LOW T AND DIRECT TO CONSUMER ADVERTISING (DTCA)

An Ethical case study

Jeff Ferguson/Peggy McNulty

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AGENDA

- Perspectives on ethical issues
- History of DTCA
- Benefits and risks of DTCA
- Challenges for brand manager
- Low T drugs and sample ads
- Legal issues with Low T drugs
- Ethical issues with Low T treatment
<table>
<thead>
<tr>
<th>Ethical Issue</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abusive &amp; Intimidating Behavior</td>
<td>Anything from physical threats, false accusations, annoying a coworker, profanity, insults, yelling, harshness, and ignoring someone to being unreasonable.</td>
</tr>
<tr>
<td>Lying</td>
<td>Distorting the truth</td>
</tr>
<tr>
<td>Conflicts of Interest</td>
<td>When an individual must choose whether to advance his or her own interests, those of his or her organization, or those of some other group</td>
</tr>
<tr>
<td>Fraud</td>
<td>Any false communication that deceives, manipulates, or conceals facts in order to create a false impression by which others are damaged or denied a benefit.</td>
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<tr>
<td>Discrimination</td>
<td>Workplace treatment based on race, color, religion, sex, age, disability, marital status, veteran status, sexual orientation, political opinion, or national origin.</td>
</tr>
<tr>
<td>Technology Issues</td>
<td>Issues relating to privacy, online marketing, and legal protection of intellectual properties</td>
</tr>
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</table>

TYPES OF ETHICAL ISSUES
ETHICAL DECISION-MAKING

1. **Facts**
   - Obtain all unbiased facts

2. **Issue(s)**
   - Identify the dilemma

3. **Stakeholders**
   - Who has an interest? What are their motivations? How much power does each hold?

4. **Alternatives**
   - What choices do you have (look not only to a & b, but also to y & z!)

5. **Impact** of alternatives on each stakeholder?
   - Consequences, both beneficial and harmful
   - Duties/principles involved?
   - Law?
   - Stakeholders’ resulting impacts on you?

6. **Action**

7. **Monitor outcomes**
HISTORY OF DTCA IN THE UNITED STATES

PRINT ADVERTISING ALLOWED BY FDA SINCE MID 1980’S

First ad was for Rufen in 1981

ROGAINE WAS FIRST BLOCKBUSTER PRODUCT TO BE ADVERTISED IN PRINT

FIRST DIRECT INTRODUCTION TO CONSUMERS OF LIFESTYLE DRUG

IN 1997, TELEVISION ADVERTISING FOR PRESCRIPTION MEDICATIONS WAS ALLOWED

(Autton, 2006)
ONLY TWO NATIONS ALLOW DIRECT TO CONSUMER ADVERTISING (DTCA)

United States – FDA and AMA objections
New Zealand – government wavered on ban
Australia - may begin allowing it
Western Europe – allowed but can’t mention drug or company

(Auton, 2006)
# SHARE OF WORLD PHARMACEUTICAL MARKET

<table>
<thead>
<tr>
<th>World market 2002</th>
<th>Sales ($ billion)</th>
<th>% world sales</th>
<th>% growth</th>
</tr>
</thead>
<tbody>
<tr>
<td>USA</td>
<td>204</td>
<td>51</td>
<td>12</td>
</tr>
<tr>
<td>Europe (EU)</td>
<td>91</td>
<td>22</td>
<td>8</td>
</tr>
<tr>
<td>Rest of Europe</td>
<td>11</td>
<td>3</td>
<td>9</td>
</tr>
<tr>
<td>Japan</td>
<td>46</td>
<td>12</td>
<td>1</td>
</tr>
<tr>
<td>Asia, Africa, Australia</td>
<td>32</td>
<td>8</td>
<td>11</td>
</tr>
<tr>
<td>Latin America</td>
<td>16</td>
<td>4</td>
<td>-10</td>
</tr>
<tr>
<td>Total</td>
<td>400</td>
<td>100</td>
<td>8</td>
</tr>
</tbody>
</table>

Source: (Auton, 2006)
QUESTIONS ABOUT DTCA

Why do you suppose that only two countries allow DTCA for prescription medicines?

What characteristic of these countries facilitate them being the only ones allowing DTCA?

