Off-label Prescribing Among Office-Based Physicians

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FROM ABSTRACT:

Background: Unlike medicines prescribed for Food and Drug Administration–approved indications, off-label uses may lack rigorous scientific scrutiny.

Despite concerns about patient safety and costs to the health care system, little is known about the frequency of off-label drug use or the degree of scientific evidence supporting this practice.

Methods: We used nationally representative data from the 2001 IMS Health National Disease and Therapeutic Index (NDTI) to define prescribing patterns by diagnosis for 160 commonly prescribed drugs. Each reported drug-diagnosis combination was identified as Food and Drug Administration–approved, off-label with strong scientific support, or off-label with limited or no scientific support.

Outcome measures included (1) the proportion of uses that were off-label and (2) the proportion of off-label uses supported by strong scientific evidence.

Results: In 2001, there were an estimated 150 million off-label mentions (21% of overall use) among the sampled medications.

Most off-label drug mentions (73%) had little or no scientific support.

Conclusions: Off-label medication use is common in outpatient care, and most occurs without scientific support.

Efforts should be made to scrutinize under-evaluated off-label prescribing that compromises patient safety or represents wasteful medication use.

KEY POINTS FROM THESE AUTHORS:

1) “The Food and Drug Administration (FDA) focuses on market entry for prescription drugs rather than regulating physicians’ prescribing practices, allowing off-label use of medications for indications beyond those formally evaluated by the manufacturer.”

2) Off-label prescribing of drugs is legal and often thought to be supported by scientific evidence.
3) “Scientific evidence documenting the efficacy of off-label uses in routine practice settings commonly falls short of what the drug’s manufacturer would be required to provide the FDA to receive approval for that indication.”

4) It is illegal to promote off-label drug use direct-to-consumer and to physicians.

5) “The NDTI reported an estimated 725 million total drug mentions [this represents slightly more than half of all drug mentions in 2001] among the sampled drugs for year 2001. Although most (575 million [79%]) were for FDA-approved indications, many drug mentions (150 million [21%]) lacked FDA approval for the condition they were used to treat.” [That’s an awful lot of drugs]

5) “Using data from a nationally representative survey of office-based physicians, we found that about 21% of all estimated uses for commonly prescribed medications were off-label, and that 15% of all estimated uses lacked scientific evidence of therapeutic efficacy.” “No more than 30% of the off-label practices we observed were supported by strong scientific evidence.”

6) “Some of the observed off-label uses were as therapy for indications distinctly different from those for which the drug was approved.”

7) We need to know more about the factors that produce off-label medication use, especially since some drug manufacturers have been investigated and convicted for inappropriate marketing of off-label uses for a drug. There is “need to better understand the determinants of off-label medication use, including the potential influence of pharmaceutical marketing.”

8) “Policy makers must begin to consider strategies for mandatory post-approval surveillance that focus on curtailing underevaluated off-label practices that jeopardize patient safety or represent economically wasteful prescribing practices.”

COMMENTS FROM DAN MURPHY:

I just finished reading Our Daily Meds: How the Pharmaceutical Companies Transformed Themselves into Slick Marketing Machines and Hooked the Nation on Prescription Drugs, by Melody Peterson (2008). Her book further details the problems with off-label drug use, including the illegal promotion of off-label uses to both consumers and medical doctors. I found Peterson’s book to be shocking, sad, and worrisome, not only for the individual patient and their family, but also for the economic well being of our entire nation. I believe that every chiropractor should read Peterson’s book, and that it should be mandatory reading for all chiropractic college students.