From Lydia Pinkham to Queen Levitra: direct-to-consumer advertising and medicalisation

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Abstract

The medicalisation of life problems has been occurring for well over a century and has increased over the past 30 years, with the engines of medicalisation shifting to biotechnology, managed care, and consumers. This paper examines one strand of medicalisation during the last century: direct-to-consumer advertising (DTCA) of pharmaceuticals. In particular, it examines the roles that physicians and the Food and Drug Administration (FDA) have played in regulating DTCA in the US. Two advertising exemplars, the late 19th century Lydia E. Pinkham’s Vegetable Compound (for ‘women’s complaints’) and contemporary Levitra (for erectile dysfunction) are used to examine the parallels between the patent medicine era and the DTCA era. DTCA re-establishes the direct and independent relationship between drug companies and consumers that existed in the late 19th century, encouraging self-diagnosis and requests for specific drugs. The extravagant claims of Lydia Pinkham’s day are constrained by laws, but modern-day advertising is more subtle and sophisticated. DTCA has facilitated the impact of the pharmaceutical industry and consumers in becoming more important forces in medicalisation.

Keywords: medicalisation, direct-to-consumer advertising, pharmaceutical

Introduction

The medicalisation of life problems has been occurring for well over a century (Conrad and Schneider 1992, Shorter 1992, Wertz and Wertz 1989) and may have increased in the past 30 years (Conrad 2005, 2007). Medicalisation occurs when previously non-medical problems are defined and treated as medical problems, usually in terms of illnesses or disorders, or when a medical intervention is used to treat the problem. In a recent article we argued that the push towards medicalisation comes more from the creation of medical markets than from professionals’ desire to expand their jurisdiction (Conrad and Leiter 2004). Conrad (2005) has recently suggested that the shifting engines of medicalisation include biotechnology, managed care, and consumers.

In this paper we examine one strand of medicalisation over the last century and a half: the role of direct-to-consumer advertising (DTCA) in the medicalisation of life problems. To do this we compare patent medicine advertising with contemporary DTCA, highlighting the role of federal regulation of pharmaceuticals and advertising as a constraint on
medicalisation during the 20th century. We rely primarily upon secondary data sources plus some primary Congressional documents on DTCA in our analyses. This historical comparison allows us to analyse current DTCA practices not as a new development, but as hearkening back to the patent medicine era, and to analyse the role that the medical profession played in creating and maintaining constraints on the advertisement of pharmaceuticals. Lydia E. Pinkham’s Vegetable Compound was an exemplar of advertising in its time, and erectile dysfunction drugs, including Levitra, are exemplars of the contemporary DTCA era. History is often a great relativiser. By contrasting drugs that were promoted 130 years apart we seek to reflect more clearly on the potentials and pitfalls of DTCA in the 21st century.

Patent medicines in the 19th century

It is important to recall the context of medicine in the 19th century. For example, in the US medicine was not a particularly prestigious profession, with often poorly trained practitioners and extremely limited medical knowledge. When the American Medical Association (AMA) was organised in 1847, among its goals were the improvement of the image of medicine and gaining control over the licensing of physicians (Freidson 1970). The public was ambivalent about the invasive and heroic medicine that most physicians offered, and hospitals were seen as places to go to die. In many communities in America there were no trained physicians, so self-help was an important alternative to medical care. One sector of medical care was so-called ‘patent medicines’.

Medicines could be divided between ‘ethical’ drugs of known composition and patent drugs of undeclared composition. After the Civil War, there was a growing division between ethical drug firms and patent medicine firms (Spillane 2004). The ethical drug firms attempted to distance themselves from patent medicine firms and to align themselves with the fledgling medical profession by adopting the AMA code of not advertising directly to the public (Starr 1982). ‘Indeed, the ethical firms took great pains to publicise the fact that they did not make direct advertising appeals to the general public, but confined their sales pitches to persuading doctors and druggists of the superiority and reliability of their brands’ (Spillane 2004: 2).

