Undercutting Diet and Exercise: The Overpromotion of Drugs in Cardiovascular Disease Prevention and Treatment

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Disclosure: Dr. Fugh-Berman is a paid expert witness at the request of plaintiffs in litigation regarding pharmaceutical marketing practices.
Will Kellogg

Dr. John Harvey Kellogg and George Bernard Shaw, in Battle Creek in 1936
The engineering of consent

• Edward Bernays, the father of PR, was hired by the American Tobacco Company to encourage smoking among women. With the help of psychoanalyst AA Brill, Bernays sold cigarettes as a symbol of freedom.
Drug reps have your number...

- What you prescribe
- Who influences you
- Personal information
It is easier to resist at the beginning than at the end.

– Leonardo da Vinci

Physicians 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 decision-making. 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. Hospitals, professional organizations, medical educators, and other stakeholders must also draw on social psychology to respond effectively to
Detailing

- About 900,000 doctors in the U.S.
- About 66,000 drug reps
- Actual ratio is about 1 rep per 2.5 targeted docs
Targeted Doctors

- High-prescribing physicians
- Physicians who influence other physicians
- Formulary Committee members
- Teachers
- Anyone who controls market share
What you prescribe
She is more than what she prescribes.

Are you limiting your brand so as by having an 'educated' view of your prescribing physicians?

It doesn't provide visibility into therapies administered outside the pharmacy channel, nor does it identify the many factors that influence prescribing behaviour.

SDI provides the deepest understanding of physicians, including professional attributes, such as typical treatment patterns and practice profiles. We also examine their consumer characteristics, including interests, media preferences, and empathy.

SDI's solutions will translate this way you segment can target prescribers, allowing you to:

- Profile activities and driving performance not common to BOTH physicians and mid-level practitioners
- Determine and measure the broader set of influences that drive prescriber decisions
- Segment based on unique drivers such as patient compliance and out-of-pocket costs
- Identify key prescribers based on demographics and own consumer characteristics

For more information, contact Melissa Johnson at 1-800-782-2561 or email us at www.sdinstitute.com/healthcare/
Insurance companies sell patient records to industry, which processes this information for promotional purposes.
Gifts

- During training, I was told, when you’re out to dinner with a doctor, “The physician is eating with a friend. You are eating with a client.”
  
  Shahram Ahari

- “The essence of pharmaceutical gifting...is ‘bribes that aren’t considered bribes.’”

  Michael Oldani

- You are absolutely buying love.

  James Reidy

CAUTION

Drug reps bearing gifts may prove persuasive
AMA’s Ethical Guidelines for Gifts to Physicians from Industry

- “Modest” meals are allowed
  - If they cost no more than the physician would normally pay for
- $100 gifts related to medical care or medical education are allowed
  - As long as there are fewer than 8 choices
- AMA accepted $600,000 from pharma to promote their gift guidelines
“Doctors are too smart to be bought by a slice of pizza”

- Studies consistently show that promotion increases prescribing*
- Studies consistently show that physicians do not believe that promotion affects prescribing**

*Chren MM et al. JAMA 1994 Mar 2;271(9):684-9
Wazana A. JAMA 2000 Jan 19;283(3):373-80

**Sigworth SK et al. JAMA. 2001;286(9):1024-5
McKinney WP et al. JAMA 1990;264(13):1693-7
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Einstein Bros.® has tons of delicious eats for any client worth wooing. Bring office-pleasing favorites like the sandwiches in our Signature Nosh Box, our salads, or our bagels, coffee, and sweet afternoon treats. Einstein Bros. offers convenience, portability, and affordability—and we’re located in just the right spots.

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• Everyone will remember the rep that brought them ice cream!
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• Spend more time presenting and selling— not shopping and picking up food.
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“I only see reps for the samples”
The Real Purpose of Samples

- Gain access to physicians
- Habituate physicians to prescribing targeted drugs
- Increase goodwill by enabling doctors to give gifts to patients
- Serve as unacknowledged gifts to physicians and staff
Try This!

- Give away all your samples as full courses of therapy
- Watch your sample supply dry up...
What Drug Reps Cost

- $114,300 Median Total Compensation (salary and bonuses)
  - Median base salary $84,700
  - Median base salary for senior specialty reps and senior hospital specialty reps $112,000
Promotion starts long before drug approval

Pre-launch marketing may emphasize the prevalence or severity of the disease state, a mechanism of action, or the problems of competing therapies.

