Advertising and the Schedule1/ Schedule 2 split – logical, necessary?

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Outline

- The current policy statement
- The current legal position
- DTCA – the global experience and impact
- Loopholes – and how to learn from them
- A way forward

National Drug Policy 1996

- **Under the rubric of "Rational use of drugs"**
  - "Care will be taken to develop among the general public a more critical attitude to advertising and commercial information, responsible self-prescribing, and confidence to interact effectively with health care providers."
  - Empowering? Informed consumer?

NDP 1996 - continued

- “The objective is to ensure that advertising and marketing of drugs shall be in keeping with the National Drug Policy, and in compliance with national regulations, as well as with voluntary industry standards.”
  - need for BOTH regulation and self-regulation?

NDP 1996 - continued

- “All promotion-making claims shall be reliable, accurate, truthful, informative, balanced, up-to-date, capable of substantiation and in good taste. They shall not contain misleading or unverifiable statements or omissions likely to induce medically unjustifiable drug use or to give rise to undue risks. Promotional material shall not be designed to disguise its real nature. Promotion in the form of financial or material benefits shall not be offered to or sought by health care practitioners to influence them in the prescription of drugs. Scientific and educational activities shall not be deliberately used for promotional purposes.”

NDP 1996 - continued

- “Ethical criteria and guidelines for the promotion and advertising of drugs will be established, widely disseminated and strictly enforced. The Ethical Criteria for Medicinal Drug Promotion adopted by the World Health Assembly (WHA) and the Pharmaceutical Manufacturers Association (PMA) Codes of Marketing Practice will be considered in the development of the national criteria (See also section 3.1). Issues related to pharmaceutical promotion and comparative independent sources of drug information will be included as a core component of all curricula of the health and pharmaceutical professions.”

NDP – the policy stance

- Regulation is needed, and will be based on national standards (enforceable?)
- The role of self-regulation was recognised
- The intent seemed to be to enable an empowered, informed consumer, especially with regard to “responsible self-medication”

The policy stance – what's missing?

- Although perhaps implied, there is no specific policy on direct-to-consumer advertising of prescription medicine (DTCA)
- No specific, detailed proposal on advertising of non-prescription medicines

Translating policy into legislation

- Medicines and Related Substances Control Amendment Act (Act 90 of 1997)

- [South African Medicines and Medical Devices Regulatory Authority Act (Act 132 of 1998)]
- Medicines and Related Substances Amendment Act (Act 59 of 2002)
- Medicines and Related Substances Amendment Act (Act 72 of 2008)
- Medicines and Related Substances Amendment Act (Act 14 of 2015)

Current wording

"**18C. Marketing of medicines, medical devices or IVDs.—**The Minister shall, after consultation with the relevant industries and other stakeholders, make regulations relating to the marketing of medicines, medical devices or IVDs and such regulations shall also provide for Codes of Practice for relevant industries."

[S. 18C inserted by s. 12 of Act No. 90 of 1997, substituted by s. 4 of Act No. 59 of 2002 and by s. 17 of Act No. 72 of 2008.]

Previously: "The Minister shall, after consultation with the pharmaceutical industry and other stakeholders, make regulations relating to the marketing of medicines, and such regulations shall also provide for an enforceable Code of Practice."

Definition

“advertisement”, in relation to any medicine, Scheduled substance, medical device or IVD, means any written, pictorial, visual or other descriptive matter or verbal statement or reference—

(*a*) appearing in any newspaper, magazine, pamphlet, electronic media (including radio and television) or other publication;

(*b*) distributed to members of the public; or

(*c*) brought to the notice of members of the public in any manner whatsoever,

which is intended to promote the sale of that medicine, Scheduled substance, medical device or IVD, and

“advertise” has a corresponding meaning;”

No. R. 510 10 April 200

GENERAL REGULATIONS MADE IN TERMS OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965(ACT NO. 101 OF 1965), AS AMENDED

LIST OF CONTENTS

Regulation 45 (2003)

“ADVERTISING OF MEDICINES

45 (1) The under mentioned requirements shall apply to any advertisement of a medicine.

(2)(a) Medicines which do not contain a scheduled substance and medicines which contain a substance appearing in Schedule 0 or Schedule 1 may be advertised to the public; and

(b) Medicines which contain a substance appearing in Schedule 2, Schedule 3, Schedule 4, Schedule 5 or Schedule 6 may be advertised only for the information of medical practitioners, dentists, veterinarians, pharmacists and other persons authorised to prescribe or in a publication which is normally or only made available to persons referred to therein;”

Regulation 45 - continued

“(c) Paragraph (b) shall not be so construed as to prohibit informing the public of the prices, names, pack sizes and strengths of medicines which contain a substance appearing in Schedule 2, Schedule 3, Schedule 4, Schedule 5 or Schedule 6.

(3) No advertisement for a medicine may contain a statement which deviates from, is in conflict with or goes beyond the evidence submitted in the application for registration of such medicine with regard to its

safety, quality or efficacy where such evidence has been accepted by the Council in respect of such medicine and incorporated in to the approved package insert of such medicine.”

Draft Regulations 2017

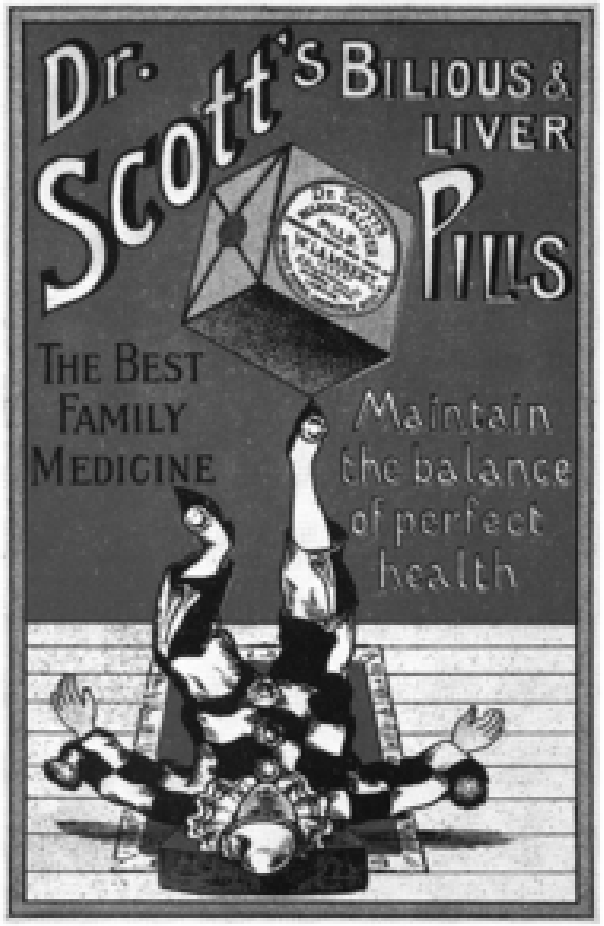
- Small changes:

