UCSF in particular
   b. Define conflict of interest
   c. Define disclosure
   d. Define resolution
e. Give an example of a conflict of interest that may occur by a lecturer

f. Give an example of a conflict of interest that may occur by a physician treating a patient

2. Altruism and patient primacy
   a. Review the professionalism pledge that all UCSF Medical Students must follow

3. Influence and reciprocity
   a. Define influence
   b. Define reciprocity
   c. Explain how positive reciprocal actions differ from altruistic ones
   d. What is the neurobiological and psychosocial evidence related to the effects of gifts on recipient's choice and decisions?

4. Role of funding sources and potential bias in reporting
   a. Identify the potential for bias in industry-supported clinical trials
   b. Learn the factors leading to use of new pharmaceutical agents that are safe and effective
   c. Understand the factors leading to the use of a new pharmaceutical agent.
   d. List ways that research studies can be used to promote drugs (e.g. concerns about questions and designs, data collection, data extraction, categorization of conclusions, selective publication, ghost authors, marketing, etc.)
   e. Specify ways to prevent bias in research studies.

5. Interactions with pharmaceutical and device company representatives
   a. List ways that pharmaceutical or device companies directly impact students' education while on clinical clerkships
   b. Learn ways to identify potential conflicts when interacting with pharmaceutical or device companies
   c. Identify strategies to use during interactions with pharmaceutical or device company representatives while on clinical clerkships.

6. Marketing
a. Define a speaker's bureau and describe conflicts of interest for the speaker and audience at speaker’s bureau events.

b. Define ghostwriting and describe the impact of ghostwriting on the content of journal articles

c. Differentiate directly-funded and independent/ACCME accredited CME. Define potential conflicts of interest that arise in both.

d. State reasons why a physician would use a medication off-label and compare and contrast how off-label usage of medications can be both beneficial and harmful to patients.

7. Methods of resolution once disclosure has occurred

The student needs assessment mentioned above inquired specifically about desired instructional methods. Results are noted in the table below:

<table>
<thead>
<tr>
<th>Question</th>
<th>Number</th>
<th>Percent of Respondents Indicating Yes</th>
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<tbody>
<tr>
<td>Case studies</td>
<td>95</td>
<td>83%</td>
</tr>
<tr>
<td>Critical appraisal of ads</td>
<td>69</td>
<td>60%</td>
</tr>
<tr>
<td>Lecture</td>
<td>68</td>
<td>59%</td>
</tr>
<tr>
<td>Role-playing (responding to COI)</td>
<td>28</td>
<td>24%</td>
</tr>
<tr>
<td>Essays</td>
<td>5</td>
<td>4%</td>
</tr>
<tr>
<td>Small Group</td>
<td>71</td>
<td>62%</td>
</tr>
<tr>
<td>Student Debates</td>
<td>21</td>
<td>18%</td>
</tr>
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From this data, it appears that respondents desire case studies and small group sessions as a primary means of learning these principles. Within such small groups, critical appraisal of advertisements would be a novel and stimulating means of engaging learners. Respondents also ranked lectures as a satisfactory means of teaching this material; a reasonable approach would be an introductory talk, followed by more active learning in a small group. An engaging educational method that should be considered is a field trip to Mission Bay or QB3 to speak with those on the front lines of industry collaboration. Another method would be to engage student representatives during the development of these relationships and collaborations.

It would be helpful if previous educational interventions were available to inform us on the most effective means of teaching this material. In fact, there is a small body of literature on the impact of educational interventions on the knowledge, skills, and attitudes of medical students toward pharmaceutical representatives and industry.
The four studies identified employed lectures, workshops, and role-playing. In two studies, either actual pharmaceutical representatives or pharmacists posing as pharmaceutical representatives were utilized to increase authenticity. The study design for three of the four studies was a pretest-intervention-post test format and one was a non-randomized controlled trial. In two of the studies, the interventions lead to more skepticism toward pharmaceutical industry claims. Interestingly, in the studies in which the pharmaceutical industry was directly involved in curriculum development and participated in delivery of the intervention, students’ attitudes were more favorable toward industry. In addition to methodological limitations, outcomes measured were short term so no conclusions could be made about durability of the attitudinal changes. There were no published studies identified that considered students interactions with medical device companies.

Assessments are important and provide legitimacy to learned materials. The Task Force concluded that the method of assessment was dependent on the educational method employed. For lectures, traditional multiple choice questions can be utilized for basic principles. For small group exercises, feedback sessions or reflective writing exercises that can be incorporated into the MD Portfolio would be appropriate for the more thorny and controversial issues.

*Charge #4: Provide recommendations for a mechanism for curricular stewardship*

This is under discussion by CONSUME and curricular committee leaders.

*References:*


