

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

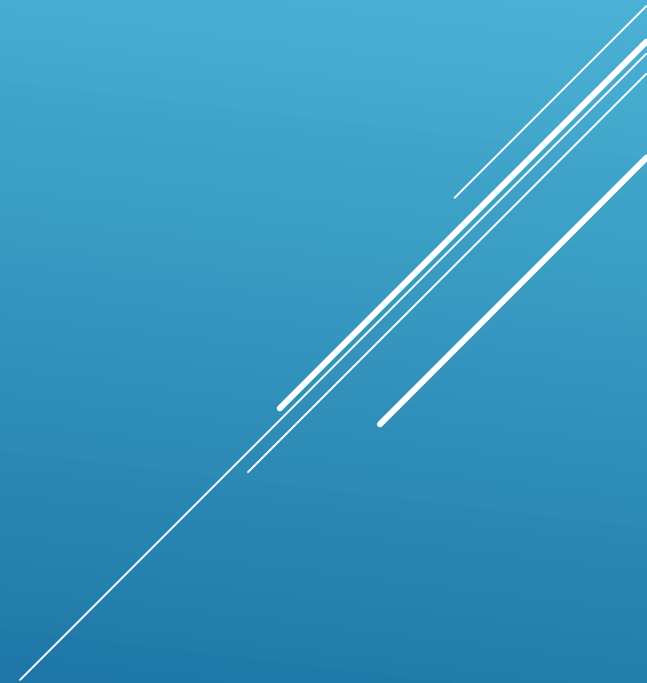
Benefits and risks of DTCA

Challenges for brand manager

Low T drugs and sample ads

Legal issues with Low T drugs

Ethical issues with Low T treatment



TYPES OF ETHICAL ISSUES

Ethical Issue	Description
Abusive & Intimidating Behavior	Anything from physical threats, false accusations, annoying a coworker, profanity, insults, yelling, harshness, and ignoring someone to being unreasonable.
Lying	Distorting the truth
Conflicts of Interest	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
Fraud	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.
Discrimination	Workplace treatment based on race, color, religion, sex, age, disability, marital status, veteran status, sexual orientation, political opinion, or national origin.
Technology Issues	Issues relating to privacy, online marketing, and legal protection of intellectual properties

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?
- Personal integrity – can you live with it? The “Wall Street Journal” test.
- *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

(Auton, 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)

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SHARE OF WORLD PHARMACEUTICAL MARKET

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

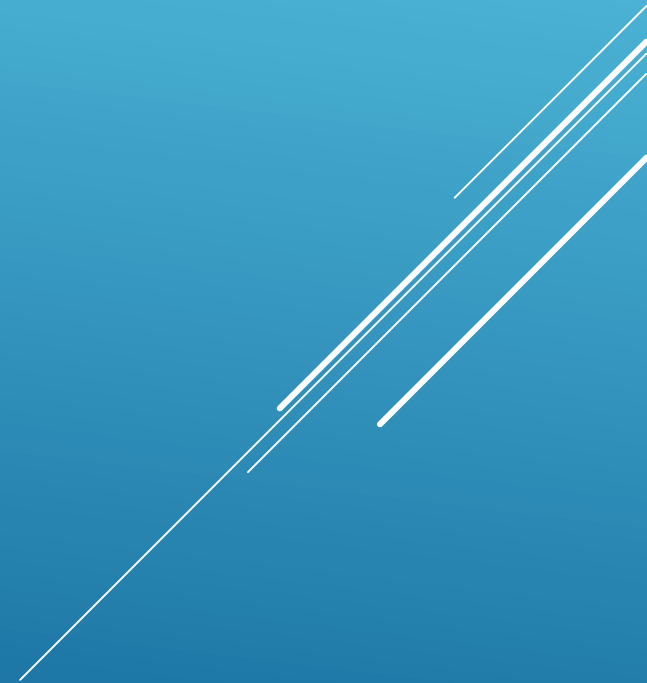
Source: (Auton, 2006)

QUESTIONS ABOUT DTCA

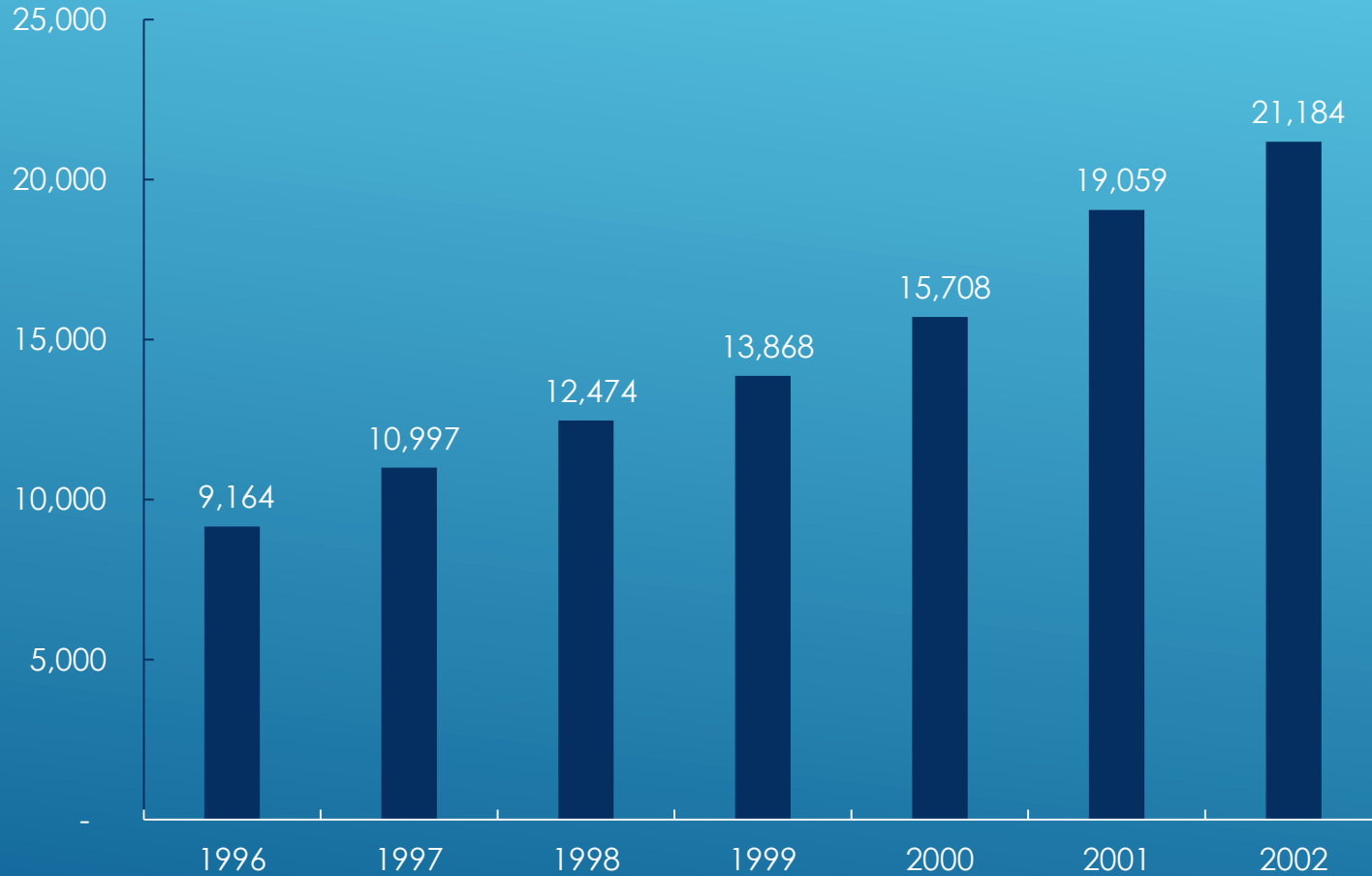
Why do you suppose that only two countries allow DTCA for prescription medicines?