"(4) No advertisement for a medicine may contain a statement which deviates from, is in conflict with or goes beyond the evidence submitted in the application for registration of such medicine with regard to its safety, quality or efficacy where such evidence has been accepted by the Authority in respect of such medicine and incorporated into the approved professional information of such medicine."

DTCA – the global situation

- Only allowed explicitly in two jurisdictions – US and New Zealand
- US evolution:
  - 1997 – change in policy allowing for television adverts WITHOUT extensive adverse event disclosure
  - Rapid growth in expenditure
    - 1989 US$12 million on DTCA
    - 2008 US$4.7 billion on DTCA alone (25% of all promotional expenditure)
    - 2012 US$3.1 billion on DTCA (health professional-directed promotions are still dominant)

Kim H. Int J Health Policy Manag 2015, 4(12), 813–821



English poster advertising medicine directly to the consumer dating from around 1901, before the practice was banned in the United Kingdom.

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Direct-to-consumer advertising under fire

Pharmaceutical companies that market medicines directly to consumers in the United States of America (USA) are under increasing pressure to rein in their inventive urges, while attempts to establish a bridgehead in Europe look doomed to failure. Gary Humphreys reports.

The distinguished doctor who has been introduced as the "inventor of the artificial heart" turns to the camera and says, "Just because I'm a doctor doesn't mean I don't worry about my cholesterol." He then recommends people use an anti-cholesterol drug, Lipitor, and to show just how confident he is in his own ticker, he rows across a lake. It was a killer advertisement, part of a campaign put together at a cost of US$ 260 million for drug company Pfizer. But it relied on the audience being unaware of several important facts: Robert Jarvik, the distinguished "doctor" in the boat, had never been licensed as a medical doctor, could not legally prescribe anything and was not the inventor of the artificial heart (at least according to three former colleagues at the University of Utah). It later turned out that he hadn't even rowed the boat. Welcome to the world of direct-to-consumer advertising.

Direct-to-consumer advertising of drugs has been legal in the USA since 1985, but only really took off in 1997 when the Food and Drug Administration (FDA) eased up on a rule obliging companies to offer a detailed list of side-effects in their infomercials (long format television commercials). Since then the industry has poured money into this form of promotion, spending just under US$5 billion last year alone.

Promotion of Prescription Drugs to Consumers and Providers, 2001–2010

Rachel Kornfield[1], Julie Donohue[2,3], Ernst R. Berndt[4,5], G. Caleb Alexander[1,6,7,8]*

1 Section of General Internal Medicine, Department of Medicine, University of Chicago, Chicago, Illinois, United States of America, **2** Department of Health Policy and Management, University of Pittsburgh, Pittsburgh, Pennsylvania, United States of America, **3** Department of Psychiatry, University of Pittsburgh, Pittsburgh, Pennsylvania, United States of America, **4** Alfred P. Sloan School of Management, Massachusetts Institute of Technology, Cambridge, Massachusetts, United States of America, **5** National Bureau of Economic Research, Cambridge, Massachusetts, United States of America, **6** Department of Epidemiology, Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland, United States of America, **7** Department of Medicine, Johns Hopkins Medicine, Baltimore, Maryland, United States of America, **8** Department of Pharmacy Practice, University of Illinois at Chicago School of Pharmacy, Chicago, Illinois, United States of America

Abstract

Background: Pharmaceutical firms heavily promote their products and may have changed marketing strategies in response to reductions in new product approvals, restrictions on some forms of promotion, and the expanding role of biologic therapies.

Methods: We used descriptive analyses of annual cross-sectional data from 2001 through 2010 to examine direct-to-consumer advertising (DTCA) (Kantar Media) and provider-targeted promotion (IMS Health and SDI), including: (1) inflation-adjusted total promotion spending ($ and percent of sales); (2) distribution by channel (consumer v. provider); and (3) provider specialty both for the industry as a whole and for top-selling biologic and small molecule therapies.

Results: Total promotion peaked in 2004 at US$36.1 billion (13.4% of sales). By 2010 it had declined to $27.7B (9.0% of sales). Between 2006 and 2010, similar declines were seen for promotion to providers and DTCA (both by 25%). DTCA's share of total promotion increased from 12% in 2002 to 18% in 2006, but then declined to 16% and remains highly concentrated. Number of products promoted to providers peaked in 2004 at over 3000, and then declined 20% by 2010. In contrast to top-selling small molecule therapies having an average of $370 million (8.8% of sales) spent on promotion, top biologics were promoted less, with only $33 million (1.4% of sales) spent per product. Little change occurred in the composition of promotion between primary care physicians and specialists from 2001–2010.

Conclusions: These findings suggest that pharmaceutical companies have reduced promotion following changes in the pharmaceutical pipeline and patent expiry for several blockbuster drugs. Promotional strategies for biologic drugs differ substantially from small molecule therapies.

Citation: Kornfield R, Donohue J, Berndt ER, Alexander GC (2013) Promotion of Prescription Drugs to Consumers and Providers, 2001–2010. PLoS ONE 8(3): e55504. doi:10.1371/journal.pone.0055504


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AMA Calls for Ban on DTC Ads of Prescription Drugs and Medical Devices
For immediate release: Nov 17, 2015
ATLANTA –Responding to the billions of advertising dollars being spent to promote prescription products, physicians at the Interim Meeting of the American Medical Association (AMA) today adopted new policy aimed at driving solutions to make prescription drugs more affordable.
Physicians cited concerns that a growing proliferation of ads is driving demand

The NEW ENGLAND JOURNAL of MEDICINE

SPECIAL ARTICLE

A Decade of Direct-to-Consumer Advertising of Prescription Drugs

Julie M. Donohue, Ph.D., Marisa Cevasco, B.A., and Meredith B. Rosenthal, Ph.D.