It's never too early to start planning or to tap into our expertise. As one of the world's first healthcare agencies, we've brought a lot of successful brands into the world. We approach every launch in an integrated way. Our patient and medical education resources will help prepare your market. Our strategists will help direct your brand unalteringly toward launch. And our global network will guarantee continuity. Give your brand the best start in life. Contact Louisa Holland at 212-614-3838 or louisa.holland@sudler.com.
KOLs Market Diseases

• Physician speakers may be unaware of the marketing messages they are responsible for

• KOL messages usually indicate that a certain disease is underdiagnosed, undertreated, or more serious than commonly believed

• KOLs do not push specific drugs
Industry may establish or redefine “new” conditions

- Hypoactive Sexual Desire Disorder (HSDD)
- Binge-eating Disorder (BED)
- Gastroesophageal Reflux Disease (GERD)
- Premenstrual Dysphoric Disorder (PMDD)
- Social Anxiety Disorder (SAD)
- Overactive Bladder Syndrome
- Osteopenia
- Pediatric Bipolar Disorder
- Excessive Sleepiness (ES)
- Late-onset hypoandrogenism (Low-T)
Condition Branding

“...the deliberate management of patient, physician, payer and other stakeholder knowledge about a condition in order to improve how the condition is treated.” (Angelmar 2007)

If “you can define a particular condition and its associated symptoms in the minds of physicians and patients, you can also predicate the best treatment for that condition” (Parry 2003)
• “elevating the importance of an existing condition”

• “redefining an existing condition to reduce a stigma” or

• “developing a new condition to build recognition for an unmet market need.”

(Parry 2003)
Severe Underarm Sweating

An award-winning ad campaign:

“Severe underarm sweating is embarrassing and challenging for sufferers, and Allergan's Botox can help. This campaign gave dermatologists tools to communicate to patients that if the condition isn't adequately managed by topical medicines, it's a medical condition that can be treated.”
Binge Eating Disorder: Vyvanse

• Regularly eating far more food than most people would in a similar time period under similar circumstances

• “The time period during which binge eating instances take place can vary by individual, but is generally considered to be less than two hours and does not have to be in one setting [sic]”

• To qualify as "regular binge eating" the instances “must take place at least once per week for three months”
According to Binge-Eating Disorder.com:

• “B.E.D. is a real medical condition”
• “B.E.D. is the most common eating disorder in US adults”
• “Although the cause of B.E.D. is unknown, these may play a role:
  – Certain chemicals in the brain
  – Family history and certain life experiences”
### Hypertension

*High blood pressure. Reported as two numbers - systolic, representing peak pressure, and diastolic, when the heart is at rest.*

<table>
<thead>
<tr>
<th>Old definition</th>
<th>New definition*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Blood pressure</strong></td>
<td><strong>Blood pressure</strong></td>
</tr>
<tr>
<td>= or &gt; 160/100</td>
<td>= or &gt; 140/90</td>
</tr>
</tbody>
</table>

*In mm Hg blood pressure*

People under the old definition: **38.7 million**
People added by new definition: **13.5 million**
Percent increase: **35%**

Definition changed in 1997 by U.S. Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure

* Prehypertension, a category created in 2003: blood pressure from 120/80 to 139/89; includes 45 million people.

### High cholesterol

*High levels of the waxy, fatlike substance in the blood are linked to heart disease.*

<table>
<thead>
<tr>
<th>Old definition</th>
<th>New definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cholesterol</strong></td>
<td><strong>Cholesterol</strong></td>
</tr>
<tr>
<td>= or &gt; 240</td>
<td>= or &gt; 200</td>
</tr>
</tbody>
</table>

*In mg/dl total cholesterol*

People under the old definition: **49.5 million**
People added by new definition: **42.6 million**
Percent increase: **86%**

Definition changed in 1998 by U.S. Air Force/Texas Coronary Atherosclerosis Prevention Study
Expansion of Diagnostic Categories

- Levels at which we diagnose hypertension, high cholesterol and diabetes have decreased over time.

- Hypertension: In May 2003, an NIH panel recommended broader use of hypertension drugs for lower blood pressures.
  - 9 out of 11 guideline authors had COI with drug companies

- Nearly half of all adults worldwide qualify for a diagnosis of hypertension or prehypertension, including three-quarters of the elderly population. (Wilson 2005)
In 2011, the American Heart Association (AHA) recommended statin therapy for women when the 10-year risk of disease was 20% or greater.
Changing Guidelines

- In 2013, the AHA and the American College of Cardiology (ACC) released guidelines that escalated the number of adults eligible for statins

- Half (7/15) of the members of this guideline panel had COIs with statin manufacturers
Why the difference?

