Industry Influence on the Practice of Medicine



Samples Gifts <u>Meals</u> **Speaking Fees**

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Course Faculty



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- Tony Scialli, MD
- Susan Wood, PhD

Conflicts of Interest Disclosure



- Adriane Fugh-Berman, MD is a paid expert witness at the request of plaintiffs in litigation regarding pharmaceutical marketing practices.
- Kofi Onumah, PharmD, RPh has no conflicts of interest.
- **Tony Scialli, MD** is the sole member of Scialli Consulting, a firm that provides consulting services on reproductive toxicology. He also is a non-CE consultant for GlaxoSmithKline.
- Susan Wood, PhD has no conflicts of interest.

Important Information





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The video can be paused and resumed later.

Course Objectives



- 1. Identify several techniques used in pharmaceutical marketing.
- 2. Recognize the obligation created by accepting small gifts or meals.
- 3. Discuss the purpose of samples from industry's point of view.
- 4. Discuss two persuasive techniques documented in social psychology.
- 5. Implement two actions to minimize the effect of industry promotion on prescribing practices.

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Will Keith Kellogg (1860 – 1951)

A master promoter:

- Branding
- Free samples
- National advertising
- Prelaunch marketing







Edward Bernays: the father of Public Relations (PR)



Edward Bernays was hired by the American Tobacco Company to encourage smoking among women.



"Torches of Freedom"

Bernays positioned cigarettes as a symbol of freedom.





www.doh.dc.gov



The best marketing doesn't look like marketing

Edward Bernays also was hired by a piano company...

PR techniques are also used to sell drugs

- Detailing (drug rep visits)
- Samples
- Meetings and events
- Continuing education





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Patient Record Forms

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Detailing

- About 850,000 physicians in the U.S.
- More than 3 million nurses (including more than 220,000 NPs)
- >100,000 PAs
- >280,000 Pharmacists
- About 63,000 drug reps





Targets

- High-prescribing physicians, nurse practitioners, and physician assistants
- Pharmacists
- Formulary (P&T) committee participants
- Healthcare providers who influence other healthcare providers
- Faculty from health professional schools
- Anyone who controls market share





What drug reps know about you...



What you prescribe or dispense

Who influences you

2

Personal information

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Assessing Clinicians



- Reps are trained to assess personalities, practice styles, and preferences.
- Reps are trained to observe objects in an office that can be used to establish a personal connection.



What HCPs prescribe

DATA

Why No Stage of Drug Development and Marketing in the Brave New World of Biologics Can Be Without It By William H. Crown

IT'S CERTAINLY NOT HEADLINE NEWS THAT THESE ARE TOUGH days for the pharmaceutical industry. More than \$60 billion in revenue from blockbuster drugs will evaporate as these products go generic over the next five years, while the productivity of clinical development has hit a particularly rough patch. Even in the companies with relatively strong pipelines, many of the new treatments are biotech products acquired out of house. The expected authorization of biogenerics will squeeze profits only further.

This shift toward biotech products portends a general evolution in healthcare. Such products are often stunningly effective. They are also typically targeted to narrow patient populations. The movement toward





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She is more than what she prescribes.



Are you limiting your brand so as by having an Reanly view of your prescribers?

An Boonly view classe't provide visibility no therapies cellisered cutside the pharmady channel, nor closs it identify the many factors that influence prescribing behavior.

SDI provides the deepost understanding of practitioners, including professional utilitaries, such as typical treatment patterns and practice profiles. We also examine their consumer anderse s, including interests, media preferences, and anuiday.

SDI's solutions will transform the way you segment and larget prescribers, allowing you kn

- Frafile activities and develop performance indicators for BOTH physicians and mic-lewel practifianers
- Determine and measure the broadest set of influences that drive prescriber decisions
- Segment based on unique drivers such as powent compliance and out of powsker costs
- Identify key prescribers introde on demographics and even consumer photocheristics

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But it's not. It takes a specialized approach to influence the patient-provider conversation.

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About
3/4of pharmacies sell
prescribing data

Insurers also sell patient records.

Steinbrook 2006



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AMA Sells Your Information



The AMA sells information about physicians to...

