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Audiology Practice and the Potential for Conflicts of Interest - Vanderbilt Audiology's Journal Club with Dr. Fred Bess

Presenter: Fred H. Bess, Ph.D.
Host: Gus Mueller, Ph.D.
Moderator: Carolyn Smaka, Au.D.

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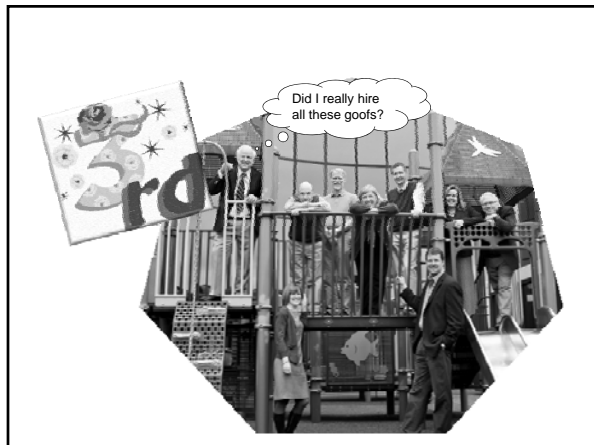


VANDERBILT V AUDIOLOGY
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Audiology Practice and the Potential for Conflicts of Interest

Fred H. Bess, Ph.D.

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Writing

What They're Reading At Vandy

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Vanderbilt University Audiology Journal Club

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Gus's Pick Of The Month

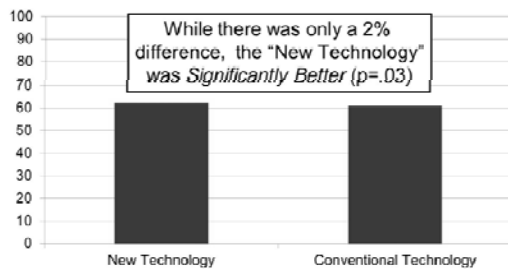
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Piers Dawes, Samantha Powell and Kevin Munro
Ear and Hearing, 2011

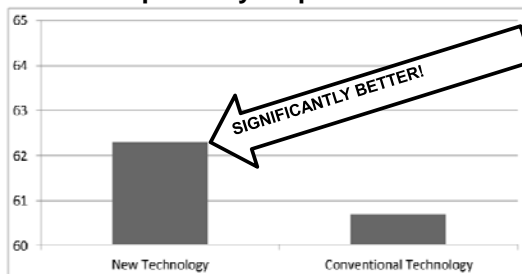
What they did:

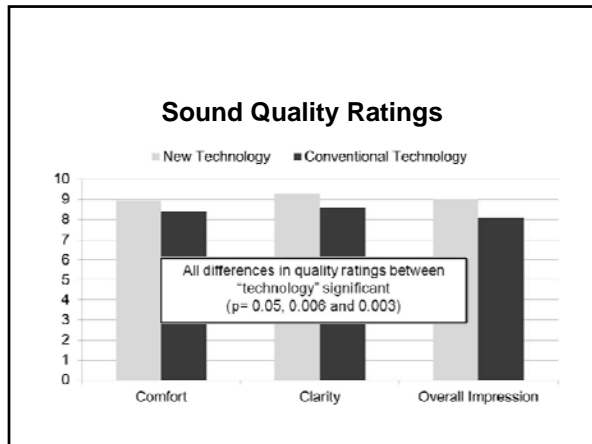
- Participants were 20 experienced hearing aid users (54 to 80 years old; mean = 69) with bilateral downward sloping hearing loss
- Used two hearing aids, that were in fact the same hearing aids, and were programmed in an identical manner
- The one hearing aid had a yellow case, the case of the other hearing aid was beige. The participants were informed that the "yellow hearing aid" had the new technology
- Three main comparative measures were conducted:
 - Speech recognition in noise (FAAF)
 - Sound quality ratings
 - Overall personal preference

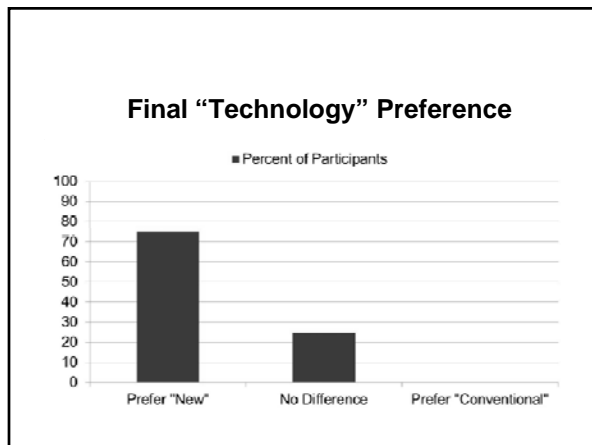
Results for the speech-in-noise test



And when you get the brochure, it will probably be plotted like this!