- The VA and DoD, using the same body of evidence, recommended a higher 10-year cardiovascular risk threshold for recommending a statin for primary prevention

- VA/DOD 10 year risk risk 12%
- ACC/AHA 10 year risk 7.5%
Adverse Effects of Statins

- Diabetes
- Rhabdomyolysis/Myopathy
- Psychiatric problems (mood disorders, amnesia, aggressive reactions)
  - Statins appear to reduce depression risk
- Liver dysfunction
- Cataracts
Cholesterol is needed for brain functioning. The brain is 2% of body mass but contains 25% of nonesterified cholesterol in the body.
In 2 Years...

- **2011**: a Cochrane systematic review recommended treatment at 20% 10-year risk levels

- **2013**: Cochrane recommended 10%
  - The change was based primarily based on Cholesterol Treatment Trialists’ 2012 study
  - BUT the study found **no reduction** in mortality, CVD deaths, MI, or stroke in **low-risk** patients (Abramson 2013)
This statement was corrected:

• “Statin therapy in low risk people does not reduce all cause mortality or serious illness and has about an 18% risk of causing side effects that range from minor and reversible to serious and irreversible.”

• Although this “was based on statements in the referenced observational study by Zhang and colleagues, that ‘the rate of reported statin-related events was nearly 18%,’

• The article did not reflect necessary caveats and did not take sufficient account of the uncontrolled nature of the study.”
Defending Science or Industry?

• Rory Collins, A CTT investigator with the Oxford Clinical Trial Service Unit (CTSU), called for a retraction
• The CTSU receives many grants from industry
• The BMJ convened an independent panel that concluded that “the only unequivocal error in the article by Abramson et al is the misrepresentation of the Zhang et al paper and considered this to be insufficient to justify retraction of the whole article”
“When diet and exercise are not enough, adding Lipitor may help” – 2009

https://www.youtube.com/watch?v=lNFuEcy5ekg
“When diet and exercise fail, adding Lipitor can help lower your total cholesterol 29 to 45%” - 2010

https://www.youtube.com/watch?v=QyNPLtvu0qE
“Diet and exercise weren’t enough for me. I stopped kidding myself” - 2010

https://www.youtube.com/watch?v=ogyC9rEjxDM
“Diet and exercise are not enough. Adding Lipitor may help” – 2011

https://www.youtube.com/watch?v=AerArM-zEiQ
“I didn’t think I could have a heart attack. I exercised, I ate well, but I just knew that wasn’t enough. So I went to my doctor and he prescribed me Lipitor” – 2012

https://www.youtube.com/watch?v=nM6EICAb7iw
When diet and exercise are not enough, adding Lipitor can help lower your bad cholesterol from 39 to 60%” - 2013

https://www.youtube.com/watch?v=2YU5cr7MLu0
ARE YOU KIDDING YOURSELF?

IF YOU STILL HAVE HIGH CHOLESTEROL, YOU MAY BE IN DEEPER WATER THAN YOU THINK.

The fact is, high cholesterol is a serious condition in both women and men. If you haven’t lowered your high cholesterol enough, it’s time to stop kidding yourself.

When healthy diet and exercise are not enough, adding Lipitor may help:

- Along with diet, Lipitor has been shown to lower bad cholesterol 39% to 60% (average effect depending on dose).
- Lipitor has been extensively studied with over 18 years of research and is backed by over 400 ongoing or completed studies.

IMPORTANT SAFETY INFORMATION:

LIPITOR is not for everyone. It is not for those with liver problems. And it is not for women who are nursing, pregnant or may become pregnant.

If you take LIPITOR, tell your doctor if you feel any new muscle pain or weakness. This could be a sign of rare but serious muscle side effects. Tell your doctor about all medications you take. This may help avoid serious drug interactions. Your doctor should do blood tests to check your liver function before and during treatment and may adjust your dose.

INDICATION:

LIPITOR is a prescription medicine that is used along with a low-fat diet. It lowers the LDL ("bad" cholesterol) and triglycerides in your blood. It can raise your HDL ("good" cholesterol) as well. LIPITOR can lower the risk for heart attack, stroke, certain types of heart surgery, and chest pain in patients who have heart disease or risk factors for heart disease such as age, smoking, high blood pressure, low HDL, or family history of early heart disease.

LIPITOR can lower the risk for your heart attack or stroke if you have heart disease or if you havecoronary artery disease or a heart attack.

If you have your first heart attack or stroke after using LIPITOR, you should stop taking it and talk to your doctor.

LIPITOR can also lower the risk of your heart attack or stroke if you have diabetes and heart disease or if you are at risk for heart disease.

