

The Lancet (January 6, 2007)
The direct-to-consumer advertising genie
EDITORIAL

Volume 369, Issue 9555

European commissioners are considering proposals to loosen Europe's ban on direct-to-consumer advertising for prescription drugs. But before they proceed, they should look carefully at the US experience.

Direct-to-consumer advertising has been allowed in the USA since 1997. The pharmaceutical industry claims the advertisements educate patients about health, inform them about new treatments, and encourage them to talk to their doctors about important health concerns. Opponents, however, argue the advertisements are simply that: advertisements, most of which push expensive new drugs even when less expensive and often safer treatments, or even no treatment at all, would suffice.

A new US government report suggests such concerns are warranted. The report was published by the US Government Accountability Office (GAO), a non-partisan investigative and research agency of the US Congress. The report reviews direct-to-consumer advertising in the USA and examines how well the US Food and Drug Administration (FDA) oversees these advertisements. The investigators found the oversight was lax. But their report also raises questions about the value of direct-to-consumer advertising and shows just how hard it is to regulate once this genie is out of the bottle.

The investigators showed that from 1997 to 2005, industry spending on direct-to-consumer advertising grew on average nearly 20% per year, twice as fast as spending on drug promotion to doctors, reaching US\$4.2 billion in 2005. By comparison, industry spent \$31.4 billion on research and development, according to the GAO report.

More than 50% of the direct-to-consumer spending went to advertisements for just 20 drugs, most for chronic conditions such as hyperlipidaemia, asthma, and allergies. Not surprisingly, these are the same drugs that drug companies are promoting directly to doctors with advertising in medical journals, drug-representative visits, and free samples. It's a smart dual-pronged strategy, because a doctor is more likely to provide a particular drug when a patient asks for it and when the doctor has free samples on hand.

Now, this is not to say that direct-to-consumer advertising does not help some patients. In many cases, patients may have been well served by advertisements that led them to discuss their concerns with their physicians. But the primary purpose of direct-to-consumer advertising remains clear: to sell lucrative, on-patent, brand-name drugs. Claims to the contrary just do not pass the straight-face test.

How well, then, does the FDA oversee this advertising? Not well, the GAO showed. Under the law, advertising materials must contain a “true statement” of information that includes a brief summary of effectiveness, side-effects, and contraindications. Broadcast materials may present only major effects and contraindications, but must provide information about where consumers can get more details. When material is shown to be in violation, FDA officials issue a regulatory letter that might call for the advertisement to be stopped or, in more serious cases, for new advertisements to correct misinformation that may have been disseminated.

In general, the FDA only reviews material after it is disseminated, although in some cases companies bring their materials to the agency for comment before dissemination. Because the FDA can review only a small proportion of advertising put out each year, FDA officials told the GAO investigators that they used informal criteria to select what to review. But the GAO investigators showed that the FDA had no written documentation detailing these criteria, no system for applying the criteria, and no record for tracking what it had reviewed. In addition, the FDA issued relatively few regulatory letters, between eight and 11 per year between 2002 and 2005. However, once the FDA began drafting a letter it took on average 4 months before it was issued. In many cases, by that time the advertising campaigns had often run their course.

Part of the FDA's performance is probably due to the influence of an industry-friendly administration that has made its antipathy towards government regulation clear. This should serve as a warning to European regulators that unless done very carefully, relaxation of direct-to-consumer advertising regulations risks creating a tidal wave of marketing that will be difficult to control.

It would be better to fund independent information sources, free of industry influence, to provide the public with unbiased evidence-based information. If industry truly wants to inform the public, it should supply no-strings-attached funds to support such efforts. Even a small portion of the \$4.2 billion being spent each year in the USA on direct-to-consumer advertising would do nicely.