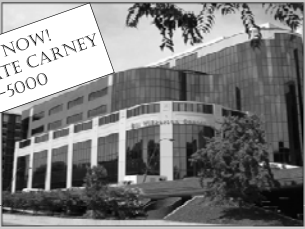










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615-936-5000



HEARING AIDS '12
VANDY "HANDS-ON" WORKSHOP
OCTOBER 4TH-6TH

 **Vanderbilt Bill Wilkerson Center**
for Otolaryngology and Communication Sciences



**Audiology Practice and the
Potential for Conflicts of Interest**

Fred H. Bess, Ph.D.

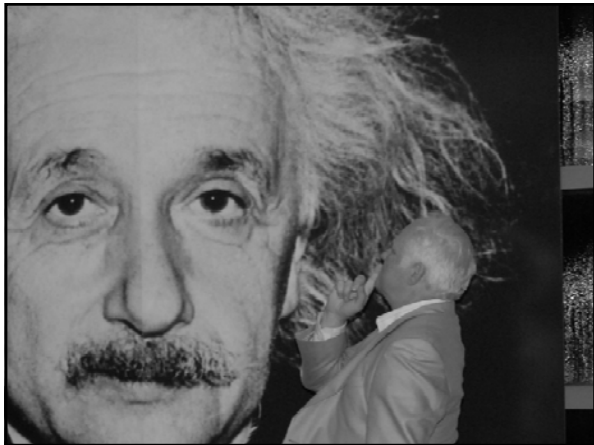
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**How do you begin to
introduce this guy?**



He even has his
own softball team!







**Audiology Practice and the
Potential for Conflicts of Interest**

Fred H. Bess, Ph.D.

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Bill Wilkerson Center (1951-1956)

BACKGROUND

A Few Comments on Ethics



What sets professions apart from other occupations?

- Professionals are assumed to put their client's interests ahead of their own interests.
- Society permits a high degree of self-governance to professions.

Ethical Standards of Conduct

- The most readily accessible standards of conduct for audiologists are codes of ethics
- Sets minimal standards for professional conduct
- Determines who is included or excluded from the profession



Morals Vs. Ethics

- Moral: Defines personal character. It is conforming to a standard of right behavior*
- Ethical: Conforming to accepted professional standards or codes of conduct

A Few Things to Remember about "Ethics"

- If something is illegal, it most likely is also unethical, but many unethical behaviors are not illegal
- Ethics are about perceptions. If your patients perceive an action as unethical, then it could be considered unethical.
- Conflicts of interest in clinical practice are considered unethical

Conflicts of Interest...



- occur when the interests of audiologists do not align with the interests of their patients.
- when systemic, such conflicts not only compromise the quality of care to individual patients but it is can also undermine the integrity of the audiology profession.

A Few Things to Remember About “Conflicts of Interest”...

- When the reimbursement of clinicians appears to encourage decisions that are not in the best interest of their patients a conflict exists
- When industry influences clinicians, whether through such activities as gift giving, support of CEU's, entertainment, or sales incentives, a conflicts exist
- Recognition and acknowledgment are the first steps in effective intervention

AAA Code of Ethics...

Rule 4c: “Individuals shall not participate in activities that constitute a conflict of professional interest.”

Seminal Events in the Evolution of Audiology

- Hearing Aid Dispensing
- American Academy of Audiology

Both Events ...

- Increased professional autonomy.
- Increased dependence on hearing aid manufacturers.

AAA Convention

- Defines Academy to members
- Excessive commercial presence/influence
- A meeting of health care professionals or hearing aid manufacturers??



