of the FDA-approved indications of commonly prescribed drugs: results of a
4. Furberg CD, Herrington DM, Psaty BM. Are drugs within a class interchang-
5. Radley DC, Finkelstein SN, Stafford RS. Off-label prescribing among office-

The Pharmacist’s Role in Off-label Prescribing

I

appreciated the lucid discussion of off-label prescribing by Largent et al1 in the Archives. I was, however, disappointed that the authors did not mention the very difficult position in which off-label prescribing places the pharmacist.

It is important to consider that the drug utilization review (DUR) provisions of the Omnibus Budget Reconciliation Act of 1990 (OBRA ’90) required pharmacists to evaluate physicians’ prescription orders prior to dispensing to ensure that prescribed medications are “appropriate, medically necessary, and are not likely to result in adverse events.”2 Following the implementation of this law in 1993, these DUR provisions were written into virtually every state pharmacy practice act, thereby making them a legal responsibility of pharmacists. This responsibility specifically includes evaluating the appropriateness of prescribed medication for the patient.

As one might imagine, fulfilling their DUR responsibility is difficult enough, given the paucity of patient information that pharmacists routinely have available to them in many practice settings. When one factors in the added complexity that off-label prescribing presents, it becomes virtually impossible.

My background as a former clinician in a very information-rich environment (Indian Health Service, US Public Health Service) and current educator and researcher in medication safety has convinced me that the patient’s diagnosis or its equivalent (eg, therapeutic objective) should be a required component of every prescription order. In those circumstances in which the drug is being prescribed for an unapproved indication, it would also seem necessary to provide the pharmacist with the rationale (ie, clinical evidence) on which the medication is being prescribed.

Fortunately, emerging technologies like electronic prescribing could serve as efficient platforms for allowing such enhanced communication between the prescriber and the pharmacist. Indeed, the electronic data interchange standard for e-prescribing already allows for the routine transmission of patient diagnosis on the e-prescription, and a task group at the National Council for Prescription Drug Programs is currently working to expand the capacity of the e-prescribing standard to support efficient 2-way communication between prescriber and pharmacist (http://www.ncpdp.org).

Once again, I appreciate the authors’ recommendations for physicians regarding the off-label use of medications. At the same time, I believe that it is important to reinforce that the generation of a prescription order is just one step in an interconnected series that involve other players also. The ultimate quality of medication delivery requires that all the players and their respective roles are considered.

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In reply

We appreciate the supportive comments from Walton and colleagues. Their previous empirical work helped define the scale and scope of off-label prescribing and is an important adjunct to any conceptual framework.1 We agree with their conclusion that promotional efforts may be an additional flag for clinicians and professional societies to scrutinize the evidence underlying prescribing decisions.

In his letter, Dr Rupp raised a salient point regarding the difficulties posed to pharmacists by off-label prescribing and the relevant regulations. Clearly, off-label prescribing is an issue confronted not merely by patients and physicians. Fortunately, these additional stakeholders might also make unique contributions in addressing our concerns about evidence-based medicine, evidence development, patient notification, and health care costs. Dr Rupp’s discussion of e-prescribing provides one example of this. We caution that any workable system should not interfere with patients receiving medications promptly or place an undue administrative burden on clinicians and pharmacists.

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