LIPITOR cannot be used to prevent heart attack or stroke in people who do not have heart disease or risk factors for heart disease.

LIPITOR can cause serious side effects in people who have heart disease or who are at risk for heart disease.

Do not start LIPITOR if you have taken a cholesterol-lowering medicine called a fibrates in the last 14 days.

Do not start LIPITOR if you have taken a cholesterol-lowering medicine called a bile acid sequestrant (such as cholestyramine or colestipol) within the last 7 days.
ARE YOU KIDDING YOURSELF?
A LOT OF PEOPLE THINK EXERCISE AND HEALTHY DIET ARE ENOUGH TO LOWER HIGH CHOLESTEROL. FOR 2 OUT OF 3, IT MAY NOT BE.

Did you know, more than 80% of people who have had heart attacks have high cholesterol? For 2 out of 3 people with high cholesterol, diet and exercise may not be enough. If you haven't been successful in trying to lower your cholesterol on your own, stop kidding yourself. Talk to your doctor about your risk and if Lipitor is right for you. You can also learn more at lipitor.com or call 1-888-LIPITOR.

- When healthy diet and exercise are not enough, adding Lipitor may help.

- Along with diet, Lipitor has been shown to lower bad cholesterol 19-60% (average effect depending on dose) and Lipitor is FDA-approved to reduce the risk of heart attack and stroke in patients who have heart disease or risk factors for heart disease. These risk factors include smoking, age, family history of early heart disease, high blood pressure and low good cholesterol.

IMPORTANT SAFETY INFORMATION
LIPITOR is not for everyone. It is not for those with liver problems. It is not for women who are nursing, pregnant or may become pregnant.

If you take LIPITOR, tell your doctor if you feel any new muscle pain or weakness. This could be a sign of rare but serious muscle side effects. Tell your doctor about all medications you take. This may help avoid serious drug interactions. Your doctor should do blood tests to check your liver function before and during treatment and may adjust your dose.

Common side effects are diarrhea, upset stomach, muscle and joint pain, and changes in some blood tests.

INDICATION: LIPITOR is a prescription medicine that is used along with a low-fat diet. It lowers the LDL ("bad") cholesterol and triglycerides in your blood. It can raise your HDL ("good") cholesterol as well. LIPITOR can lower the risk for heart attack, stroke, certain types of heart surgery, and chest pain in patients who have heart disease or risk factors for heart disease such as age, smoking, high blood pressure, low HDL, or family history of early heart disease.

LIPITOR can lower the risk for heart attack or stroke in patients with diabetes and risk factors such as diabetic eye or kidney problems, smoking or high blood pressure.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see additional important information on next page.
Which would you rather have, a cholesterol test or a final exam?

For many, the first sign of heart disease is a heart attack. Did you know that one out of two adult Canadians is at risk of developing heart disease because they have high cholesterol? And that cardiovascular disease is the leading cause of death in Canada? High cholesterol is a major risk factor for heart disease but managing your cholesterol can be quite simple.

If any of these apply to you, cut this screening test out and ask your doctor about getting your cholesterol tested:

- Woman 50 years or older
- Man 40 years or older
- Heart disease (angina, heart attack, coronary bypass, stroke, angioplasty)
- Diabetes
- Family history (mother, father, sister, brother or grandparent) of heart disease or high cholesterol
- Two or more of the following:
  - Overweight
  - Physically inactive
  - Smoker
  - High blood pressure

Call toll-free at 1-877-4-LOW-LDL (1-877-456-9535) or visit www.makingtheconnection.ca and you will receive this free booklet describing the connection between cholesterol and heart disease.
CONSIDER THE LIPITOR EVIDENCE
AND SEE OTHER STATINS
IN A WHOLE NEW LIGHT

In patients with multiple risk factors but without CHD
LIPITOR is indicated to significantly reduce the risk of...

Revascularization
42%
IN ASCOT-LLA
Relative risk reduction
(9% vs 0%)

Nonfatal MI
45%
IN ASCOT-LLA
Relative risk reduction
(9% vs 0%)

Stroke
48%
IN CARDIS
Relative risk reduction
(12% vs 0%)

Along with diet, LIPITOR provides potent LDL-C reductions
up to 50% with a starting dose of 40 mg, along with a
proven safety profile.

LIPITOR is indicated to reduce the risk of myocardial infarction,
revascularization procedures, angina, and stroke in adult patients with
multiple risk factors but without clinically evident CHD; to reduce
the risk of myocardial infarction and stroke in patients with type 2 diabetes
and without clinically evident CHD, but with multiple risk factors; as an
adjunct to diet to reduce elevated total-C, LDL-C, apo B, and TG levels;
and to increase HDL-C in patients with primary hypercholesterolemia
(heterozygous familial and nonfamilial) and mixed dyslipidemia.

