Payers Raise the Bar by Lowering Barriers To Medications for Chronically Ill Enrollees

While simultaneously enhancing the education and preventive services components and implementing its own disease management (DM) program, Pitney Bowes Inc. (PB) in January 2002 redesigned its employees’ pharmacy benefit to enhance medication compliance for asthma, diabetes and cardiovascular disease patients. By lowering the prescription coinsurance to 10% for categories that had poor utilization of early preventive services and low rates of medication compliance, and by implementing what Corporate Medical Director Jack Mahoney, M.D., calls a “structural change,” the company already has saved an estimated $2.5 million.

“So much of health care is putting out fires,” says Mahoney. For instance, when companies see the use of emergency room services go up, one common response is to increase the ER visit copay, he says.

Health plans and employers have been lowering or waiving copayments or coinsurance for people with certain conditions for years, but it’s a more personalized and holistic approach that can really effect change in member behavior, suggests Dan Johnson, who is president of CDJ Consulting in Spokane, WA. In other words, reduce members’ out-of-pocket (OOP) expenses — the greatest barrier to obtaining health care — wherever they might be interfering with the treatment process.

This is close to what A. Mark Fendrick, M.D., and other researchers at the University of Michigan Medical School had in mind when they developed the “benefit-based
copay” (BBC) or “personalized formulary.” Simply put, the BBC approach recommends lowering copays for people with certain conditions depending on the severity of their illness. This concept was first detailed in a September 2001 article published in The American Journal of Managed Care.

Fendrick, who is an associate professor at the UM Medical School, tells DBN this approach has nothing to do with type of drug (e.g., brand vs. generic) but instead deals with the “expected clinical benefit” of the drug. He says he is not recommending that payers lower or waive copays on all drugs in a certain category, as some are doing, but rather do it just for people for whom there’ll be a benefit. For example, according to Fendrick, if a patient has had a heart attack and is taking a cholesterol-lowering agent, then his statin copay should be lower than that of a patient who has not had a major coronary event and has comparatively low levels of LDL, or “bad cholesterol.”

“The core of this concept that differentiates us from what PBMs and large health plans are doing is that it goes to the level of the research within subsets of patient groups so much so that individual patient information can be used to personalize the drugs they’re on and the copays for them.” This, of course, presents additional administrative challenges for health plans, which could explain why plans are somewhat slow to fully adopt the BBC model.

**CIGNA Uses 'Tiered Clinical Utility' Approach**

CIGNA HealthCare has adopted its own version of the BBC approach, which Assistant Vice President of Clinical Pharmacy John Poniatowski calls “tiered clinical utility.” Looking at clinical, outcomes and other data, the insurer structured a four-tier BBC option that became available in January although no clients have chosen it yet.

On the first, lowest-cost tier are the “life saving” drugs, which prevent immediate or near-term consequences, as opposed to therapies that have effects on health outcomes but tend to be more maintenance medications. An example of the former would be asthma inhalers to treat acute asthma attacks. Those are drugs that plans want a patient to have on hand and that therefore should cost patients the least, explains Poniatowski. Drugs in the second tier would include medications to lower blood pressure or asthma controllers to prevent asthma attacks. The third and fourth tiers are “life enhancing” and “lifestyle” drugs, respectively. These tiers can vary by copayment or coinsurance levels, depending on the client’s preference.

To some, this four-tier approach could easily be confused with reference-based pricing, another benefit option that has been adopted by both CIGNA and WellPoint, Inc. (DBN 12/24/04, p. 1). “Both benefit designs are based on clinical evidence and reaching conclusions about therapies and interventions,” explains Poniatowski. “But reference-based pricing doesn’t necessarily align the copay of the drug class with what the expected health outcome would be.” Instead, it evaluates a class that has several drugs with safety and efficacy profiles, determines which drugs are clinically interchangeable and then puts the least expensive of those drugs on the lowest tier.

PB’s approach, on the other hand, makes “no assumptions about efficacy,” says Mahoney. “We really wanted to get it to a position where we would lower the access barrier as low as we could.” In some cases, even the most expensive, tier three brand-name drugs were placed at the 10%, first-tier level coinsurance. Mahoney says he was not familiar with Fendrick’s concept when Stamford, CT-based PB started this initiative. The PB model does not favor certain patients based on their severity of illness.