Industry Supported Academy Programs

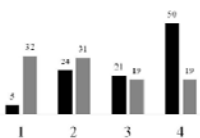
- When there is no apparent connection between program and sponsor's business interests . . .
- The sponsor is simply buying influence.
- The potential for conflict of interest exists (objectivity compromised).

Member vs. Patient Attitudes

- 20 item questionnaire (Teri Hamill)
- Describe 20 professional/business activities
- Response categories:
 1. "nothing wrong with this practice"
 2. "may not be in the patient's best interest"
 3. "borders on unethical practice"
 4. "clearly unethical"

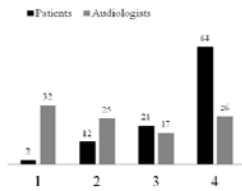
Audiologist earns credits for each hearing aid purchased.
Credits redeemed for gifts or cruises.

■ Patients ■ Audiologists



1. "nothing wrong with this practice"
2. "may not be in the patient's best interest"
3. "borders on unethical practice"
4. "clearly unethical"

Manufacturer gives \$100 traveler's check for each aid purchased.



1. "nothing wrong with this practice"
2. "may not be in the patient's best interest"
3. "borders on unethical practice"
4. "clearly unethical"

Are you concerned about potential conflicts that can arise from audiology/industry relationships





★ SEC CHAMPS (2012)

MILESTONES

Audiologists Who Made an Ethical Difference



Barry Elpern



David Resnick



Brian Walden



Milestones in Ethics (AAA)

- David Resnick crafts the 1st code of ethics*(1990-91)
- Presidential Task Force (2001)
- Awareness Campaign (2002-2003)
- Ethical Practices Board established (~2002-03)
- Ethical Practice Guidelines (2003;2011)
- Giveaway Ban at Conventions (2012)



BILL WILKERSON CENTER (1958-2004)

JOURNAL ARTICLES

Magnitude of Problem in Medicine

- 12-15 billion annually (8-10k/physician)
- Pharm industry spends 30-40% of its revenues on selling products
- 90,000 drug representatives (1/4.7 office based physicians)
- Interactions with industry include receipt of gifts, drug samples, free meals, entertainment, subsidized attendance to meetings, and honoraria to speak
- 900 million of 1 billion spent annually on CME provided by pharm industry

Parallels in Audiology

- Estimated 5-7 billion in HA sales annually
- 25-30% of employees are dedicated to marketing
- Interactions with industry include gifts, free meals, & subsidized travel to meetings.
- Millions of \$\$ spent annually on continuing education activities

PHYSICIANS AND THE PHARMACEUTICAL INDUSTRY—Is a Gift Ever Just a Gift?

Wasana, A. JAMA; 283: 373-380, 2000

What they asked . . .

- What is the extent of and attitudes toward the relationship between physicians and the pharm industry?; and,
- What is the impact of the above on the knowledge, attitudes and behavior of physicians?.

What they did . . .

- Conducted a critical examination of the evidence using Medline Search of articles published (1994-2000)
- An internet database was also searched
- 538 studies were 1st identified; 29 peer reviewed studies that included an analytic design (control group) were used in the analysis
- 16 addressed physician/industry interaction; 16 identified attitudes toward the interaction; 16 examined the effect of interaction on practitioner

What they found . . .

- Physician interactions with pharm reps were generally endorsed, began in medical school and continued well into practice
- Meetings with pharm reps influenced prescription behavior
- Gifts and the number of gifts received correlated with the belief that gifts do not influence behavior
- Drug-company sponsored CME events preferentially highlighted their own drugs
- Attending sponsored CME events and accepting funding for travel or lodging were associated with increased prescription rates of the sponsors medication*

Why is this important?...

- One of the early studies to show (using the scientific method) the negative impact associated with frequent physician/industry interactions
- Patterns of physician/industry interactions begin in school
- Calls for the development of policies and guidelines for associations and medical schools

**A NATIONAL SURVEY OF
PHYSICIAN-INDUSTRY
RELATIONSHIPS**

Campbell, EG., Gruen, RK., Mountford, J.
et.al., N Engl J Med; 356:1742-1750, 2007

What they asked . . .

- What do physicians receive from industry?
- How often do physicians meet with industry representatives?
- What characteristics are associated with the frequency and nature of physician-industry relationships?

What they did . . .

