The Elephant in the Pharmacy: Patient Choice Is the Big Challenge That No One Talks About in Affordability of Prescription Drugs

In May 2004, 66-year-old retired electrician Raymond Lindell was arrested in Mexico a few minutes after filling a prescription for 270 tablets of Valium 10 mg at a pharmacy in Nogales, Sonora. Lindell, an Arizona resident, was charged with failing to obtain a duplicate prescription for the controlled substance from a Mexican physician as required by Mexican law. He was further charged with obtaining the medication for another person, his 73-year-old chronically ill wife, and with obtaining more than the legally permissible 30-day supply. Lindell was released after 8 weeks in a Mexican prison, but not before triggering a highly publicized political fracas that included a citizens’ petition drive on his behalf, a boycott of Mexican border town pharmacies by frightened senior citizens, a media campaign by Nogales business leaders to restore customer confidence, and high-level discussions among government officials from the states of Arizona and Sonora. When asked why he had chosen to travel to Nogales, a driving distance of nearly 4 hours, to purchase brand-name Valium rather than fill his wife’s prescription for a much less expensive generic medication in the United States, Lindell answered that their insurance company had stopped paying for brand-name Valium and his wife was dissatisfied with generic alternatives because they “didn’t seem to work.”

When health care professionals speak of prescription drug affordability, they typically refer to several important factors: rising medication cost, escalating copayments, and increasing health insurance premiums, to cite a few. But the problem that we too often fail to acknowledge openly—perhaps because it is so much more difficult to address than the others—is the ubiquitous and sometimes counterproductive effects of the choices made by patients and family members.

Human beings do not always make wise decisions, and there is much about consumers’ health care decision making that we do not know. How many of the uninsured could afford health insurance premiums but are simply taking the gamble that they are young and healthy now and do not need coverage? Among non-elderly adults in the United States, the likelihood of being uninsured peaks in the 18- to 24-year-old age group at 50%, compared with 33% for those aged 25 to 44 years and 17%-20% for those aged 45 to 64 years. How many of those who report that they have foregone medical insurance coverage because of its cost choose to spend the money on leisure activities or consumer goods? Lower income is clearly associated with lack of medical coverage; of those with annual incomes below 200% of poverty level ($37,320 for a family of 4), 57% are uninsured. Yet of 81.8 million Americans under age 65 without health insurance in 2002-2003, 13.5 million, about 16%, had incomes exceeding 400% of poverty level ($74,040 annually for a family of 4), and 22.6 million, about 28%, had incomes exceeding 300% of poverty level ($55,980 annually for a family of 4). Medication choices are not always made wisely either, as the Lindell case illustrated with nearly tragic results. How often do patients seek an expensive brand drug out of ignorance of the benefits and therapeutic or chemical equivalence of generic medications, with the unfortunate consequence that they find full compliance too expensive and curb or even terminate their treatment? In a study of medication-taking behavior following the initiation of chronic therapy, patients initially treated with generic medication were less likely (13.6%) than those treated with preferred brands (19.9%) or nonpreferred brands (28.3%) to switch to a product in a different tier. The percentage of days covered (PDC) was 6.6 percentage points higher for generic users (58.8%) than for users of nonpreferred brands (52.2%), and the odds of adherence (defined as PDC > 80%) were 62% higher for generic users than for nonpreferred brand users.

National Medical Expenditure Panel Survey data suggest that only 61% of U.S. multisource drug sales from 1997 to 2000 were dispensed as generic; an estimated 11% savings would have resulted from generic conversions on the basis of chemical equivalence alone. An unpublished pharmacy benefits manager study estimated unrealized potential savings from combined therapeutic and chemically equivalent substitution in 6 therapy classes (antidepressants, antihyperlipidemics, antihypertensives, calcium channel blockers, gastrointestinal, and nonsteroidal anti-inflammatory drugs) at $21.7 billion for commercially insured members in 48 states during 2005.

Yet, in surveys, about 20%-40% of health care consumers express the belief that generic medications are lower in quality or effectiveness than brand medications. Moreover, the perceived risk of using a generic instead of a brand medication varies with seriousness of illness, with the percentage increasing for the chronic illnesses most often targeted by generic substitution programs. In a willingness-to-pay survey assessing the likelihood of generic use by health condition, the percentage of consumers rating a generic drug as riskier than a brand drug to treat a heart condition (53.8%) was higher than comparable ratings for hypertension (44.0%), strep throat (22.0%), pain (18.9%), or cough (14.2%).

In addressing the question of health care choices, including patients’ decisions about whether to comply with treatment, policy analysts too often limit their focus to out-of-pocket cost, sometimes ignoring human idiosyncrasy. The willingness-to-pay survey results suggest that a single-minded focus on out-of-pocket cost is likely to yield limited results; when rating how much of a generic versus brand cost differential would be necessary to encourage the acceptance of generic medication to treat a heart condition, 27.2% of respondents said that they would not use a generic at any cost saving. Given the reality that evidence does not always support the choices that human beings make, how can we do a better job of promoting good choices?

