Direct-to-consumer advertising (DTCA) of pharmaceutical and health-care services: From hemp oil to hair transplants

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Abstract Healthcare leaders are faced with more and greater financial challenges than ever before. They are being mandated to preserve any existing sources of revenue and aggressively seek out potential new sources of revenue generation. This paper discusses the elephant in the room among many institutions' boldly stated 'missions': financial success. The paper also connects this with the growth of consumer-targeted marketing strategies to attract new patients, including media advertisements. Healthcare executives and providers must be sensitive to the perceived conflict of interest between revenue generation and serving the public. While the culture may continue to shift, one component must remain unwavering — the needs of the patient must always supersede the financial interests of the provider or the institution.

KEYWORDS: advertising in healthcare, Healthcare leaders, consumer-targeted marketing strategies, revenue generation

INTRODUCTION

When it comes to everyday consumer products, everyone wants something different. 'Higher quality' in a spaghetti sauce depends on the whims of individual preference.[1] With health care, everyone wants the same things: accessibility, convenience, access, impeccable safety and high quality at a fair price. Unlike with consumer products, marketing in healthcare goes only so far. Its objective nature means that long-term success requires tangible results, sound metrics and clearly defined outcomes. Healthcare organisations understand, and work hard to achieve, excellent outcomes for metrics such as safety and quality to help enhance and protect brand reputation. They also make for great marketing. Conversely, bad outcomes destroy consumer confidence, alter perception, damage brand strength and drive customers to the competition.[2] Getting care at a high-ranking, highly branded and marketed healthcare organisation gives many people great comfort. Is this higher quality or perception?

HISTORICAL PERSPECTIVE OF DIRECT-TO-CONSUMER PHARMACEUTICAL ADVERTISING (DTCPA)

1962: the Food and Drug Administration (FDA) acquired jurisdiction over direct-to-consumer advertising (DTCA) of prescription drugs.
1962–1980: manufacturers promoted their products to physicians through 'in-office' visits.
1980: the American Medical Association (AMA) reversed its 133-year-old ban on advertisements for health-care services. This was followed promptly by the first print advertisement in 1981 from Merck. Manufacturers began adding journal advertisements to their in-office promotions to physicians. Television and radio advertisements remained rare, as the FDA required that pharmaceutical manufacturers provide proof of effectiveness and safety. By including even brief summaries of potential adverse reactions/contraindications, long and expensive advertisements resulted.
1997: regulations on the DTCA of prescription drugs were liberalised. The FDA made it easier to advertise on television by ruling that 'adequate provision' of information about drug risks and benefits could be made by referring consumers to a toll-free number, print advertisement or website. Diminished FDA barriers resulted in more television advertisements promoting treatments for a wide array of conditions. The pharmaceutical industry increased DTCA spending and shifted its budget from print to broadcast media.[3] Physicians were up against weak or uncertain clinical indications, suggested but unproven harm and strong patient demand.[4]

Today, DTCA for health-care products and services is a US$1bn per year industry experiencing double-digit annual growth.[5] This parallels a rise in DTCPA, which is legal only in the USA and New Zealand (among industrialised countries) and has FDA oversight to limit uninformed patients requesting and receiving inappropriate medications, negatively impacting their welfare and burdening the system. There is a direct relationship between advertising and physician and patient behaviour, such that every US$1.00 spent on DTCA increases sales by US$2.20–US$4.20. Although a significant percentage of physicians report being asked about an advertised drug, a smaller percentage actually lead to a prescription. Yet it is difficult to determine the full extent to which medication inquiries were directly influenced by advertisements as against other sources of information (family, friends or the Internet) indirectly influenced by DTCA.[6]

FDA regulations state that an advertisement must (a) not be false or misleading, (b) present balanced information describing the risks and benefits, (c) include facts material to advertised uses and (d) include every labelled risk.[7,8] Regulatory violations with subsequent large fines have been frequent, despite explicit FDA guidance.[9] Additional oversight comes from the Federal Trade Commission (FTC), which mandates that testimonials include disclaimers and descriptions of the results a 'typical' patient may expect to see.[10] Despite these guidelines, many television, social media and print advertisements exist that linger in the 'grey zone' of compliance as well as information about drug risks and benefits. For example, through DTC promotion, 'stem cell centres' claim to offer patients non-FDA-approved stem cell therapy for heart failure. Patients may seek out this option and expose themselves to uncertain medical risks at considerable cost.[11]