LIPITOR is contraindicated in patients with active liver disease or
unexplained persistent elevations of serum transaminases; in women
who are or may become pregnant or who are nursing; in patients with
hypersensitivity to any component of this medication.

Rare cases of rhabdomyolysis have been reported with LIPITOR and other
statins. With any statin, tell patients to promptly report muscle pain,
tenderness, or weakness. Discontinue drug if myopathy is suspected, if
creatine phosphokinase (CPK) levels rise markedly, or if the patient has
risk factors for myopathy.

Due to increased risk of myopathy seen with LIPITOR and other
statins, physicians should carefully consider combined therapy with fibric acid
derivatives, niacin, immunosuppressive drugs, azole antifungals, or
micafungin and caprylic monotherapy for signs or symptoms of myopathy
early during therapy and when titrating dose of either drug.

THE PROOF IS IN THE OUTCOMES

LIPITOR
atorvastatin calcium

It is recommended that liver function tests be performed prior to and
12 weeks following both the initiation of therapy and any elevation of
dose, and periodically thereafter. If ALT or AST values >3 x ULN persist,
dose reduction or withdrawal is recommended.

In clinical trials, the most common adverse events were constipation,
fatigue, dyspepsia, and abdominal pain.

References:
Why does this matter?

• There are more than 10,000 drugs in the U.S. pharmaceutical market
• More than half of all promotional expenditures are concentrated on the top-selling 50 drugs (Ma 2003)
• Physicians and other prescribers are only familiar with the most-promoted drugs
• Diet, exercise, and other non-pharmacological therapies are underused
The Differing Interests of Medicine and Industry

- Physicians are responsible for representing the best interests of their patients
- Pharmaceutical companies are responsible for representing the best interests of their stockholders
What You Can Do

- Don’t see drug reps
- Don’t accept gifts or food from industry
- Forego samples
- Don’t attend industry-funded CME or other events
- Don’t provide patients with industry-funded material
- Trust unbiased sources of therapeutics information
- Do your own research on MEDLINE
- Prescribe more classic drugs
- Create your own formulary
- Spread the word!
This office does not allow visits from pharmaceutical salespeople because we rely on scientific information, not marketing, to decide what treatment is best for you.

This policy also means that we don't provide drug samples. "Free" drug samples cost you money. Samples are only available for the most expensive, most-promoted drugs, and are a tactic to get you to use drugs that may not be the best therapy for you.
What is available at PharmedOUT.ORG
SAVE THE DATE
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Managing Medical Knowledge
June 16th and 17th, 201
8:00am-5:30pm
Georgetown University
Lorfhink Auditorium

Topics include
Academic Research
Relationships
Direct-to-Consumer Promotion
Should Academic Medical Centers be Pharma-free?
New Targets of Pharma Marketing

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Harvard University, former editor of NEJM
Carl Elliott MD
Center for Bioethics, University of Minnesota
Donald L. Kennedy Insti
Georgetown University
Edmund Pellet
University of South Carolina

Virginia Barbour MD
Chief Editor, PLOS Medicine

Joel Lexchin MD
York University

Charles Bennett MD PhD
University of South Carolina,
College of Pharmacy

Diana Zuckerman
President, National Research
Women & Family

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Author of White Coat, Black Market
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Speakers include:

Carolyn Clancy MD
Association Executive, Director of the Center for Clinician Success and Physician Health

Lisa Congrove PhD
Professor of Counseling and School Psychology, University of Massachusetts-Boston

Tom Finucane MD
Professor of Geriatric Medicine and Gerontology, Johns Hopkins University

Andrew Kolody MD
President, Physicians for Responsible Opioid Prescribing; Chief Medical Officer, Prevention Point

John Powers MD
Assistant Clinical Professor of Medicine, George Washington University School of Medicine, former Medical Director, Office of Anesthesiology Products, Center for Drug Evaluation and Research, FDA

Ruth Liptor MD
Associate Professor of Health Policy, George Washington University

Sharon Levine, MD
Associate Executive Director of the Center for Medical Innovation and Impact

Thomas Moore
Senior Scientist at the Institute for Safe Medication Practices; Patient Advocate, Consumer boycott author of Prescriptions for Disaster and Deadly Medicine

Mary Lynn McPherson-Pharm D MA RBCS
Professor and Chair of Exercise in the Department of Pharmacy Practice and Science, University of Maryland School of Pharmacy in Baltimore

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