Patent medicines in the US originated in Britain and were imported until entrepreneurs discovered the potential domestic market (Young 1961). They were not actually patented but were proprietary drugs with secret or unlisted formulations, with a copyrighted trademark. Patent medicines were advertised directly to the public, encouraging consumers to medicalise everyday symptoms, such as being tired or nervous, through self-diagnosis and self-medication. By the 1850s ‘the medicine taking habit was instilled by large usage in the American people. People wanted to take something and many doctors prescribed to demand’ (Young 1961: 158). Patent medicines were advertised widely in Britain as well. For example, Thomas Holloway, a patent medicine merchant and later philanthropist, in 1880 spent 50,000 pounds, a great sum at the time, on advertising nostrums that made him wealthy but were later deemed to have little medicinal value (Harrison-Barbet 1994).

There were no limits on what manufacturers or sellers could claim; it was caveat emptor for consumers. At first, cure-alls of the snake oil variety were promoted but manufacturers soon discovered that marketing drugs for specific ailments was more profitable (Applegate 1998). Most of these nostrums were promoted with wildly excessive claims as cures for cancer or arthritis, remedies for baldness or small busts, or restorers of manhood. Almost any possible problem could yield to patent medicine cures.
Advertising for patent medicines went directly from the manufacturer to the consumer. The invention of cheap pulp paper for newsprint helped create an important route for patent medicine advertising. Nostrum advertising accounted for nearly one-third of profits in the newspaper business. ‘In 1847, 2000 newspapers ran 11 million medicine ads’ (Anderson 2000: 38). By the 1870s, a quarter of all advertising was for proprietary drugs. Dr. James C. Ayer pioneered saturation advertising for his best-selling Cherry Pectoral, by running ads in every newspaper in the US (Anderson 2000: 41).

Ads often emphasised symptoms most people experienced (e.g. fatigue, pains, indigestion, sleeplessness, headaches), contributing to a cultural medicalisation of life problems. These drug companies borrowed from the rising prestige of medicine while at the same time distancing themselves from doctors, advertising their treatments as cheaper, safer, less brutal and quicker. Nostrum advertisers ‘recognised that nearly every man (sic) is vulnerable to the power of suggestion and sought to make him sick so they could make him well’. (Young 1961: 184). As one analyst suggests, ‘Medicine manufacturers didn’t collect orders and then fill them, as was the practice with other goods. Rather, they created a steady supply of the product, and then generated the demand’ (Anderson 2000: 11). By the early 20th century Americans shelled out $75 million a year, which translates into $1.6 billion in current buying power for patent medicines (Crossen 2004: B1). Patent medicines were at their zenith at the turn of the century, with over 28,000 nostrums, few as successful or well known as Lydia E. Pinkham’s Vegetable Compound (Young 1961).

Lydia E. Pinkham’s Vegetable Compound

After the financial ‘panic’ of 1873, the 54-year-old Lydia Pinkham, an abolitionist and school teacher, saw a business opportunity. She added ingredients to a herbal formula that her husband had received as part of a settlement for a debt and made it into a proprietary medicine, which she brewed and bottled in her cellar in Lynn, Massachusetts. Two years later, upon the advice of her son, she began marketing her product as Lydia E. Pinkham’s Vegetable Compound for ‘women’s weaknesses,’ including menstrual cramps. Lydia’s motto was ‘Only a woman understands women’s ills’ (Pinkus: 2002). The compound had a pungent odour and a sharp aftertaste, and is thought to have contained black cohosh (roots and stems of a perennial herb), fenugreek seed, and at least 18 per cent alcohol (as a preservative, because Pinkham was a temperance supporter).

Pinkham was a pioneer in DTCA. After placing an elaborate first page newspaper ad in the Boston Herald in 1876, sales of the product rose significantly, and Pinkham became convinced of the value of advertising. In 1879, her son suggested that she place a likeness of herself on the label, replete with her grandmotherly features. Sales of her product increased dramatically and her picture became one of the most well known female images in print at the time (Simmons 2002). She encouraged women to write to her in confidence for counsel, and answered their letters, a service which continued even after her death in 1883. These letters offered sterling testimonials of the product’s efficacy.