The largest behavior changes achieved with PB's approach were among asthma patients, who are now...
using fewer drugs to treat asthma-related complications and visiting the ER and hospital on markedly fewer occasions, says Mahoney. In 2003, the overall cost of the company’s asthma population went down 15%, including costs for people who were not enrolled in a DM program. “If you look at just people who were managed, [the savings were] much higher and their prescription drug costs actually went down,” says Mahoney. Enrollment in the DM programs is not mandatory to get the coinsurance discount.

The FORTUNE 500 employer, which has approximately 24,000 employees in the U.S., also saw a slight decrease in the use of ER services and improved medication compliance among diabetes patients. The company has not, however, seen significant changes among patients taking hypertension medications. “We expect that to take years,” says Mahoney. The company’s next step is to design a depression management program that will be more intertwined with the DM model, he adds.

**Insurers Test Different Approaches**

Other insurers that are warming up to the BBC approach include Blue Cross and Blue Shield of North Carolina and Mutual of Omaha. In August 2004, the North Carolina Blues plan put all inhaled corticosteroids, including nonpreferred brand, on the lowest copay level for patients enrolled in the company’s asthma care management initiative. Enrollment in the asthma program jumped 30% the first month the copays were lowered, says spokeswoman Michelle Douglas.

And Mutual of Omaha is now developing plan options that will include a “disease-based formulary,” in which members will have the lowest copay for medications that have “the greatest potential to impact major medical expenses due to inaccessibility or lack of compliance,” according to Vice President and Product Manager Brad Utoft.

Utoft says he is not a proponent of waiving copays altogether for any type of condition because that can disengage the consumer.

**Challenges to Increasing Medication Access**

Mahoney says PB initially had to spend more on medications while trying to manage the overall health care trend. With certain brand-name drugs no longer on the third tier, the employer had some “difficult discussions” with pharmaceutical manufacturers about rebates and market share, but was able to work through some of the challenges with its PBM, Caremark Rx, Inc. (formerly AdvancePCS).

Adverse selection of members is another potential issue, warns Johnson. “A health plan would be ill-advised to offer a plan to its members that offered better OOP rates when compared to its competitors.” He also recommends plans do something positive for healthier members, too, so that certain members don’t become upset when others are suddenly paying less for their medications or have lower deductibles.

“Administration is an issue, too, but only to the extent that administration must be considered and not be an afterthought,” he says. Plans’ claims systems must be able to handle designs that alter copays and deductibles for certain patients, and testing is key, he urges.

Fendrick says his research team is now conducting several retrospective studies to figure out how best to identify where payers could see the greatest return on investment with the BBC approach. The researchers also have prospective studies in the field to evaluate whether lowering medication copays will actually improve adherence and ultimately improve clinical outcomes. He says he hopes to have some results later this year.

Contact Marianne Fulgenzi of PB at (203) 351-6974, Johnson at (509) 979-4667, Kara Gavin of UM at (734) 764-2220, Lindsay Shearer of CIGNA at (603) 268-7721 and Douglas of BCBCNC at (919) 765-2825.

**HRAs vs. HSAs: Which CDH Plans Favor the Pharmacy Benefit?**

Starting Jan. 1, 2006, health savings account (HSA)-based plans cannot have a separate carved-out pharmacy arrangement, meaning employees will have to use the same account for their medical and pharmaceutical expenses. While this may be a good thing for employers that wish to quickly reduce prescription drug costs by prompting employees to look closer at the prices of their drugs, these plans do not provide the same flexibility as health reimbursement arrangement (HRA)-based plans, suggests consultant Vince Kuraitis.

For employers that have a significant chronic-disease population, it is important that they understand the
difference between these two “consumer-directed health” plans before implementing CDH.

Employers are essentially in a transition period allowed by the Treasury Department that enables individuals covered by a separate pharmacy benefit policy to continue to contribute to their HSAs until the end of this year. HSAs and HRAs are common components of CDH, which most major insurers have adopted but few PBMs yet have incorporated into stand-alone pharmacy benefit designs.

CDH plans typically combine a high-deductible health plan (HDHP) with an HRA or an HSA. The main difference between the two is that both employers and employees can make pre-tax contributions to an HSA and that account is portable, meaning a person can bring the money to his or her next employer.

HRAs typically are unfunded, notional (virtual) accounts that are accessible only when claims are filed. An employee’s $1,000 HRA, for example, is never sitting in an account. Rather, the employer covers claims as they occur up to $1,000. That makes it easy for employers to restrict HRAs to specific health care expenses. Unused HRA dollars typically revert back to the employer when an employee leaves or when the CDH plan is discontinued. HSAs, by contrast, belong solely to the employee, and are funded with real dollars.