ABSTRACT

BACKGROUND

Evidence suggests that direct-to-consumer advertising of prescription drugs increases pharmaceutical sales and both helps to avert underuse of medicines and leads to potential overuse. Concern about such advertising has increased recently owing to the withdrawal from the market of heavily advertised drugs found to carry serious risks. Moreover, the Food and Drug Administration (FDA) has been criticized for its weak enforcement of laws regulating such advertising.

METHODS

We examined industry-wide trends in spending by pharmaceutical companies on direct-to-consumer advertising and promotion to physicians during the past decade. We characterized the drugs for which such advertising is used and assessed the timing of advertising after a drug is introduced. Finally, we examined trends in the FDA's regulation of drug advertising.

RESULTS

Total spending on pharmaceutical promotion grew from $11.4 billion in 1996 to $29.9 billion in 2005. Although during that time spending on direct-to-consumer advertising increased by 330%, it made up only 14% of total promotional expenditures in 2005. Direct-to-consumer campaigns generally begin within a year after the approval of a product by the FDA. In the context of regulatory changes requiring legal review before issuing letters, the number of letters sent by the FDA to pharmaceutical manufacturers regarding violations of drug-advertising regulations fell from 142 in 1997 to only 21 in 2006.

CONCLUSIONS

Spending on direct-to-consumer advertising has continued to increase in recent years in spite of the criticisms leveled against it. Our findings suggest that calls for a moratorium on such advertising for new drugs would represent a dramatic departure from current practices.

From the Department of Health Policy and Management, University of Pittsburgh Graduate School of Public Health, Pittsburgh (J.M.D.); the Department of Health Policy and Management, Harvard School of Public Health, Boston (M.C., M.B.R.); and Vanderbilt School of Medicine, Nashville (M.C.). Address reprint requests to Dr. Donohue at the Department of Health Policy and Management, University of Pittsburgh Graduate School of Public Health, Crabtree Hall A613, 130 DeSoto St., Pittsburgh, PA 15261, or at jdonohue@pitt.edu.

N Engl J Med 2007;357:673-81.

Direct-to-consumer campaigns generally begin within a year after the approval of a product by the FDA.

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Direct-to-Consumer Pharmaceutical Advertising

Therapeutic or Toxic?

C. Lee Ventola, MS

Vol. 36 No. 10 • October 2011 • P&T® 669

The average American TV viewer watches as many as nine drug ads a day, totaling 16 hours per year, which far exceeds the amount of time the average individual spends with a primary care physician.

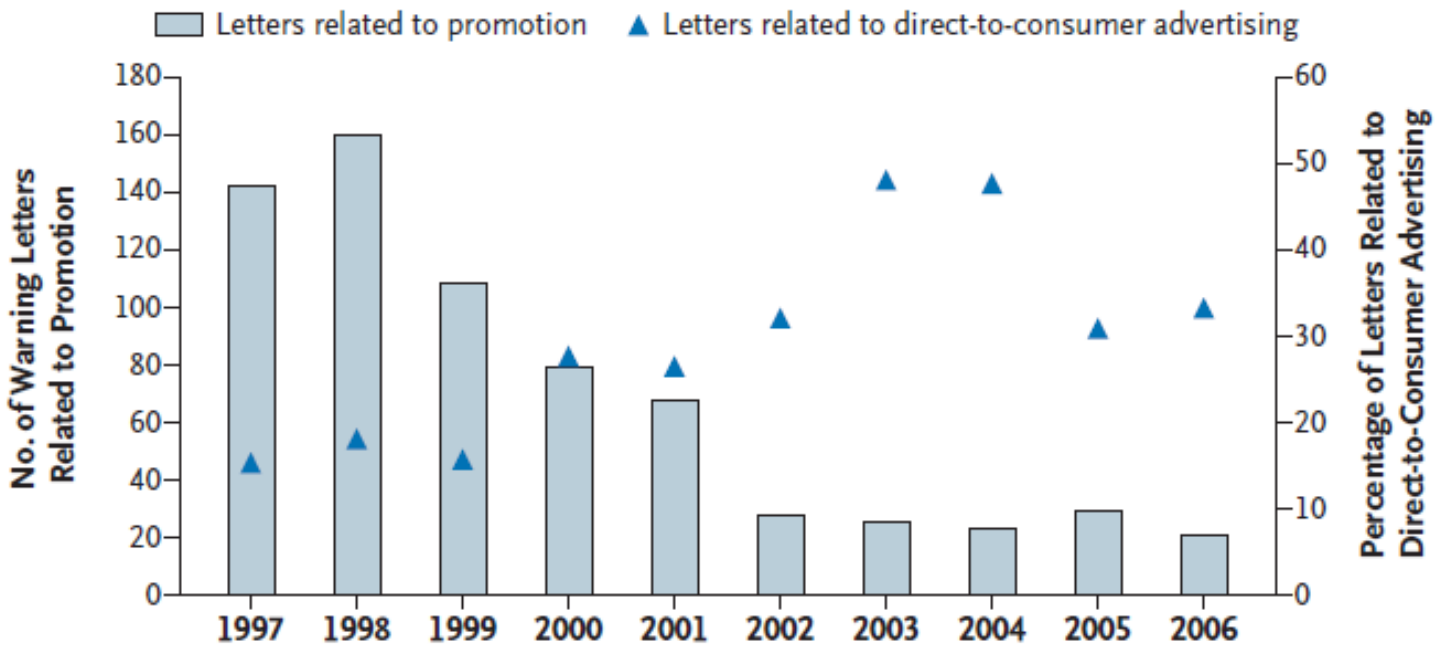


Figure 1. Trends in FDA Enforcement of Regulations Regarding Direct-to-Consumer Advertising, 1997–2006.