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?

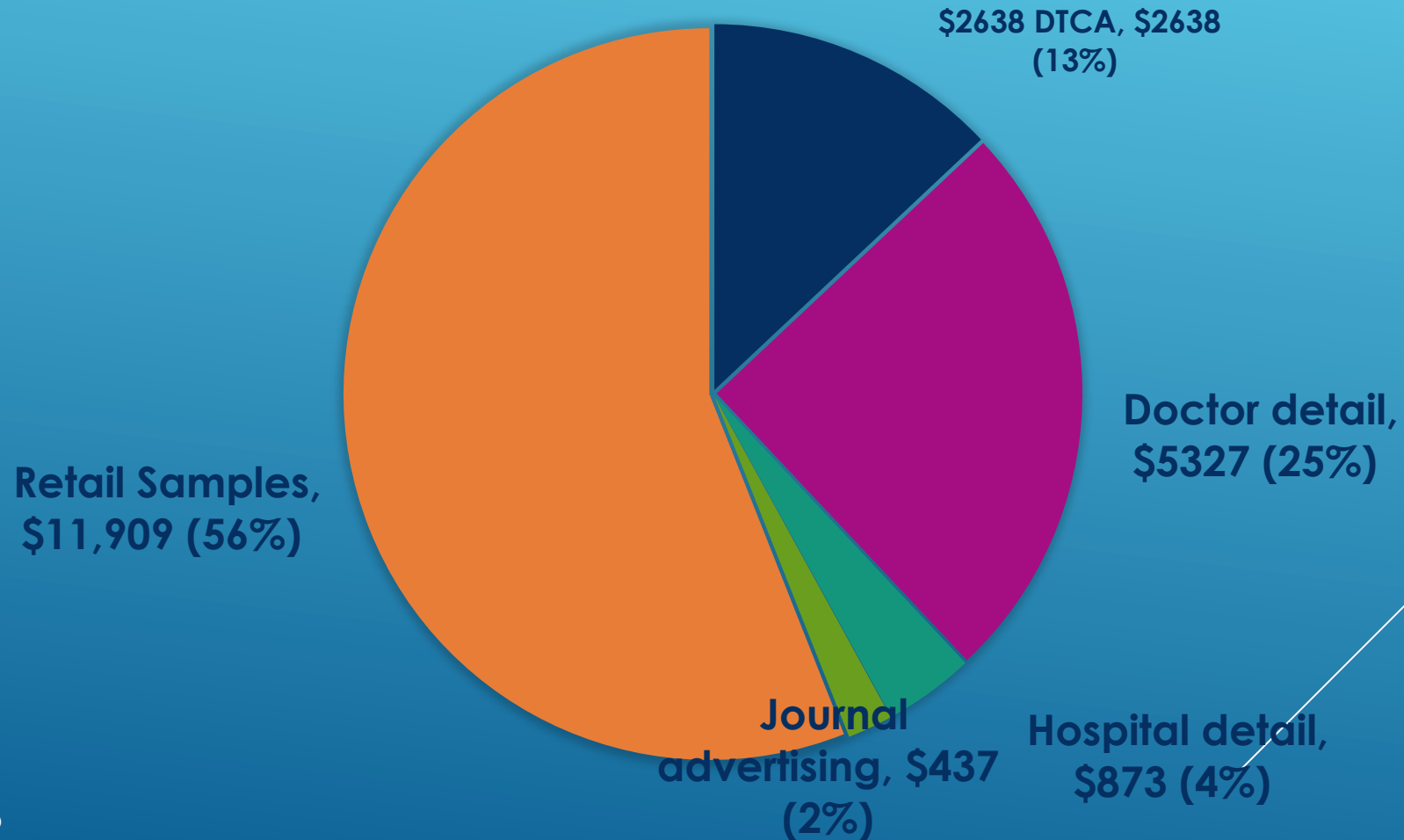


US PHARMACEUTICAL PROMOTION EXPENDITURE (\$ MILLION)



Source: Pharmaceutical Manufacturers' Association

US PHARMACEUTICAL PROMOTIONAL SPEND BY CATEGORY, 2002 (\$ MILLION)



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)

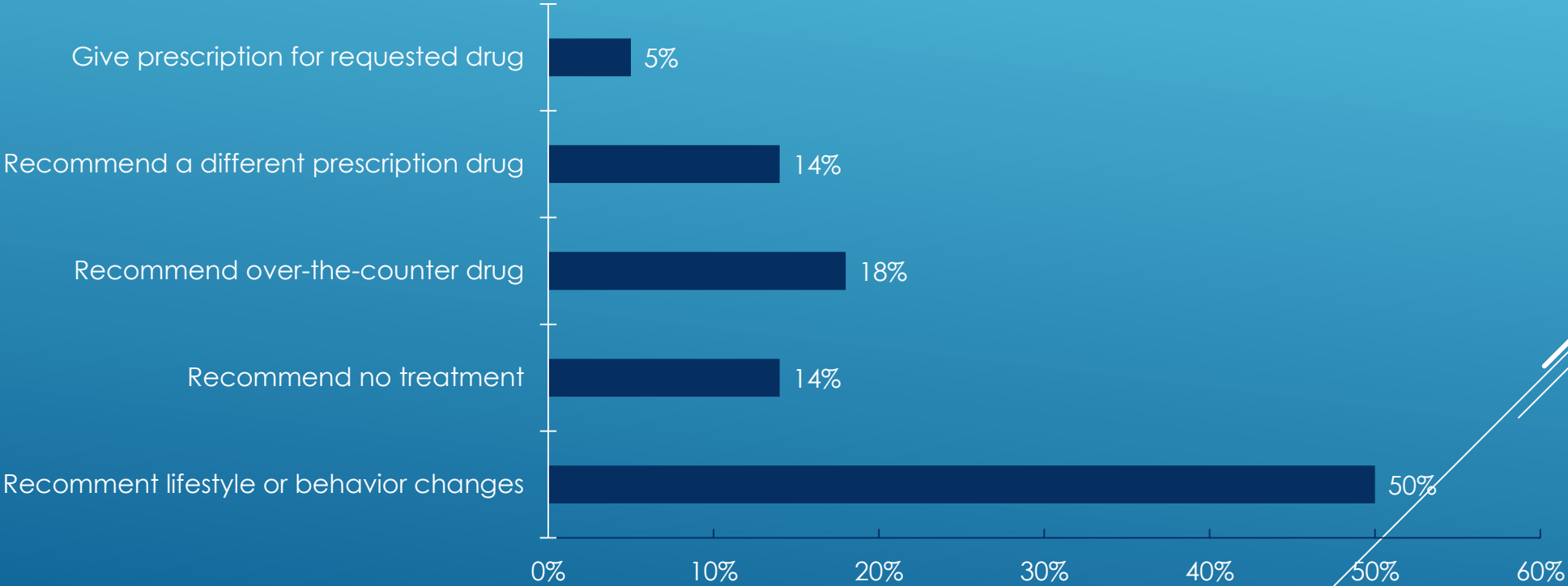
HARMFUL EFFECTS OF DTCA (CONTINUED)

- 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...



