

# MAKING BEST CHOICES

This book is about choices. Our goal is to help you and your doctor select the most effective and affordable treatments for you and your family. In some cases, this may be a home remedy or a dietary supplement. But in many others, the best option could be a prescription medication.

We all make decisions about where to go for dinner, what movie to see, and which car to buy. Surprisingly, we have more information to help us make these choices wisely than we do about our health-care options.

We can check restaurant or movie reviews from trusted critics or consult *Consumer Reports* magazine for an impartial analysis of the best buys on toasters, mattresses, or automobiles. But where can you find objective information about the best way to treat arthritis, high cholesterol, or migraines?

Once upon a time most people relied primarily on physicians to make the decisions about treating these kinds of conditions. There were relatively few medicines, so doctors could know a lot

about the handful they were prescribing. Doctors learned about these drugs in medical school or depended on research published in medical journals. People trusted their doctors to select the best medicine for them.

Now, there are thousands of medications to choose from, and there is no way a physician can master all the information about so many. In addition, the pharmaceutical industry has developed sophisticated strategies to influence doctors' prescribing patterns. Drug companies advertise their prescription drugs directly to you on television and the Web and in magazines and newspapers. They spend almost \$5 billion a year trying to get you to "ask your doctor" about one of their products.

Physicians, nurses, pharmacists, and even medical office receptionists are also targets

of a full-court press by drug companies. Sales reps routinely provide lunches, dinners, and doodads like pens and notepads in an effort to influence your doctor to prescribe their latest and most expensive medicine. They leave lots of free samples for the doctor to give away. This may seem like a great deal, but after the pills run out, you are stuck paying the bill for what is often a pricey prescription.

These tactics work amazingly well. Patients do ask their doctors for specific medicines that they see advertised, and physicians prescribe them quite often.<sup>5</sup> And physicians are also influenced by drug company marketing.<sup>6</sup> Even their conferences and continuing medical education are often supported by the pharmaceutical industry.<sup>7</sup> That, too, influences prescribing, but does not necessarily lead to the most cost-effective, safest choice for the patient.

### **PAYING FOR THE FREE LUNCH**

- There are more than 100,000 drug sales reps in the United States<sup>1</sup>
- That's one sales rep for every four doctors
- Drug marketing costs \$12 billion to \$15 billion per year<sup>2</sup>
- That's \$8,000 to \$15,000 spent on marketing per year per doctor<sup>3</sup>
- 90 percent of continuing medical education materials for physicians are produced by drug companies<sup>4</sup>

## **DRUG PRICES**

Whether or not prescription drug commercials on television actually increase the cost of the medicines, they certainly help these pricey pills sell. Americans are paying more than ever for their medications. We have been tracking prices for 30 years. As you look at the following table, you may be astonished to see that between 1975 and 1985 the cost of some popular prescriptions rose very little. But starting in the 1990s, prices took off. They've been climbing ever since.

PRICE INCREASES OF POPULAR DRUGS				
DRUG*	1975	1985	1995	2005
Coumadin (10 mg)	\$9.40	\$13.85	\$86.19	\$133.49
Lanoxin (0.25 mg)	\$1.00	\$3.00	\$8.59	\$24.69
Lasix (40 mg)	\$9.73	\$8.95	\$19.99	\$39.49
Premarin (1.25 mg)	\$6.90	\$15.95	\$46.89	\$140.99
Valium (5 mg)	\$8.99	\$20.30	\$62.29	\$193.89
*Price is for 100 tablets from chain drugstores.				

Drug companies frequently justify the cost of their pills by citing the expenses of pharmaceutical research and development. All of these drugs were on the market before 1975, however, so their research costs were paid for decades ago. If cars or computers were priced like drugs, we would be paying tens of thousands for a laptop and no one could afford a Buick.

