Statement of Consumers Union
William Vaughan, Senior Policy Analyst
before the
US Food and Drug Administration
Public Meeting
on
Behind the Counter Availability of Drugs
November 14, 2007

Consumers Union is the independent, non-profit publisher of *Consumer Reports*[1]. One of our major projects is helping consumers make informed decisions about prescription drugs. Our free website, BestBuyDrugs.org, utilizes scientific evidence to help consumers save thousands of dollars a year by identifying the most safe, affordable and effective medications in over twenty categories.

Like others here today, we are very conflicted on the FDA's proposal on behind-the-counter medications, but thank you for raising the issue.

Our readers tell us what the newspapers tell us every day: the cost of health care is the number one domestic economic issue for consumers—and is only getting worse. Unless we make major changes, in 43 years, the nation will be spending about 50 percent of its Gross Domestic Product on health care, compared to about 16 percent today.[2]

These cost pressures are why Consumers Union is working to promote more efficient purchasing of safe, effective drugs, easier access to generic drugs, and why we support Medicare drug price negotiating, re-importation of safe drugs, and different ways of researching and developing breakthrough drugs.

We also support the judicious movement of some prescription drugs to Over the Counter (OTC). For example, on July 10, 2007, we filed a letter of support for the petition on moving Allegra and Zyrtec to the same status as Claritin, on the grounds that this OTC competition will lower the price of Allegra, Zyrtec and Claritin, and save consumers the cost of seeking a physician's permission for a prescription for a safe anti-allergy medicine.

---

[1] Consumers Union is a nonprofit membership organization chartered in 1936 under the laws of the State of New York to provide consumers with information, education and counsel about goods, services, health, and personal finance. Consumers Union's income is solely derived from the sale of Consumer Reports and ConsumerReports.org, its other publications and from noncommercial contributions, grants and fees. In addition to reports on Consumers Union's own product testing, Consumer Reports and ConsumerReports.org, with approximately 6.5 million combined paid circulation, regularly carry articles on health, product safety, marketplace economics and legislative, judicial and regulatory actions that affect consumer welfare. Consumers Union's publications carry no advertising and receive no commercial support. EXPERT • INDEPENDENT • NONPROFIT®

[2] Peter Orszag and Philip Ellis, 'The Challenge of Rising Health Care Costs—A View from the Congressional Budget Office,: N. Engl J Med 357;18, November 1, 2007.

But how many other drugs are there like Allegra/Zyrtec that could safely move from the prescription pad to OTC or BTC?

We do not recommend statins for such a move. The United Kingdom's experience with a 10mg OTC statin apparently has not been particularly useful. A Lancet editorial of May 22, 2004, entitled "OTC statins: a bad decision for public health," urges research on the hazards of OTC simvastatin. We do not see those research questions answered, and are raising this problem in a separate letter to the FDA.

The FDA's warning to Takeda Pharmaceuticals earlier this month about its high dose trials of the cholesterol drug TAK-475 due to liver damage is a reminder of the dangers. Some consumers believe that if a small dose is helpful, a larger dose is more helpful. It would be easy to see some OTC or BTC consumers shopping at multiple drug stores and overmedicating themselves with statins.

Perhaps a wiser course would be for the FDA to convene an Advisory Committee for a once-a-year review of one to three drugs the FDA staff believes could be considered for movement from prescription to OTC or BTC status. Rather than wait on random petitions for a change in status, the FDA could organize a process of seeking out safe, effective, medicines for conditions that a prudent purchaser could use to self-medicate.

Before moving a drug to BTC or OTC status, the FDA should focus some of the research called for by FDAAA's section 905 to ensure that we really understand the side effects and long-term impacts of the drug. The new law calls for the routine but active surveillance of drug effects through the use of massive medical record databases—hopefully as many as 100 million records by mid-2012.

BTC raises such conflicting issues—possible cost savings versus increased safety problems—that it may be wisest to try a one or two state demonstration of the concept so that the FDA can monitor, for a year or two, the pros and cons.

Following are our responses to some of the questions posed for today's Public Meeting.

General

1. Should there be BTC availability of certain drug products?

   Depends on FDA analysis of relative safety.

   If so why?

   Saving consumers the cost and time of a physician visit

   If not why?

Unless FDA develops an effective system of ensuring the consumer-patient understands the risks, the cost of treating adverse side effects could easily exceed the savings.

2. What might the impact of BTC be on patient access?

Easier, but it should be made clear that this is not grounds for insurers dropping coverage; an insurance policy (including Medicare and Medicaid) that covers prescription drugs should also cover BTC drugs.

3. What might the impact of BTC be on patient compliance with drug therapy?

It could be diminished. Will pharmacists be able to ensure that appropriate blood, liver, or other monitoring is done?

While a single pharmacist or chain of pharmacists could see whether a patient was taking their prescriptions (whether refills were sought at appropriate times), how would they prevent over-prescribing when a patient used multiple pharmacies?