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](#)
- [adhttp://www.youtube.com/watch?v=ZMBPuuqTk_M](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?

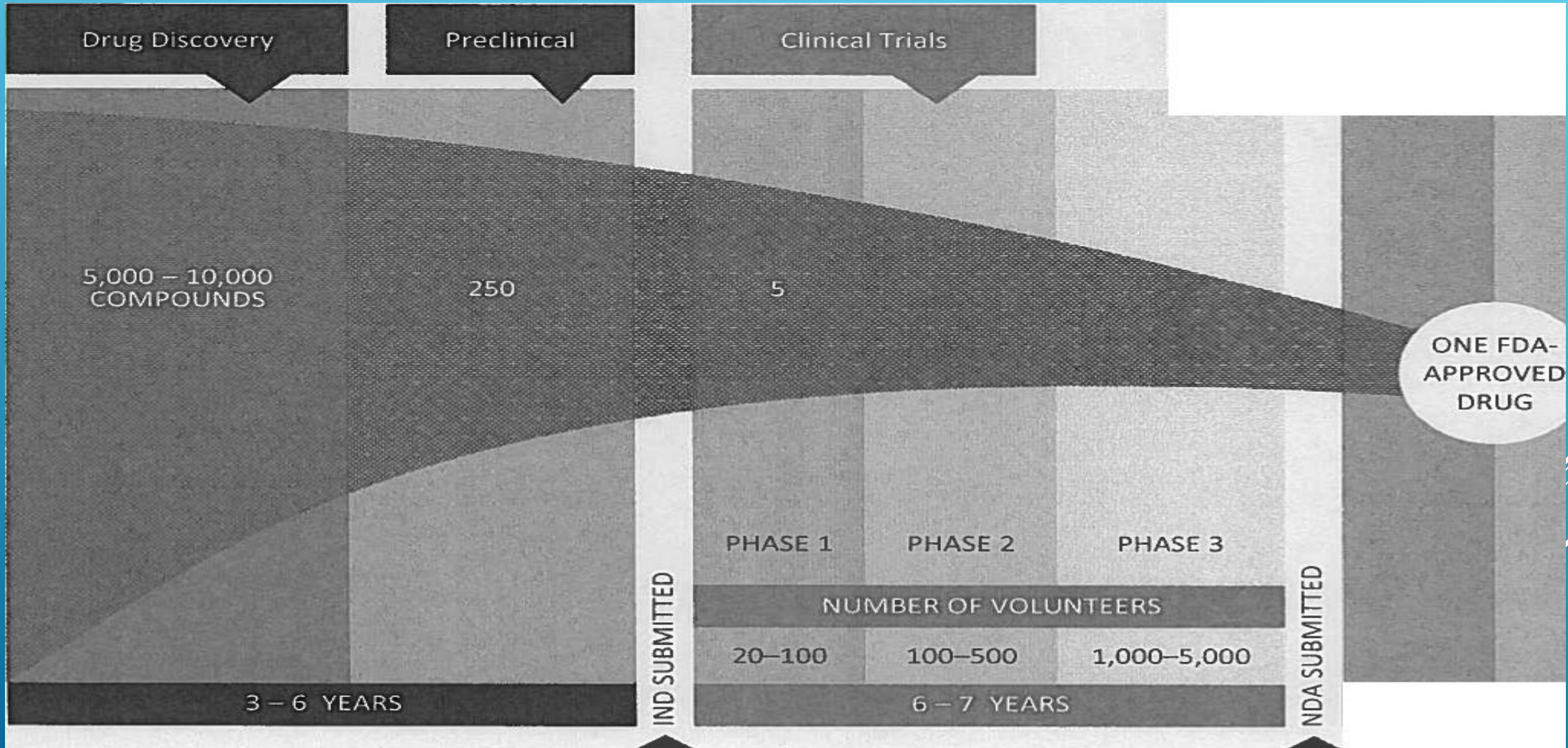
- Should marketers be allowed highlight positive aspects of their products/services?

BRAND MANAGERS' PERSPECTIVE

- Pharmaceutical Manufacturers' Association Information, published in ChartPak, 2012.
 - Presents industry data on research costs, new drug profits and insights on how DTCA impacts physicians.
- 