AARP conducted a survey of prescription drug manufacturers' prices and discovered that they have been accelerating for years, dramatically outpacing the overall rate of inflation.<sup>8</sup> Its analysis of 150 popular products shows that price tags on these brand-name drugs rose an average of 35 percent between 1999 and 2004. That's almost three times higher than overall inflation during that time, which amounted to 13.5 percent.<sup>9</sup>

The result of this trend is per-pill prices that take your breath away. The cost of the sleeping pill Ambien (zolpidem), which is advertised directly to consumers, jumped 11.9 percent in 1 year. A month's supply could cost about \$100, more than \$3 per pill. It's enough to keep you

awake at night worrying about how to pay for your prescriptions. But if prescription drug prices give you a headache, beware. One of the most successful migraine medicines, Imitrex (sumatriptan), will cost you nearly \$20 a tablet.

## HEAD-TO-HEAD

People don't mind paying top dollar if they believe they are getting their money's worth. That's why so many consult *Consumer Reports* magazine when they are trying to decide what microwave oven, digital camera, or cell phone to purchase. Consumers Union makes an effort to test many of the brands buyers are likely to find in their local stores. All equipment is subjected to the same tests, and products are rated on how well they perform. Consumers can choose the product that is most appropriate based on the features that matter most to them. With cars, people can compare models based on cost, reliability, owner satisfaction, safety, and miles per gallon.

When it comes to drugs, however, such

## DRUG APPROVAL

**“We just don’t have a good enough process for really evaluating drugs prior to market. We know they may work better than a sugar pill, but that’s probably not a standard that the American public deserves. I think we deserve a higher standard than that.”<sup>10</sup>**

—Jerry Avorn, MD, Harvard Medical School

head-to-head comparisons are rare. All a pharmaceutical company needs to do to get FDA approval for a new drug is show that the medicine is better than nothing (a placebo). If a sugar pill relieves headache symptoms for 38 percent of the test subjects and Drug X works for 50 percent, the FDA is likely to give the new compound the green light. That doesn’t tell you beans about whether Drug X is better than Drug Y or Z or whether it is more or less likely to cause complications.

When a drug company does spend money for a clinical trial that compares its prized compound to a competing brand, it may be very cautious about how the experiment is conducted. Richard Smith, MD, former editor of the *British Medical Journal*, tells how pharmaceutical companies around the world stack the deck:

- “• **Conduct a trial of your drug against a treatment known to be inferior**
- **Trial your drugs against too low a dose of a competitor drug**
  - **Conduct a trial of your drug against too high a dose of a competitor drug (making your drug seem less toxic)**
  - **Present the results that are most likely to impress<sup>11</sup>”**

What all this means is that doctors have a very hard time determining how one medicine stacks up against another, or even against alternative approaches. Is Nexium (esomeprazole) really

better than Prilosec (omeprazole) or Prevacid (lansoprazole) for relieving heartburn? Does Zoloft (sertraline) alleviate depression better than Prozac (fluoxetine)? Which one has fewer side effects?

You might not mind paying a lot for the latest blood pressure medicine if it works better than everything else on the market and has the fewest side effects. Unfortunately, in one huge head-to-head trial, that’s not how it worked.

Many physicians were shocked when a government-sponsored study (ALLHAT, the Anti-hypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial) showed that an old-fashioned, dirt cheap diuretic outperformed newer and more expensive blood pressure-lowering drugs.<sup>12</sup> This was the largest hypertension study (more than 42,000 patients were enrolled) ever conducted. A 15¢ water pill called chlorthalidone did as well as or better than blood pressure drugs like Norvasc (amlodipine), Zestril (lisinopril), and Cardura (doxazosin) that can cost 10 times as much (Norvasc and Zestril can run more than \$1.50 per pill). For the extra money, people got less protection from heart disease, heart failure,

and stroke, as well as the possibility of experiencing more serious side effects.

Would you be amazed to learn that chlorthalidone is prescribed infrequently? It isn't even among the "top 300" prescription drugs. In contrast, Norvasc was the number three most-prescribed drug in the United States in 2004, with 30,929,000 prescriptions filled.<sup>13</sup>

Most physicians like to think they practice "evidence-based medicine." That's the catchword for rational medical care based on scientific research. But in this case, it's pretty clear that many doctors have ignored the data from this important head-to-head trial and bowed to the marketing muscle of Big Pharma. Our goal in this book is to let you know about this type of research so you can work with your doctor to get the best treatments for your money.