Since most countries have access to Youtube and other internet advertising, are bans on advertising really effective?
US PHARMACEUTICAL PROMOTION EXPENDITURE ($ MILLION)

Source: Pharmaceutical Manufacturers’ Association
US PHARMACEUTICAL PROMOTIONAL SPEND BY CATEGORY, 2002 ($ MILLION)

- Retail Samples, $11,909 (56%)
- Doctor detail, $5327 (25%)
- Hospital detail, $873 (4%)
- Journal advertising, $437 (2%)
- DTCA, $2638 (13%)

Source: Auton 2006
BENEFITS OF DTCA

- Establishes a base of better informed patients about disease conditions and treatments
- Reduces under-treatment and under-diagnosis, often in critical conditions such as hypertension and depression
- Promotes pharmaceuticals which are a less expensive alternative to surgery or chronic untreated disease
- Improves drug treatment compliance
- Encourages physician/patient communication
- DTCA produces revenue results – 75% of brands show 50% or more ROI

(Auton, 2006)
HARMFUL EFFECTS OF DTCA

• Marketing is primarily for profit and not consumer health
• Leads patient to pressure their doctors for prescriptions they may not need or may not be best for them
• Misleads patients if advertisement is unbalanced
• Viewer remember benefits up to 4 times more than risks
• Increases pressure on doctors to prescribe drugs
• Rarely present non-pharmacological alternatives such as diet, exercise, therapy and other lifestyle changes

(Auton, 2006)
HARMFUL EFFECTS OF DTCA (CONTINUED)

- Medicalizes conditions that are typical to aging
- Diverts pharmaceutical company funds from R and D
- Leads to greater use of lifestyle drugs which may not be necessary
- Consumers perceive pharma ads as educational and not persuasive (Wilson & Till 2007)
- Harmful drugs may be advertised before adverse effects become apparent (Vioxx)

(Auton, 2006)
PHYSICIANS RESPOND TO PATIENTS’ REQUESTS FOR SPECIFIC TREATMENTS WITH A BROAD RANGE OF ALTERNATIVES

When Asked by a Patient About a Specific Treatment, Physicians Frequently...

- Recommend lifestyle or behavior changes: 50%
- Recommend a different prescription drug: 14%
- Recommend over-the-counter drug: 18%
- Recommend no treatment: 14%
- Give prescription for requested drug: 5%

Source: Pharmaceutical Manufacturers’ Association
SAMPLE PHARMACEUTICAL TV COMMERCIALS

- Vioxx ad
  - http://www.youtube.com/watch?v=bkk5urmgRNQ

- Procrit ad
  - http://www.youtube.com/watch?v=QDWqkeiGiYE

- Lipitor ad
  - http://www.youtube.com/watch?v=cHuKjBcwb7U

- Vytorin ad
  - http://www.youtube.com/watch?v=hV2w0YZRjBs

- Nasonex bee
  - http://www.youtube.com/watch?v=ZMBPuuqTk_M
IS DTCA A GOOD IDEA?

What do you believe are the key arguments both supporting and opposing DTCA of prescription medicines?

Which group of arguments is most compelling? Justify your thinking.

Do first amendment rights apply to this situation? Why or why not?

What issues can you identify from the previous commercials?
  - Do they educate the public?
  - Are benefits and risks properly explained?
  - Should marketers be allowed to highlight positive aspects of their products/services?
BRAND MANAGERS’ PERSPECTIVE

- Presents industry data on research costs, new drug profits and insights on how DTCA impacts physicians.
Product Development Timeline

Source: Pharmaceutical Manufacturers’ Association
The Biopharmaceutical Sector is the Most R&D-Intensive in the U.S.

Biopharmaceutical companies invested more than ten times the amount of R&D per employee that manufacturing industries overall.