Put 20 health care economists in a room, and you might get 20 different opinions about the crucial question of aligning
consumer and provider behavior with desired outcomes. Critics of tiered copayment structures or other cost-sharing schemes point out that an insured worker's average out-of-pocket cost for a brand drug has increased considerably in recent years, by 84% for preferred brand medications (from $13 in 2000 to $24 in 2006) according to recent estimates, but rarely mention that the average out-of-pocket cost per prescription for a generic medication—$11—is much lower than the brand cost. Nor do these critics typically put the problem into context by pointing out that the share of total pharmaceutical spending paid by consumers has dramatically declined over time. In 1990, consumers paid 56% of prescription drug expenditures out of pocket. Just 10 years later, the consumer share of prescription drug cost declined to 28%. In 2005 it was 25%, and in 2006 it is projected to decline even further to 19% in large part because of the Medicare Part D program. Are further declines in the share paid by consumers the solution to the (as yet not completely understood) problem of prescription drug affordability? Would such declines be sustainable over the long term, or even the short term, in any third-party coverage system?

Some have argued that the solution to aligning consumer behavior with desired outcomes lies in value-based insurance design in which out-of-pocket cost would be highly targeted based on the presumed value of the medication in a patient’s particular clinical situation. For example, a very low copayment would be charged for beta-blocker therapy in congestive heart failure patients. A similar proposal in England would require the National Health Service to pay for branded medication based on value, with higher payments for more effective drugs and lower payments for “me too” and less effective drugs. While the value-based approach is promising, it is also under test; the industry awaits comparative studies of its merit, much as it implemented 3-tier copayment designs some 15 years ago, before their outcomes had been assessed. And when long-held assumptions are tested using strong research designs, they are not always supported. For example, in the run-up to passage of Medicare Part D coverage, assertions that better access to prescription drugs would reduce medical expenses were common. Yet in a well-controlled study of the effect of providing prescription coverage to seniors, Briesacher and colleagues found that acquiring prescription drug coverage resulted in increased expense for prescription medications without any observable consistent effect on medical service costs.

While we await evidence, payers, providers, and patients seek solutions to the problem of prescription drug affordability as they understand it. This issue of JMCP has 2 commentaries regarding the value versus cost of prescription assistance or patient (medication) assistance programs (PAPs). In a previous article in JMCP, Clay et al. found that a medical clinic incurred administrative costs of $10.42 per patient for a brand drug that requires 1 application per year and up to $46.30 per patient for a drug in a PAP that requires 4 (re)applications per year. Chen and Summers assert in their follow-up commentary in this issue of JMCP that PAPs are an essential part of the frayed fabric that supports health care services for low-income persons who don’t qualify for Medicaid or other public programs. Carroll, in a second follow-up commentary in this issue, presents an alternative view, that PAPs may incent providers to adopt a short-term solution—providing a “free” brand-name drug to a lower-income patient instead of a generic medication that might be less expensive and equally effective.

Examples of potentially perverse incentives associated with PAPs abound. Paroxetine (Paxil) CR costs approximately $107 per month of therapy in mid-2007 compared with generic paroxetine at $21 per month of therapy, both dosed once per day. Paxil CR has no generic equivalent but is the same molecule as generic paroxetine, with no evidence of therapeutic inequivalence to paroxetine, meaning that 5 patients can be treated with generic paroxetine for the same cost as 1 patient treated with brand paroxetine CR. Or consider the cost of generic simvastatin at $26 per month of therapy in mid-2007 versus $100 per month of therapy with therapeutically equivalent atorvastatin (Lipitor). All of this leaves us with another fundamental question: Is subsidizing poor decisions necessary or even prudent?

These are difficult questions, perhaps even offensive questions to some, but they are essential questions if we are to define accurately the problem of affordability of prescription medications and to face head on and realistically the challenge of healthcare reform. To find evidence-based solutions, we need more answers—specifically, more answers to questions about why some patients comply with treatment, including prescribed medication, and why some do not. We need better information about the degree to which out-of-pocket cost reductions and cost differentials influence patient behavior and how pharmacist-directed intervention such as that described previously by Stebbins et al. and suggested by Chen and Summers might affect the actual realized value of pharmacotherapy. Clay et al. helped define the administrative cost incurred by a medical clinic in assisting patients with PAPs but did not address pharmacist intervention or other systematic education of patients in how to use the drugs. However, Clay et al. opened the door a little wider for others to measure what patients do with these brand drugs obtained via PAPs and how these outcomes compare with a more comprehensive pharmacist-directed intervention in which PAPs are a relatively small part of attaining affordable drug therapy.

Finally, to base decision making on evidence instead of presupposition, we need rigorous studies to determine which interventions effectively influence patient choice and which do not. Much of the research in benefit design policy is plagued by weak cross-sectional and pre-post analyses, which are prone to confounding even after appropriate statistical controls are used. We call for studies employing stronger quasi-experimental
and experimental research designs to provide solid information about how to persuade the elephant in the pharmacy to move in the desired direction—at least occasionally.

Kathleen A. Fairman, MA
JMCP Associate Editor
kathleenfairman@qwest.net

Frederic R. Curtiss, PhD, RPh, CEBS
Editor-in-Chief
fcurtiss@amcp.org

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