

Welcome, New House Staff

On behalf of the Department of Pharmacy Services at the University of Washington Medical Center, Harborview Medical Center, Seattle Cancer Care Alliance, and UW Medicine Neighborhood Clinics, I would like to welcome you. We look forward to working with you during your residency.

You will be receiving copies of the *Drug Therapy Topics* newsletter on a monthly basis. This newsletter is a source of current pharmacotherapy-related information as well as a major communication between the Department of Pharmacy Services, the Pharmacy & Therapeutics Committee, and the Medical Staff. It is intended, in part, to keep you updated on additions and deletions to the medical centers' formulary, along with changes in policies and procedures as approved by the Pharmacy and Therapeutics Committee. Your input into its content is welcome.

The medical centers' *Drug Formulary* provides key information regarding drug availability, along with procedures pertaining to medication use. You will be provided with a personal copy of the formulary. For expanded and updated clinical details on all drugs and for "alerts" regarding formulary drugs, you may also access the formulary and the UW Drug Information Center web site electronically at <http://uw.pnrx.org>.

If you have any questions regarding pharmacy services, please ask the clinical pharmacist on the unit or in the clinic (see other side of this insert for a directory) or call one of the following pharmacy phone numbers. Again, a sincere welcome from all of us.



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This article updates UW Medicine practitioners on the trends driving the increase in R_x drug costs and presents the latest statistics on the associated patient burden.

For a review of drug cost fundamentals see: Maximizing value - what every practitioner should know about drug costs. DTT 2002;31(7):1-4. at http://depts.washington.edu/druginfo/DTT/2002_Vol31_Files/V31N7.pdf

Table I: Some Drugs in the Pipeline⁴

New Drug	Use
Alvimopan	Post-op ileus
Dalbavancin	Serious infections
Indiplon	Insomnia
Nebivolol	Hypertension
Panitumumab	Cancer
Rimonabant	Smoking; Obesity
Sipuleucel-T	Prostate cancer
Vildagliptin	Diabetes

In 2001, pharmaceutical companies spent \$19.1 billion to market their products.⁸ Approximately \$2.7 billion of this was spent on direct-to-consumer (DTC) ads. DTC promotions play a significant role in stimulating sales of new and existing drugs. A recent study found that about 12% of drug growth trends could be attributed to DTC advertising.

Sticker Shock:

Trends Driving Rising Drug Costs

True or False: One in 10 health care dollars is spent on prescription drugs.¹

Prescription (R_x) drugs are a mainstay in most Americans' lives.² Fifty-four percent of Americans report that they are regular users of R_x drugs, 24% say that they take three or more drugs regularly, 30% have more than five R_x drugs in their medicine cabinets, and 8% spend \$1000 or more per year on R_x drugs.² Seventy-four percent of Americans believe that drug company profits or marketing costs are the largest contributors to the price of R_x drugs.³ Eighty-one percent of Americans say that drug costs are not justified because companies charge more for medications than necessary.³ Sixty-nine percent say high profits made by drug companies are a "very important" reason for higher health care costs, followed by greed and waste in the health care system (62%).³ Ninety percent of Americans have seen or heard an ad for R_x drugs, 26% have talked to a doctor about a specific drug after seeing an advertisement, and half of these people said the doctor prescribed the particular medication.³ In 2005, 64% of the public said there should be more government regulation of R_x drug prices, and 46% of all adults support more regulation of prices even if it leads to less R&D of new drugs.³ Finally, in 2004, 73% of adults supported the idea of allowing Americans to buy lower-priced R_x drugs imported from Canada.³

Health care spending in the United States reached \$1.9 trillion in 2004.¹ Currently at 16% of the gross domestic product (GDP), national health spending is projected to account for 20% of GDP within the next 10 years.¹ Outpatient R_x drug expenditures increased by 8.7% in the United States in 2004,⁴ marking the first time in recent years that growth in this category has dipped below double digits. While the increase in R_x drug expenditures was slower than in previous years, it remained higher than the projected growth in total health care expenditures and higher than the growth in expenditures for hospitals and physician services. Thus, R_x drug costs remain at the forefront of local and national health policy debates.

R_x drug expenditure growth is largely a function of three factors: new drugs, price, and utilization.⁴ New drugs with the potential to substantially affect drug expenditures include several recently approved therapies for diabetes (e.g., inhaled insulin, exenatide, pramlintide) and drugs in the pipeline for cancer, serious infections, and other diseases (see Table I). With regard to price, the slower growth in 2004 drug expenditures mainly reflects constraint in the rate of manufacturer price increases. The main factors thought to have contributed to the deceleration in growth of 2004 drug prices include patent expirations and first-time generics (e.g., omeprazole, fluoxetine, lisinopril), increased competition among generic drug manufacturers, conversion of commonly used R_x drugs to nonprescription status (e.g., nonsedating antihistamines, proton pump inhibitors), reductions in the demand for products with emerging safety concerns (e.g., hormone replacement therapy, COX-2 selective NSAIDs, SSRIs), and higher cost sharing by consumers (e.g., higher premium payments, deductibles, co-payments).