- Biopharmaceuticals*
- Communications Equipment*
- Semiconductors*
- Computers and Electronics
- Chemicals
- Machinery
- Electrical equipment, appliance
- All Manufacturing
- Petroleum, coal
- Transportation Equipment
- Motor Vehicles, trailers, parts*
- Aerospace products*
- Navigational, measuring equipment*
- Electrical equipment, appliance
- Machinery
- Chemicals
- Computers and Electronics
- Semiconductors*
- Communications Equipment*
- Biopharmaceuticals*

*Asterisks indicate manufacturing subsectors.
Few Approved Medicines are Commercially Successful
Just 2 in 10 Approved Medicines Produce Revenues that
Exceed Average R & D Costs

Source: Pharmaceutical Manufacturers’ Association
Drug Development Costs have Increased

<table>
<thead>
<tr>
<th>Decade</th>
<th>Billions (Constant Dollars, Year 2000)</th>
</tr>
</thead>
<tbody>
<tr>
<td>mid-1970s</td>
<td>$140M</td>
</tr>
<tr>
<td>mid-1980s</td>
<td>$320M</td>
</tr>
<tr>
<td>late-1990s</td>
<td>$800M</td>
</tr>
<tr>
<td>early 2000s</td>
<td>$1.2B</td>
</tr>
</tbody>
</table>

Source: Pharmaceutical Manufacturers’ Association
Increasing Competition Within Therapeutic Categories

**Time Between Approval of First and Second Drugs in a Therapeutic Class**

- **1970s**: 10.2 years
- **1980s**: 4.1 years
- **1990-2003**: 1.2 years

Source: Pharmaceutical Manufacturers' Association
Percentage of Patented Drugs Facing Patent Challenges from Generic Companies

Source: Pharmaceutical Manufacturers’ Association
MORE THAN THREE-QUARTERS OF U.S. PRESCRIPTIONS ARE FILLED WITH GENERICs
IN 2010, GENERICs ACCOUNTED FOR 19 OF THE 20 MOST COMMONLY PRESCRIBED MEDICINES

Generic Share of Prescriptions Filled 1984-2010

Source: Pharmaceutical Manufacturers’ Association
Newly Introduced Generics are Adopted Rapidly

When a generic version of a medicine becomes available for the first time, it can capture as much as 84% to 94% of the market within the first month.

Generic share of filled prescriptions following the launch of a new generic osteoporosis treatment.
ADVERTISING INCREASES AWARENESS OF THE BENEFITS AND RISKS OF NEW MEDICINES

Awareness of Benefit and Risk Information Among People Who Saw an Advertisement on TV

Source: Prevention Magazine National Survey Data
SUMMARY OF BRAND MANAGER’S DILEMMA

• Drug development costs are high and continue to escalate, yet
• Success rate of new drugs is very low, and
• The number of years of exclusivity is shrinking
• When generics hit the market sales plummet by as much as 94%
• Increased legal challenges by generic companies to end patents early. Therefore, pressure to generate revenue quickly
“Lifestyle drug is an imprecise term commonly applied to medications which treat non-life threatening and non-painful conditions such as baldness, impotence, wrinkles, erectile dysfunction, or acne…” (Wikipedia)
LOW TESTOSTERONE – THE LATEST “LIFESTYLE DRUG”

• Advertising for Low T until 2010 was under $5 million/year, with sales slightly over $1 billion annually.

• Advertising in 2012 was up to $100 million/year, with sales approaching $2.4 billion annually.

• During this time, drug prescriptions have risen from just over 4 million per year to almost 8 million/year.

(Source: Consumer reports, July 2013)
WHAT CAUSES LOW T IN MEN?

- Normal aging
- Injury or infection affecting the testicles (which make most of the testosterone in men)
- Certain treatments for cancer, including radiation, chemotherapy, and hormone therapy for prostate cancer
- Disorders that affect the pituitary gland, a gland at the base of the brain that controls all hormone-producing organs
- Other medical problems, such as liver and kidney disease, obesity, diabetes, and AIDS

The ads describe the risks while “a vibrant middle-aged man is cruising in a convertible with a lady friend, or a peppy guy is canoodling with his wife in the kitchen” (Consumer Reports, July 2013, p 6).

- Androfen [http://www.youtube.com/watch?v=-hn3qJzayo8](http://www.youtube.com/watch?v=-hn3qJzayo8)
- Androgel [http://www.youtube.com/watch?v=hhbhNGebrVw](http://www.youtube.com/watch?v=hhbhNGebrVw)
- Axiron [http://www.youtube.com/watch?v=S9hban1vVns](http://www.youtube.com/watch?v=S9hban1vVns)
- Low T Center [http://www.youtube.com/watch?v=kSI0EFRkWpc](http://www.youtube.com/watch?v=kSI0EFRkWpc)
AXIRON
the only underarm testosterone treatment
For appropriate patients with low testosterone

His lawn. His time. His therapy.