- Pharmaceutical and medical device companies
- Consultants
- Market researchers
- Insurance companies

- Commercial organizations
- Medical publishers
- CME providers
- Investment firms

AMA Sells Your Information



AMA Income in 2015:

Database sales: **\$40.3 million**

Membership dues: \$30.7 million

AMA 2015

www.doh.dc.gov

Detailing: Minimizing adverse effects



A study of 255 physicians in the US, Canada, and France examined 1,692 interactions with drug reps

Physicians were rarely informed about serious adverse effects

Mintzes 2013

www.doh.dc.gov

Can you separate facts from promotion?



Studies show that physicians believe they can separate out objective information from promotion.

Studies have found that physicians routinely fail to distinguish between correct and incorrect information provided by sales representatives.

Shaughnessy 1994, Molloy 2002

$\mathbf{\nabla}$

Another study found that although physicians claim to rely more on scientific materials, their beliefs about two commonly used drugs correlated far more strongly with promotional than with scientific materials.

Avorn 1982

Not only physicians...



A systematic review of 15 studies found that nurses, advanced practice nurses, physician assistants, pharmacists, dieticians, and physical or occupational therapists all interacted with pharmaceutical companies.



Not only physicians...



- Clinicians received information and sponsored education from drug companies and acted as distributors for similar materials targeted at patients.
 - Clinicians generally felt they could separate promotion from accurate "information."
 - Clinicians approved of free samples. Grundy 2013

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Physician Assistants and NPs



- In 2015, physician assistants and nurse practitioners wrote 15% of prescriptions. IMS Health 2016
 - Per visit, NPs and PAs write just as many prescriptions as physicians. *Cipher 2006*
- PAs, NPs, and other non-physician prescribers write about 1/3 of the 92 million prescriptions for opioids written by primary care clinicians. Fauber 2014



Nurses

- An ethnographic survey of 56 nurses found that all reported interactions with industry in the previous year.
 - Nurses met with reps an average of 13 times a year.
 - Nurses thought that drug reps were a vital resource for drug information.
 - 71% of nurses reported offers of gifts.
 - 70% reported attending sponsored lunches, dinners, or events.
 - 61% reported offers of product samples.
 - 27% reported paid travel or payments for participation in market research, speakers bureaus, or consulting.



70%

reported problems with reps including introduction of unapproved devices, lack of accountability for product failure, and threats to patient safety and privacy.

Grundy 2016

Pharmacists



Industry provides information to pharmacists through



 Industry sponsors medication therapy management/disease management programs, particularly adherence and compliance programs.

Pharmacists

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- Ethnographic survey of nine pharmacists
 - All interviewees had negative views of industry rationales for increasing drug costs.
 - Pharmacists expressed concern that drug reps failed to address complex disease states, adverse effects, and drug interactions on patient safety.
 - Pharmacists believed that industry interactions had little or no effect on their professional behaviors.



Saavedra 2017

Drug Rep Perspectives on Meals and Other Gifts



When a drug rep is having a meal with a HCP, "The physician is eating with a friend. You are eating with a client." Shahram Ahari

"You are absolutely buying love." James Reidy The essence of pharmaceutical gifting is "bribes that aren't considered bribes." *Michael Oldani*

Fugh-Berman 2007

How well do you track spending on Healthcare Professionals?



Gift Payments to HCPs in DC





In 2015, health care providers in DC accepted \$13.8 million in industry gifts and payments.

- Physicians: \$13,067,818
- Advanced practice nurses: \$317,118
- Registered nurses:\$122,312
- Physician assistants: \$68,696
- Pharmacists: \$33,348

DC DOH 2017


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the Reps Representative

"I'm too smart to be bought by a slice of pizza"

BUT



Studies consistently show that promotion increases prescribing

> Brax 2017, Wazana 2000, Chren 1994, Lurie 1990

Studies consistently show that physicians do not believe that promotion affects prescribing

> Sigworth 2001, McKinney 1990

Marketing Works!



 Physicians, nurse practitioners, and physician assistants who receive food and other gifts prescribe more expensive drugs and more branded drugs.

Yeh 2016, Fleischman 2016, Perlis 2016, Ornstein 2016, Jones 2016, Wood (submitted)

 Physicians who accepted even a single meal had higher rates of prescribing Crestor (rosuvastatin), Bystolic (nebivolol), Benicar (olmesartan) and Pristiq (desvenlafaxine), compared to other drugs in the same classes.