Data are from regulatory letters posted on the Web site of the Division of Drug Marketing Advertising and Communication of the FDA (www.fda.gov/cder/ddmac/lawsregs.htm).

http://ijhpm.com
Int J Health Policy Manag 2015, 4(12), 813–821
doi 10.15171/ijhpm.2015.157
IJHPM International Journal of Health Policy and Management
Original Article

Trouble Spots in Online Direct-to-Consumer Prescription Drug Promotion: A Content Analysis of FDA Warning Letters

Hyosun Kim*

The results reveal that approximately 95% of the alleged violations were found on branded drug websites, in online paid advertisements, and in online videos. Of the total 179 violations, the majority of the alleged violations were concerned with the lack of risk information and/or misrepresentation of efficacy information, suggesting that achieving a fair balance of benefit versus risk information is a major problem with regard to the direct-to-consumer advertising (DTCA) of prescription drugs.

Conclusion: Presenting drug information in a fair and balanced manner remains a major problem.

Comment on Kim's paper

- The study and its conclusions appear to make some implicit assumptions. The first assumption is that pharmaceutical firms have a selfless motive and their interests are aligned with those of consumers and the FDA. While some interests are aligned, there is a world of conflict and motivation to act in ways that are at odds with each other. In addition, warning letters imply serious violations, and there is no way of knowing whether these were deliberate or honest mistakes. Kim's study found that major violations were based on the lack of risk information and/or misrepresentation of efficacy information. The fact that some pharmaceutical firms did not include these essential attributes in a drug points to an underlying problem of self-interest-seeking behavior and possibly deceptive marketing.8 Kim's findings appear to highlight the conundrum of marketing efforts that are focused on increasing sales. Deception, whether calculated or unintended, that continues to prevail.

Wanasika I. Int J Health Policy Manag 2016, 5(6), 391–392

Comment on Kim's paper

- The most common were omissions or minimizations of information on risks, followed by overstatements of efficacy, unsubstantiated claims, and misrepresentation of the indication for use. The most common treatment area was cancer; nearly one fourth of the letters were about advertisements of cancer treatments. This raises additional concerns because of extra vulnerability of cancer patients when faced with a life-threatening disease.

Mintzes B. Int J Health Policy Manag 2016, 5(5), 329–331

But it's not only medicines

Industry Responsibilities in Tackling Direct-to-Consumer Marketing of Unproven Stem Cell Treatments

Z Master[1], W Fu[2], D Paciulli[3] and D Sipp[4,5,6]

The direct-to-consumer marketing of unproven stem cell interventions (SCIs) is a serious public health concern. Regulations and education have had modest impact, indicating that different actors must play a role to stop this unfettered market. We consider the role of the biotech industry in tackling unproven SCIs. Grounded in the concept of corporate social responsibility, we argue that biotech companies should screen consumers to ensure that products and services are being used appropriately and educate employees about unproven SCIs.

Pharmaceutical Marketing for Rare Diseases
Regulating Drug Company Promotion in an Era of Unprecedented Advertisement

JAMA June 27, 2017 Volume 317, Number 24

General Hospital, the longest running US soap opera, advanced a plotline whereby a star character was diagnosed as having polycythemia vera (PV) and a blood clot.

Culmination of a partnership between the Incyte Corporation and the producers of General Hospital to raise awareness as part of the rare disease month.

Incyte has only 1 FDA-approved product, ruxolitinib, a Janus kinase 2 (JAK2) inhibitor used for the treatment of myeloproliferative neoplasm, including PV.

Ruxolitinib is not first-line therapy for PV; approved only for patients with an inadequate response or intolerance to hydroxyurea, who are dependent on phlebotomy, and who have an enlarged spleen.

A new concern – off-label advertising

The Promotion of Medical Products in the 21st Century
Off-label Marketing and First Amendment Concerns

Joshua M. Sharfstein, MD
Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland.

Alta Charo, JD
University of Wisconsin Law School and School of Medicine & Public Health, Madison.

JAMA November 3, 2015 Volume 314, Number 17

"The case centers on Amarin's request to promote its drug, an FDA-approved icoasapentaenoic acid type of omega-3 fatty acid made from fish oil, for reducing triglyceride levels. After consulting with its advisory committee, theFDA rejected this request on the grounds that there is insufficient evidence that triglyceride reduction prevents cardiovascular disease.2 Without a "clinical rationale" for the claim, the FDA determined its use would be misleading. Amarin objected and sued on the basis that its representatives have a constitutional right under the First Amendment to promote the reduction in triglycerides, even without compelling evidence of clinical value."

"The Amarin case and related court decisions fail to respect the FDA's evolving approach to First Amendment concerns. Physicians are generally free to prescribe medications as they judge best, and payers make their own evidence-based judgments about reimbursement. The FDA's rules already permit scientific journals and conferences to present information about off-label uses for drugs. Sponsors can respond to questions from physicians, even if related to off-label uses, and provide reprints of peer-reviewed journal articles. The agency's goal is not to restrict speech or to keep patients and physicians uninformed. It is to facilitate physician decision making by supporting independently verified information, rather than information of unknown quality from a self-interested source. Contrary to the assertion in the court decisions, the marketplace of ideas and physician discretion does not work well without accurate information from well-designed studies."

So, what evidence is there of an effect on utilisation of specific products?

The Effect of Competing Direct-to-Consumer Advertising Campaigns on the Use of Drugs for Benign Prostatic Hyperplasia: Time Series Analysis

Sean C. Skeldon, MD[1,2,3], Katy B. Kozhimannil, PhD[4], Sumit R. Majumdar, MD, MPH[5], and Michael R. Law, PhD[1]

[1]The Centre for Health Services and Policy Research, School of Population and Public Health, The University of British Columbia, Vancouver, BC, Canada; [2]Division of Urology, Department of Surgery, University of Toronto, Toronto, ON, Canada; [3]Department of Urological Sciences, The University of British Columbia, Vancouver, BC, Canada; [4]Division of Health Policy and Management, University of Minnesota School of Public Health, Minneapolis, MN, USA; [5]Department of Medicine, Faculty of Medicine and Dentistry, University of Alberta, Edmonton, AB, Canada.