Product Development Timeline

Source: Pharmaceutical Manufacturers' Association

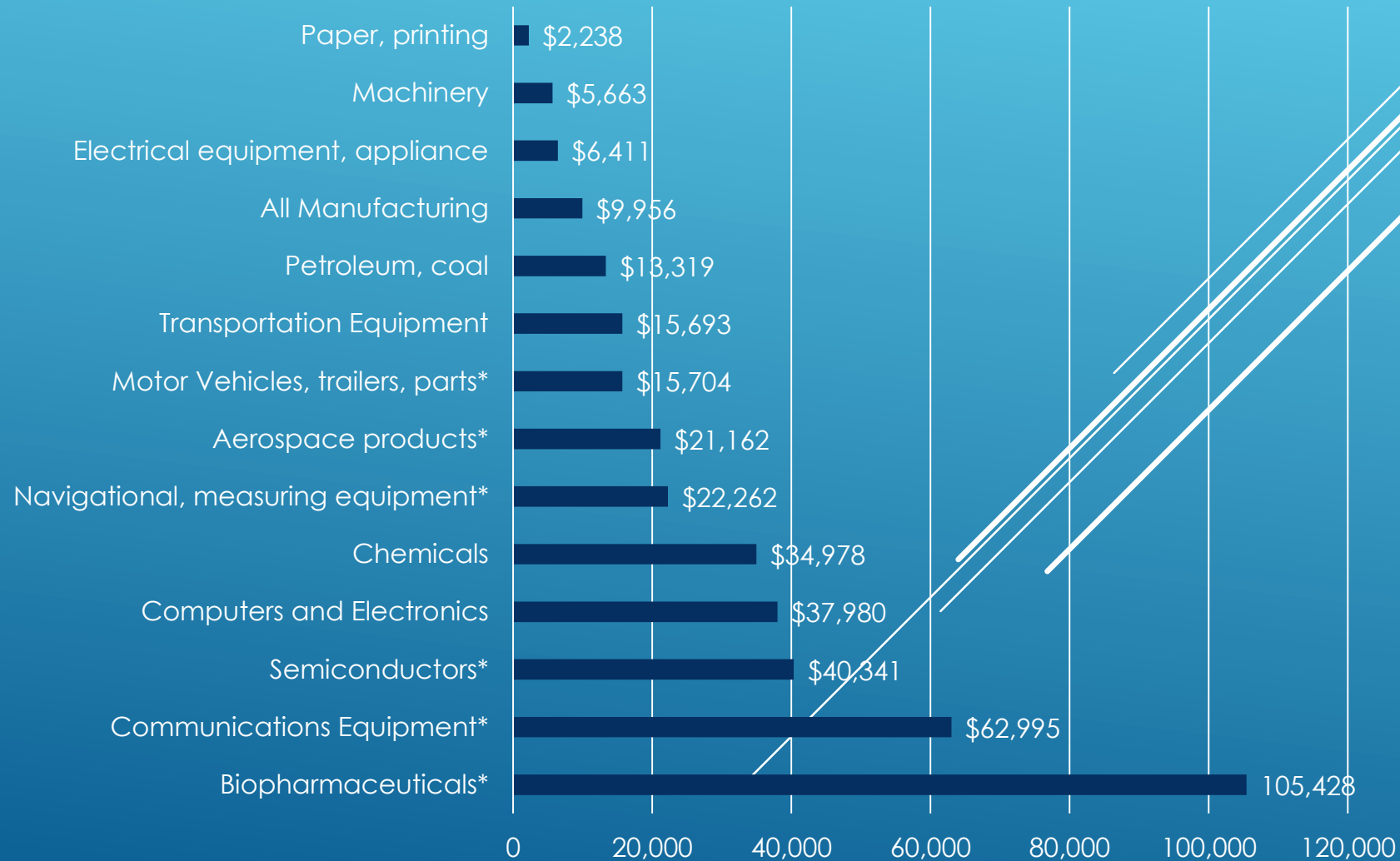


Source: Pharmaceutical Manufacturers' Association

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.

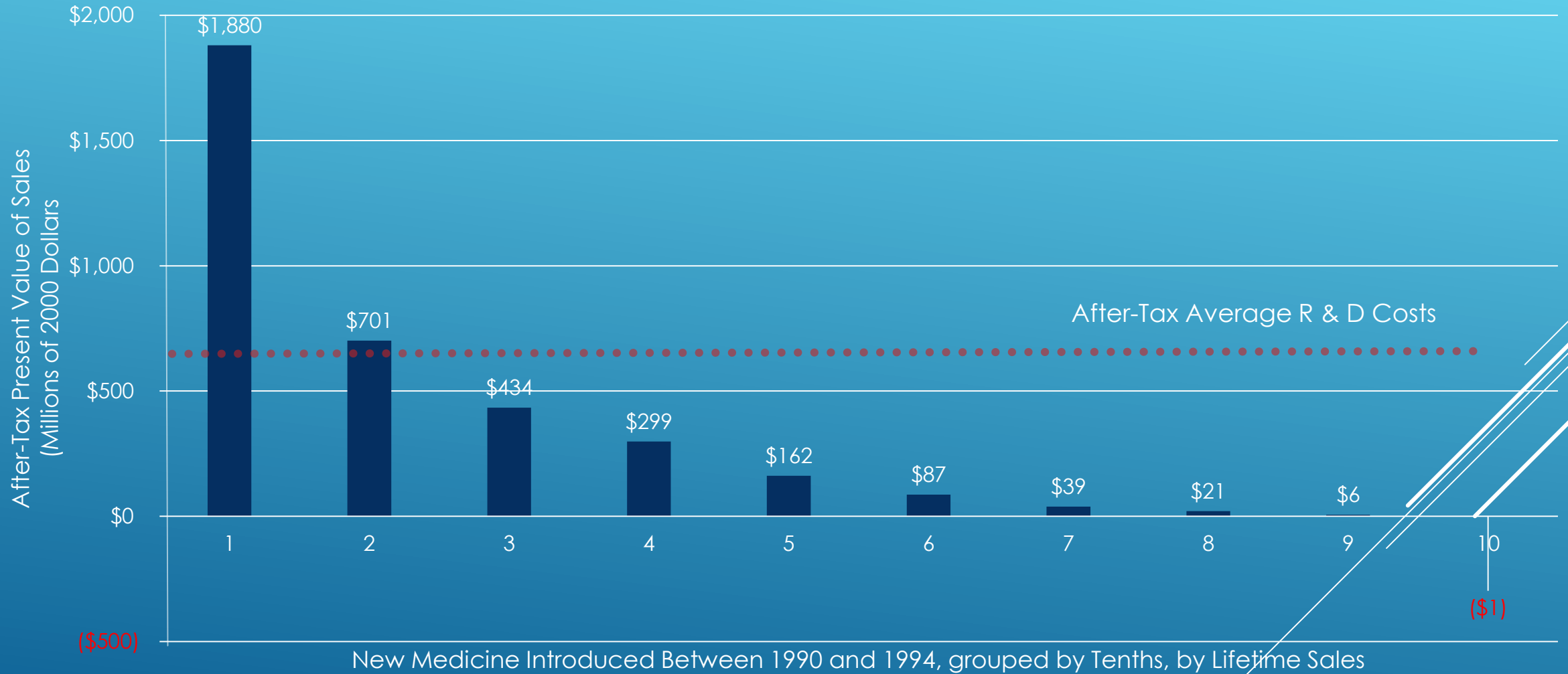
R&D Expenditures, by Manufacturing Sub-sector and Industry, 2000-2007



*Asterisks indicate manufacturing subsectors.

