MedicalXpress

Off-label marketing of medicines in the US is rife but difficult to control

April 5 2011

Despite Federal Drug Administration regulation of the approval and use of pharmaceutical products, "off-label" marketing of drugs (for purposes other than those for which the drug was approved) has occurred in all aspects of the US health care system. In a study published in this week's *PLoS Medicine*, Aaron S. Kesselheim from Brigham and Women's Hospital, Boston, USA and colleagues report that the most common alleged off-label marketing practices also appear to be the most difficult to control through external regulatory approaches. They identified three main goals of alleged off-label marketing programs: expansion of drug use to unapproved diseases, expansion to unapproved disease subtypes, and expansion to unapproved drug dosing strategies, typically higher doses.

In their study, the authors classified the strategies and practices used in off-label marketing by examining 41 complaints filed by whistleblowers related to 18 alleged cases of off-label marketing in federal fraud cases that were settled or unsealed between January 2004 and October 2010. These findings provide a snapshot of off-label marketing strategies and practices allegedly employed in the US, and this analysis may help to develop new and effective regulatory strategies.

All of the whistleblowers alleged prescriber-related practices (including providing financial incentives and free samples to physicians), and most alleged internal practices intended to bolster off-label marketing, such as sales quotas that could only be met if the manufacturer's sales representatives promoted off-label drug use. Payer-related practices (for

example, discussions with prescribers about ways to ensure insurance reimbursement for off-label prescriptions) and consumer-related practices (most commonly, the review of confidential patient charts to identify consumers who could be off-label users) were also alleged. However, these practices were alleged by whistleblowers in cases intervened by the US Department of Justice, and were not the subject of testimony in a full trial; thus, some of the practices identified by the researchers could not be confirmed.

The authors say: "Off-label marketing has been ubiquitous in the health care system and features some behaviors and strategies that may be resistant to external regulatory approaches."

They continue: "Aside from sales representatives and other company insiders, who play important roles as whistleblowers, physicians are alone in having a full view of many of the most insidious forms of illegal marketing outlined in the complaints we reviewed. As physicians' understanding of these practices and the consequences of inappropriate off-label promotion for public health evolves, so may their enthusiasm for shutting them down."

More information: Kesselheim AS, Mello MM, Studdert DM (2011) Strategies and Practices in Off-Label Marketing of Pharmaceuticals: A Retrospective Analysis of Whistleblower Complaints. PLoS Med 8(4): e1000431. doi:10.1371/journal.pmed.1000431