

Direct-to-consumer advertisements for prescription drugs: what are Americans being sold?

Steven Woloshin, Lisa M Schwartz, Jennifer Tremmel, H Gilbert Welch

Summary

Background Pharmaceutical companies spent US\$1.8 billion on direct-to-consumer advertisements for prescription drugs in 1999. Our aim was to establish what messages are being communicated to the public by these advertisements.

Methods We investigated the content of advertisements, which appeared in ten magazines in the USA. We examined seven issues of each of these published between July, 1998, and July, 1999.

Findings 67 advertisements appeared a total of 211 times during our study. Of these, 133 (63%) were for drugs to ameliorate symptoms, 54 (26%) to treat disease, and 23 (11%) to prevent illness. In the 67 unique advertisements, promotional techniques used included emotional appeals (45, 67%) and encouragement of consumers to consider medical causes for their experiences (26, 39%). More advertisements described the benefit of medication with vague, qualitative terms (58, 87%), than with data (9, 13%). However, half the advertisements used data to describe side-effects, typically with lists of side-effects that generally occurred infrequently. None mentioned cost.

Interpretation Provision of complete information about the benefit of prescription drugs in advertisements would serve the interests of physicians and the public.

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Introduction

The first direct-to-consumer advertisement for a prescription drug appeared in *Reader's Digest* in 1981 in USA.^{1,2} Over the next few years, other such advertisements were published, and the US Food and Drugs Administration (FDA) became worried that little was known about the potential effect of such advertisements on the public. Consequently, in 1983, the FDA initiated an advertising moratorium while it studied the issues and considered the regulatory options.^{2,3} Although they concluded that "direct to the public prescription advertising was not in the public interest,"³ the FDA lifted the moratorium in 1985 because of concerns about freedom of speech and a general consensus that regulations already in place were sufficient to protect the consumer.⁴ After the moratorium had been lifted, direct-to-consumer advertising was permitted provided that the advertisements met certain criteria; specifically, that they presented true and balanced information about the side-effects of the drugs, and their contraindications and effectiveness.⁵ The FDA monitors compliance with these criteria. However, prior approval of drug advertisements is not required.

Reaction to direct-to-consumer advertisements for prescription drugs is mixed. Proponents argue that it provides consumers with information about treatment options, and might help to increase public awareness, and consequently treatment, of serious diseases such as diabetes, hypertension, or depression.⁶ Opponents, however, are worried that direct-to-consumer advertisements might inappropriately increase patient demand for specific, and generally costly, agents, and that this demand might have a negative effect on medical practice and on the physician-patient relationship.^{7–11}

Over the past few years, investment in direct-to-consumer advertising in this field has risen, and now exceeds US\$1.8 billion (figure 1).¹² Concurrently, many pharmaceutical companies have reduced the amount spent on direct-to-physician advertising, which suggests a tactical shift in their focus from physicians to patients. Last year, for example, drug companies spent more on advertisements in newspapers and popular magazines than they did in medical journals (\$685 million *vs* \$473 million, respectively) (www.imshealth.com accessed on Aug 25, 1999).

The content of advertisements aimed at physicians has been researched,^{13–17} but those aimed at patients has received less attention.^{18,19} Our aim was to establish what messages are being received by the public from direct-to-consumer advertisements. Although such advertisements for prescription drugs only appear in the USA and New Zealand, the lessons drawn from the American experience might be of relevance in the UK, where the debate over this type of advertisement is just beginning.^{20–22}

VA Outcomes Group, Department of Veterans Affairs Medical Center, White River Junction, VT 05009, USA (L M Schwartz MD, S Woloshin MD, H G Welch MD); **Center for the Evaluative Clinical Sciences, Dartmouth Medical School, Hanover, NH** (L M Schwartz, S Woloshin, H G Welch); **Norris Cotton Cancer Center, Lebanon, NH** (L M Schwartz, S Woloshin); and **Department of Medicine, Dartmouth Hitchcock Medical Center, Lebanon, NH** (J Tremmel MD)

Correspondence to: Dr L M Schwartz
(e-mail: lisa.schwartz@dartmouth.edu)