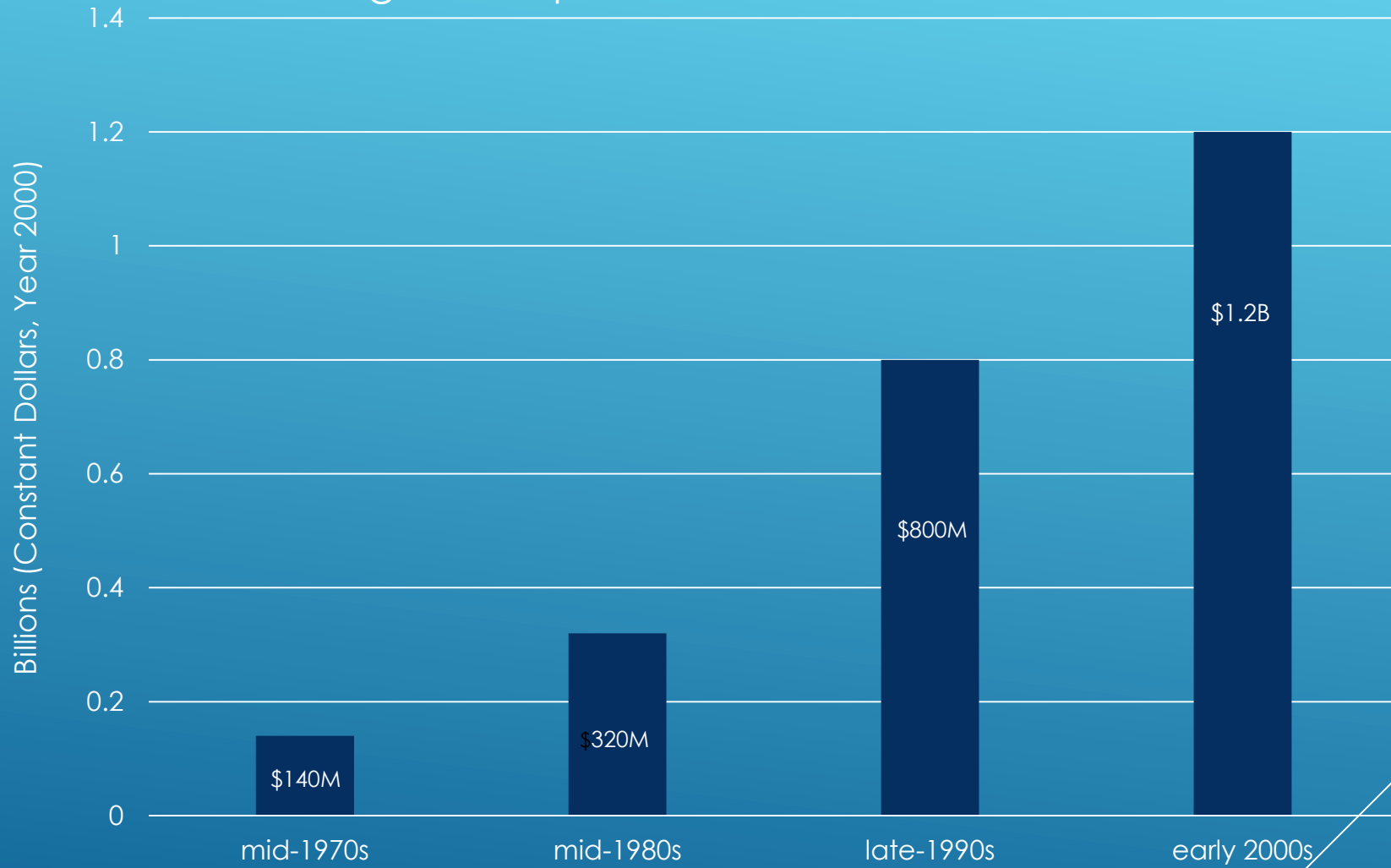
Few Approved Medicines are Commercially Successful

