

## INFORMED PRESCRIBING TO FURTHER PATIENT ACCESS

By David Charles, MD and Anna Molinari

State-of-the-art, 21st century health care requires informed prescribing—physicians prescribing medical therapies based upon current guidelines and evidence from a comprehensive, balanced array of data sources. By remaining fully informed, physicians can offer patients access to the full range of appropriate clinical care options.

But the sheer volume of data required to stay current can prove daunting. The field of medicine constantly changes as new studies and therapies emerge, and physicians can obtain information from an array of sources: the government, medical journals, the pharmaceutical industry, research presentations, compendia published by medical societies, insurance payers, and online resources such as UpToDate®. Staying abreast of therapeutic options by reviewing multiple data sources firsthand can require more time than many physicians have to offer.

### SOURCES OF PHYSICIAN KNOWLEDGE OF MEDICAL THERAPIES

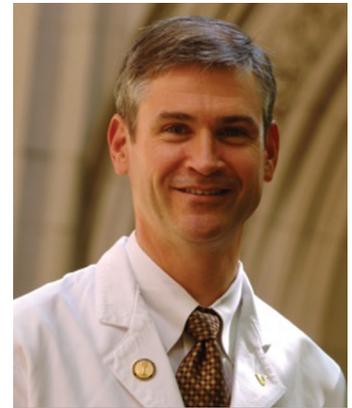
Medical journals  
Research presentations  
Compendia & Medical societies  
Pharmaceutical industry  
Online resources  
Insurance payers  
Government

To help physicians stay informed, representatives from pharmaceutical, medical device, and biologics manufacturers regularly meet with physicians to discuss and promote their products through a practice known as “drug detailing.” These representatives provide information regarding the approved indications, risks, and benefits of their products, and they

serve an important role in helping improve patient access to approved therapies.

Meanwhile, the government is growing more proactive in attempting to influence prescribing practices.

Through what’s known as “academic detailing,” the federal government now employs trained clinicians, primarily nurses and pharmacists, to brief physicians on the results of federally funded comparative-effectiveness research about current therapies. The program targets physicians in population-dense metropolitan areas, who can often receive continuing education credit from their accrediting organization for participating in the meeting.<sup>1</sup> The American Recovery and Reinvestment Act of 2009 allocated \$1.1 billion to funding and disseminating results from comparative-effectiveness studies through academic detailing.<sup>2</sup>



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### IN CONSIDERING DATA, PHYSICIANS MUST WEIGH BIASES AND MOTIVATIONS

While some sources are considered more objective than others, one thing is certain: no source is completely void of bias. Even with medical journals and academic compendia, physicians must consider the predispositions of the researchers, the selection of articles and the source of funding.

Likewise, information provided by detailers reflects the inherent biases and objectives of its source. Drug detailers represent for-profit companies, manufacturers who have a

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## REGULATIONS AND RESTRICTIONS

### GIFT BAN LAWS

PhRMA's "Code of Interactions With Health Care Professionals," revised in 2009, details how pharmaceutical companies should interact with physicians.<sup>4</sup> The code states that pharmaceutical companies should not provide gifts of any kind to healthcare professionals or provide payment for entertainment or recreational expenses. This so-called "gift ban" has been adopted and further expanded by several states including Massachusetts, Vermont, and Minnesota to almost entirely restrict physician payments from industry.

### SUNSHINE ACT

As a provision of the Affordable Care Act, all pharmaceutical, medical device, biologics, and medical supply companies must publicly disclose payments exceeding \$10 made to physicians and academic medical centers as part of the Physician Payments Sunshine Act.<sup>5</sup> The regulation encourages transparency regarding industry spending and financial relationships between physicians and industry.

### OFF-LABEL USES

Federal regulations ban industry representatives from discussing off-label uses of therapies, even if the off-label use is widely prescribed, commonly accepted in the medical literature, and recommended in compendia and practice guidelines. The Food and Drug Administration (FDA) characterizes discussions between industry personnel and physicians about off-label use as "misbranding," which it considers a threat to patient safety.