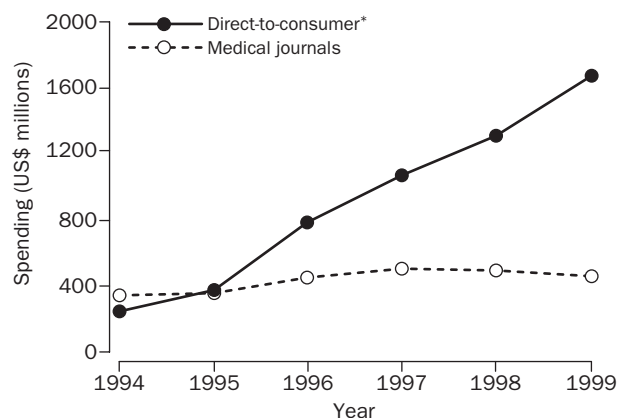


Figure 1: Amount spent by pharmaceutical companies on advertisements for prescription drugs

*Television, print, and other. Amount spent in 1999 was projected on the basis of data from first 9 months of the year.

Methods

Sample selection

We selected ten popular magazines with large distribution and varied readership in the USA.²³ The magazines fell into one of three readership categories: those largely read by women (>70%), by men (>70%), and by the general population (50% women and 50% men) (table 1).²⁴ In terms of circulation, every magazine was in the top five in its category. To create a sample with equal numbers of issues of every magazine, and to avoid seasonal differences in advertising, we examined the first issue of every magazine in every other month between July, 1998, and July, 1999. Thus, we assessed seven issues of every magazine. We found 211 direct-to-consumer advertisements for prescription drugs. Recommended international non-proprietary names and manufacturer details for all drugs mentioned are shown in the panel.

Content analysis

We identified 67 different advertisements and coded their content. We did not include in our analysis the content of the brief summary written in small print on the advertisement. This text must be present for the advert to conform with FDA regulations, but is designed for use by healthcare professionals and few consumers

Magazine	Total circulation (million)	Readership		
		Median age (years)	Women	Median household income (US\$)
Men's				
<i>Gentleman's Quarterly</i>	0.7	30	26%	50 000
<i>Men's Health</i>	1.5	35	16%	54 000
<i>Sports Illustrated</i>	3.3	37	22%	48 000
Women's				
<i>Better Homes & Garden</i>	7.6	45	77%	45 000
<i>Family Circle</i>	5.1	47	90%	42 000
<i>Good Housekeeping</i>	4.5	47	90%	42 000
<i>Ladies' Home Journal</i>	4.6	48	93%	40 000
General				
<i>Newsweek</i>	3.3	43	45%	57 000
<i>People</i>	3.5	40	66%	49 000
<i>Time</i>	4.3	43	47%	55 000

Table 1: Description of 10 popular magazines studied²⁴

read or understand it.²⁴⁻²⁶ We entered codes directly into a computer database (FileMaker Pro, version 5.0, Santa Clara, CA, USA). The codes allowed us to measure several factors: (1) type of product—we categorised the indications for every medication and then grouped these indications into those intended to ameliorate symptoms, to treat disease, and to prevent disease; (2) description of benefit and side-effects—we noted whether the benefit of the product was described with qualitative language (eg, it works) or with quantitative statements (eg, it lowers the chance of dying by 30%). We coded the presentation of the product's side-effects in much the same way. We also coded four other aspects of the presentation of benefit: what studies were cited to support this benefit, whether the benefit was compared to that of other similar medications, the use of personal testimonials about benefit, and whether the widespread use of the drug was mentioned (eg, most prescribed medication); (3) emotional appeal—we coded whether the advertisements appealed to the reader's desire to avoid a feared outcome (ie, cancer or death) or to get back to normal (ie, suggest a return to some normal degree of functioning or being able to do usual daily activities); (4) self diagnosis—we considered advertisements that provided a list of symptoms, or suggested that a particular symptom implied a specific diagnosis, as encouraging self diagnosis; and finally (5) cost—we noted whether the cost of the drug was mentioned, whether a free trial was offered, and whether a financial rebate was proffered in the advertisement