Over the years, more maladies were added to the advertisements. For example, an 1887 ad in the New York Times proclaimed:

LYDIA E. PINKHAM’S VEGETABLE COMPOUND Offers the SUREST REMEDY for the PAINFUL ILLS AND DISORDERS SUFFERED BY WOMEN EVERYWHERE. It relieves pain, promotes regular and healthy reoccurrence of periods and is a great help to young girls and women past maturity. It strengthens the back and the pelvic organs, bringing relief and comfort to tired women who stand all day in home, shop and factory.
Leucorrhea, Inflammation, Ulceration and Displacements of the Uterus have been cured by it, as women everywhere gratefully testify. Regular physicians often prescribe it. Sold by all Druggists $1.00 (cited in Applegate 1998: 80).

Lydia Pinkham’s advertising to consumers was innovative and ubiquitous. Her Vegetable Compound was everywhere; her face was on labels, in newspaper ads, on fences in rural America, on trading cards, and in drug store displays. Very few nostrums had such wide recognition. In 1912 sales exceeded $1 million. In 1914, in response to federal regulation, the company changed the formula to remove the alcohol so it would not be taxed as an alcoholic beverage and modified its claims about effectiveness (Applegate 1998). After 1925 or so, sales of the product declined. The patent medicine companies’ DTCA had been wildly successful for some companies but, increasingly, it was opposed by the medical profession and other articulate critics.

Campaigns against patent medicines and DTCA

In Paul Starr’s (1982: 128) words, ‘The nostrum makers were the nemesis of physicians’. They competed with physicians for medical business, offered supposedly safer but unproven ‘cures’, and undercut the authority of medicine. Patent medicines, with secret formulas and advertising to the public, posed a threat to physicians’ still fledgling professional aspirations. Both patent medicines and physicians grew in popularity and use in the late 19th century. In fact, despite the competition, physicians also used patent medicines in their practices; by one count, in 1874 one per cent of physicians used patent medicines, increasing to over 20 per cent by 1902 (Starr 1982: 130). By another count, 90 per cent of doctors were prescribing proprietary medicines (Young 1961: 160).

The medical profession’s concern about patent medicines manifested itself in a variety of campaigns against the industry. In 1900 the AMA started a campaign ‘to make the “legitimate proprietary drugs” respond to the ethics of medicine’, which included disclosing formulas and not advertising directly to the public (Starr 1982: 129). The AMA announced it would stop taking patent medicine advertisements around this time, then relaxed their standards for revenues’ sake. As Young notes, ‘In 1905, JAMA did not have as many bad ads as many medical journals, but that is only faint praise’ (1961: 207). Medical journals and newspapers continued to rely on patent medicine advertising as a major source of revenue.

In 1906, the AMA set standards for both advertising and prescribing medications with the publication of New and Nonofficial Remedies (Starr 1982: 131). Drugs were not accepted if their manufacturers made false advertising claims, refused to disclose their drugs’ composition, advertised directly to the public, or whose ‘label, package or circular listed the diseases for which the drug was used’ (Starr 1982: 132). Ethical drug companies had a ‘gentleman’s agreement’ with physicians, under which physicians would legitimise the drugs with the ‘ethical’ label and the drug companies would acknowledge physicians’ authority to diagnose illness and determine treatments. This agreement did not guarantee that drugs were safe, as ethical drugs might contain poisons such as arsenic. Rather, the term ‘ethical’ meant that the drug companies would be honest about the contents of their wares, would not knowingly make fraudulent claims about their efficacy, and would not bypass physicians’ authority. The line was drawn. Companies could advertise to physicians only or they could not advertise to physicians at all. Despite losing revenues, newspapers began to cut back on DTCA for drugs that the AMA listed as fraudulent.
Muck-raking journalists were also on the case of exposing useless potions that were sold in the name of health. In 1903 the *Ladies Home Journal* published an exposé on the dangers of patent medicines. Samuel Hopkins Adams’ in-depth investigative series, ‘The Great American Fraud’, published in *Colliers Weekly* in 1905, really made the public case against patent medicines. The articles named specific names and identified specific false promises and deceptions made in patent medicine advertising. The writers and editors of these magazines advocated for federal regulation on the promotion and sale of patent medicines (Applegate 1998).