- Analyzed a survey of US physicians conducted by the Institute on Medicine as a Profession (IMAP)
- Surveyed 3167 physicians in six specialties
- Survey had 47 questions on professionalism, 3 of which focused on physician-industry relations (1 of the 3 was comprised of 10 sub-test items)
- *“Which of the following have you received in the last year from drug, device or other medically related companies”?* Responses were: food or beverage in the workplace; free drug samples; honoraria for speaking; payment for consulting services;

What they did . . .

- *“Which of the following have you received in the last year from drug, device or other medically related companies”?*
 - food or beverage in the workplace; free drug samples; honoraria for speaking; payment for consulting services; free tickets to sporting events; payments in excess of costs for enrolling patients; costs of travel, time, meals, lodging, payment for service (scientific board, advisory board) or other expenses for attending meetings; and gifts received for prescribing practices

What they found . . .

- 94% of physicians reported some type of relationship with industry*
- More than a third received reimbursement for meetings or CME
- More than a quarter received payments for consulting, lectures, or enrolling patients in trials
- Frequency of interactions varied significantly as a function of specialty
- Physicians in solo, two-person or group practices met more frequently with industry than physicians in hospitals or clinics*

Why is this important?...

- Physician-industry relationships continue to be very common in medicine—in fact more so than previous studies
- Relationships vary according to specialty (pediatricians were significantly less likely than family practitioners to receive samples, reimbursements and payments)
- Industry appears to target opinion leaders
- Need to consider developing guidelines and recommendations are specific to the context of each specialty and setting

MEDICAL STUDENTS' EXPOSURE TO AND ATTITUDES ABOUT DRUG COMPANY INTERACTIONS-A NATIONAL SURVEY

Sierles, FS, Brodkey, AC., Cleary, LM
et.al. JAMA, 294:1034-1042, 2005

What they asked . . .

- What is the frequency of medical student's exposure to drug companies gifts?
- What are the medical student's attitudes toward gifts?
- How many medical schools have policies regarding pharm representatives and students?

What they did . . .

- Surveyed 3rd year medical students from eight medical schools
- Survey instrument sought 1. demographic information, 2. the student's perception re whether the school had a policy on physician-industry interactions, 3. experiences with specific types of drug-related activities, and 4. beliefs about whether their school had taught them enough about physician-industry relationships
- Queried students about frequency and nature of gifts, attitudes, and their perceived appropriateness of drug-related gifts

What they found . . .

- Student interaction with industry is very common—(average 1 sponsored activity attended or 1 gift received per week—almost all of the student's had been asked or required by a physician to attend a sponsored lunch 1 or more times/month)*
- As a group they appear to be influenced by marketing strategies*
- Most students believed that sponsored grand rounds and sponsored materials were helpful, sponsored meals and textbooks were appropriate, gifts, could not influence them or their colleagues, and that students may be entitled to gifts because of financial hardship
- Many students who perceived that gifts were inappropriate had actually received them
- Of the 8 schools, 7 had no school-wide policies regarding industry-related contacts
- A survey of Deans—89% reported that there was no policy re industry

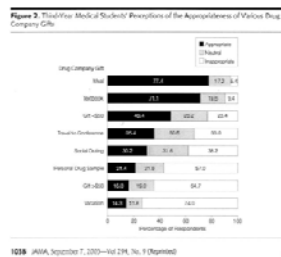
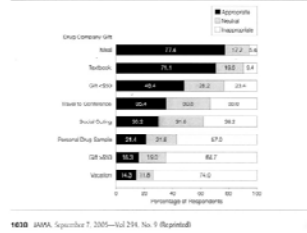


Figure 2. Third-Year Medical Students' Perceptions of the Appropriateness of Various Drug Company Gifts



1638 JAMA, September 7, 2005—Vol 294, No. 9 (September)

Why is this important?...