Two investigators (SW, JT) independently coded 21 elements of the content of every advertisement. Inter-rater agreement was good for coding the benefit and potential harms of the drugs (average kappa 0.81).²⁷ As expected, kappa was lower for the more subjective judgments, but remained moderate to substantial (0.52 for encouraging self diagnosis, and 0.62 and 0.53 for emotional appeals relating to fear and getting back to normal, respectively). Inter-rater agreement was less than moderate (<0.4) in only three of the 21 items coded: if the advertisement suggested anyone who cared about themselves would use the product, whether the product was life-enhancing, and the overall focus of the advertisement. To focus on our most reliable findings, we excluded these three items from analysis. In all other instances, wherever the coders disagreed, a third researcher (LS) did an independent assessment. We then resolved disagreements by consensus.

Statistical analysis

We compared the median number of advertisements per issue across the three types of magazines with Kruskal-Wallis tests. This comparison was two-sided and was judged significant at $p < 0.05$. For all analyses we used STATA version 6.0 (College Station, TX, USA).

Results

Advertisement frequency

During the 1 year study, we identified 211 direct-to-consumer pharmaceutical advertisements in 70 issues of selected magazines (median 2.5 advertisements per issue, range 0–12). 59 (84%) issues contained at least one advertisement. Advertisements for products designed for symptom relief were most frequent (133, 63%). Drugs for symptoms of allergies and those related to menopause (eg, hot flashes and vaginal dryness) accounted for most of the advertisements in this category. Those for treatment of urinary incontinence, hair loss, Alzheimer's-related memory loss, erectile

Details of advertised drugs

Trade name	Recommended international non-proprietary name	Manufacturer name and address	Indication
Aricept	Donepezil	Pfizer, Eisai, Teaneck, NJ, USA	Alzheimer's disease
Glucophage	Metformin	Bristol-Myers Squibb, Princeton, NJ, USA	Diabetes
Humalog	Lispro insulin	Eli Lilly, Indianapolis, IN, USA	Diabetes
Rezulin	Troglitazone	Pfizer, New York, NY, USA	Diabetes
Crixivan	Indinavir	Merck, Whitehouse Station, NJ, USA	HIV-1
Combivir	Lamivudine/zidovudine	Glaxo SmithKline, Middlesex, UK	HIV-1
Zithromax	Azithromycin	Pfizer, New York, NY, USA	Otitis media
Prozac	Fluoxetine	Eli Lilly, Indianapolis, IN, USA	Depression
Lamisil	Terbinafine	Novartis, East Hanover, NJ, USA	Fungal infections
Diflucan	Fluconazole	Pfizer, New York, NY, USA	Fungal infections
Monistat	Miconazole	McNeil-PPC, Skillman, NJ, USA	Fungal infections
Synvisc	Hyaluronate	Wyeth-Ayerst, St David, PA, USA	Arthritis
Cardizem CD	Diltiazem	Aventis, Bridgewater, NJ, USA	Hypertension or angina
Evista	Raloxifene	Eli Lilly, Indianapolis, IN, USA	Osteoporosis
Zyban	Bupropion	GlaxoSmithKline, Middlesex, UK	Smoking
Nicotrol inhaler	Nicotine	Pharmacia, Peapack, NJ, USA	Smoking
Nolvadex	Tamoxifen	AstraZeneca Pharmaceuticals LP, Wilmington, DE, USA	Breast cancer
Lipitor	Atorvastatin	Pfizer, New York, NY, USA	Hypercholesterolaemia
Lymerix	Lyme disease vaccine	GlaxoSmithKline, Middlesex, UK	Lyme disease
Premarin	Oestrogen	Wyeth-Ayerst, St David, PA, USA	Osteoporosis/ menopausal symptoms
Accolate	Zafirlukast	AstraZeneca Pharmaceuticals LP, Wilmington, DE, USA	Asthma
Propecia	Finasteride	Merck, Whitehouse Station, NJ, USA	Hair loss
Detrol	Tolterodine	Pharmacia, Peapack, NJ, USA	Bedwetting
Renova	Tretinoin	McNeil-PPC, Skillman, NJ, USA	Skincare
Prempo	Oestrogen/medroxyprogesterone	Wyeth-Ayerst, St David, PA, USA	Osteoporosis/ menopausal symptoms
Zyrtec	Cetirizine	Pfizer, New York, NY, USA	Allergies
Flonase	Fluticasone	GlaxoSmithKline, Middlesex, UK	Allergic rhinitis
Imitrex	Sumatriptan	GlaxoSmithKline, Middlesex, UK	Migraine
Nasonex	Mometasone	Schering, Kenilworth, NJ, USA	Allergic rhinitis
Claritin	Loratidine	Schering, Kenilworth, NJ, USA	Allergy
Flomax	Tamsulosin	Boehringer Ingelheim, Ridgefield, CT, USA	Symptoms of benign prostatic hypertrophy (BPH)
Nasocort	Triamcinolone	Aventis, Bridgewater, NJ, USA	Allergic rhinitis
Zomig	Zolmitriptan	AstraZeneca Pharmaceuticals LP, Wilmington, DE, USA	Migraine headache
DDAVP	Desmopressin	Aventis, Bridgewater, NJ, USA	Diabetes insipidus
Propulsid	Cisapride	Janssen Pharmaceuticals, Ann Arbor, MI, USA	Gastro-oesophageal reflux disease (GORD)
Allegra	Fexofenodine	Aventis, Bridgewater, NJ, USA	Allergy
Viagra	Sildenafil	Pfizer, New York, NY, USA	Erectile dysfunction
Prilosec	Omeprazole	AstraZeneca Pharmaceuticals LP, Wilmington, DE, USA	Heartburn