J Gen Intern Med 30(4):514–20
DOI: 10.1007/s11606-014-3063-y

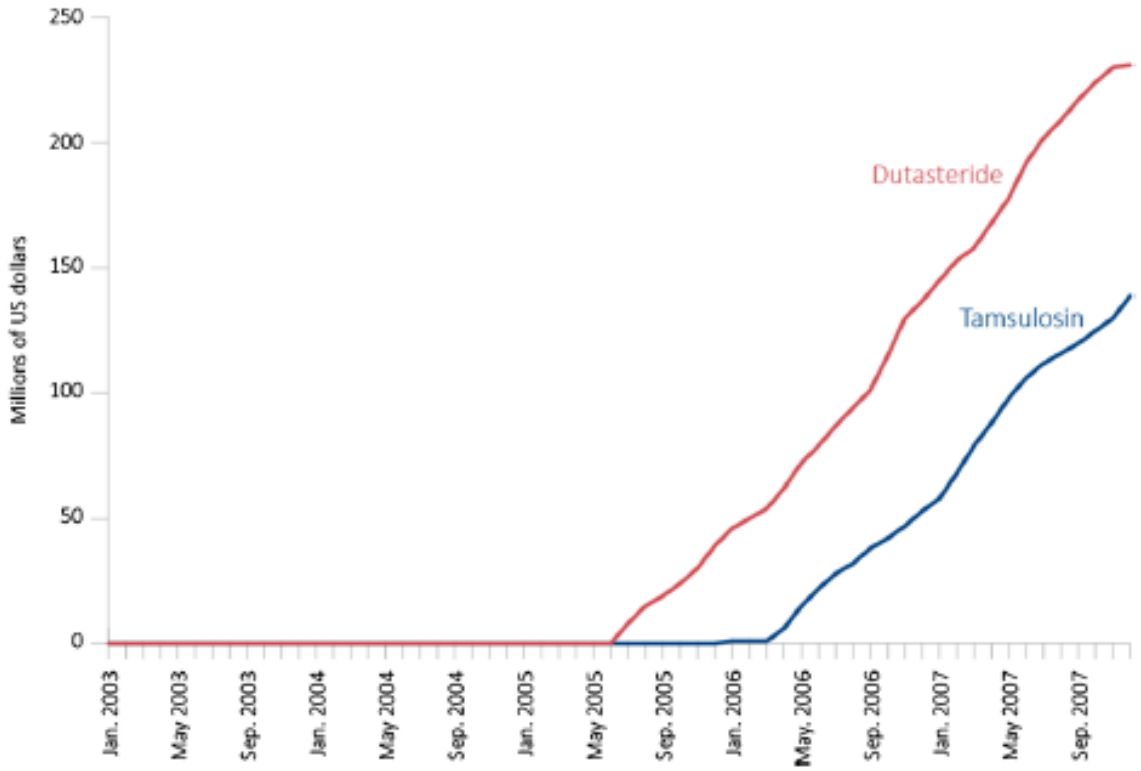


Figure 1. Estimated cumulative expenditure on direct-to-consumer advertising (DTCA) for dutasteride (red) and tamsulosin (blue) from 2003 through 2007.