Some states had already considered regulating patent medicines, but they were ‘easily outmatched by the well funded lobby of the Proprietary Association of America’ (Crossen 2004). The AMA distributed 150,000 copies of these articles from 1905 to 1910 (Starr 1982: 130). Adams’ investigation, along with Upton Sinclair’s *The Jungle*, a muckraking exposé of the meat packing industry, the AMA’s campaign against nostrum marketing, and scientist and crusader Harvey W. Wiley’s work with Congress, finally resulted in the Pure Food and Drug Act of 1906, the first federal legislation to control drugs and medications.

**Federal regulation and drug advertising**

The Act put constraints on advertising and marketing, stating that manufacturers had to print accurate ingredients on the label, they could not make false or exaggerated claims on the label, and that drugs had to meet certain standards of purity. As one indicator of the Act’s impact, the 1897 Sears Roebuck catalogue had 17 out of 770 pages dedicated to the ‘Drug Department’; the 1908 catalogue had fewer than two pages of 1200 on drugs (Isreal 1968 cited in Pinkus 2002). The federal law was amended in 1912 to include claims of effectiveness and in 1920 to cover newspaper advertising (Starr 1982: 132). By 1915, Lydia E. Pinkham’s Vegetable Compound had to cease advertising specifically for women’s disorders and instead made the innocuous claim, ‘Recommended as a Vegetable Tonic in conditions for which the preparation has been adapted’ (Starr 1982: 132).

Between 1906 and 1980, the FDA consolidated regulatory authority over prescription drugs and gained jurisdiction over all communication from the pharmaceutical industry. Likewise, in the first half of the 20th century, physicians continued to solidify their medical authority over diagnosis of illness and prescribing drugs as treatments (Starr 1982). Both the profession of medicine and the FDA operated to constrain the advertising of pharmaceuticals during most of the 20th century, thereby also constraining consumers’ access to pharmaceuticals to treat their aches and troubles. This concurrent consolidation of medical and regulatory authority began to break down in the 1980s.

**The emergence of DTCA of prescription drugs: 1981–1996**

Direct-to-consumer advertising for prescription medications has fuelled the medicalisation that analysts noted as increasing in Western societies in the 1980s (Conrad 1992). DTCA has become a major source of expanding medical markets and public engagement with medical solutions for life’s conditions and problems (Conrad and Leiter 2004).

In 1981, Boots Pharmaceutical (a British firm) issued the first DTC broadcast ad for an ibuprofen product called Rufen and Merck Sharp & Dohme advertised a pneumonia vaccine called Pneumovax (Pines 1999). According to Pines, who was at the FDA at the time, the FDA’s first response was shock, and ‘Physicians at the FDA generally felt that such
advertising was inappropriate’ (1999: 492). Yet the very next year, FDA Commissioner Arthur Hull Hayes, Jr. gave a speech before the Pharmaceutical Advertising Council, in which he stated that, ‘In sum, my impression is that we may be on the brink of the exponential growth phase of direct-to-consumer promotion of prescription products’ (U.S. House of Representatives 1984: 1).

In that speech, Hayes describes the changing dynamics between patients, physicians, and pharmaceutical companies:

There was a time when prescription product advertising to consumers was limited to an occasional institutional ad. Physicians were your industry’s sole target audience. Patients had an insignificant voice in choosing prescription products they were given. Generic drugs were not yet an issue. The demographics of consumer publications were such that a very high percentage of the exposures paid for by a prescription product advertiser would be to people who could not possibly use the product. And members of the advertising profession did not want to run the risk of offending physicians by appearing to circumvent them or undercut their freedom of judgment.

It is no longer so. One result of the consumer movement has been increasing numbers of patients who demand a role in the selection of all their health care products. The Physicians Desk Reference – as Charlie Baker would be pleased to tell you – is a best seller. It’s difficult to remember the last time that the weekly book best seller lists didn’t include several volumes about prescription drugs and health care. Specialised health magazines have proliferated. And 90 per cent of prescriptions are now for drugs no one heard of only a generation ago (U.S. House of Representatives 1984: 23–24).

Hayes’ speech describes a shift to more consumer-demanded healthcare, with lay persons playing a larger role in determining their own needs and treatments, opening the door to increased medicalisation by health ‘consumers’.