dysfunction, and wrinkles all appeared ten or more times. Other symptoms targeted included migraines (five), heartburn (five), motion sickness (four), being overweight (three), and bedwetting (one).

The second most frequently advertised medications were those to treat a diagnosed disease (54, 26%), including Alzheimer's (ten Aricept), diabetes mellitus (seven Glucophage, three humalog insulin, and two Rezulin), HIV-1 (seven Crixivan, one Combivir), otitis media in children (six Zithromax), depression (four Prozac), fungal infections (two Lamisil, one Diflucan), arthritis (two Synvisc), and hypertension (one Cardizem CD). Furthermore, 24 (11%) advertisements promoted drugs as preventive medicines, including those for prevention of osteoporosis (six Evista), smoking (four Zyban, three Nicotrol inhalers), breast cancer (four Nolvadex),

hypercholesterolaemia (three Lipitor), and Lyme disease (three Lymerix).

Figure 2 shows that advertisements appeared more often in magazines targeting women (median 4.5, 25%-75% 3-7) than men (2, 0-3) or a general readership (1, 1-2) ($p=0.0001$). Figure 2 also shows that the advertisements differed by readership category, with advertisements for hair loss the most popular in men's magazines and those for allergies most popular in the other two categories.

Advertisement content

We analysed the content of the 67 unique advertisements. Table 2 shows some examples of the headlines from 15 advertisements; few explicitly described the benefits of a product. Instead, most (58, 87%) described the benefit of a medication in vague,

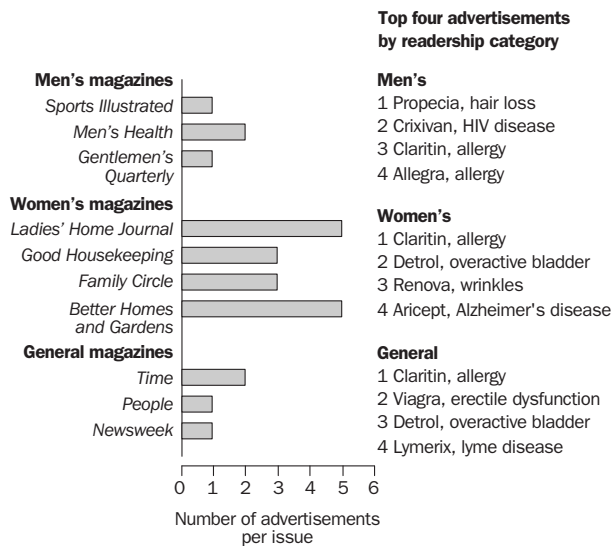


Figure 2: Direct-to-consumer advertisements for prescription drugs in popular magazines

