Prescribing....

Marketing Strategies Sept 2015

- This month's bulletin looks at the changing marketing strategies used by the industry.
- The industry is now closely involved with patient support groups and societies.
- There is also widespread use of senior clinicians in peer-to-peer marketing.
- Information from societies or professionals with any industry financial involvement should be regarded as, the very least, biased.

Pharmaceutical firms commit significant resources to medical innovation in developing new treatments, but recent research suggests that the money spent on marketing surpasses investment in research and development. Independent data on drug marketing vs manufacturing costs are difficult to come by, but one study in 2008 estimated that the industry spent US$57.5bn in 2004 on marketing in the United States alone, nearly twice as much as was invested in R&D.

A variety of methods have been used to promote greater prescribing of newer, more expensive drugs, which may provide little or no absolute benefit over older treatments. In the United States and New Zealand, direct-to-consumer (DTC) advertising of prescription medicines is extremely common. Such DTC campaigns are effective but represent just a sliver of marketing efforts.

Prescribers are the primary marketing target, although patient advocacy groups, public sector payers, and private insurers are also important targets. The marketing toolbox includes sales reps' visits, sponsored "education", free drug samples, physician-to-physician marketing, funding patient support groups, and presentation of evidence in medical journal articles. Although regulatory agencies only allow marketing of drugs for approved conditions, drug firms have paid out billions of dollars in recent years to settle claims of marketing for a wide variety of unapproved indications.

New diseases

In one case, a psychiatric diagnosis "complicated mood" was created by a pharma to justify treatment of primary care patients with its antipsychotic drug olanzapine. Marketers targeted the drug to treat "symptoms and behaviours found in mood, thought and behaviour disturbances", a much broader target than the narrow bipolar I disorder and schizophrenia indications for which the drug was licensed. Internal documents detailed "complicated mood" as consisting of at least one of the following symptoms: anxiety, irritability, disruptive sleep, and minor mood swings (not bipolar I mood swings). Furthermore, only one of these symptoms was needed to qualify a patient for a diagnosis of "complicated mood" and for a prescription for olanzapine.

Although documents from most legal settlements remain sealed, documents from several firms have either been released as part of court proceedings or leaked. These materials tell a consistent story. Initial regulatory approval gets a drug onto the market for a narrow indication. Then marketers sell it for a spectrum of unapproved condition, as has been the case for many psychiatric medicines. For instance, atypical antipsychotics were originally approved as treatments for schizophrenia and then bipolar I disorder. Before long, various federal lawsuits in the United States alleged that atypical antipsychotics were promoted for treating conditions ranging from aggression, anxiety, attention deficit-hyperactivity disorder (ADHD), dementia, depression, post-traumatic stress disorder, pre-med and sleeplessness. Claims regarding off-label marketing of bestselling atypical antipsychotics have been settled with US federal authorities to the tune of between US$300m and US$1.4bn, with some drug firms admitting guilt but others denying wrongdoing.

Many US states have also reached multimillion dollar settlements with drug companies for similar charges. The shady marketing of antipsychotics has been the biggest target of federal investigators compared with other drug classes, but other psychotropics have shared the spotlight. One example is a US$1.5bn US federal settlement with Abbott in 2012 over its anti-seizure drug, valproate semisodium, which was marketed illegally to treat schizophrenia and dementia. In addition, GlaxoSmithKline and Forest Labs both admitted to marketing their antidepressants (paroxetine and citalopram, respectively) for treating youth depression — despite evidence indicating these drugs were ineffective for such a purpose.

Peer-to-peer marketing

Although sales representatives are highly influential, many doctors view them with at least some scepticism. Recent years have seen an explosion in peer-to-peer marketing — paying prescribers to market to their peers. The content is often developed in large part or in whole by sponsoring drug companies or firms that are paid by them. Material emanating from doctors feels more independent and credible than information from the sales force. These doctor "educators" are known as key opinion leaders (KOLs) and their involvement in drug sales is heavily emphasised in both internal documents and publicly available pharmaceutical industry publications.

For instance, as the campaign to push olanzapine to primary care doctors was about to launch, the brand manager for olanzapine enthused at a US national sales meeting that Lilly had primary care physicians "who are chomping at the bit to help you sell Zyprexa".

Several years ago, stories of relatively low-level KOLs enticed to extol the virtues of a drug to peers in their local area emerged. High-level KOLs are much more in vogue now. They are perceived as important and also appear as authors on clinical trials. In many cases, these KOLs have little or no involvement in the study design or the analysis of data.

Manuscript drafts have been known to be developed by hired medical writers. Thus, KOLs often appear to lend an appearance of external oversight in the presentation of data. These high-level KOLs shape perceptions about mental health, often referring to the scourge of various untreated disorders. They engage in "disease awareness" campaigns, such as the surge in media coverage regarding binge eating disorder, a condition first recognised by the American Psychiatric Association in 2013. Lisdexamfetamine for ADHD has recently become the first drug approved for binge eating disorder by the US Food and Drug Administration. In the only published clinical trial of lisdexamfetamine so far, binge eating episodes were cut by 78% from the start to the end of the first published clinical trial among people taking a placebo. Although the drug resulted in even greater reductions in binge eating, it did not improve overall mental health.

Deterrents

The vast majority of relevant legal cases have occurred in the United States. Yet drug marketing is a global business. Fines of over US$13bn for off-label promotion in the United States over the past few years sound like a powerful deterrent. However, the drug industry consistently maintains among the highest profit margins of any industry. So when Eli Lilly paid US$1.4bn and pleaded guilty to criminal charges in settling claims of olanzapine's off-label marketing, this was a trivial expense in the context of a drug netting around US$50bn in sales during its patent-protected lifespan. It would seem that financial penalties, however high, are simply not a sufficient deterrent. Prosecution of key officials would be far more effective.

Most worryingly of all the industry now relies on emerging markets for around 30% of sales, and bribery is sometimes one of its tools. An investigation by news agency Reuters in 2012 found that eight of the top ten drug companies in the world informed investors of costs related to corruption charges in such markets.

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