Just 2 in 10 Approved Medicines Produce Revenues that Exceed Average R & D Costs



Source: Pharmaceutical Manufacturers' Association

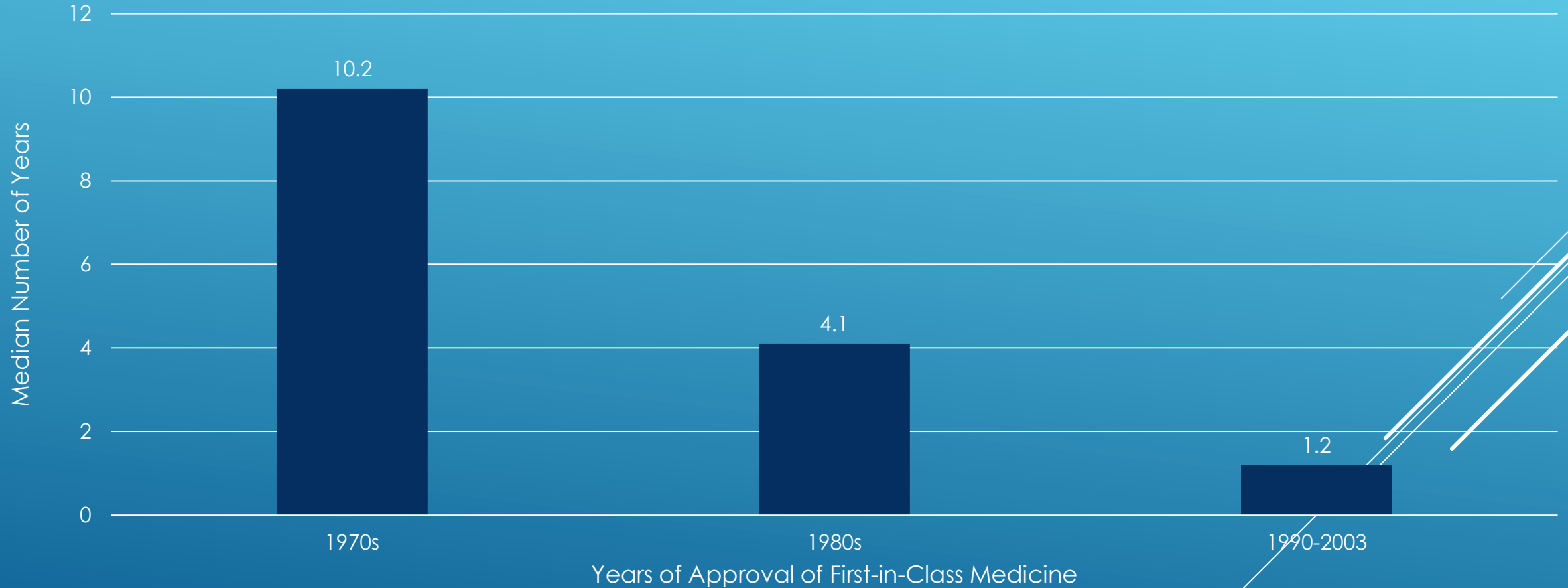
Drug Development Costs have Increased



Source: Pharmaceutical Manufacturers' Association

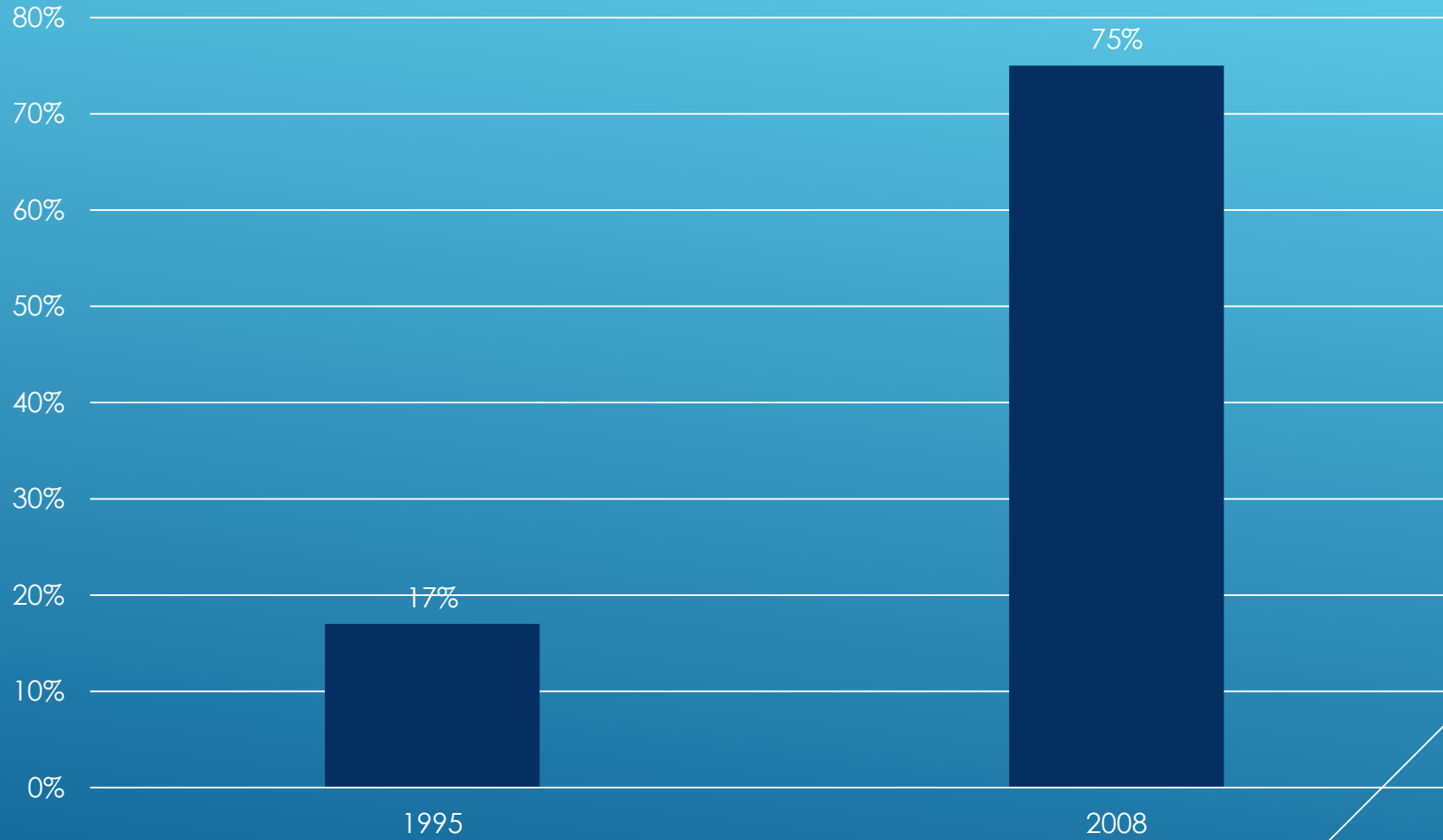
Increasing Competition Within Therapeutic Categories

