## Schools Group, Not AMA, Says No to Industry Gifts

BY CATHY DOMBROWSKI AND DENISE PETERSON

"The Pink Sheet"

edical schools and teaching hospitals should prohibit their physicians, faculty, residents, and students from taking gifts and services from drug companies, according to the Association of American Medical Colleges.

Industry support for continuing medical education activities also should be limited, according to a report unanimously adopted by the AAMC executive council. The association is urging member institutions to adopt policies consistent with the report by July 1, 2009.

AAMC cites the medical schools at the University of Pittsburgh, the University of Pennsylvania, Stanford University, the University of California at Davis, UCLA, and Yale University as among the institutions that have implemented policies in the past

The association represents 129 U.S. and 17 Canadian medical schools, about 400 teaching hospitals and health systems, and a number of scientific societies.

AAMC's strong stance against industry gifts to physicians comes as drug and device makers are signing on to federal legislation that would bring transparency to their financial interactions with doctors by requiring public disclosure of gifts.

The Institute of Medicine also is assessing the effectiveness of transparency in preventing conflicts of interest arising from such interactions, with a report due

The medical schools report, titled "Report of the AAMC Task Force on Industry Funding of Medical Education to the AAMC Executive Council," calls on members to take the following actions:

- ▶ Ban acceptance of industry gifts by doctors, faculty, students, and residents, whether given on- or off-site.
- ► Either end acceptance of drug samples or manage their distribution through a centralized process.
- ▶ Restrict visits to individual doctors by industry representatives to nonpatient areas and by appointment only.
- ► Create a central office to receive and coordinate distribution of industry support for CME.
- ► Strongly discourage faculty participation in industry-sponsored speaking bu-
- ► Bar physicians, residents, and students from using presentations ghostwritten by industry members.

At the same time, most medical students have "limited understanding" of such issues. Medical curricula should include information on topics such as the process of drug development, nature of the pharmaceutical industry, product marketing, "meaning and limitation" of FDA product approval, and physician role in adverse event reporting, the report asserts.

But the report affirms that "substantive, appropriate, and well-managed interactions between industry and academic medicine are vital to the public health."

The American Medical Association also reviewed industry funding and gifts at its June 14-18 House of Delegates meeting but declined to take a clear-cut position. The AMA's Council on Ethical and Judicial Affairs recommended that individual physicians and institutions of medicine not accept industry funding for education. But the delegates referred the report for further review after the Committee on Amendments to the Constitution and Bylaws said that testimony on the report lacked clarity in some areas. The panel also cited concern for unintended consequences.

The delegates also declined to get embroiled in the debate over reporting of industry gifts. Pending was a resolution for AMA to back annual reporting by drug and medical device firms of all physician payments with a value of more than \$100.

An AMA committee advised delegates that testimony on the measure generally was unfavorable, with concerns raised about the logistics and how and to whom the information would be disclosed.

Noting that legislation on the issue "is pending and may serve to answer many of these questions," the committee recommended that the resolution not be adopted, and the delegates concurred.

On the question of conflicts of interest in CME, the delegates accepted the recommendation of AMA's Council on Medical Education to monitor implementation of ACCME standards.

PLAVIX® clopidogrel bisulfate tablets

ICATIONS AND USAGE AVIX (clopidogrel bisulfate) is indicated for the reduction of atherothrombotic ex

tent MI, Recent Stroke or Established Peripheral Arterial Disease alatents with a history of recent myocardial infarction (MI), recent stroke, or established otheral arterial disease, PLAVIX has been shown to reduce the rate of a combined end-to fine wis chemic storke (fatal or not), new MI (fatal or not), and other vascular death. (E Coronary Syndrome patients with non-SI-segment elevation acute coronary syndrome (unstable nainon-Q-wave MI) including patients who are to be managed medically and those are to be managed with percutaneous coronary intervention (with or without stent) ABG, PLAVIX has been shown to decrease the rate of a combined endpoint of iovascular death, MI, or stroke as well as the rate of a combined endpoint of lauf death, MI, stroke, or refractory sichemia.

to affect bleeding before any surgery is scheduled and before any new drug is taken. 
teractions
of specific drug interactions yielded the following results.
A spirin did not modify the clopidogra-herolated inhibition of ADP-induced
aggregation. Concomitant administration of 500 mg of aspirin twice a day for 1 day
significantly increase the prolongation of bleeding time induced by PLAVIX. PLAVIX and
asses been administreed together for up to one year.
In a study in healthy volunteers, PLAVIX did not necessitate modification of the
dose or after the effect of heparin on coagulation. Coadministration of heparin had
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latric Use the total number of subjects in the CAPRIE, CURE and CLARITY controlled clinical stud-approximately 50% of patients treated with PLAVIX were 65 years of age and older, and were 75 years and older. In COMMIT, approximately 58% of the patients treated with VIX were 60 years and older, 26% of whom were 70 years and older, of whom of the patients were observed risk of thrombotic events with clopidogrel plus saprinin versus placebo plus in by age category is provided in Figures 3 and 6 for the CURE and COMMIT trials, sectively (see CLINICAL STUDIES). The observed risk of bleeding events with clopidogrel asprin versus placebo plus asprin by age category is provided in Tables 5 and 6 for CURE and COMMIT trials, respectively (see ADVERSE REACTIONS).