## DO THESE LAWS AND RESTRICTIONS BENEFIT PATIENTS?

In light of increasing regulations, physicians must step back and ask: How do these laws and restrictions affect patient care? Do they allow physicians to gather the breadth of data needed to knowledgeably treat patients when selecting among available therapies?

financial interest in physicians' prescribing their products. These detailers provide information about appropriate use of the manufacturer's therapy so that physicians may, when appropriate, make this therapy available to their patients. So long as physicians recognize and weigh the manufacturer's motivation, the data can inform a physician's balanced understanding of a therapy's usefulness.

Similarly, academic detailers' presentations likely reflect the government's interest in containing costs. The federal government is the largest purchaser of health care in the United States, purchasing over 50% of healthcare through Medicare, Medicaid, active military, Veteran Affairs, and federal workers.<sup>3</sup> And the comparative-effectiveness research presented by academic detailers is government funded. Thus, academic detailers' ability to deliver objective, unbiased, and unmotivated information seems questionable. Granted, cost-effectiveness is an important goal; but it should not be achieved at the expense of quality patient care.

Academic detailers' data also reflects both the usefulness and the shortcomings of comparative-effectiveness research. Comparative-effectiveness studies focus on large groups and make general conclusions based on the average patient. Such data can be useful in determining overarching trends but does not encompass individual nuances among patients. Though certain treatments benefit the majority of patients, they may actually harm a segment of the population; thus, physicians must make prescribing decisions based on individual patients' needs.

Therefore, physicians should consider all available information, but make decisions regarding choice of therapy and course of treatment based on the best interests of their patients.

## CURRENT REGULATIONS IMPACTING INFORMED PRESCRIBING

To address outside influences on physicians' prescribing behaviors, Pharmaceutical Research and Manufacturers of America (PhRMA) and federal and state governments have in recent years placed new guidelines and restrictions on how third parties interact with physicians. These regulations are described in the following table.

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Regulations that disproportionately limit one source of data—or unduly deregulate another source—may actually skew physicians’ perspective on medical therapies, interfering with their ability to make fully informed decisions. In particular, prohibiting discussions of off-label use with drug detailers may limit physicians’ full understanding of how these medications can serve their patients.

## WHAT IS OFF-LABEL USE?

Off-label use occurs when physicians prescribe a medical therapy for a condition other than the one for which the therapy received FDA approval. Though therapies may effectively treat multiple health conditions, pharmaceutical manufacturers seldom pursue approval for more than one indication because of the time and cost required to obtain FDA approval. However, if a therapy is already approved for one indication, physicians may elect to prescribe that therapy “off-label” when medically appropriate.

## INFORMATION ABOUT APPROPRIATE OFF-LABEL USE

Off-label uses are important components of patient management, particularly for rare disorders and conditions with few therapeutic alternatives. They are often part of standard of care regimens established in practice guidelines. Furthermore, both private insurers and the Centers for Medicare and Medicaid Services (CMS) reimburse many off-label uses. Unsurprisingly, approximately 21% of frequently prescribed drugs are prescribed for off-label uses<sup>6</sup>, and off-label uses exist in “every specialty of medicine.”<sup>7</sup>

Despite the benefits of and support for off-label prescribing, however, the FDA bars industry representatives from discussing unapproved uses of their products, even in informational and non-promotional ways. The FDA considers the practice “misbranding” because it pertains to uses not validated for safety and efficacy through rigorous clinical trials, as required for approved indications.

Ironically, though the manufacturer of the product cannot discuss with physicians the potential benefits of off-label use, individuals unaffiliated with industry can discuss these uses freely. In addition to physicians and medical societies, insurance companies and government detailers can discuss and promote the use of off-label therapies with no regulatory restraint.

Industry outcry about this discrepancy has led some to question whether the FDA’s stance violates industry firms’

First Amendment right to free speech. The precedent established by several recent court cases suggests that the FDA may need to reconsider its approach in the near future.<sup>8</sup>

In addition to limiting physicians’ information about available therapies, imbalanced regulations on discussing off-label use can also encourage the use of cost-centered approaches such as

step therapy. “Fail first,” as it’s commonly known, requires patients to first fail using generic off-label drugs before they can access name-brand therapies. Though step therapy can decrease prescription drug costs for insurance companies and government-sponsored health plans, it can also impede physicians’ prerogative to select the therapy that best suits each individual patient. Restricting discussion on off-label use presents an opportunity for cost-conscious third parties to sway physicians toward off-label uses as a means of protecting profits and lowering care expenditures.