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



Source: Pharmaceutical Manufacturers' Association

Percentage of Patented Drugs Facing Patent Challenges from Generic Companies

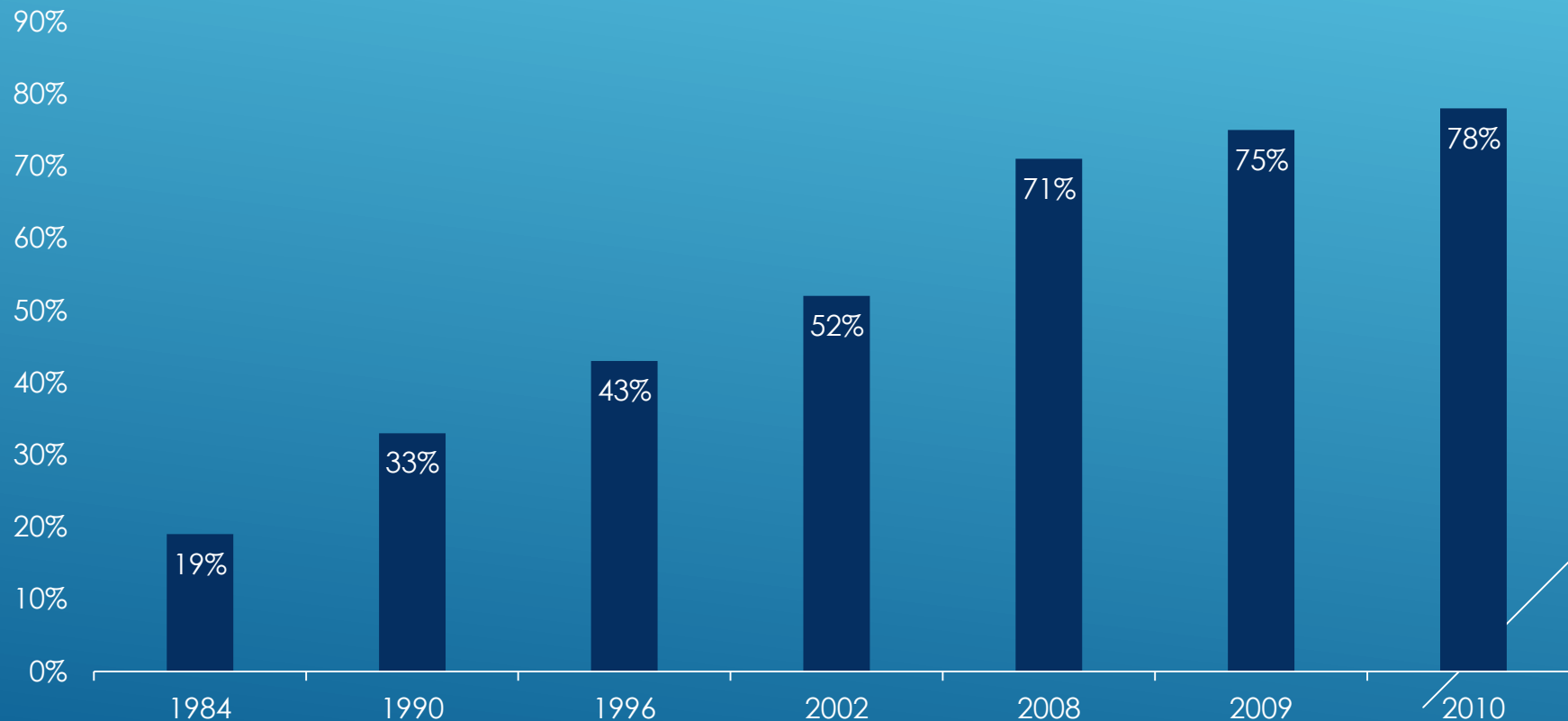


Source: Pharmaceutical Manufacturers' Association

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

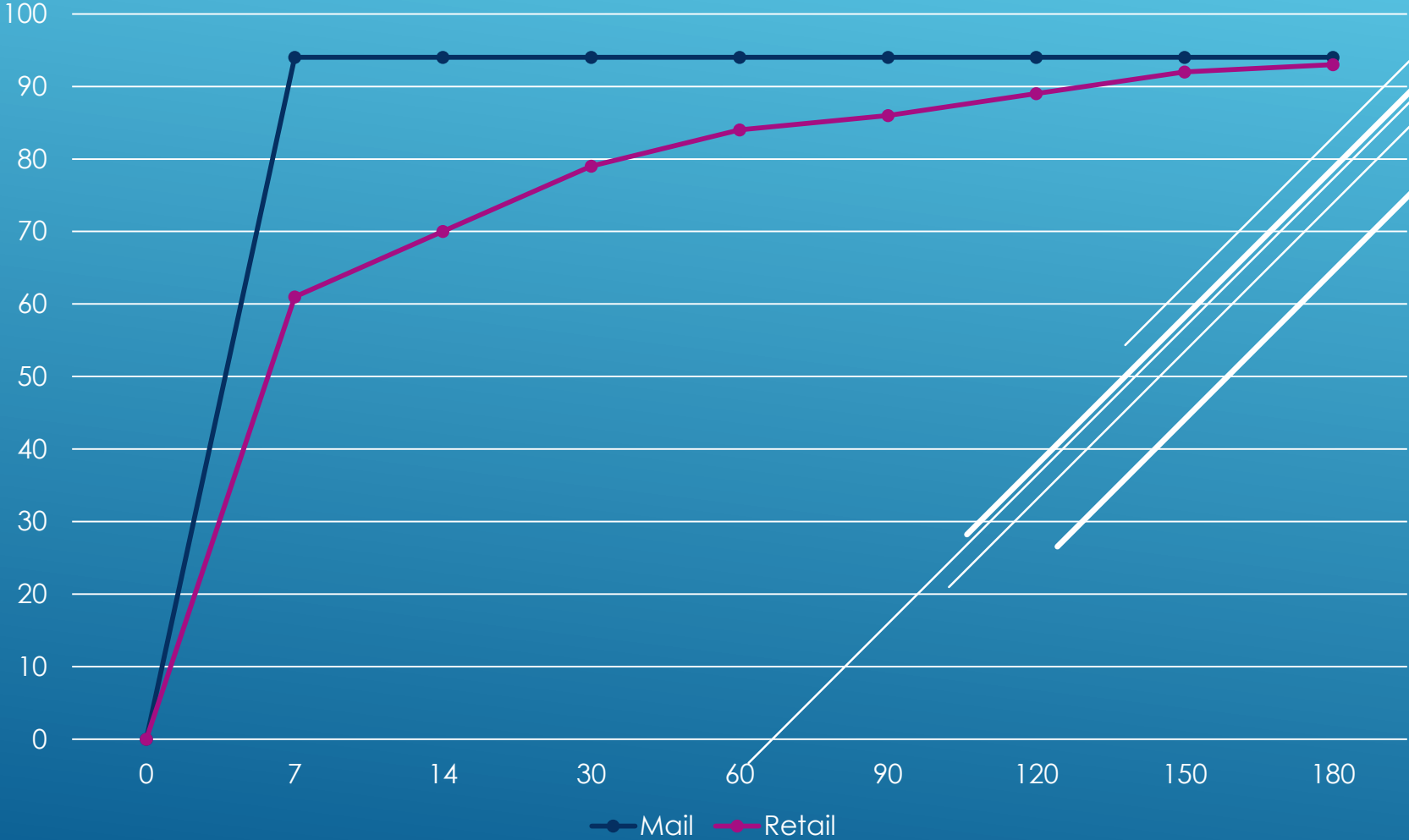


Source: Pharmaceutical Manufacturers' Association

Newly Introduced Generics are Adopted Rapidly

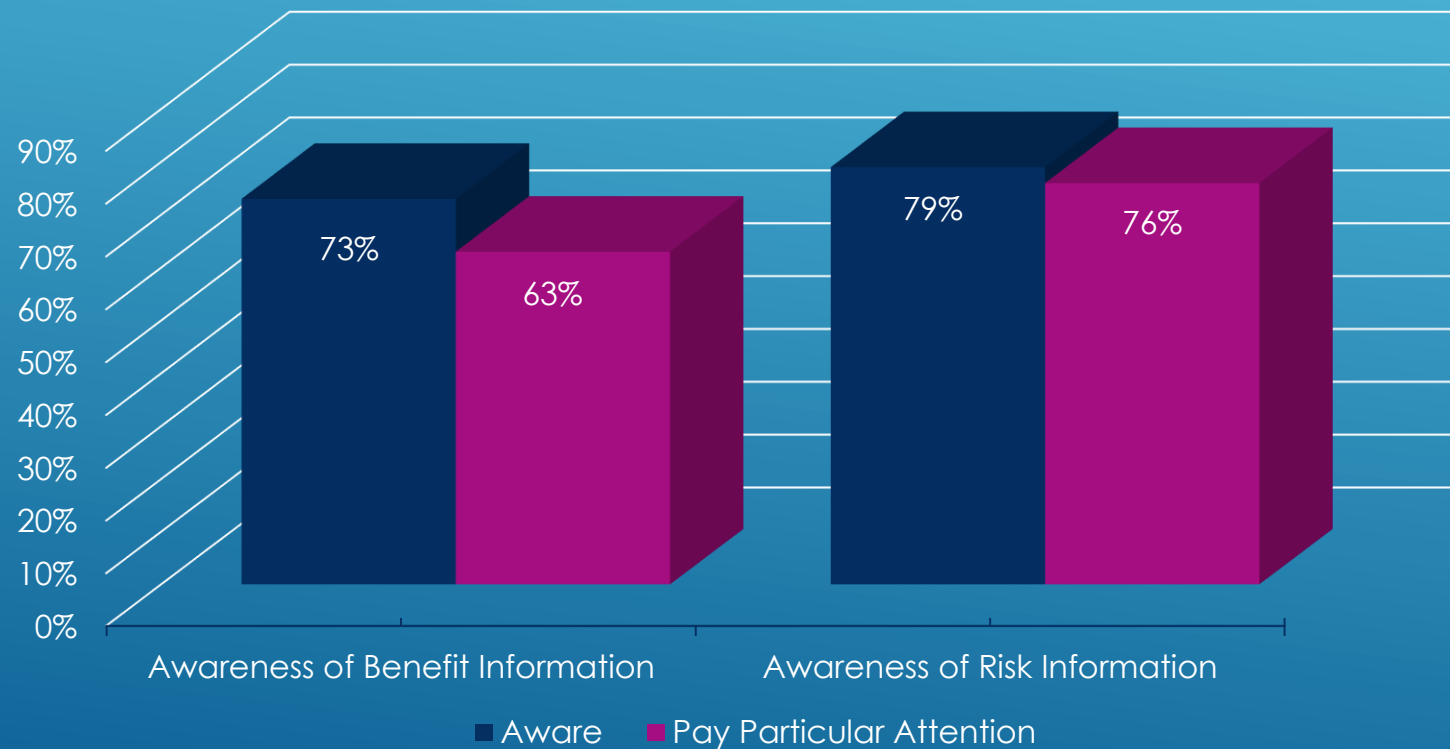
When a generic version of a medicine becomes available for the first time, it can capture as much as 84% to 94% of the market within the first month.