Employees can first use the funds in these accounts to pay for their medical and pharmacy expenses. Once those funds are depleted, they must meet a high deductible (upwards of $1,000 for single coverage). After the deductible is met, traditional health care coverage kicks in.

Are CDH Plans ‘Pharma-Friendly’?

“Out of the box, most of these plans are not very pharma-friendly,” says Kuraitis, who is a principal with Better Health Technologies in Boise, ID. He suggests that most early adopters of CDH are motivated by the need to cut costs, and where pharmacy fits into CDH plans is “all over the map.” HRAs give employers more flexibility to structure their benefits in the way that they want to, while HSAs can no longer have carved-out pharmacy benefits as of Jan. 1, 2006. “That has tremendous implications for PBMs and pharmaceutical companies,” he says, although “it’s unclear how many people could buy HSAs.”

For example, under an HRA, employers using a carved-out pharmacy benefit could create employee incentives for utilizing certain drugs, put in higher copays for certain kinds of drugs, or provide “first-dollar coverage” for patients taking asthma medication, for example, and consider that preventive care. These plans are likely to be bought by “sensitive” employers that have an older work force and want to be able to encourage their employees to use drugs in a way that promotes long-term compliance, suggests Kuraitis.

On the other hand, employers that adopt HSAs are more likely to see their pharmacy costs go down because without that flexibility in pharmacy design, they’re directly shifting cost to the consumer, he says. Some critics of these plans argue that they don’t do much to improve members’ medication compliance, and that in turn could lead to higher medical expenses, more hospital visits and so on. Yet, “there’s no evidence of what will happen,” he adds.

**Mutual of Omaha CDH Plan Separates Pharmacy**

To help support members with chronic conditions, Mutual of Omaha offers a CDH plan that combines a high-deductible PPO with an HRA, and has a separate deductible for prescription drugs. Vice President and Product Manager Brad Utoft says this benefits members with chronic conditions in that they pay a separate, smaller calendar-year deductible on prescription drugs (e.g., $100 vs. $2,000 for medical expenses), and then the plan pays the majority of their prescription drug costs through a tiered coinsurance system.

Coinsurance, he says, further encourages members to be health care consumers because it allows them to better see the cost of the drugs they are taking. Members also have a separate out-of-pocket maximum (e.g., $1,000 per person) for prescription drugs in addition to the deductible.

Utoft explains that this approach is different from the traditional HRA or HSA models in which the member would first utilize those accounts and then have to satisfy the large deductible before the plan again begins paying a portion of his or her prescription drug costs. “This [separate-deductible] approach has the plan covering the majority of the prescription drug costs so the member can afford to take their medications,” says Utoft. Combined with the insurer’s disease management programs, this can enhance medication adherence, he adds. The plan is aimed at insured and self-funded groups of 51 employees or more.

Mutual of Omaha has also introduced an HSA-based HDHP that combines the medical and prescription drug deductible, as required by the Medicare reform law. In other words, there is one deductible and one out-of-pocket maximum that apply to both medical and prescription drug costs.

Utoft says this approach can benefit members with chronic conditions if the employer makes a reasonable contribution to the HSA and the employee chooses to contribute the balance. “With a reasonable employer contribution to the HSA, those with chronic conditions may not have that large of a gap to fund before the plan begins to pay the majority of their costs,” he says, such
as if the employer contributes 50% and the employee contributes 50%.

Contact Kuraitis at (208) 395-1197, Lisa Waddell of Mutual of Omaha at (402) 351-5941. Visit www.ustreas.gov for more information on HSAs. 

**Plans Tweak Part D Formularies**

While many insurers and PBMs say they don’t expect their Medicare Part D formularies to deviate too far from their existing commercial and senior population ones, potential Part D sponsors may face some challenges as they put the final touches on their submissions to CMS. All Medicare Part D formularies are due to CMS on April 18 and will be reviewed for a two-to-four week period, depending on the amount of back-and-forth between CMS and plans to get approval (DBN 3/25/05, p. 1).

“Drugs currently covered under the commercial benefit plan needed to be considered and in some cases added to meet the CMS guidelines,” says Ron Smith, Pharm.D., director of corporate pharmacy at Blue Cross and Blue Shield of North Carolina, which is applying to be a Prescription Drug Plan (PDP) under the Medicare drug benefit that takes effect next Jan. 1.