In response to this speech, the FDA commissioned a study of physicians and pharmacists regarding patients and prescriptions, and the US House Subcommittee on Oversight and Investigations sent out letters to 37 pharmaceutical companies asking for their position on DTCA (U.S. House of Representatives 1984). Not surprisingly, almost all of the response letters said that the companies would engage in DTCA if their competitors did so. What is striking about the letters is that they were almost unanimous in their negative responses to the potential of DTCA. Wayne Davidson, president of the U.S. Pharmaceutical and Nutritional Division of the Bristol-Myers Company, wrote:

It will be very difficult, if not impossible, for a federal agency (FDA or FTC) to distinguish between when self-diagnosis is possible and when it is not. Where the line is drawn will be the subject of much legal controversy. We are of the opinion it is much better not to attempt to draw the line, but to prohibit this type of advertising to the patient consumer. This type of advertising will also put the prescribing professionals on the defensive in the relationship with their patients, just the reverse of the most productive relationship. . . . (U.S. House of Representatives 1984: 89).

Similarly, Thomas Collins, president of Smith Kline & French Laboratories, replied:

We do not believe that PDAC [Prescription Drug Advertising to the Consumer] is a good idea. . . . We believe that the chances for damaging doctor-patient relations and for
encouraging costly competitive battles are real, while the likelihood that meaningful patient education will occur is small. We certainly welcome, let me stress, the increased consumer participation in health decisions in recent years. It is well for patients to take part, to the extent they wish, in decisions affecting their care. It is however very important to differentiate the capabilities of advertising from those of educational programs. Advertising can inform, but it is not education; and PDAC should not be portrayed as part of the education process (U.S. House of Representatives 1984: 152–3).

Both of these letters voice concerns about consumers’ ability to self-diagnose, essentially questioning consumers’ medicalisation of their own problems and highlighting the important role that physicians play as gatekeepers in the medicalisation process.

In September of 1982, at the beginning of these explorations, the FDA requested a formal, voluntary moratorium on DTCA (Feather 1998 cited in Pines 1999). In 1983, the FDA issued a policy statement calling for a ‘period of cautious restraint on the part of would-be prescription drug advertisers’ (50 Fed. Reg. 36677 (1985)). Then in 1985, the FDA withdrew its moratorium, concluding that ‘for the time being, current regulations governing prescription drug advertising provide sufficient safeguards to protect consumers’ (50 Fed. Reg. 36677 (1985)). According to Pines, the FDA’s policy change was ‘not intended to open the floodgates for DTC advertising. On the contrary, it was a reluctant recognition by the agency of a new trend, and was intended to ensure that FDA had jurisdiction and that the industry had a framework within which to consider DTC advertising’ (1999: 493).

After the FDA withdrew the moratorium, companies increased their print advertising considerably, with companies spending $12 billion in DTCA in 1989 (Medical Advertising News 1999 cited in Pines 1999). However, the cumbersome ‘fair balance’ and ‘brief summary’ requirements indirectly kept companies from engaging in DTC broadcast advertising, constraining their outreach to consumers.

**DTCA comes to TV: 1997 onward**

On 8th, August 1997, the FDA issued draft guidelines for DTCA of product-specific prescription drug broadcast advertisements (62 Fed. Reg. 43171), which described how television and radio ads might fulfill FDA requirements for ‘adequate provision’ of product information and a ‘major statement’ of the drug’s major risks. Prior to this, these requirements made TV drug advertising all but impossible.

Under this new interpretation of the regulations, the FDA would allow DTC broadcast advertising if the advertising would provide consumers with the product’s approved labelling information through one of four sources: a toll-free telephone number that consumers could call; a concurrent print advertisement containing a brief summary of risk information; a web page (URL) that included the package insert; or additional product information from pharmacists, physicians, or other healthcare providers (Food and Drug Administration 1999). The FDA also announced that it wanted the industry to conduct studies of the effects of DTCA and that it would evaluate the policy in two years (Pines 1999). On 6th, August 1999, the FDA issued its final guidance for DTCA of prescription drugs (64 Fed. Reg. 43197), making very few changes to its original guidelines.