qualitative terms. For example, “Help your child out of the jungle of allergies”, “Naturally, the response has been positive”, and “If your diabetes is uncontrolled . . . Glucophage can help”. We identified three other techniques used to imply the benefit of a product: 12 (18%) advertisements appealed to the drug’s widespread use (eg, “more than 1000 000 people have begun using Rezulin to help manage diabetes”), 16 (24%) used phrases such as clinically proven, proven relief, or proven effective, and 8 (12%) used personal testimonials from ordinary people not experts (eg, “taking Premarin is something I do for myself every day” and “John wanted to tell you about Accolate for asthma . . . but he’s off to the park”).

Even when the benefit was explicit, only nine (13%) of the advertisements actually provided any evidence to support their claims. Advertisements for two products, Propecia and Detrol, presented absolute rates of the relevant clinical outcomes for patients taking the drug compared with those on placebo, thereby allowing the readers to judge for themselves whether the product works. None of the other advertisements provided such complete or balanced information. For example, an advertisement for Renova provided rates for various outcomes for patients on the drug, but did not provide comparable data for a placebo group, and an advertisement for Diflucan presented data that suggested that the drug was as effective as one of its competitors (Monistat), but did not define what clinical cure means. Furthermore, advertisements for Prempro and Lipitor presented only relative risk reductions (in hip or wrist fractures and cholesterol concentrations, respectively) without specifying the base rate—a presentation format known to exaggerate the apparent benefit.²⁸ An advertisement for Lipitor told readers by what proportion their LDL cholesterol might fall, but never mentioned that it was unknown at the time of the advertisement whether Lipitor reduced rates of myocardial infarction or death from myocardial infarction. Additionally, an advertisement for Crixivan quoted data on intermediate endpoints only (HIV-1 viral load) despite its focus on a long life. Finally, three advertisements (two for Zyrtec and one for Combivir) referenced studies that appeared in the text in a footnote. These advertisements did not, however, provide any data from the studies cited. Only the study

Drug	Headline*
Symptom relief	
Viagra	Viagra. Let the dance begin.
Detrol	Overactive bladder is a treatable medical condition. Take clear control. Take Claritin.
Claritin	Everyday they are learning more about estrogen loss. That's why I'm glad I take my Premarin.
Premarin	If your heartburn medicine works so well, why do you keep getting heartburn?
Prilosec	
Disease treatment	
Aricept	Is it just forgetfulness . . . or Alzheimer's disease? Why cheat? When now, it's OK to dose and eat!
Humalog	If you are HIV+, Crixivan may help you live a longer, healthier life.
Crixivan	Your son has another bacterial ear infection. He may need an antibiotic, and remember, he has to take all of it.
Zithromax	Cardizem CD and CardiSense may help you live well.
Cardizem CD	
Disease prevention	
Lipitor	If you're trying to lower your cholesterol, but your numbers still come up high. Ask your doctor for the low down on Lipitor.
Lymrix	"I got Lyme disease last spring and I'm being treated for serious health problems. I couldn't prevent it then, but now you could".
Zyban	On to the nicotine-free pill.
Nolvadex	If you care about breast cancer, care more about being a 1.7 than 36B.

*Advertisement message that appears in the largest font.

Table 2: Headlines of 15 selected advertisements

cited in the Combivir advertisement was published; the Zyrtec advertisements cited unpublished studies done by drug companies.

By contrast with details about the benefit of a drug, 66 (98%) advertisements explicitly specified the medication’s side-effects (in compliance with FDA regulations). 34 (51%) went beyond the FDA requirement and named side-effects and provided quantitative data about their frequency. Statements typically consisted of a list of side-effects, some qualitative judgment about their frequency or severity, and a comparison of the occurrence of side-effects with the drug and the placebo (or sugar pills). For example, “[Side-effects] which occurred about as often as they did with placebo. Most common were headache occurring in 12% of people, drowsiness 8%” and “Like all prescription products, Propecia may cause side effects. A very small number of men experienced certain side effects, such as: less desire for sex, difficulty in achieving an erection, and a decrease in the amount of semen. Each of these side effects occurred in less than 2% of men”.