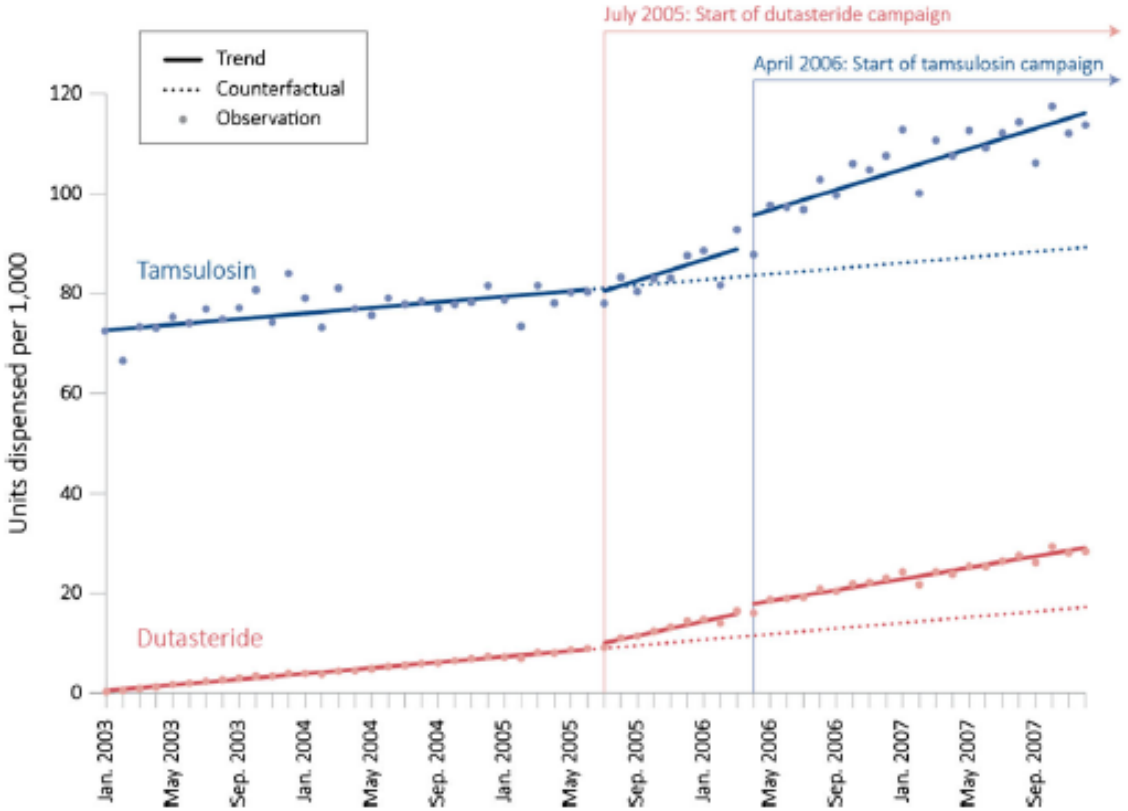


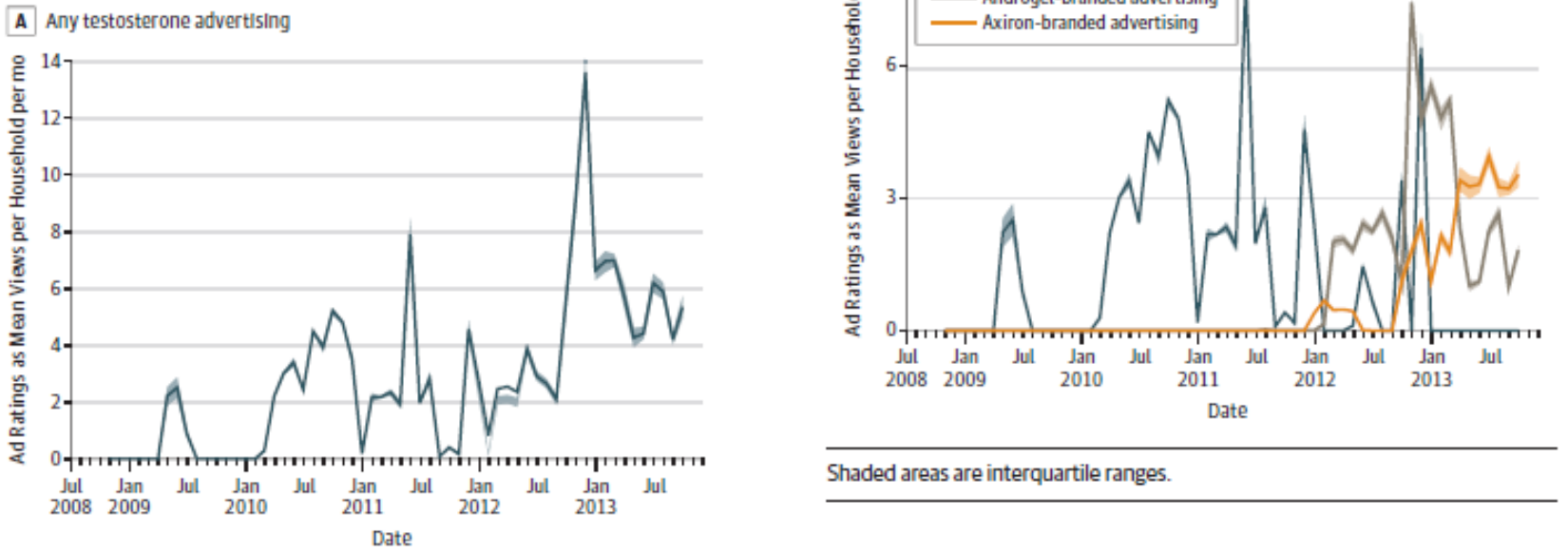
Figure 3. Number of units dispensed for dutasteride (red) and tamsulosin (blue) per 1,000 population per month in the United States from 2003 through 2007. The dutasteride campaign was associated with a greater increase in trend for tamsulosin units dispensed (0.76, 95 % CI: 0.02–1.50) than for dutasteride (0.45, 95 % CI: 0.33–0.56). The tamsulosin campaign was associated with an immediate increase in the number of tamsulosin units dispensed (5.76, 95 % CI: 1.79–9.72). Source: IMS Health National Prescription Audit™, January 2003–December 2007, IMS Health Incorporated.

Association Between Direct-to-Consumer Advertising and Testosterone Testing and Initiation in the United States, 2009-2013

J. Bradley Layton, PhD; Yoonsang Kim, MPH, PhD; G. Caleb Alexander, MD, MS; Sherry L. Emery, MBA, PhD

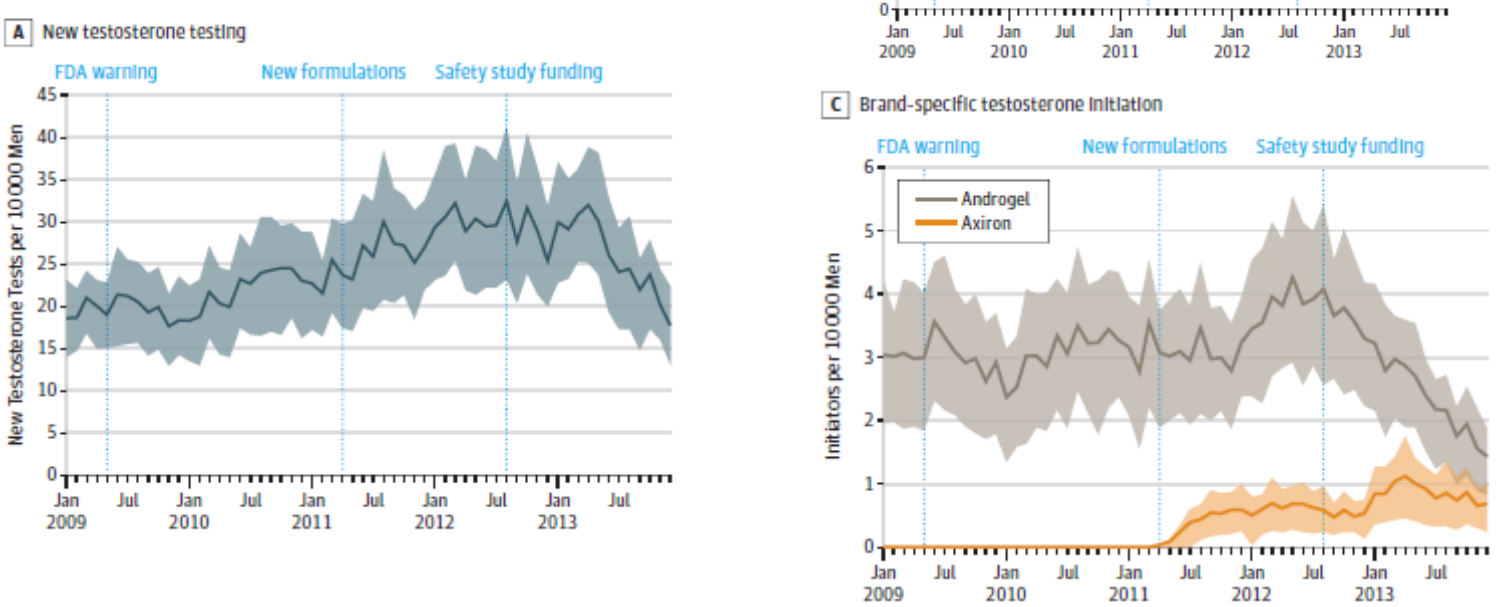
JAMA. 2017;317(11):1159-1166. doi:10.1001/jama.2016.21041

Figure 2. Mean Household Testosterone Advertisement Exposures From Nielsen Television Ratings Across the 75 Largest Designated Market Areas in the United States, November 2008–October 2013



Shaded areas are interquartile ranges.