Three types of prescription DTCA would be permitted: product claim advertisements, which included the product name and specific therapeutic claims; reminder advertisements, which gave the name of the drug but did not state its use; and so-called help-seeking advertisements, which told consumers about unspecified treatment possibilities for diseases...
or conditions (Goldman 2005). From our perspective, all three contribute to medicalisation, with the help-seeking ads the most likely to promote it.

This shift in policy was controversial. Those supporting the change suggested that there would be a public health benefit, depicting broadcast DTCA as ‘an excellent way to meet the growing demand for medical information, empowering consumers by educating them about health conditions and possible treatments’ (Holmer 1999 quoted in Hollon 2005). Critics voiced reservations, especially regarding how DTCA could lead to overprescribing, how it emphasised newer and more expensive medicines over cheaper existing ones, and regarding ‘the medicalising of normal human experience’ (Mintzes 2002, Frosch et al. 2007).

Broadcast DTCA has grown enormously in the past years, up from $55 million in 1991 to $4.2 billion in 2005 (USGAO 2006), with 330 per cent growth in DTCA from 1996 to 2005 (Donahue et al. 2007). The ads focus on chronic problems affecting relatively healthy people, with large potential treatment populations and long-term usage, including drugs for allergy, anxiety, obesity, arthritis, erectile dysfunction, and high cholesterol. About 20 prescription drugs make up 60 per cent of the pharmaceutical company spending on DTCA (Hollon 2005) and advertising for one specific drug can have ripple effects for all drugs that are touted for a particular condition. The US Government Accountability Office has estimated that ‘each 10% increase in DTC spending within a drug class increases sales in that class by 1%’ (2002: 15). DTC ads for drugs to treat erectile dysfunction have become common, especially on television.

**DTCA and erectile dysfunction**

The Viagra story is by now a familiar one. We need not repeat it in detail here (see Conrad and Leiter 2004, Loe 2004) but will review some points that are relevant to DTCA and medicalisation. In 1992 a consensus conference officially labelled what used to be called impotence as ‘erectile dysfunction’ and as a biogenic rather than psychogenic problem. In March 1998, the FDA approved Viagra (sildenafil citrate) as a treatment for this condition. In the early days it was marketed primarily to older men with erectile problems and for erectile dysfunction associated with prostate cancer, diabetes, and other medical problems (Loe 2004). Estimates for prevalence ranged from 10 million to half of all American men (Laumann et al. 1999). The market potential was not lost on the drug companies, so within a short time Pfizer Pharmaceuticals began advertising Viagra more broadly. With an ageing population, a high prevalence of erectile dysfunction, and an even broader concern with sexual performance, the potential market was huge. DTCA expanded the market to include virtually any man who might consider himself as having erectile problems or just wanted a boost in performance (Conrad and Leiter 2004). Within a few years of Viagra’s introduction, pharmaceutical competitors came on the scene.

Levitra was introduced in 2003 as a faster drug with fewer adverse effects than Viagra. Levitra ads focused more on recreational uses, targeting ‘men who may have successful sexual relationships but simply want to improve the quality or duration of their erections’ (Harris 2003). The most visible DTCA spokesman for Levitra was Mike Ditka, a former hardnosed football coach and Hall of Fame player. Levitra became an official sponsor of the National Football League (NFL) and in 2004 became the first pharmaceutical ad during the Super Bowl with its ‘Levitra Challenge’. In the week after the Super Bowl, Levitra prescriptions grew by 15 per cent (GSK news release 2004). However, there may be limits to what kind of DTC ads are acceptable for television. The FDA asked Bayer Pharmaceuticals, maker of Levitra, to pull its 15-second spot of ‘My Man’ ads that promoted
Levitra. The ads starred an attractive actress, Marie Silvia – hailed as ‘Queen Levitra’ by the *Wall Street Journal* – who said how the drug’s ‘strong and lasting effects’ provide a ‘quality experience’ (Snowbeck 2005). Apparently the ad did not include enough safety information and made a misleading comparison with other drugs for the condition. While the short version of the Queen Levitra ad was pulled, the 45-second version continued to be aired (Snowbeck 2005).