- Study documents the frequency and nature of physician-industry relationships in medical schools
- Educational institutions plays an important role in the students perceptions and attitudes toward physician-industry relationships
- Medical schools need to set the example—and faculty need to serve as role models
- Institutions and medical associations need to develop guidelines and recommendations

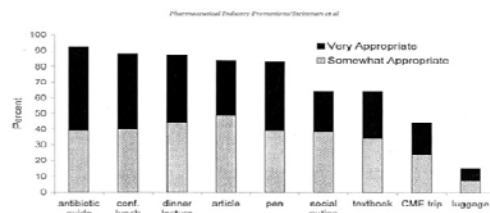
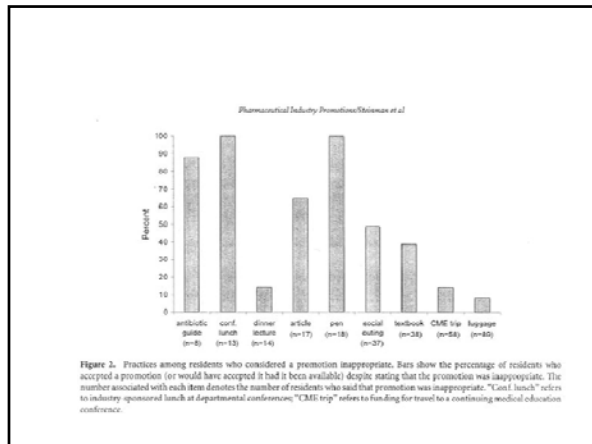
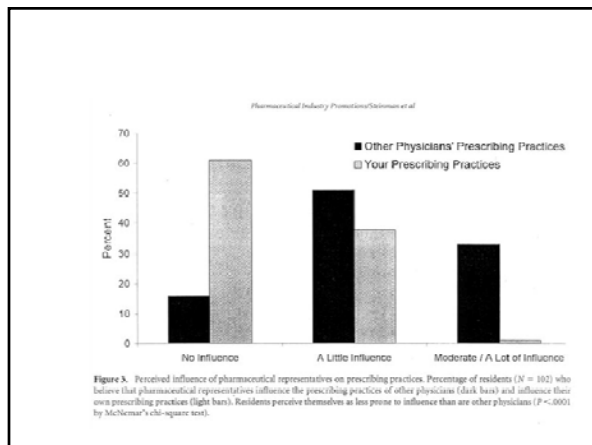


Figure 3. Attitudes toward promotions. Figure shows the percentage of residents (N = 105) who considered each promotion "very appropriate" (dark bars) or "somewhat appropriate" (light bars). "Conf. lunch" refers to industry-sponsored lunch at departmental conferences; "CME trip" refers to funding for travel to a continuing medical education conference.







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And now it's time for . . .

Vandy Vignettes

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Professional Accomplishments of Judy Gravel (1985-2008)

- ☐ 100+ articles, chapters, books
- ☐ 300+ presentations in US and abroad
- ☐ Embedded in tutorial video tapes
- ☐ Served on 39 taskforces
- ☐ Consultant to NIH, MCHB, Corp's
Hospitals and Foundations



ETHICAL ISSUES IN HEARING AIDS REVISITED: A SURVEY

Hawkins, DB, Hamill, T, and Kukula, J. Audiology
Today, 18: 22-28, 2006

What they asked . . .

- What are the attitudes/opinions of audiologists concerning the ethics of relationships with industry?
- Do the attitudes/opinions of audiologist's differ from that of consumers?
- Have the attitudes/opinions changed since 2002 survey?

What they did...

- 17 item questionnaire
- Survey completed by 1,633 members of AAA
- Describe professional/business activities
- Response categories:
 1. "nothing wrong with this practice"
 2. "may not be in the patient's best interest"
 3. "borders on unethical practice"
 4. "clearly unethical"

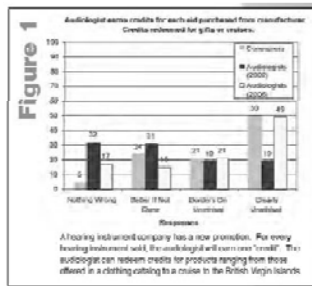
Content Areas of Survey Questions

- Business Incentives from HA Manufacturers
- Entertainment, Small Gifts, and Visits from Manufacturers
- CEU Events Sponsored by HA Manufacturers
- Business Practices

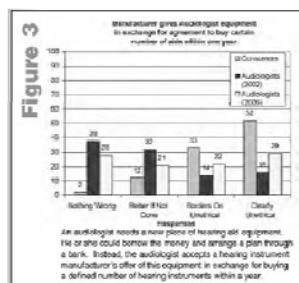
What they found . . .