Constitutional protection of speech must be balanced with the need to protect public health. Banning DTCA is unlikely given First Amendment concerns. In addition to protecting the rights of pharmaceutical and medical device manufacturers to market, including protecting First Amendment rights, proponents argue that DTCA informs consumers of new therapies; motivates them

to seek care; provides valuable information about options; empowers and engages patients to participate in their own health care by informing them about treatment options; averts underuse of effective treatments; increases medication adherence; strengthens patients' relationships with physicians; makes patients more aware of treatments and feel more engaged in their own care; encourages the making of appointments to discuss conditions they had not previously discussed; educates, informs, promotes dialogue and strengthens relationships with providers; encourages compliance; reduces underdiagnosis and undertreatment; removes stigma associated with diseases; and encourages competition, which lowers prices. Contrary arguments contend that DTCA provides incomplete and biased information; leads to inappropriate prescribing; increases costs as a result of added costs of advertising; consumes physician–patient time (discussing advertised illnesses and medications); fails to present accurate and balanced analysis of benefits/harms; results in less appropriate prescribing, less cost-effective treatments, taking medication the patient does not need and is unlikely to benefit from, and choosing medications less safe/effective than alternatives; convinces people to use expensive products that are no better than alternatives, and experimental procedures without proven results; encourages false hope and false expectations; misinforms; overemphasises benefits; promotes new drugs before their safety is fully known; encourages overutilisation and inappropriate/overprescribing; strains relationships with health-care providers; wastes appointment time; is poorly regulated; increases costs; creates a need where one did not exist; increases the likelihood of services being used inappropriately; exposes patients to unnecessary risks; perpetuates the perception that more is better and higher tech is better; encourages unproved or unnecessary procedures; highlights benefits without quantifying positive claims; and promotes the utilisation of brand name drugs over generics.[12–15]

The potential to exaggerate or overestimate expectations or potential therapeutic benefits of treatment drives demand for inappropriate and unnecessary demand for services and raises costs. Marketing strategies that capitalise on misleading, persuasive, emotional appeals with incomplete promotional claims and misperceptions are very effective in changing behaviour and influencing expectations. But they may also take a human toll if patients and their families are guided by fear or given false hopes and unrealistic expectations for cures or high survival rates. Cancer centres may tout patient testimonials focusing on survival, sometimes without disclaimers or complete information about prognosis, indications, risks, benefit quantification, cost, coverage, options or alternatives.[16]

Other than vague ethical guidelines suggested by the ethics committees of individual societies or organisations, physician, institutional and other health-care services ads are not formally regulated, despite well-recognised risks of inappropriate or excessive testing and procedures.[17] The American College of Obstetrics and Gynecology (ACOG) ethics committee states that it is ethical for physicians to market practices provided that communication is truthful, honest, and transparent and not misleading or deceptive. Paid advertising must be identified as such. Advertising should not denigrate the competence of colleagues.[18] These are subjective and fraught with the potential for abuse.

The significant changes described earlier were prompted by a major cultural shift occurring in the 1980s and 1990s, which saw patients actively participating in their own health-care decision-making. A business opportunity was identified for DTCA. Until then advertising and promotion were considered beneath the dignity of the medical profession. In the

past, the predominant means of gaining new patients came via 'old school' sources; published papers, academic talks and, mainly, word-of-mouth referrals and recommendations from satisfied patients and colleagues.

Today, much more is required. Branding — strategically creating, communicating and delivering a message of value to the market from the 'why' — is now a science unto itself. The financial challenges are real. Financial success is an unspoken mission of healthcare organisations, which must find ever more innovative ways to ensure revenue. Serving their public mission requires financial viability, which requires marketing strategies to attract more patients, which requires . . . advertising.

Further changes are needed in the future, including stronger, more explicit and comprehensive guidelines and regulations to avoid misleading the public. Logical strategies presenting objective benefit, risk and cost analysis must guide DTCA, not emotion. Physicians want to promote innovative treatment advances but need to do so while providing information that helps guide good decisions by their patients.