DTCA has shaped and developed the erectile dysfunction drug market. In 2004, drug companies spent over $382 million in advertising these drugs in the US, with sales of $1.36 billion (Snowbeck 2005). The demand for these drugs may have stabilised; doctors wrote 10 per cent fewer new prescriptions in October 2005 than the year before (Berenson 2005). While erectile dysfunction has been firmly medicalised, there may be limits to the demand for medical solutions for sexual difficulties.

From Queen Lydia to Queen Levitra

Lydia Pinkham was the queen of patent medicine. Her product, cooked up in her cellar and composed of herbs and alcohol, epitomises the patent medicine industry in the late 19\textsuperscript{th} and early 20\textsuperscript{th} centuries, which was built largely upon proprietary recipes and grand promises printed on cheap, pulp paper. Patent medicines contributed to a cultural medicalisation of life problems. Advertisements told consumers that they could diagnose their own symptoms and use patent medicines to alleviate those symptoms, without having to resort to consulting physicians. These symptoms ranged from everyday aches and pains, such as being tired or nervous, to serious diseases such as tuberculosis. While over-the-counter medications have continued to fill this self-help niche, during most of the 20\textsuperscript{th} century the profession of medicine and the FDA successfully constrained the advertising of pharmaceuticals to the public, making physicians key gatekeepers to prescription drugs.

More recently, ‘Queen Levitra’ was on television, touting Levitra’s ability to produce ‘strong and lasting effects’ and a ‘quality experience’, alluding to the sexual ability that men may gain (to women’s benefit) by taking Levitra. We have come a long way since the days of patent medicine 100 years ago. Yet DTCA hearkens back to those days, in that the pharmaceutical industry is once again reaching out to consumers directly when selling their products and creating wider avenues to the medicalisation of life problems. In this way, the advertising of pharmaceuticals is becoming more like the advertising of over-the-counter medications. In fact, the distinction between prescription drugs and these medications may be less clear now than in the mid-20\textsuperscript{th} century, due to DTCA as well as some pharmaceuticals shifting from prescription to over-the-counter status. For example, Claritin, a well-known antihistamine that was advertised heavily on broadcast media early in the contemporary DTCA era, is now available over the counter.

Pharmaceutical companies’ advertising activities have changed considerably, with important implications for medicalisation, as summarised in Table 1. Before 1906, drug manufacturers were split into two increasingly distinct camps: ethical drug manufacturers and patent drug manufacturers. Much of the distinction between these two types of manufacturers was based on the type of advertising that they used to sell their wares: ethical drug companies advertised to physicians only, while patent medicine companies advertised directly to consumers. This gentleman’s agreement allowed physicians to legitimise ethical drugs and ethical drug companies to defer to physician’s authority in diagnosis and prescribing. During this period, physicians, patent medicine manufacturers, and consumers contributed to expansion of medical definitions and treatments for life problems.
After Congress passed the Food and Drug Act of 1906, the AMA stepped up its efforts to police the boundaries between ethical and patent drug firms, working with the federal government to identify firms that violated the Act. Through this legislation, the government could disrupt the direct relationship between patent drug producers and consumers, protecting consumers in the name of public health. As a result of these efforts, advertising for prescription medications became restricted between 1906–1980 to physicians only and drug companies had a limited role in medicalisation. It is important to note that drug companies always had direct access to consumers for over-the-counter medications. They did not require a medical prescription and were advertised widely. These were typically cold remedies and headache medications, although they would occasionally also encourage medicalisation of new ills such as the ‘halitosis’ (bad breath) mentioned in Listerine mouthwash advertisements. However, physicians’ control over access to pharmaceuticals limited medicalisation.

Around 1981 pharmaceutical companies began to test the gentleman’s agreement concerning prescription advertising by initiating limited forays of DTCA. There were no laws against advertising drugs but firms were unsure of what was permissible. A 1985 FDA statement permitted the pharmaceutical industry sufficient latitude to allow a broader engagement with print ads for prescription drugs. The drug companies did not yet venture into broadcast ads due to the difficulty of fulfilling the FDA’s requirements regarding the ‘major statement’ of risks and side effects of drugs.