- A significant positive change in attitudes from 2002-2006 re the acceptability of activities such as gifts and cruises*
- There is little concern about sales reps bringing small items/gifts such as pens and notepads
- All groups expressed more concern about expenses paid for out of town company sponsored workshops*
- Discrepancies in attitudes continue to exist between audiologists and consumers
- Wide differences of opinion continue to exist among audiologist's on some practice behaviors

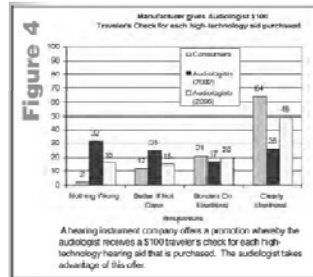
Consumer Vs Audiologists



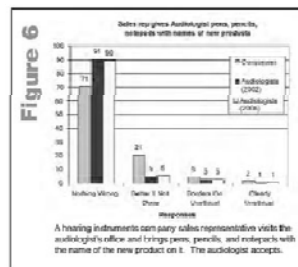
Consumer Vs Audiologists



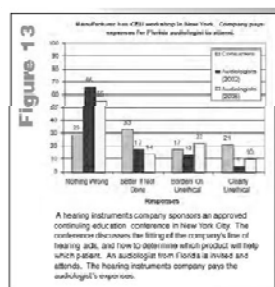
Consumers Vs Audiologists



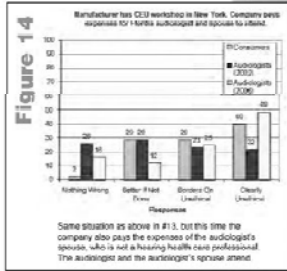
Consumer Vs Audiologist

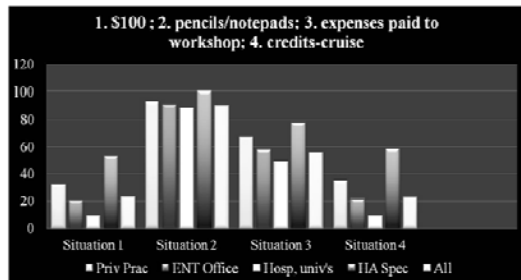


Consumer Vs Audiologist



Consumer Vs Audiologist





Why is this important?...

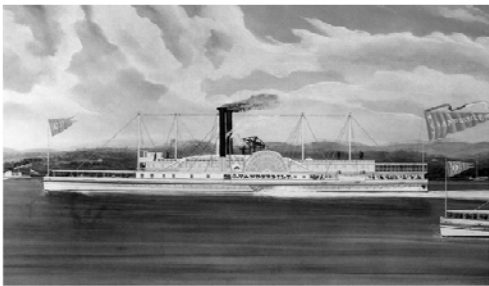
- Only existing large scale evidence-based study exploring conflicts of interest
- Demonstrates that AAA's efforts to educate members about potential conflicts is working
- Identifies target areas for future discussions and educational training



Commodore Cornelius Vanderbilt

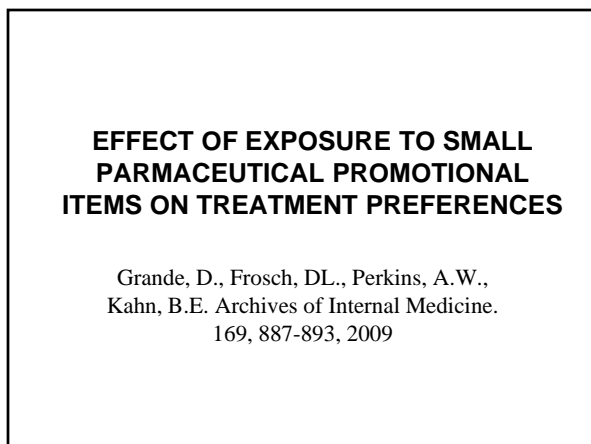


Commodore Vanderbilt Steamship (circa 1860)









What they asked...

- Will exposures to small pharmaceutical promotional items result in more favorable attitudes toward marketed products and,
- Will a policy that restricts pharmaceutical marketing mitigate the effect?

What they did. . .