## GETTING RESULTS

We all hope that whatever treatment we use will help us rather than harm us. That's why FDA approval seems so important. It surprises both physicians and patients to learn that many of the medications endorsed by the FDA fall far short of our expectations.

A few years ago, a podiatrist took us to task for suggesting home remedies for nail fungus. He wrote:

***“There are real, doctor-prescribed, FDA-approved, clinically tested medications to treat toenail fungus. These include topical Penlac or oral***

***Lamisil or Sporanox. I have successfully treated hundreds of patients with these drugs.***

***The unproven treatments you mentioned are little more than urban legends. In 23 years in practice, I have never seen even one patient who has responded favorably to Vicks VapoRub, dilute vinegar soaks, or vitamin E oil. Don't make me waste time dispelling these myths.”***

Initially we felt chastised. What were we thinking by offering folk wisdom against FDA-approved "real" medicine? Then the mail started pouring in. Dozens of people responded to the podiatrist who had pooh-poohed home remedies. They reported having positive experiences with approaches such as Listerine or dilute vinegar soaks, with applications of Vicks VapoRub or tea tree oil. One pharmacist made the following arguments in our defense:

***“I would like to point out some facts about the FDA-approved drugs the podiatrist prefers (Lamisil, Penlac, Sporanox). Does this doctor know that Penlac's success rate for a complete cure, according to the manufacturer's prescribing information, is only 5.5 to 8.5 percent after 48 weeks? When using Sporanox, the percentage of overall success rises to a dizzying 35 percent.***

***Also, does he know the costs of these medications? A bottle of Penlac costs \$72.99. To reach 48 weeks of treatment once a day to a single affected nail, I conservatively estimate that the patient will need six bottles of the lacquer (one bottle approximately every other***

**month). So Penlac will cost the patient, without insurance, \$437.94 to reach an outstanding 8.5 percent cure rate.**

**For Sporanox, one pulse-pak costs \$255.99. This is a 14-day supply. The manufacturer recommends 12 weeks of treatment, bringing the patient cost, without insurance, to \$1,535.94! No wonder people are looking for alternatives to these medications.”**

Most consumers have no idea what the actual success rate is for any prescription medication. One industry insider captured headlines when he told a scientific meeting: “The vast majority of drugs—more than 90 percent—only work in 30 or 50 percent of the people.” This is a secret that drug companies would just as soon keep under wraps. Allen Roses, MD, worldwide vice president of genetics at GlaxoSmithKline, was discussing the value of genetically targeted therapy in overcoming the limitations of several classes of medicines.<sup>14</sup>

<b>RESPONSE RATES<sup>15</sup></b>	
<b>THERAPEUTIC AREA</b>	<b>DRUG EFFICACY RATE</b>
Alzheimer’s disease	30%
Asthma	60%
Depression (SSRI)	62%
Diabetes	57%
Incontinence	40%
Migraine (acute)	52%
Oncology (cancer)	25%

As you can see, selective serotonin reuptake inhibitor (SSRI) antidepressants like Prozac, Paxil (paroxetine), and Zoloft are effective almost two-thirds of the time. When you compare that rate of efficacy to the effectiveness of inactive sugar pills, though, the benefits are surprisingly slim. Placebos generally produce improvement in 30 to 50 percent of depressed patients, so the drugs are just a bit better than the dummy pills. A review (called a meta-analysis) of many antidepressant studies in the *British Medical Journal* concluded that “selective serotonin reuptake inhibitors have no clinically meaningful advantage over placebo” and that “antidepressants have not been convincingly shown to affect the long-term outcome of depression or suicide rates.”<sup>16</sup>