The reinterpretation of FDA advertising guidelines in 1997 had major implications for DTCA, especially on television. Now drug companies could market directly to consumers. Physicians became gatekeepers for drugs advertised direct to consumers rather than initiators of pharmaceutical treatments: ‘Ask your doctor if [name of drug] is right for you’. The drug industry and consumers, facilitated by DTCA, have become major players in medicalisation with physicians relegated to somewhat less of a role (Conrad 2007). In fact, direct access to consumers has increased the pharmaceutical industry’s incentive to medicalise human problems, encouraging consumers to self-diagnose and request drugs that they see on TV. Furthermore, the Internet has become another direct avenue from pharmaceutical companies to consumers, and one that is not limited to national boundaries. This electronic form of DTCA can already be considered as a factor in internationalising medicalisation. Some Internet sites bypass physicians altogether with a veneer of medical oversight.

The impacts of DTCA on medicalisation and health are complicated. DTCA can raise awareness about disease and risk, and provide some useful medical information for

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Table 1 Summary of drug advertising activities and implications for medicalisation
consumers, although most physicians believe that DTCA does not provide balanced information (Perri et al. 1999, Hollon 2005). DTCA has significant impact on patient demands, physicians prescribing, and by implication, medicalisation. DTC advertising leads to increased requests for advertised medicines and more prescriptions (Mintzes et al. 2003). A study by Kravitz et al. (2005) sent trained standardised patients to physicians. The ‘patients’ presented symptoms of either major depression or adjustment disorder and made DTC-related requests of a brand specific drug, a general class of drugs, or no request. ‘Patients’ who made brand-specific requests or general requests for drugs were much more likely than patients who made no requests for drugs to receive a prescription. Requesting medications increased the amount of prescribing, at least for these two disorders. What is disturbing here is that although there are no data to support the use of antidepressants for adjustment disorder, half of those who requested it, based on DTCA, received prescriptions. The authors conclude that DTCA ‘may stimulate prescribing of more questionable than clear indications’ (Kravitz et al. 2005: 2000).

The scrutiny and criticism of DTCA appears to be increasing from various quarters. U.S. Senate Majority Leader Bill Frist (a physician) expressed concerns that DTCA creates a wedge between physicians and patients (Henderson 2005). An article in Advertising Age questioned whether recent drug safety scares may shift the balance of power back to physicians (Thomaselli 2005) as consumers respond to cases such as Vioxx’s well-advertised entry and quick removal from the market. In July 2005, the drug industry drafted guidelines that called for a period of notifying doctors about new drugs before advertising to consumers (Saul 2005a). These new voluntary guidelines would ‘virtually eliminate 15-second spots’ because they do not provide enough time to list risks, and require that all ads will be submitted to the FDA for review before they are used (Saul 2005b). While it is too early to judge the impact of these changes on medicalisation, it seems doubtful that these changes would significantly decrease the roles of DTC advertising and consumers on medicalisation.

Conclusion

While DTCA appears to be flourishing, even FDA personnel seem concerned about its effects on medicalisation. In a meeting about DTCA, Janet Woodcock, the director of the FDA’s Center for Drug Evaluation and Research, highlighted two concerns: ‘First, that many common and relatively minor complaints of daily life represent diseases. This has been called the medicalisation of life. And second, the perception that all life complaints can and perhaps should be treated with a pill’ (Food and Drug Administration 2003: 22). Broadcast DTCA is now only permitted in the US and New Zealand and is prohibited in the United Kingdom and most developed countries. Should DTC advertising be introduced in Europe (Watson 2003), most of the same issues would exist (Metzl 2007).

One of the ironies of DTCA is that it expands the relationship of drug companies, physicians and consumers, returning it to a situation similar to Lydia Pinkham’s day, when the drug manufacturers had a direct and independent relationship with consumers. It encourages self-diagnosis and requests for treatment. It allows pharmaceutical companies to create specific markets for their products and promote them to waiting customers. Of course, with stronger government regulation and a more powerful medical profession, the situation is also different from what it was a century ago. The extravagant claims of Lydia Pinkham’s day are constrained by laws, but modern advertising is both more subtle and sophisticated than what was available to the patent medicine peddlers. It seems clear that
the pharmaceutical industry and consumers are becoming increasingly important players in medicalisation and that DTCA facilitates this shift.

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