45 (67%) advertisements made one of two emotional appeals to readers. The most common appeal (40, 60%) was to the desire to get back to normal (eg, “a pill that helps men with erectile dysfunction respond again”). Less frequent, were advertisements (5, 7%) that focused on a feared outcome (eg, “if you care about breast cancer, care more about being a 1.7 than a 36B”). 26 (39%) advertisements encouraged people to consider a medical cause for their experiences. These messages ranged from symptom checklists (eg, common symptoms of overactive bladder) to the labelling of a specific symptom. Typical statements encouraging self-diagnosis were: “Is it just forgetfulness, or is it Alzheimer’s?”, and “If your heartburn is persistent and occurs on 2 or more days a week, you probably don’t have ordinary heartburn. You may have a potentially serious condition called acid reflux disease (also known as gastroesophageal reflux disease or GERD)”.

None of the advertisements mentioned cost, two (Imitrex and Nasonex) offered free trials, and 16 (24%) offered a rebate of some sort (\$5 for Claritin, Zyban, Flomax, Flonase, Nasocort, Zomig; \$10 for Renova; and a rebate programme for DDAVP).

Discussion

The results of our study suggest that direct-to-consumer advertisements are common in popular magazines, particularly in those aimed at women. Furthermore, they all share a similar structure: they link the advertised product with its target condition and invite consumers to share in their own health management. Although most advertisements addressed the relief of common symptoms that many consumers would normally treat themselves with over-the-counter remedies (eg, runny nose), a substantial number targeted more complex treatment decisions usually made by physicians (eg, choice of antibiotic or type of insulin). Additionally, many of the advertisements presented quantitative data about potential side-effects, but very few provided any such data about benefit.

Our study had three limitations. First, we only looked at popular magazines, and did not assess television, radio, or newspaper advertisements. Our results might have differed for advertisements in these other media. We chose to focus on magazine advertisements for several reasons. Logistically, the systematic sampling and analysis of such advertisements is easier than with those that are broadcast. For example, whereas there might be much discussion about which phrase stood out in a radio spot, there was no ambiguity about the headline for a magazine advertisement, which was simply defined as the words with the largest font. Consequently, we believe that our results are more reliable than they would have been had we examined other media. Moreover, several studies suggest that magazines provide the most effective format for direct-to-consumer advertising, since consumers find advertisements for prescription drugs in magazines the most memorable and are more likely to ask physicians about products advertised in magazines than in other media.^{29,30}

Second, content analysis involves subjective judgments. We tried to make our study as reproducible as possible through development of an explicit coding instrument to characterise the advertisements. Furthermore, two authors independently coded the advertisements, and we restricted our analyses to characteristics for which inter-rater agreement had a kappa greater than 0.4.

Finally, we do not know to what extent consumers were actually affected by the advertisements. However, we do know that pharmaceutical advertisements in general succeed in reaching consumers. In a nationally representative survey,³¹ two thirds of adult Americans recalled seeing a prescription advertised, and about 10% asked their doctor for that prescription (of these, 73% said the prescription was made). In another survey,²⁹ about 70% of respondents said that they had seen at least one prescription drug advertisement in the past 3 months (on average, respondents reported seeing five such advertisements in that time frame). Results of a study of physicians³¹ showed that about 80% of dermatologists, cardiologists, internists, and obstetricians or gynaecologists, and 97% of allergists, reported that patients had requested at least one brand name medication. Sales figures also suggest that direct-to-consumer advertisements work. Total US drug

expenditures increased by almost 19% from 1998 to 1999. Prescriptions for the top 25 drugs directly marketed to consumers rose by 34% during this time, compared with 5.1% for all other prescription drugs.³²