DeJong 2016

Promotion increases prescribing

- A systematic review found that most (15/19) studies found that pharmaceutical interactions promoting a medication
 - Inappropriately increased prescribing rates
 - Lowered prescribing quality, and/or increased prescribing costs
- A meta-analysis of six of these studies found a statistically significant association between exposure and physician prescribing behaviors (OR = 2.52).

Brax 2017





Promotion increases prescribing



A study with a dataset of 189 million psychotropic prescriptions written between 2005 and 2009 found that:

- Uptake of expensive new drugs was significantly lower in states with marketing regulations than in states with no restrictions on pharmaceutical marketing.
- Gift bans reduced market shares of new drugs 39% to 83%, compared to other states.
- Policies banning or restricting gifts were associated with the largest reductions in uptake.

King 2017

www.doh.dc.gov





gifts to patients

- Samples are the most effective marketing tool.
- The real purpose of samples is to:

Gain access to physicians

Habituate physicians to prescribing targeted drugs

Serve as unacknowledged gifts to physicians and staff

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Samples:

Samples cost patients money!



• Prescribers believe they give out drug samples to patients as a form of financial assistance.



- In reality, poor and uninsured Americans are less likely than wealthy or insured Americans to receive samples. *Cutrona 2008*
- A study using the Medical Expenditure Panel Survey ("MEPS") found that patients who got samples had higher medication expenditures than patients who didn't get samples.



Alexander 2008





The availability of samples leads physicians to dispense and prescribe drugs that differ from their preferred drug choice.

Chew 2000

Sample Use



- Sample use has decreased recently.
- Prevalence of sample use among Americans is decreasing.



Generics Increase Adherence



- In a 2005 survey, 25% of insured patients and 51% of uninsured patients said that they or a family member had not filled a prescription, or had cut pills or skipped medical treatment because of cost. Kaiser Family Foundation 2007
- In 3-tiered plans, patients who received generics filled 12.6% more prescriptions in the next year than those who received nonpreferred branded drugs. Shrank 2006





Don't Accept Samples!

The basic economic premise here is you keep investing until your marginal return is zero. You keep sampling until a point of saturation, where additional samples are not going to make a physician write any more prescriptions.

Burns 2005

Try this



- Give away all your free samples as full courses of therapy.
- Watch your sample supply dry up...



What Drug Reps Make



- In 2016, the average drug rep's salary was \$122,107 (median \$115,000).
 - Average base salary \$90,862 (median \$85,000)
- The average specialty rep's salary was \$138,150 (median \$125,000).
 - Average base salary \$97,784 (median \$95,000)





- The PDRP restricts allowing sales reps from accessing prescribing data.
- You can fill out a form to opt out at the AMA website:





Physicians under the Influence: Social Psychology and Industry Marketing Strategies

Sunita Sah and Adriane Fugh-Berman It is easier to resist at the beginning than at the end.

- Leonardo da Vinci¹

hysicians often believe that a conscious commitment to ethical behavior and professionalism will protect them from industry influence. Despite increasing concern over the extent of physician-industry relationships, physicians usually fail to recognize the nature and impact of subconscious and unintentional biases on therapeutic decisionmaking.² Pharmaceutical and medical device companies, however, routinely demonstrate their knowledge of social psychology processes on behavior and apply these principles to their marketing. To illustrate how pharmaceutical marketing strategies use psychological techniques to promote targeted therapies, we draw on the relevant social psychology literature on conflicts of interest and on the six principles of influence articulated by the eminent social psychologist Robert Cialdini.³ Hospitals, professional organizations, medical educators, and other stakeholders must also draw on social psychology to respond effectively to

Cialdini's Principles of Influence





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Reciprocation

- Every culture has a tradition of reciprocation.
- Even small gifts can influence gift recipients.
 - A small gift strongly affected recipients' decisions in favor of the gift-giver, even at the expense of a third party. *Malmendier 2011*
 - A single piece of candy can increase tips to food servers. *Friedman 2011*
 - A small gift of personalized address labels in a mailed solicitations doubled contributions to a charity. *Smolowe 1990*
 - Raffle tickets were much more likely to be bought by participants who received a soft drink than by those who did not receive a gift. *Regan 1971*