Figure 1. Mean Testosterone Testing and Initiation Rates Among Adult Men in the 75 Largest Designated Market Areas in the United States, January 2009–December 2013



Shaded areas are interquartile ranges. Vertical dotted lines in all panels indicate 3 key events that may be associated with overall use: (1) May 2009, US Food and Drug Administration warning of transfer of testosterone gel from men to women and children; (2) April 2011, release of new testosterone gel formulations; and (3) August 2012, increased concern about cardiovascular safety of testosterone products as evidenced by the National Institutes of Health funding safety studies of testosterone in older men.

But what of the “information” loophole?

Marketing in the lay media and prescriptions of terbinafine in primary care: Dutch cohort study

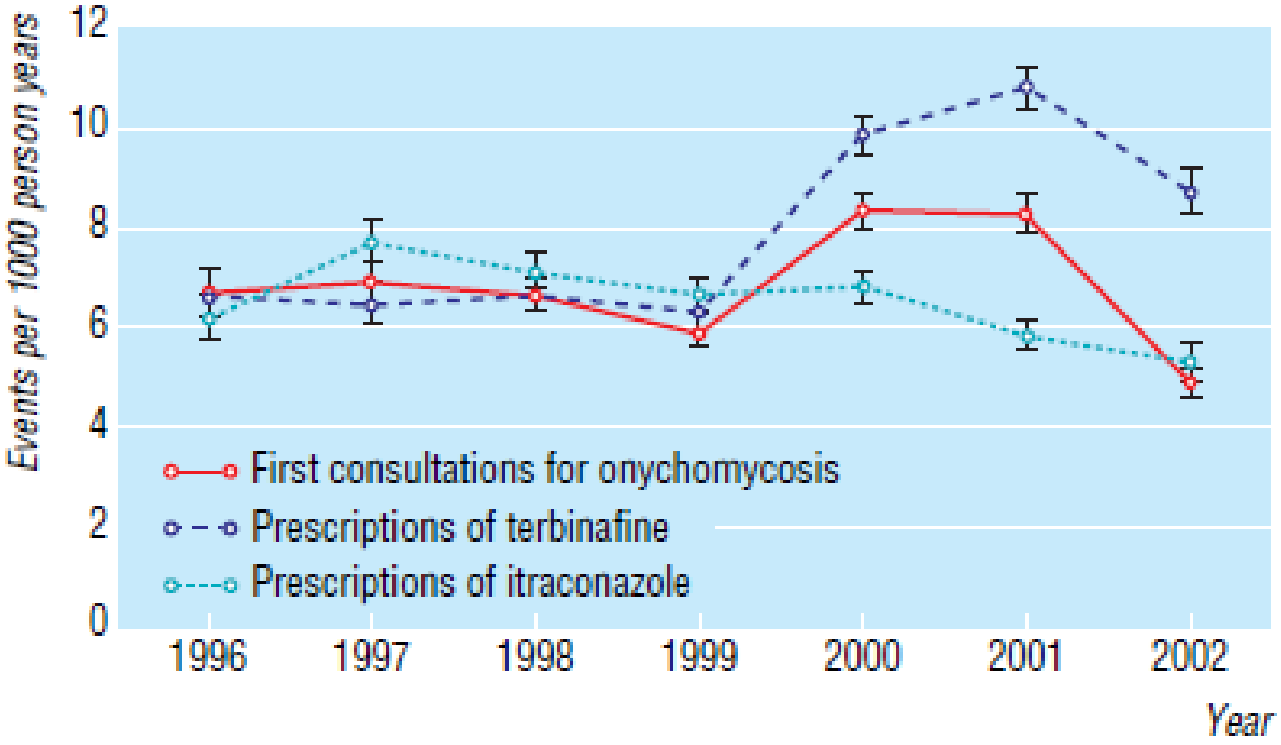
Geert W ’t Jong, Bruno H Ch Stricker, Miriam C J M Sturkenboom

BMJ 2004;328:931

In May 2000 in the Netherlands, the manufacturer of terbinafine, Novartis, started a nationwide “information campaign” which included television advertisements advising people with onychomycosis to visit their general practitioner.

The Dutch Society of General Practitioners objected to this campaign as an unnecessary focus on an unimportant health problem.

In May 2002, a Dutch court decided that Novartis’s campaign did not violate laws prohibiting advertising of prescription drugs as neither Novartis nor terbinafine were specifically named; however, Novartis stopped the campaign in July 2002.



Prescription rates and consultation rates before (1996-9) and during the campaign (2000-2) (averages are calculated per year)

Prescribers do respond to specific requests

Med Care. 2014 April ; 52(4): 294–299. doi:10.1097/MLR.0000000000000096.

EFFECTS OF PATIENT MEDICATION REQUESTS ON PHYSICIAN PRESCRIBING BEHAVIOR: RESULTS OF A FACTORIAL EXPERIMENT

John B. McKinlay, Ph.D., FACE, FAHA[1], **Felicia Trachtenberg, Ph.D.**[1], **Lisa D. Marceau, MPH**[1], **Jeffrey N. Katz, MD, MSc**[2], and **Michael A. Fischer, MD**[3]

[1]New England Research Institutes (NERI) and Division of Medicine, Massachusetts General Hospital, Harvard Medical School, 9 Galen Street, Watertown, MA 02472 USA

[2]Orthopedic and Arthritis Center for Outcomes Research, Department of Orthopedic Surgery and Division of Rheumatology, Brigham and Women's Hospital, Harvard Medical School; Department of Epidemiology, Harvard School of Public Health, 75 Francis Street, Boston, MA 02115 USA

[3]Division of Pharmacoepidemiology and Pharmacoeconomics, Brigham & Women's Hospital, Harvard Medical School, 1620 Tremont Street, Suite 3030, Boston, MA 02120 USA

The experiment

- Two experiments were conducted among 192 primary care physicians, each using different video-based scenarios; an undiagnosed “patient” with symptoms strongly suggesting sciatica, and a “patient” with already diagnosed chronic knee osteoarthritis. Half of patients with sciatica symptoms requested oxycodone, while the other half requested something to help with pain. Similarly, half of knee osteoarthritis patients specifically requested Celebrex and half requested something to help with pain.