Direct-to-consumer advertisements for prescription drugs undoubtedly help to educate consumers about available options. At the same time they encourage consumers to believe that a problem might exist (where they previously would not) and that a pharmacological solution is the appropriate way to deal with it. These characteristics are shared by advertisements for over-the-counter drugs. What is unique in this case, however, is that consumers are also being asked to see their doctor. Does consumer drug advertising therefore promote the medicalisation of an ordinary experience? Our findings suggest that most prescription drugs advertised to consumers target common symptoms (eg, sneezing, hair loss, being overweight), which many patients would have managed without a physician. Although a pharmacological approach might be appropriate for some, the danger is that by turning ordinary experiences into diagnoses—by designating a runny nose as allergic rhinitis—the boundaries of medicine might become unreasonably broad. That the advertised medications require a prescription automatically validates the process of medicalisation. If you have to see the doctor to get a prescription, the experience is officially recognised as a symptom of disease, and the affected person is now a patient. In addition to the difficulties of labelling,³³ this process can result in harm, by exposure of people to medication side-effects and by starting other medical processes in motion (ie, testing). When the symptoms being treated are obvious to patients, and they do not need a doctor to ascertain whether the medication helped, the problem of medicalisation could be mitigated by reclassification of many prescription drugs to over-the-counter status.

Our results indicate that few advertisements present any quantitative data to support claims of benefit. Findings of a study by Moynihan and colleagues³⁴ suggest that news media coverage about medications also frequently lacked information about benefit. Although the lack of detail is less of a concern for products intended to ameliorate symptoms, since patients are reasonably well positioned to judge the medication's effectiveness after a brief trial, it is a major concern for those products meant to treat established disease, such as diabetes, or prevent them. Because the relevant outcomes (eg, end-stage renal disease, development of cancer, myocardial infarction, or dying) are rare and occur in the distant future, patients have no way to judge a medication's effectiveness for themselves. The judgment instead requires quantitative data obtained from randomised trials and, ideally, informed discussion with a physician.

To address this difficulty, the FDA might consider a standardised presentation of benefits and side-effects in advertisements. The format might be one with which consumers are already familiar—ie, a prescription facts box similar to the nutrition facts box required on food products.³⁵ Although the precise structure would require input from many sources, three basic areas might be addressed. First, is the setting. This section would address the questions: What illness is this medication for? and who should consider taking it? Second, what is the potential benefit? This section would include a standard presentation of data (preferably absolute event rates) for both treatment and control groups. Clinical endpoints would be required (or explicit statements that

clinical endpoints are unknown). Finally, what are the potential harms? These should be prioritised. For example, side-effects might be separated into life-threatening and less serious, and might only list the two most frequent (or bothersome) side-effects in each category. For new drugs, a special warning should alert patients that FDA approval is based on limited data, and that the most compelling evidence of safety is a drug's track record over time. The recall of Propulsid, Rezulin, and Baycol, three heavily advertised drugs, should serve to temper the public's enthusiasm about new medications.

Consumers are increasingly exposed to direct-to-consumer advertisements for prescription products. In turn, physicians are increasingly confronted with patients who ask questions, or who make suggestions, on the basis of these advertisements. We hope that our study has provided clinicians with some sense of the content of direct-to-consumer advertisements. Our findings indicate that these advertisements rarely quantify a medication's expected benefit, and instead make an emotional appeal. This strategy probably leaves many readers with the perception that the drug's benefit is large and that everyone who uses the drug will enjoy the benefit. In view of the fact that FDA standards focus on truth and balance, but do not address whether or how data should be presented, our results are not surprising. The provision of complete information about benefit would serve the interests of physicians and the public.

Contributors

Steven Woloshin and Lisa Schwartz conceived and designed the study, coordinated data collection, created the coding instrument, coded advertisements, did statistical analyses, interpreted results, and wrote the report. They are the joint first authors of the paper and the order of their names is arbitrary. Jennifer Tremmel helped create the coding instrument, coded advertisements, interpreted data, and edited the manuscript. H Gilbert Welch helped to design the study, do analyses, interpret results, and was closely involved in writing the report.

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