It is important before any such BTC system starts that we have a system of e-prescribing and even Health Information Technology in place. There is some evidence today that a substantial number of fee for service patients are receiving multiple prescriptions for the same category of drugs[3]. Because so many patients have no medical home, multiple doctors prescribe similar medicines, and there is no system to detect how dose piles on dose, until the patient is in danger. Without a comprehensive database on what medicines an individual is taking, BTC would probably make this problem even more serious.

4. What should the criteria or standards be for a drug to be treated as BTC?

Obviously, only drugs with manageable and understandable side effects should be BTC. There is data that only about half the warning label changes on a drug occur in the first seven years it is on the market, therefore we recommend requiring many years on the market before a move to BTC.

Drugs with known highly dangerous drug-drug interactions should not be BTC. The economic cost of drug interactions and resultant adverse drug events have

[3] One 2005 study reported that 44% of frail elderly patients had one or more unnecessary prescriptions at the time of discharge from a hospital, with about 8% of those considered duplicative. Sixteen percent of Medicare patients starting home health services have been found to have duplicate prescriptions. See ER Hajjar et al., 2005 and S. Meredith et al, 2001 in the Journal of the American Geriatrics Society.

been estimated at as much as $177.4 billion.[4] We should not be encouraging anything that increases access to potentially dangerous drugs without the coordination of a medical home and a provider who can review the total picture. Similarly, drugs that may be inappropriate for seniors (or other age groups) should not be BTC. This would include the Beers list (as updated) type drugs.

5. Please comment on the following criteria for what roles a pharmacist or other health professional might play, which are included below for discussion purposes. For example, a pharmacist or other practitioner licensed by law to dispense prescription drugs prior to sale might:
(A) Review or conduct an initial screening for clinical laboratory test results, contraindications, or drug interactions;
(B)Counsel the patient on safe use;
(C)Monitor for continued safe or effective use.

At a time when studies show that patients only get about half the services or counseling they should when they encounter their physician, what specific steps can be taken to ensure a higher quality of service rate among already busy pharmacists? In other words, if doctors are often failing to provide the above quality service, can we assume it will be any more do-able at the pharmacist level? And who will do the monitoring to ensure the quality of the above services?

6. Should BTC availability be used as a temporary or transitional status for drugs that move from prescription status to OTC versus a permanent status?

We think this can be a very useful step. As the FDA's long and drawn-out hearings on moving Claritin OTC show, there can be uncertainty about the wisdom of such actions. As stated, we supported moving Allegra/Zyrtec to OTC, only after a tremendous amount of research and with great caution. A BTC interim step might provide more safety for all concerned.

7. Should there be criteria or standards for a drug to transition out of BTC status to OTC status? If so, what should these criteria or standards be?

Yes, we encourage planning for such a transition. OTC is where the true consumer savings can arise because of intensified competition and reduced physician visit expense.

8. If safety concerns arise, should there be criteria or standards for a drug to transition out of BTC status to prescription status? Or from OTC status to BTC status? If so what should these criteria or standards be for each scenario?

If safety concerns arise, action should be immediate, not 'transition.'

---

[4] Ernst & Grizzle, "Drug related Morbidity and Mortality," Journal of the American Pharmacist Association, 2001

What effect would BTC availability have on patient access to medications in this category?

Again, assuming insurance coverage continues, it should help, not hurt.

10. How could we evaluate whether BTC improves patient access to medications?

A FDA press release of November 1 raises interesting questions:

"The data lead us to believe that many people are buying drugs online not to save money but to bypass the need for a prescription from their doctor since these Web sites typically do not require the purchaser to have a prescription," said Randall Lutter, Ph.D., FDA's deputy commissioner for policy. "In essence, they seem to be getting and using prescription drugs without a prescription, an intrinsically risky practice."

We agree that is a risky practice—but is there any data on how many of these people are resorting to mail order and international purchases because they can't afford doctor visits? We know that the uninsured use far fewer prescriptions than those with insurance. Is part of that reduced use due to reduced access to doctors, and would BTC be especially helpful to that population? This is the kind of question that could be addressed through a state demonstration project.

11. Would BTC availability be cost-effective to patients? Please explain.

We believe it would be, assuming no costs from adverse events.

12. What effect would BTC availability have on patient safety?

See previous comments

13. What measures would be necessary to ensure patient safety?

Perhaps a key step would be to concentrate Routine Active Surveillance analysis on a drug before it goes BTC. Section 905 of the FDAAA calls for a new system of post approval safety analysis. The goal by July 2012 is to have 100 million de-identified patient records available for analysis of adverse side effects and, in essence, the relative effectiveness and safety of the drug. Before a drug is proposed for BTC, some special section 905 research should be done to ensure that we are not missing side effects and long-term problems that are not easily visible or detectable by the current Medwatch system.

Also before dispensing, the patient could be asked to sign a simple, easy-to-read statement of the known side-effects, dosage, etc., and the pharmacist counseling would consist of going over the key issues. This would certainly be more information that most consumers receive or absorb in the current system.

14. In general, what are the benefits and costs to the healthcare system as a whole related to BTC availability?

If designed carefully and tested in one or two states, there could be dollar and time saving benefits.

Logistics

We have no special comments to add to the remaining questions.