The biggest adjustment for CareFirst Blue Cross and Blue Shield, which also submitted a PDP application, was adding the home infusion, long-term-care drugs and vaccines to its formulary, says Director of Pharmacy Management Winston Wong, Pharm.D. This meant including therapies such as immune stimulants, immune suppressants and tumor necrosis factor inhibitors, which were included in the United States Pharmacopeia guidelines and might not traditionally be on health plans’ formularies.

**No Enteral Nutrition Coverage Required**

According to the final rule issued by CMS in January, Part D covers the following home infusion therapies: parenteral nutrition (in the case that it is medically necessary and not covered under Part A or B), antibiotics, pain management, chemotherapy and immune globulin. Part D plans are not, however, required to cover enteral nutrition, vitamins and minerals added to total parenteral nutrition, and heparin when it is used as a flush.

One potential issue for plans in the future could be the addition of drugs covered under Part D that were previously Part B drugs. According to a March HHS report, “Transitioning Medicare Part B Covered Drugs to Part D,” there are 13 categories of Part B drugs that are “separately billable” and might be considered for Part D coverage. These would include drugs used in immunosuppressive therapy; certain vaccines, parenteral nutrition in certain medical situations, and certain oral drugs used in cancer treatment. Because adding these drugs could create further complexities for potential Part D sponsors when developing their initial bids, HHS recommended to Congress not moving coverage of any drugs now covered under Part B to Part D until the new Medicare benefit has about two years of experience.

The next major due date for the drug benefit is June 6, when all Part D sponsors must submit their bids for coverage starting Jan. 1, 2006. The savings that plans expect to generate from rebates and discounts on formulary drugs must be factored into companies’ bids.

Go to www.cms.hhs.gov/researchers/reports/2005/RTC_PtbtoPtD.pdf to download the HHS report. For additional guidance, visit www.cms.hhs.gov/medicareform/pdbma/general.asp. 

![Figure 1. Market Share of Major PBMs And PBAs as of First Quarter 2005](image-url)
Monroe County, NY Sues 77 Drug Firms for Allegedly Inflating Prices

In a lawsuit filed April 1 in U.S. District Court for the Western District of New York, Monroe County, NY is charging 77 pharmaceutical manufacturers with inflating the prices for prescription drugs purchased by the county for its Medicaid beneficiaries. Monroe, which includes the city of Rochester, joins a growing number of counties in the state that have filed similar suits against multiple drug companies in the last year.

The Monroe Medicaid program spent more than $111 million on prescription drugs for Medicaid beneficiaries in 2003, according to the suit. The suit is seeking recovery of the excessive Medicaid pharmacy costs allegedly paid on behalf of Monroe residents by the county, the state and the federal government. The complaint did not include figures for the total estimated damages. The allegations date from 1992 to the present.

The suit alleges that the companies reported “grossly inflated” average wholesale prices (AWPs) prices to the publishing services that disseminate this information. In doing so, companies can create a large spread between the actual prices that pharmacies pay to acquire drugs and the reimbursement that those same entities receive from Medicaid, Medicare and private third-party payers, says the complaint.

In 2002, for example, Monroe spent more than $1 million on the generic antidepressant fluoxetine and claims it was overcharged between 56% and 95% on each pill as a result of the allegedly false fluoxetine AWPs. In an exhibit submitted with the complaint, Monroe says the 2002 AWP reported by Barr Laboratories, Inc. for fluoxetine was $2.67 per pill, compared with the county’s “true” AWP estimate of 79 cents. The county says it paid a total of $264,157 on the Barr product in 2002, with a total overestimated charge of $176,776, or 67% of the fraudulent AWP.

Barr spokeswoman Carol Cox explains that it’s up to Medicaid and the retail pharmacies how Medicaid is reimbursed and that it’s widely understood that AWP is just a reference price. Cox could not comment on the specifics of the Monroe litigation since she says Barr has not yet seen the complaint.

The lawsuit also charges drug makers with reducing the amounts of rebates that they pay to the states for brand-name drugs by omitting certain items from their calculation of “best price,” or the lowest price paid by any purchaser. The county is seeking full payment of the amount of rebates owed, which it did not quantify.

Charges Aren’t New to Defendants

In 2003, Pfizer Inc. paid $49 million in a multistate settlement to resolve allegations of failing to accurately report federally mandated “best price” information for Lipitor (atorvastatin), and providing unrestricted “educational grants” of $250,000 to an HMO in exchange for keeping the cholesterol-lowering drug on the HMO’s patient drug coverage list (DBN 4/1/03, p. 12). Monroe County names Pfizer in the lawsuit and says it overpaid at least $513,000 for Lipitor in 2002 because of the allegedly inflated AWP.