## HOW CAN PHYSICIANS GET BALANCED DATA FROM DIVERSE SOURCES?

To ensure that physicians have access to the full range of information they need to make informed prescribing decisions, current regulations should:

- **Expand manufacturers’ ability to discuss off-label uses,** particularly those that are accepted in compendia and practice guidelines or reimbursed by government and insurers. Allowing industry to provide physicians with data from off-label use in clinical practice could broaden physicians’ knowledge of available therapies, equipping them to better treat patients.
- **Ensure that government detailing is inclusive.** The data provided should cover all therapeutic options and reflect advantages, disadvantages, safety considerations and efficacy in patient sub-populations.

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■ **Require payers to publish evidentiary basis for coverage and payment policies.** This would deter insurance companies from determining coverage based solely or predominantly on cost.

■ **Encourage an open, transparent process for promulgating practice guidelines.** The evidence and data relied upon in the promulgation of practice guidelines should be made publicly available and posted on the Internet.

## CONCLUSIONS

Patients benefit when their physicians have a current, comprehensive understanding of available medical therapies. Thus, policymakers should consider how current regulations can facilitate the exchange of appropriate information that can improve prescribing decisions and ultimately benefit patients.

Government and insurance company efforts to influence physicians should be gauged to ensure that physicians maintain the authority to ultimately decide what's best for their patients. Meanwhile, regulations on industry should be balanced to prevent infringement on freedom of speech and allow for the exchange of objective, scientific, and evidence-based information that benefits patients.

## REFERENCES

1. U.S. Department of Health & Human Services. About the Academic Detailing Project. Available at: <http://effectivehealthcare.ahrq.gov/index.cfm/who-is-involved-in-the-effective-health-care-program1/about-the-academic-detailing-project/>. Accessed July 12, 2014.
2. U.S. Department of Health & Human Services. AHRQ and the Recovery Act. November 2011. Available at: <http://archive.ahrq.gov/funding/arra/>. Accessed June 22, 2014.
3. Centers for Medicare and Medicaid Services. CMS Roadmaps Overview. Available at: [https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/downloads/RoadmapOverview\\_OEA\\_1-16.pdf](https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/downloads/RoadmapOverview_OEA_1-16.pdf). Accessed June 22, 2014.
4. Pharmaceutical Research and Manufacturers of America. Code on Interactions with Healthcare Professionals. 2009. Available at: [http://www.phrma.org/sites/default/files/pdf/phrma\\_marketing\\_code\\_2008.pdf](http://www.phrma.org/sites/default/files/pdf/phrma_marketing_code_2008.pdf). Accessed June 22, 2014.
5. Centers for Medicare and Medicaid Services. Creating Public Transparency of Industry-Physician Financial Relationships. 2014. Available at: <http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/index.html>. Accessed June 22, 2014.
6. Radley DC, Finkelstein SN, Stafford RS. Off-label prescribing among office-based physicians. *Archives of internal medicine* 2006;166:1021-6.
7. Christopher M. Wittich, et; al., Ten Common Questions (and Their Answers) About Off-label Drug Use, *Mayo Clinic Proceedings*, available at [http://www.mayoclinicproceedings.org/article/S0025-6196\(12\)00683-0/fulltext#sec3](http://www.mayoclinicproceedings.org/article/S0025-6196(12)00683-0/fulltext#sec3).
8. Dennis B. FDA has free-speech, safety issues to weigh in review of "off-label" drug marketing rules. *The Washington Post*. July 9, 2014. Available at: [http://www.washingtonpost.com/national/health-science/fda-has-free-speech-safety-issues-to-weigh-in-review-of-off-label-drug-marketing-rules/2014/07/09/3708dd6a-fbc4-11e3-8176-f2c941cf35f1\\_story.html?hpid=z1](http://www.washingtonpost.com/national/health-science/fda-has-free-speech-safety-issues-to-weigh-in-review-of-off-label-drug-marketing-rules/2014/07/09/3708dd6a-fbc4-11e3-8176-f2c941cf35f1_story.html?hpid=z1). Accessed July 10, 2014.

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