Commitment and Consistency



- Consistency is highly valued in our society and associated with rationality and stability. *Cialdini 2008*
- After committing to a decision or opinion, people justify that choice or opinion by remaining consistent with it. *Goldstein 2008*
 - After making a decision, people view that decision more positively, and other decisions more negatively. *Kenrick 2002*
 - Betters are much more confident that their horse will win after they have bet on it. *Knox 1968*
 - In medicine, a prescriber is likely to be more positive about a drug after rather than before prescribing it. *Fugh-Berman 2008*

Commitment and Consistency



- Written commitments work better than oral commitments. Fugh-Berman 2008
 - Sales representatives know that having a customer write in the details of a contract reduces the chances that a customer will cancel the deal. *Kenrick 2002*
 - A prescription is a written commitment.



Social proof



- Studies show that peer pressure—following the crowd determines whether:
 - Bystanders help an emergency victim
 - People pay taxes
 - Juveniles decide to commit crimes
 - Homeowners recycle

Kenrick 2002

- In medicine, trainees in an institution are affected by:
 - Policies
 - What they see their mentors do



Social Proof: The Hidden Curriculum





- Students' attitudes tended to become more favorable towards industry as their training progressed from the preclinical to the clinical years.
- Graduates of programs that limited or prohibited interactions with industry representatives are just as likely as graduates of programs without such restrictions to see drug reps in their practices. *McCormick 2001, Ferguson 1999*
- 29-62% of preclinical students reported that promotional information provides useful information about new drugs, compared to 53-71% of clinical students. *Austad 2011*
- Observing mentors accepting hospitality and funds from industry may be more powerful than institutional policies or formal curricula...







Liking, or rapport, increases with familiarity. Drug reps are experts at befriending healthcare providers.

www.doh.dc.gov

"But my drug rep is my friend"



"I frame everything as a gesture of friendship" "A lot of doctors just write [prescriptions] for who they like."

"I provide office lunches because visiting them is such a pleasant relief from all the other docs."

Shahram Ahari MD and Jordan Katz, former drug reps

"I give them free samples not because it's my job, but because I like them so much."

Fugh-Berman 2007, Sismondo 2013

Drug reps usually do not continue relationships with physicians who are not prescribing or promoting a targeted drug.



Fugh-Berman 2007

Detecting Bias



- Both physicians and NPs believe their own prescribing behavior is unaffected by industry but believe their colleagues are influenced. *Lurie 19990, Wazana 2000, Chren 1994, Crigger 2009*
- The bias blind spot: We are more likely to identify the existence of cognitive and motivational biases in others than in ourselves.

Pronin 2002, Pronin 2004



Denials and Rationalizations



Cognitive dissonance is discomfort that arises from a discrepancy between conflicting beliefs, or between beliefs and behaviors.

Denials:

- 1. Avoiding thinking about the conflict of interest
- 2. Rejecting the notion that industry relationships affect physician behavior
- 3. Universalizing responsibility for problems ("there's always a conflict of interest...")

Rationalizations:

- Reasoning that meetings with drug reps were educational and benefited patients
- 2. Asserting techniques that would help maintain impartiality

Chimonas 2007

Rationalization of gift acceptance



A study of 230 family medicine and 90 pediatrics residents asked the same questions, ordered differently.

- Doctors in the **implicit reminder group** were asked first about sacrifices and then asked about the acceptability of receiving industry-funded gifts.
- Doctors in the **explicit reminder group** were asked first about their sacrifices then asked to indicate their level of agreement with the statement: "Some physicians believe that the stagnant salaries and rising debt levels prevalent in the medical profession justifies accepting gifts and other forms of compensation and incentives from the pharmaceutical industry." Finally, they were asked the questions about the acceptability of accepting industry-funded gifts.
- Doctors in the **control group** were asked first about gift acceptability, then about personal sacrifices and then whether such sacrifices justified accepting gifts.

Sah 2010

Rationalization of gift acceptance



The percent of physicians who reported willingness to accept gifts in each group was:

48% in the group who had been implicitly reminded of the burdens of medical training

22% in the control group 60% in the group who were given an explicit potential rationalization

Sah 2010

KOLs



- Nationally known, influential academic physicians are called "thought leaders," "opinion leaders," or "key opinion leaders".
- KOLs are part of a "third party" strategy.