While the landscape is clearly changing, what cannot change is the duty to market health care with strict ethical guidelines, transparency, responsibility and professionalism. All stakeholders, including consumers, public health and healthcare professionals, drug manufacturers, payers and policymakers should collectively advocate for these common goals so as to better understand the influence of DTCA on pharmaceutical and healthcare utilisation and consumer behaviour.[19] They are all affected by significant prior, and inevitable future, changes. More change and solutions are needed that will optimise the benefits and minimise the risks of DTCA, which is apparently here to stay. If products and services are promoted directly to the public, evidence-based criteria must be used, ensuring that providers, not celebrity endorsements, guide patients in making optimal decisions. Patient requests have dramatic effects on prescribing and service utilisation, with patient expectations sometimes shaped by marketing before they have been clinically evaluated. Beyond these local considerations, the reach of US health-care promotion has a significant global health and economic impact, making this a fiduciary responsibility for all ethical providers, given their considerable influence on patient demands and prescribing decisions. Health care is big business, making it no surprise that DTC marketing has evolved so robustly. Clinicians and organisations feel the pressure to influence health-care information to attract patients and promote services. But health-care advertisements should be different from those for consumer goods (persuasiveness = revenue). The advertising techniques of other industries pose potential ethical risks if used similarly by healthcare institutions. Standards for health-care advertisements should promote informed decisions, in keeping with provider responsibility for patient well-being. Standards could adapt components of FDA regulations already in place for drug advertisements, including guidelines for risk disclosure to avoid deception and to inform about benefits and harms. Specific criteria and broader scrutiny of health-care advertisements are needed well beyond what currently exists.

The prestige and trustworthiness of organisations and individuals in healthcare provide a level of consumer confidence with regard to quality and altruistic motivations. For the time being, consumers may still be slightly less sceptical about health services advertisements compared with those of other industries, believing in the motivation to assist the public in making good decisions by providing balanced (benefit versus harm) and objective information while promoting only clear value. Marketing inundates people with things they may not really need or can get

for less. Brand promotion may aim at hitting the largest audience possible but may dilute a brand, without portraying value to the market or describing its *raison d'être* (reason for being).

Social media sites are ubiquitous, and they significantly impact people's lives 24/7. These are a modern-day source of innovative, calculated, targeted marketing; engaging billions of potential customers, and influencing matters of both individual and population health. When informative and educational, they raise consumer awareness and positively influence health care. Inaccurate or incompletely evaluated claims promoted online may, however, advance ill-advised health practices and requests for inappropriate products. There is a moral and ethical responsibility to assure that health-care information is scientifically valid and from a reputable and trustworthy source.[20]

FDA regulation of DTCPA means that off-label promotion or advertisement for an indication that is not FDA approved is prohibited. Guidelines mandate a balanced presentation of risks and benefits, while prohibiting misleading claims. There is clearly an enormous grey zone of what constitutes 'compliance'. Klar et al.[21] found that few broadcast DTCAs were fully compliant with FDA guidelines. Greater enforcement may include mandatory FDA prospective review of prescription drug advertisements prior to release to ensure that they are informative and compliant.[22]

The Institute for Healthcare Improvement instituted a framework describing the optimisation of health system performance, stating that three mutually reinforcing dimensions must be simultaneously pursued. They promoted the 'triple aim' construct of a) improving the patient care experience of care (including quality and satisfaction), b) improving population health and c) reducing the cost of health care.[23,24] The emphasis, however, seems to be squarely on costs. Financial challenges are the new norm for healthcare executives. There is a relentless drive to protect existing, and seek out new, sources of revenue to satisfy the 'less-than-secret' mission of financial success. Consumer-targeted marketing strategies to attract new patients are a growing trend, one that risks invoking an even greater degree of consumer scepticism if consumers fail to differentiate between information intended to inform the public and advertisements designed to generate revenue.[25]

There is no doubt that DTCA is a powerful tool affecting patient and physician behaviour. But does it improve individual or population health outcomes? To minimise the potential harm and maximise the benefits of DTCA for population health, advertisement content should enable consumers to better identify whether a treatment is indicated, more realistically appraise the benefits, and better attend to the risks associated with prescription drugs as well as evaluate the effects of DTCA on drug expenditures.[26]

Improving the quality of DTCA will protect consumers. Clinicians and patients are very accustomed to medication requests and DTCA. Yet marketing designed to attract patients must remain keenly sensitive to the perceived conflict of interest between income generation and a mission to serve the public. The financial interests of a healthcare institution or company must remain secondary to maintaining the best interests of the patient.

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