- 3rd and 4th year medical students (N=352) from 2 schools; *one school (University of PA) had restrictive policies that prohibited gifts, meals, and samples; one (University of Miami) permitted such marketing practices.*
- Randomized experimental design—S's assigned to a control or exposure condition. Exposure group (GP) was exposed to Lipitor branded promotional items prior to completing a computer-based study instrument.
- Exposures included Lipitor logos on a clipboard (when signed in) and notepaper (used to provide ID). Controls completed the same procedures but with plain notebook and paper

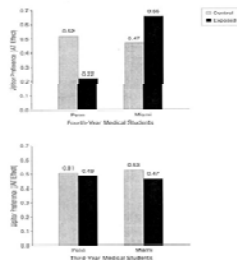
What they did. . .

- Studied the influence of exposure to branded products on relative attitudes toward 2 statins—Lipitor and Zocor
- Outcome measures—implicit (unconscious) attitudes and explicit (self-reported) attitudes.
- Implicit Association Test (IAT)—tool used in marketing and psychology
Conceptually, the IAT pairs targets (eg, *Lipitor* and *Zocor*) with attributes (eg, *pleasant* or *unpleasant* and requires S's to sort corresponding images and words
- Differences in reaction times when pairing targets and attributes are a clue to implicit attitudes (eg, greater speed when *Lipitor* and *pleasant* are paired or when *Zocor* and *unpleasant* are paired reflects a more favorable attitude toward *Lipitor* than *Zocor*—<https://implicit.harvard.edu/implicit>)

What they found . . .

- Students in both class years at both schools demonstrated implicit attitudes favoring Lipitor.
- There were significant differences between the exposed and control GPs among the 4th year students.
- At Miami, 4th years exposed to Lipitor promotional items demonstrated stronger preferences to Lipitor compared to control GP.
- In contrast, Penn 4th year students exposed to Lipitor-branded items exhibited weaker preferences toward Lipitor compared to control.

Lipitor preference among 3rd and 4th year medical students



Why is this important?...

- First evidence-based study to demonstrate that subtle branding exposures are important and influential.
- Suggests that institutional policies can make a difference—their influence on student attitudes toward marketing could lead to different responses to branded promotional items.

Some Facts About Gift Giving

- Gift giving is a common marketing strategy especially in educational institutions
- Gifts create networks of obligation/indebtedness*
- Gifts influence prescription behavior
- Even small gifts, such as pens and notepads, influence student attitudes toward marketed products

Accepting Gifts Have Repercussions

- Gifts cost patients money
- Establishes a relationship between practitioner and company--obliges a response
- Relationship between practitioner and patient may be compromised
- Practitioner's character may be tarnished by a practice that fosters self-interest



Student Conflict of Interest--Vanderbilt University

Vanderbilt Student COI Policy—Guiding Principles

- It is common for audiologists to be carried by industry
- Gifts create networks of obligation (Chren, et.al., 1989; Steinbrook, 2009)
- Ethics and behavior practiced in university settings influence student behavior (Kassirer, 2000)
- Training in COI can influence clinician behavior (Agrawal et.al., 2004)
- Vanderbilt should have a policy representing the highest possible ethical standards



Vanderbilt Student COI Policy

- Students may attend industry supported educational meetings provided that meeting is not under the control of industry (CME needs, objectives, content, methods, evaluation)
- Students may not accept support from industry over and above food served before, during and after the event—travel, lodging, honoraria etc. not acceptable
- Students may not apply directly to industry to obtain scholarships to defray education expenses
- The value of gifts should not exceed \$100 or less





BILL WILKERSON CENTER (2005-)

“TAKE AWAY”

“Take Aways” to Consider



- Interactions of physicians and audiologists with industry appear to be prevalent
- Frequent interactions with industry can potentially affect professional behavior and decision making
- Student experiences and attitudes suggest that they are at risk for unrecognized influence by marketing efforts
- Gifts, even small gifts can influence attitudes toward marketing products
- Attitudes and behaviors are developed in education programs—institutions need to develop policies/guidelines concerning audiology/industry relationships
- More audiologist's today are concerned about potential conflicts with industry

Guiding Questions Re Relationships with Industry (AAA, 2011)

- *How might my patients feel about my relationship with industry?*
- *How might patients view my receiving gifts from industry?*
- *How would independent colleagues view my association with industry?*
- *Would I be willing to have the details of my involvement with industry made public?*
- *Could my relationship with industry be viewed as one which may influence my professional judgment in patient care?*