Authority & Scarcity: KOLs (Key Opinion Leaders)



- KOLs are not as objective as they seem.
- KOLs influence the prescribing behavior of their audience. *Goldfinger 1987*
 - They also convince themselves; KOLs' prescribing practices favor their sponsors' drugs.

Goldfinger 1987, Chren 1994

- Publicly exhibited norms are gradually internalized. Kelman 1953
 - One's private opinion often changes to correspond with one's overt behavior. *Festinger 1959*

KOLs Market Diseases



- KOLs do not push specific drugs.
- KOLs' messages usually indicate that a certain disease is underdiagnosed, undertreated, or more serious than commonly believed.
- KOLs are sponsored because what they are saying aligns with a product's marketing messages, and are supported only as long as they do so.
- Physician speakers may be unaware of the marketing messages for which they are responsible.

Drug promotion starts long before approval

 Pre-launch marketing usually emphasizes the prevalence or severity of the disease state ("disease awareness")



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Industry's view of continuing education



CME activities are most valuable in introducing products early in their life cycles or for promoting mature brands with new indications and new clinical data.

Bottiglieri, Pharmaceutical Executive, 2001

Commercially-sponsored CME



- CME activities sponsored by a pharmaceutical company describe drugs more favorably. Bowman 1986, Korn 2013
- 34-48% of total CME funding derives from commercial support.
 - 98% of commercial support comes from pharmaceutical companies. ACCME 2012
- A targeted drug is prescribed more frequently after a sponsored activity. Orlowski 1992

Industry Funds Many CMEs



- The top 500 accredited CME providers accounted for 90% of physician interactions.
 - 72% of the popular providers received commercial support.
- The Accreditation Council on CME (ACCME) has loopholes that allow industry employees to control the content of a CME module when:
 - It is not related to the business lines or products of their employer
 - It is limited to basic science research or the processes/ methodologies of research

Fugh-Berman 2016

90% of physician interactions

72% of the popular providers received commercial support

Detecting Bias



• Physicians do not perceive a difference in commercial bias between industry-funded and non-industry-funded CME.

However, physicians are not trained to identify bias.

Ellison 2009, Mueller 2007, Rutledge 2003, Katz 2002, Cornish 2006

CME on Breakthrough Pain

- Participants evaluated a non-industry-funded article on opioid use (n=18) or an industry-funded article on breakthrough pain (n=20) and were asked to summarize the messages in the article.
 - Participants who read the non-industry-funded article noted that the effectiveness of opioids for chronic pain was unclear and there was a risk of abuse or addiction.
 - Participants who read the industry-funded article viewed opioids more positively.

Infeld (submitted)





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Statements from an Anonymous Pharmaceutical Executive



"...expected return on investment is the bottom line for determining the distribution of CME cash"

Bioethics Forum 2010

"CME contributions are commercial decisions. Commercial does not equal unethical or lacking in value, but it does represent a focus on a particular business objective. The nature of the return may be subtle, nonbranded, or indirect."

Benefits of Avoiding Industry-Funded Continuing Education





Physicians who avoided industryfunded CME prescribed fewer branded drugs and more generic drugs.

Lieb 2014

Why does this matter?





There are more than 10,000 drugs in the US pharmaceutical market More than half of promotional expenditures are concentrated on the top-selling 50 drugs



Ma 2003





Pharmaceutical company promotion utilizes sophisticated social psychology techniques to manipulate therapeutic choices.

Promotion distorts perceptions of benefits and harm.

Pharmaceutical companies should not be involved in educating HCPs.

Rational drug use is compromised.

What You Can Do



Don't see drug reps

Don't accept gifts or food from industry

Forego samples/copay vouchers/ coupons

Don't attend industryfunded CME/ CPE or other events

Don't provide patients with industry-funded material

Trust unbiased sources of therapeutics information

Other DCRx Modules





Taking a Sexual History to Reduce HIV Risk



Myths and Facts about Opioids



Medical Cannabis: An Introduction to the Biochemistry & Pharmacology



Medical Cannabis: Evidence on Efficacy



Medical Cannabis: Adverse Effects and Drug Interactions



What You Need to Know about PrEP



Getting Patients Off of Opioids



Rational Prescribing in Older Adults



Drug Approval and Promotion in the United States



Generic Drugs: Myths and Facts





More resources available at the DC Center for Rational Prescribing doh.dc.gov/dcrx