He does things his way.

And when it comes to low testosterone, his way is new AXIRON—a testosterone solution that’s applied under the arm.

Quick-drying AXIRON has a no-touch applicator designed to fit his daily routine.

Axiron™
(testosterone solution) 2% /

His choice. His routine.
Do you have fatigue?
Do you lack initiative?
Do you have depressed moods?
Do you have lack of Drive?
Are you frequently irritable?
Do you lack stamina and endurance?
Have you gained body fat?
Have you lost muscle mass and tone?

Low T Center

www.lowTcenter.com
1-877-544-5698

Feel Like You’re Running on Empty?

What is Low T?

- Prostate
- Cholesterol
- Testosterone

Do you know your numbers?

Get tested today! It only takes 30 minutes AND no appointment is necessary!

13 Million men in the U.S. over the age of 40 have low testosterone.

Are you one of them?

Low T Center

www.lowTcenter.com
Low T Center

Have you lost your edge?

Testosterone plays a role in focus, self-confidence, and overall health.

At the bio-chemical level, Testosterone is what makes a man look, act, and feel like a man.

Live Better!
Increase your quality of life.

Benefits Include:
• Improved Muscle Mass
• Boosted Energy
• Weight Loss
• Improved Strength
• Increased Bone Density
• Decreased Irritability
• Improved Sexual Desire

Get tested now! It only takes 30 minutes AND no appointment is necessary!

Most Insurance Accepted

Call Today! It's Time to Live Again!

www.lowTcenter.com
1-877-544-5698
“Low testosterone can be treated with testosterone replacement, which comes in shots, patches, gels, and tablets you put on your gums. But low testosterone is not always treated, especially in men older than 60. That’s because it’s normal for testosterone to drop in men as they age. In fact, normal aging causes some of the same changes that happen in men with low testosterone, such as less energy or interest in sex.”

Men older than 60 might have androgen replacement if:

- More than 1 blood test shows very low testosterone
- They have symptoms of low testosterone that bother them
- The symptoms are not caused by another disease or condition that doctors can treat
- Older men who have androgen replacement need regular screening tests for prostate cancer

PATIENT RISK FROM TESTOSTERONE THERAPY

- More heart attacks and other cardiovascular events.
- Reduced sperm counts/infertility
- Might fuel growth in prostate cancer
- Blood clots in legs
- Sleep apnea
- Enlarged or painful breasts
- Swollen feet and ankles

Source: Consumer Reports, July 2013
Children exposed to testosterone have physical and emotional affects

Exposed women can experience acne and increased body hair.

Women who are exposed and breast feeding can pass the testosterone to the baby.

Stress, lack of sleep or exercise, feelings about a partner, diabetes, obesity, and pituitary tumors, and other drugs can contribute to low testosterone and should be ruled out and/or treated separately first.

Source: Consumer Reports, July 2013
WHAT DO YOU THINK?

- How well does the information in the ads compare with the Consumer Report and the physician web site, UptoDate.com?
- Overall, how complete and accurate is the information in Low T ads?
- How likely is it that the public could be misinformed?
LOW T LEGAL ADS

HTTP://WWW.LAWYERSANDSETTLEMENTS.COM/LAWSUIT/TESTOSTERONE.HTML#.UX4GCV4YD6C

SOKOLOVE LAW
HTTP://WWW.YOUTUBE.COM/WATCH?V=5BPZVQC7A9E
HTTP://WWW.YOUTUBE.COM/WATCH?V=EVCZJIMJQKG
HTTP://WWW.YOUTUBE.COM/WATCH?V=EVCZJIMJQKG

WHY ARE THERE SO MANY LEGAL PROBLEMS WITH LOW T?
QUESTIONS ABOUT LOW T

Do you have all the relevant information about the Low T case? If not, what additional information do you need? Be specific.

How would you articulate the key issues in this case?

Who are the key stakeholders?

What is the primary motivation(s) of each stakeholder?

What is the relative power of each stakeholder?
QUESTIONS ABOUT LOW T (CONTINUED)

What choices does the Low T product manager have?

What will be the impact on each stakeholder of the decision alternatives?

How would you articulate the key principles involved with the decisions?

What are the action alternatives and likely consequences of each?

How will the outcome play out in the WSJ?