Utilization, the third factor contributing to drug expenditure growth, is a composite of volume and mix. Volume is simply the aggregate amount of any drug prescribed/patient and mix is defined as the aggregate pattern of prescribing between differently priced options (e.g., generic vs. brand-name).⁸ Current drivers of the growth in utilization include the increased prescribing of existing drugs (e.g., colony-stimulating factors, "life-style" drugs), the prescribing of existing drugs for expanded or off-label indications (e.g., NovoSeven[®] to treat intracerebral hemorrhage⁷), aggressive adoption of tighter clinical guideline targets (e.g., blood pressure, glucose, and cholesterol goals), and the prescribing of more multi-drug treatment regimens.

Nationally, biologics and other specialty drugs administered by infusion or injection are the fastest-growing R_x drug expenditures. Specialty pharmaceuticals include oncology agents and other high-cost injectables for the management of chronic diseases such as hepatitis C, multiple sclerosis, cystic fibrosis, hemophilia, and rheumatoid arthritis. By one count, a total of 108 specialty drugs were on the market in 2004 and another 324 were in

Table II: 2005 Top 10 National Drug Expenditures⁴

Clinic	Drug	Hospital
1	Epoetin alfa	1
	Enoxaparin	2
2	Darbepoetin	3
3	Pegfilgrastim	4
4	Infliximab	5
	Ondansetron	6
5	Rituximab	7
	Piperacillin-tazobactam	8
	Propofol	9
	Ceftriaxone	10
6	Oxaliplatin	
7	Docetaxel	
8	Zoledronic acid	
9	Trastuzumab	
10	Gemcitabine	

Table III: Some Potential 2006-07 Patent Expirations⁴

Amlodipine (Norvasc)
Bupropion (Wellbutrin XL)
Carvedilol (Coreg)
Cetirizine (Zyrtec)
Finasteride (Proscar)
Ondansetron (Zofran)
Pantoprazole (Protonix)
Pravastatin (Pravachol)
Sertraline (Zoloft)
Simvastatin (Zocor)
Sumatriptan (Imitrex)
Zidovudine (Retrovir)
Ziprasidone (Geodon)
Zolpidem (Ambien)

An analysis of outpatient drug use published in 2005 estimated that greater generic drug use by outpatients in 2000 would have reduced national drug spending by \$8.8 billion, approximately 11% of total drug expenditures for the sample studied.¹¹

development.⁴ Specialty products are used by only about 0.2% of the U.S. population.⁸ However, at an average annual cost of treatment estimated at \$71,000/patient, specialty drugs account for a disproportionately large share of total medical costs and present a significant challenge for national cost containment efforts.^{8,9} Biologicals, such as epoetin alfa, darbepoetin, pegfilgrastim, and infliximab are consistently among the top expenditures for hospitals and clinics (see Table II). Equivalent generics for these and other specialty drugs would likely lead to important cost savings for the U.S. healthcare system. Despite expired patents for some, however, FDA has yet to adopt a framework for the market approval of biologic generics and U.S. drug manufacturers are lobbying for tough regulatory standards for such products.^{8,10} For the next several years, rapid product development and the lack of generic competition are likely to sustain high growth rates for specialty drug spending.

Over the past two years, hospital outpatient costs have increased disproportionately to other components of health care expenditures, largely because of an increase in the number of patients being treated in this setting. Expenditures for clinic-administered medications increased by 12.3% in 2004, a rate significantly greater than growth in outpatient and hospital expenditures.⁴ Clinic drug expenditures more than doubled over the 5-year period between 2000 and 2004. However, clinic drug expenditures represented only 9% of total 2004 medication expenditures. The top three clinic drugs in 2004 (epoetin, infliximab, and darbepoetin) accounted for 29% of all clinic-administered drug purchases.

In contrast, hospital drug expenditures increased by 7.9% in 2004, an increase over the growth seen in 2003.⁴ Anti-infectives account for almost 12% of national hospital drug expenditures and this expense increased by 9% in 2004 and by 15.4% in 2005. Growth in 2004 anti-infective expenditures was largely driven by caspofungin, linezolid, and piperacillin-tazobactam. Diagnostic aids, hospital solutions, and antineoplastic agents also experienced significant growth in 2004.