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

LOW TESTOSTERONE – THE LATEST “LIFESTYLE DRUG”

- “**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

SAMPLE LOW T ADS

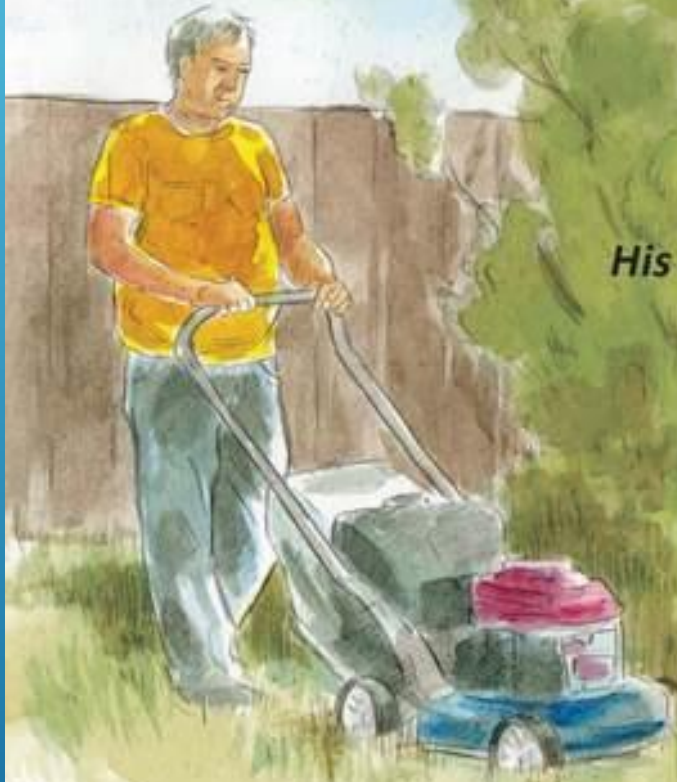
- The ads describe the risks while “a vibrant middle-aged man is cruising in a convertible with a lady friend, or a peppy guy is canoodling with his wife in the kitchen” (Consumer Reports, July 2013, p 6).
- **Androfen** <http://www.youtube.com/watch?v=-hn3qJzayo8>
- **Androgel** <http://www.youtube.com/watch?v=hhbhNGebrVw>
- **Axiron** <http://www.youtube.com/watch?v=S9hban1vVns>
- **Low T Center** <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.

Axiron™
(testosterone) topical solution E
30 mg of testosterone per 1.5 mL



**30-DAY
FREE TRIAL**

DOWNLOAD VOUCHER ▶

Ask your doctor if AXIRON is right for you

AXIRON is a prescription medication used to treat adult men who have low or no testosterone. It is not known if AXIRON is safe and effective in children younger than 18 years old. Improper use of AXIRON may affect bone growth in children.

IMPORTANT SAFETY INFORMATION FOR AXIRON

testosterone through skin to skin contact with men using topical testosterone products like AXIRON. Women and children should avoid contact with the unwashed or unclothed area where AXIRON has been applied. If a woman or child makes contact with the application area, the contact area on the woman or child should be washed well with soap and water right away.

To lower the risk of transfer of AXIRON from your body to others, follow these important instructions:

- Apply AXIRON **only** to your armpits.
- Wash your hands **right away** with soap and water after applying AXIRON.
- After the solution has dried, cover the application area.

Safety Information & Food & Drug Administration Prescribing Information Medication Guide

Recharge your T levels.
What you do next is up to you.

AndroGel

ANDROGEL

Coupon

Member ID: Enter Year & Time
(Example: Year 2013; Time 9:14; Enter ID 2013914)

PCN: 7777

RxBIN: 610709

RxGrp: FDCUSC2

Pharmacy Instructions:
Use the processing information on this coupon/card to process prescription just like an Rx claim card. If you have any problems please call the help line below.

THIS IS NOT INSURANCE

Complements of:

Processor:

Powered by:

Customer Service
800-726-4232
(Toll Free)

Pharmacy Helpline
877-321-6755
(Toll Free)

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 ?

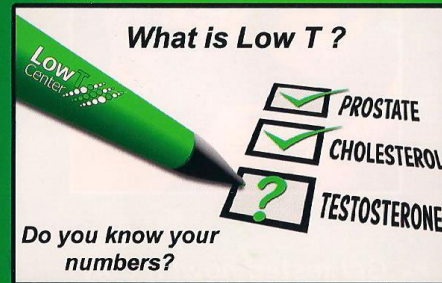


www.lowTcenter.com



www.lowTcenter.com

1-877-544-5698



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



Feel Like You're Running on Empty?



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

Are you one of them?



Have you lost your edge?

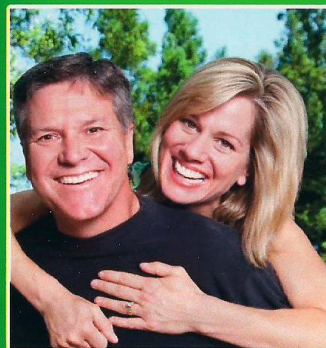
Testosterone plays a role in focus,
self confidence,
and overall health

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



www.lowTcenter.com

*Live Better!
Increase your quality of life.*



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

Most Insurance Accepted



1-877-544-5698

Benefits Include:

- *Improved Muscle Mass*
- *Boosted Energy*
- *Weight Loss*
- *Improved Strength*
- *Increased Bone Density*
- *Decreased Irritability*
- *Improved Sexual Desire*

*Call Today!
Its Time to
Live Again!*



PATIENT INFORMATION ON LOW T FROM UPTODATE.COM

- ▶ “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.”

Source: www.uptodate.com.

PATIENT INFORMATION ON LOW T FROM UPTODATE.COM

- ▶ 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

Source: www.uptodate.com.

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

PATIENT RISK FROM TESTOSTERONE THERAPY (CONTINUED)

- ▶ 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?
- 
- A decorative graphic consisting of several parallel white lines of varying lengths, slanted diagonally from the bottom right towards the top right, set against a blue gradient background.

LOW T LEGAL ADS

[HTTP://WWW.LAWYERSANDSETTLEMENTS.COM/LAWSUIT/TESTOSTERONE.HT
ML#.UX4GCV4YD6C](http://www.lawyersandsettlements.com/lawsuit/testosterone.html#UX4GCV4YD6C)

SOKOLOVE LAW

[HTTP://WWW.YOUTUBE.COM/WATCH?V=5BPZVQC7A9E](http://www.youtube.com/watch?v=5BPZVQC7A9E)

[HTTP://WWW.YOUTUBE.COM/WATCH?V=EVCZJIMJKQG](http://www.youtube.com/watch?v=EVCZJIMJKQG)

[HTTP://WWW.YOUTUBE.COM/WATCH?V=EVCZJIMJKQG](http://www.youtube.com/watch?v=EVCZJIMJKQG)

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?

A decorative graphic consisting of several parallel white lines of varying lengths and orientations, located in the bottom right corner of the slide.

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?