The outcome

- 19.8% of sciatica patients requesting oxycodone would receive a prescription for oxycodone, compared with 1% of those making no specific request (p=0.001).
- 53% of knee osteoarthritis patients requesting Celebrex would receive it, compared with 24% of patients making no request (p=0.001).
- Patients requesting oxycodone were more likely to receive a strong narcotic (p=0.001) and less likely to receive a weak narcotic (p=0.01).
- Patients requesting Celebrex were much less likely to receive a non-selective NSAID (p=0.008).
- No patient attributes, physician or organizational factors influenced a physician's willingness to accede to a patient's medication request.

One last study – a qualitative paper on patient's attitudes to OTC pain medication

"Just Advil": Harm reduction and identity construction in the consumption of over-the-counter medication for chronic pain

Emery R. Eaves

Department of Family and Community Medicine, University of Arizona College of Medicine, USA

Social Science & Medicine 146 (2015) 147–154

Contrast

- Patient statements
  - “Deanne: I don't take medication. I never take any medicine unless, you know, I really, it's like a kind of life or death kind of thing … I take a lot of herbs … I never take pain medication.
  - ERE: Never? Okay. Even with the, stuff like Excedrin?
  - Deanne: Codeine with Aspirin … yeah, but that's not pain medication. I think it's an aspirin, I don't think of Excedrin for tension headache as being pain medication. (Deanne, 56)”
  - “I'm not sure what the recommended dose is anymore. I think it's probably two or something, and just today I took four. I'll take four of them at once. I'll take what I can take without them making me feel funny or something. I may make it through the day with just those four. And then if it's a normal day it's going to be four in the afternoon. (Lloyd, 54)”

- Advertising messages
  - “No pain. No limit” (Advil).
  - “I take Advil because my kids deserve a mom without a headache.”
  - “for everything we do, you do so much more” (Tylenol)
  - “we eased your back pain, you made it the best playdate ever” (Tylenol).
  - “The brand hospitals use most” (Tylenol)
  - “you can't get a stronger pain reliever without a prescription” (Tylenol)
  - “advanced medicine for pain” (Tylenol)
  - “Get back to normal, whatever your normal is”(Tylenol)

Coming back to SA

- In the flurry after SAMMDRA, a draft Schedule was distributed:
  - Schedule 1: “Medicines which may be sold by authorised or licensed persons without a prescription”
  - **Schedule 2: “Pharmacy prescription medicines”**
  - Schedule 3: “Frequently repeated prescription medicines”
  - Schedule 4: “Main group medicines”
  - Schedule 5: “Substances with an abuse potential”
  - Schedule 6: “Substance of abuse”
  - Schedule 7: “Prohibited substances”
- Did not appear in the 2003 gazetted versions (R509; GG 2472)

Questions

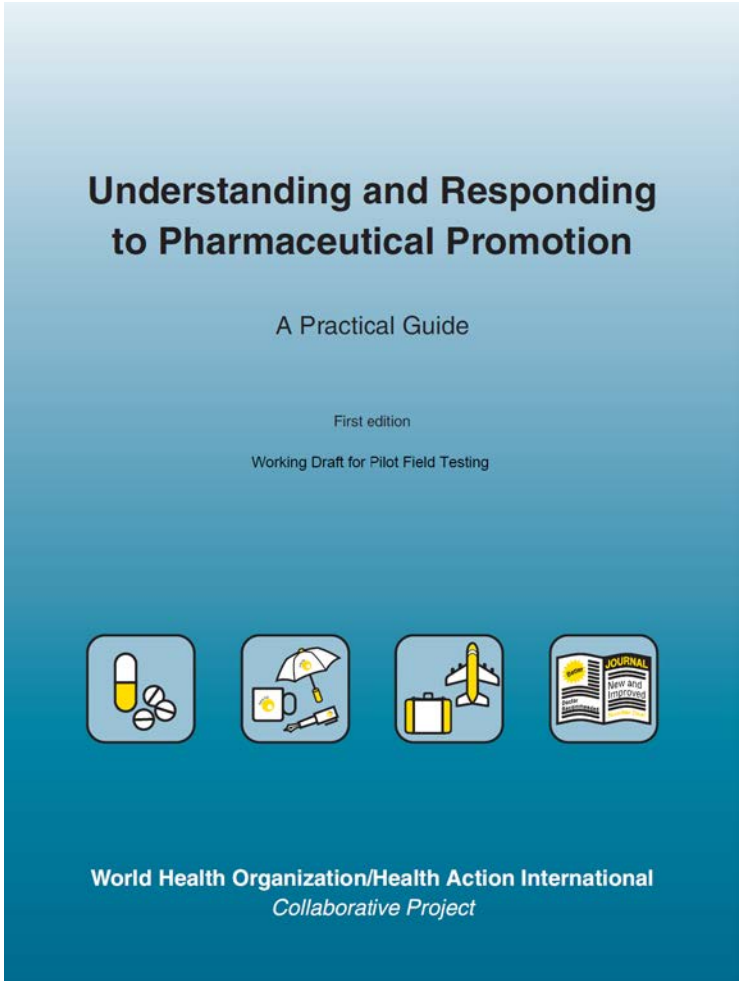
- Should only those medicines that are available for self-selection and purchase be advertised directly to the public?
- Is the “information” loophole being abused?
- Are there legitimate reasons to engage in “marketing” of S2, such as the EPI vaccines?

And what of that “enforceable” code?

Some (radical) ideas

- Reduce the number of Schedules
- Clarify the line between DTCA and permitted advertising
- Publish the marketing code(s) as regulations, binding on all
- Sub-contract enforcement to an industry-funded structure BUT with a fall-back option for necessary sanction (fines, loss of licensure)

Thanks!



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