In a statement released to DBN, Pfizer calls the allegations of AWP abuse “misplaced” and “without legal merit,” suggesting that the issue should be addressed in the state legislature and not in the courts. “The State of New York and its counties are well aware that the AWP does not reflect the lowest price available for a medicine,” said Pfizer. “But New York has chosen to leave its current pricing practices in place to ensure ready access to medicines by Medicaid patients.”

Monroe will be represented by the New York City law firm Kirby, McInerney and Squire, which is working with 43 other New York counties and the city of New York on similar lawsuits.

View the complaint at www.monroecounty.gov, or call Joanne Cicala of Kirby, McInerney and Squire at (212) 371-6600.
Medco Gets Two State Contracts
continued from p. 1

Under the arrangement with Medco, the state will pay an administrative fee in exchange for full transparency and pass-through of all rebates for all retail drugs. Under mail order, however, the state will get full transparency and pass-through only on the brand-name drugs and not on the generic drugs.

Medco spokeswoman Jennifer Leone explains that the company typically offers plans a contractually agreed-upon discount off the average wholesale price (AWP) for generics dispensed through the mail. Since the AWP level is published by an independent third party, the state can easily benchmark Medco’s mail-order generic pricing against competitive offers, she says.

But Jack McClurg, CEO of Colorado-based pharmacy benefits administrator HealthTrans, tells DBN it’s not a total stretch for PBMs to disclose generic pricing on the mail side. Refraining from doing so, however, is still a common practice among larger PBMs, he says. “It’s simply a matter of choice.”

Medco Will Disclose Drug Company Fees

While Medco will collect certain administrative fees from pharmaceutical manufacturers, Neff says the PBM agreed to disclose those fees and for what purposes it is receiving them. None of those fees will be passed on to the state. “We wanted disclosure and, where appropriate, we wanted the full pass-through and the ability to audit,” says Neff.

The state will pay Medco a mail/retail claims fee of 9 cents per member per month, with a 74-cent PMPM administrative fee. There is a $2 dispensing fee for each retail prescription and a $2.50 dispensing fee for each specialty claim. And there is a $15 per case fee for DAS’s initiated prior authorizations and a $40 per case clinical appeal charge. “Additionally, as DAS gets rebates from Medco, the true fee we’ve paid for administration can’t be known until the end of each quarter,” says Neff.

At the end of 2003, the Ohio state attorney general filed a lawsuit alleging that Medco and its former parent Merck & Co., Inc. overcharged the State Teachers Retirement System by as much as $50 million (DBN 1/16/04, p. 4). The PBM contracted with the pension fund from 1988 to 2001. As an agency that is separate from the teachers’ retirement system, DAS did not consider the lawsuit to be a hindrance to its decision, says Neff. The suit is ongoing, and Medco “vigorously denies the allegations,” according to Leone.

Meanwhile, the Pennsylvania Employees Benefit Trust Fund (PEBTF) in Harrisburg intends to award a three-year pharmacy benefit contract to Medco, the company said April 6.

PEBTF had previously contracted with National Prescription Administrators, which was acquired by Express Scripts in 2002. Working with Aon Consulting, PEBTF determined which vendors could handle a group of its size (about 300,000 lives) and sent out the RFP to just those vendors, according to spokeswoman Christy Leo. PEBTF declined to say how many vendors were evaluated. The selection was based on which vendor could offer the best price and handle the group’s size, says Leo. While rebates were part of the negotiations, Leo declined to provide details of any rebate-related aspects of the contract.

Pennsylvania was one of 20 states that accused Medco of drug “switching” practices that resulted in a 2004 settlement (DBN 4/30/04, p. 1). As part of that settlement, Medco paid $1.8 million to Pennsylvania to assist residents with their prescription drug costs. The Pennsylvania Department of Aging said on April 6 that the money is being used to offer a free prescription drug benefit featuring $600 worth of generic medications to residents of any age who are low-income, disabled and without health insurance coverage. That drug-switching investigation was also not a “roadblock” in PEBTF’s decision to select Medco, adds Leo.

Contact Gretchen Hull of DAS at (614) 752-9521, Medco’s Leone at (201) 269-6402 and PEBTF’s Leo at (717) 531-4750.