Event	PLAVIX	Placebo	P-value
	(+ aspirin)* (n=6259)	(+ aspirin)* (n=6303)	
Major bleeding †	3.7 ‡	2.7 §	0.001
Life-threatening bleeding	2.2	1.8	0.13
Fatal	0.2	0.2	
5 g/dL hemoglobin drop	0.9	0.9	
Requiring surgical intervention	0.7	0.7	
Hemorrhagic strokes	0.1	0.1	
Requiring inotropes	0.5	0.5	
Requiring transfusion (≥4 units)	1.2	1.0	
Other major bleeding	1.6	1.0	0.005
Significantly disabling	0.4	0.3	
Intraocular bleeding with			
significant loss of vision	0.05	0.03	
Requiring 2-3 units of blood	1.3	0.9	
Minor bleeding ¶	5.1	2.4	< 0.001

Table 6: Number (%) of Patients with Bleeding Events in COMMIT					
Type of bleeding	PLAVIX (+ aspirin) (N=22961)	Placebo (+ aspirin) (N=22891)	P-value		
Major* noncerebral or cerebral bleeding** Major noncerebral Fatal Hemorrhagic stroke Fatal	134 (0.6%) 82 (0.4%) 36 (0.2%) 55 (0.2%) 39 (0.2%)	125 (0.5%) 73 (0.3%) 37 (0.2%) 56 (0.2%) 41 (0.2%)	0.59 0.48 0.90 0.91 0.81		
Other noncerebral bleeding (non-major)	831 (3.6%)	721 (3.1%)	0.005		
Any noncerebral bleeding	896 (3.9%)	777 (3.4%)	0.004		

years 0.770. ing in ≥2.5% of patients on PLAVIX in the CAPRIE controlled clinical regardless of relationship to PLAVIX. The median duration of therapy

	% Incidence (% Discontinuation		
Body System Event	PLAVIX [n=9599]	Aspirin [n=9586]	
Body as a Whole – general disorders			
Chest Pain	8.3 (0.2)	8.3 (0.3)	
Accidental/Inflicted Injury	7.9 (0.1)	7.3 (0.1)	
Influenza-like symptoms	7.5 (<0.1)	7.0 (<0.1)	
Pain	6.4 (0.1)	6.3 (0.1)	
Fatigue	3.3 (0.1)	3.4 (0.1)	
Cardiovascular disorders, general			
Edema	4.1 (<0.1)	4.5 (<0.1)	
Hypertension	4.3 (<0.1)	5.1 (<0.1)	
Central & peripheral nervous system disorders			
Headache	7.6 (0.3)	7.2 (0.2)	
Dizziness	6.2 (0.2)	6.7 (0.3)	
Gastrointestinal system disorders			
Any event	27.1 (3.2)	29.8 (4.0)	
Abdominal pain	5.6 (0.7)	7.1 (1.0)	
Dyspepsia	5.2 (0.6)	6.1 (0.7)	
Diarrhea	4.5 (0.4)	3.4 (0.3)	
Nausea	3.4 (0.5)	3.8 (0.4)	
Metabolic & nutritional disorders	, ,		
Hypercholesterolemia	4.0 (0)	4.4 (<0.1)	
Musculo-skeletal system disorders			
Arthralgia	6.3 (0.1)	6.2 (0.1)	
Back Pain	5.8 (0.1)	5.3 (<0.1)	
Platelet, bleeding, & clotting disorders			
Purpura/Bruise	5.3 (0.3)	3.7 (0.1)	
Epistaxis	2.9 (0.2)	2.5 (0.1)	
Psychiatric disorders			
Depression	3.6 (0.1)	3.9 (0.2)	
Respiratory system disorders			
Upper resp tract infection	8.7 (<0.1)	8.3 (<0.1)	
Dyspnea	4.5 (0.1)	4.7 (0.1)	
Rhinitis	4.2 (0.1)	4.2 (<0.1)	
Bronchitis	3.7 (0.1)	3.7 (0)	
Coughing	3.1 (<0.1)	2.7 (<0.1)	
Skin & appendage disorders			
Any event	15.8 (1.5)	13.1 (0.8)	
Rash	4.2 (0.5)	3.5 (0.2)	
Pruritus	3.3 (0.3)	1.6 (0.1)	
Urinary system disorders	•		
Urinary tract infection	3.1 (0)	3.5 (0.1)	

No additional clinically relevant events to those observed in CAPRIE with a frequency 22.5%, have been reported during the CURE and CLARITY controlled studies. COMMIT collected only limited salely data.

Other adverse experiences of potential importance occurring in 1% to 2.5% of patients receiving PLAVIX (clopidogrel bisulfate) in the controlled clinical trials are listed below regardless of relationship to PLAVIX. In general, the incidence of these events was similar to that in patients receiving aspirin (in CAPRIE) or placebo + aspirin (in the other clinical risks)

Body as whole:
-hypersensitivity reactions, anaphylactoid reactions, serum sickness
-entral and Peripheral Nervous System disorders:
-contusion, hallucinations, taste disorders:
-thepate-biliary disorders:
-abnormal liver function test, hepatitis (non-infectious), acute liver failure
-Platelet, Bleeding and Otiting disorders:
-cases of bleeding with fatal outcome (especially intracranial, gastrointestinal and retroperitoneal hemorrhage)
-thrombotic thrombocytopenic purpura (TIP) – some cases with fatal outcome –

PLAVIX can be administered with or without food.

No dosage adjustment is necessary for elderly patients or patients with renal disease (See Clinical Pharmacology: Special Populations.)

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