In summary, increases in generic drug utilization (see Table III), the continued impact of emerging drug safety issues, decreases in R_x drug coverage, and higher overall utilization are key factors driving drug expenditure trends.⁴ With cost-sharing by patients on the rise, prescribers and pharmacists have a heightened mandate to minimize the sticker shock (see Table IV) and maximize the value of R_x drugs for UW Medicine patients.

Table IV: Sticker Shock - Some AARP Statistics¹²

For the 12 months ending March '06 the cumulative average manufacturer price increase for the 187 brand name R _x drugs most widely used by seniors was 6.2%, nearly twice the general inflation rate of 3.5%.
For the 12 months ending March '06, the average annual increase in the cost of therapy for the 187 brand name R _x drugs most widely used by seniors was \$59.57/R _x , compared with a \$47.43 increase in 2005. A typical older American (who takes 4 brand name R _x drugs) likely experienced a \$238.28 increase in the cost of therapy for the 12 months ending with the 1st quarter of 2006, compared to \$189.72 in 2005.
The 6 brand name R _x drug products with the highest % change in manufacturer price in 2005 were Combivent [®] (22.1%), Ambien [®] (19.5%), Flovent [®] (19.3%), Atrovent [®] (18.6%) Lantus [®] (14.9%), and Premarin [®] (13.8%). For the 1st quarter of 2006 these drugs are Ambien [®] (13.3%), Combivent [®] (12%), Atrovent [®] (12%), Proscar [®] (8.9%), Lexapro [®] (8%), and Seroquel [®] (8%).
On average, manufacturer prices of the 153 most widely used brand name R _x drugs that have been on the market since 1999 have increased by more than 40.5% during the subsequent 6-year period, compared with a general inflation rate of 17.3%. For a typical senior who takes 4 brand name R _x drugs, the average increase in the cost of therapy for drugs used to treat chronic conditions rose by close to \$1200 during this period.
Through the end of the 1st quarter of 2006, a period that includes the months when Medicare drug coverage was first available, annual increases in manufacturer prices charged to wholesalers for the most widely used brand name R _x drugs used by seniors, on average, continued to exceed the rate of general inflation. In fact, the increase (3.9%) was the highest 1st quarter recorded during AARP's 6 years of study.

References available upon request.

Pharmacy & Therapeutics Committee Actions

Formulary Additions	Dosage Form(s), Strength(s), & Cost [‡]	Therapeutic Classification	Use	Usual Adult Starting Dose*
Natalizumab (Tysabri)	Injection: 300mg/15mL	Immunomodulator	Multiple sclerosis	300mg IV q 4 weeks.
	Added to formulary as a second-line therapy for multiple sclerosis with prescribing restricted to Drs. Lucas and Craft at UWMC. The prescribing physician must obtain prior authorization for patients with private insurance or obtain patient assistance from the manufacturer prior to initiating therapy. In addition patients and prescribers are required to be enrolled in the Touch™ risk minimization action plan.			
Other Actions				
COPD Treatment Guidelines Revised	Revisions to the UW Medicine COPD treatment guidelines were approved. The revised guidelines can be accessed via the UW Medicine eDrug Formulary (http://www.formchecker.com/FormChecker/servlet/Viewer?form=guidelines&formid=2glp104).			
Guidelines for Monitoring Ambulatory Patients Receiving IV Antibiotics	Infectious Diseases Subcommittee guidelines for ambulatory patients receiving IV antibiotics for longer than one week were approved. The revised guidelines can be accessed via the UW Medicine eDrug Formulary (http://www.formchecker.com/FormChecker/servlet/Viewer?form=guidelines&formid=ci1neo4). While the new guidelines are primarily intended for the ambulatory setting the principles are also applicable to inpatients. The monitoring recommendations do not replace clinical judgement and may be modified PRN for individual patients.			

* Refer to product labeling for full prescribing information. ‡ Contact pharmacy for information on drug costs.

Prescription Legibility: Hand Printed, Typewritten, or Electronically Generated

UW Medicine procedures and Washington State laws require that physicians write legible prescriptions.

Washington law now requires all prescriptions to be hand printed, typewritten, or electronically generated. Health care providers cannot write prescriptions in cursive. Effective June 7, 2006, prescriptions issued in cursive writing are considered illegible. The intent of the change is to protect patients from receiving the wrong medication because of illegible prescriptions. Prior to dispensing, pharmacists in Washington State are required to clarify illegible prescriptions. UW Medicine procedures require that physicians rewrite any illegible prescription.

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drug therapy topics