NEWS BRIEFS

♦ Although a Maine law that designates PBMs as fiduciaries was upheld on April 13 in U.S. District Court for the District of Maine, the Pharmaceutical Care Management Association (PCMA) says it will appeal the ruling in the First Circuit Court of Appeals in Boston and ask the Maine court to preserve the injunction until the appeal is heard.
PCMA President Mark Merritt called the decision “disturbing” and said it undermines the competitive model that PBMs rely on to negotiate lower drug prices. The law also imposes thorough disclosure and transparency requirements on PBMs that would essentially put PBMs’ “proprietary and confidential business information” in the public eye, said Merritt in an April 13 conference call. Only one other jurisdiction, the District of Columbia, has
approved similar legislation, but PCMA obtained an injunction against that law (DBN 12/24/04, p. 8). Contact PCMA’s Phil Blando at (202) 207-3614.

◆ NDCHealth, an information solutions company that serves the health care industry, said on March 29 it has sold its 49.5% membership interest in Colorado-based pharmacy benefit administrator HealthTrans. The company says it sold the interest to executives who hold the rest of its equity, and received cash proceeds of approximately $8.8 million, which it says will be used to pay down senior debt. The HealthTrans Pharmacy Benefit Services segment contributed $18.7 million, or 15.9% of total NDCHealth revenue in the second fiscal quarter, which ended Nov. 26, 2004, says NDCHealth. Jack McClurg, CEO of HealthTrans, tells DBN the transaction will not cause any organizational changes, since HealthTrans has always been an “autonomous operation,” but that it might enable the company to look into acquisition opportunities that previously could have been more difficult to explore. Contact Robert Borchert of NDCHealth at (404) 728-2906 or Mary Ann McCauley for HealthTrans at (952) 401-1983.

◆ In an effort to improve patient safety and to reduce prescription drug costs, Blue Cross of Northeastern Pennsylvania says it will distribute 250 hand-held personal digital assistants (PDAs) to network physicians. In addition, the health plan will offer another 250 subscriptions to physicians who already have PDAs. The PDAs and subscriptions will provide physicians with access to Epocrates Essentials mobile clinical reference suite, which allows providers to easily check formulary status, prior-authorization requirements, alternatives, generic substitutes and quantity limits. The Blues plan estimates that 28% of its physicians are now using products from Epocrates. The Essentials suite also features capabilities for checking drug-drug interactions and contraindications, thus reducing the chances for adverse drug reactions. Contact Gerry Snyder of Blue Cross of Northeastern Pennsylvania at (570) 200-6310.

◆ Pfizer Inc. on April 7 said it would suspend sales of Bextra (valdecoxib) even though it disagrees with FDA’s position that the overall risk vs. benefit profile of the drug is unfavorable. FDA recommended the voluntarily withdrawal after concluding there is a lack of adequate data on the cardiovascular (CV) safety of long-term use of Bextra and after reviewing reports of serious and potentially life-threatening skin reactions. In addition, FDA is asking manufacturers of all marketed prescription non-steroidal anti-inflammatory drugs (NSAIDs), including Pfizer’s other Cox-2 Celebrex (celecoxib), to revise their products’ labeling to include a boxed warning and a medication guide. The boxed warning should highlight the potential for increased risk of CV events and potentially life-threatening gastrointestinal (GI) bleeding associated with their use, FDA said April 7. Makers of over-the-counter NSAIDs (e.g., Motrin, Aleve) are also being asked to revise their labeling to include more specific information about the potential for GI and CV risks. Pfizer said it would continue discussions with FDA regarding ways to resume selling Bextra, and it has agreed to conduct additional long-term clinical studies evaluating the risks and benefits of Celebrex. Consumers Union said the withdrawal “underscores the need for major reform” at FDA and noted that FDA’s recommendations did not address limits on direct-to-consumer advertising, which the consumer group contends played a significant role in the rapid growth of Cox-2 use. Contact Kathleen Quinn of FDA at (301) 827-6242 or visit www.pfizer.com for more information.

◆ Two states this month took action to protect women’s access to contraceptives, responding to recent refusals by pharmacists to dispense prescriptions based on moral grounds. On April 2, Illinois Gov. Rod Blagojevich (D) issued a 150-day emergency rule that requires pharmacies in that state to fill contraceptive prescriptions without delay. And California Senate Bill 644, now being reviewed by the Senate Committee on Business, Professions and Economic Development, would allow a pharmacist to object to dispensing a lawful prescription on ethical, moral or religious grounds, but also stipulates that the pharmacy must ensure the patient has timely access to the prescription. Visit www.legislature.ca.gov and www.state.il.us for more information on the actions.
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