In any other business, people would demand better results, especially when they have to pay so much. But patients rarely question their doctors’ prescriptions. They mostly assume their medicine has a much better track record than has actually been proven. They may be quite disappointed when they discover that their pricey medicine does not perform as well as they expected. Here’s one reader’s story:

**“Last year, I spent \$1,200 on Lamisil to cure nail fungus. This 3-month program required a prescription, a blood test, and, of course, a visit to the doctor. Despite all this time and money, there was absolutely no improvement in my nails.**

**I wrote to the company that makes Lamisil**

***and asked for some answers. Novartis replied with a form letter saying Lamisil did not necessarily cure nail fungus, and the company did not guarantee the efficacy of the product.***

***This flippant attitude made me mad. I could have used nothing and saved a great deal of money with the same result.”***

To add to the complexity, the medicine may cause a serious reaction. But if the doctor doesn't mention risks, a patient might not weigh the danger of side effects. We heard this tragic story from a reader:

**“*My husband took Lamisil to treat toenail fungus. The drug worked, but was ultimately responsible for his death.***

***The fine print for this prescription drug noted that it might cause neutropenia. For my husband, it did. This led to MDS (myelodysplastic syndrome), which was followed thereafter by AML (acute myeloid leukemia) and his subsequent death.***

***He had suffered with periodic flare-ups of toenail fungus and athlete's foot for most of his life. Neither of these conditions was life threatening. The Lamisil was!”***

## **WHO'S GUARDING THE CHICKEN COOP?**

How could a drug to cure toenail fungus cause a life-threatening blood disorder? Before any medication can be marketed, it has to be

proven “safe and effective.” We hope you now realize that effectiveness is only relative. Sadly, so is safety. The FDA routinely approves medications that can trigger dangerous, if not deadly, reactions.

The best-known example of this came to light in 2004 when Vioxx (rofecoxib) was taken off the market by the manufacturer. Renowned cardiologist Eric Topol, MD, was provost at the Cleveland Clinic Lerner College of Medicine. In an editorial in the *New England Journal of Medicine*, Dr. Topol estimated that as many as 160,000 people may have suffered heart attacks or strokes while taking Vioxx.<sup>17</sup> FDA safety officer David Graham, MD, estimated that 30,000 to 40,000 people may have died as a consequence.<sup>18</sup>

In Senate hearings, Dr. Graham declared, “I would argue that the FDA as currently configured is incapable of protecting America against another Vioxx. We are virtually defenseless. It is important that this committee and the American people understand that what has happened with Vioxx is really a symptom of something far more dangerous to the safety of the American people. Simply put, FDA and its Center for Drug Evaluation and Research are broken.”<sup>19</sup>

More than 20 million people took Vioxx before it was yanked.<sup>20</sup> But tens of millions more have taken Celebrex (celecoxib), Bextra (valdecoxib), and other nonsteroidal anti-inflammatory drugs (NSAIDs) like diclofenac, ibuprofen, and naproxen. A disturbing analysis suggests that these medicines may also

increase the risk of cardiovascular complications.<sup>21</sup>

What this means is that the FDA has let us all down. We asked Robert Temple, MD, one of the FDA's most senior scientists, why the agency hadn't detected the problem with Vioxx before Merck took the drug off the market. He admitted that MedWatch, the agency's surveillance system, can't detect common health problems. Instead, it catches unusual things like liver injury or strange blood disorders.<sup>22</sup>

If a drug causes an "ordinary" problem like heart attack, stroke, depression, or cancer, the FDA is unlikely to notice it. Perhaps that is why it took the National Institutes of Health's Women's Health Initiative study to discover that menopausal hormones such as Premarin and Prempro could cause heart attacks, strokes, or breast cancer. Consider that Premarin has been on the market since 1942. It took almost 60 years before physicians and patients were officially alerted to these potentially deadly complications.

The FDA was also slow to pick up on antidepressants' dangers. Prozac was launched in 1987 and within a few years became the most prescribed antidepressant on the market. Despite its popularity, questions began to arise about whether it might trigger suicidal thoughts. Most psychiatrists pooh-poohed this idea, maintaining that depressed people sometimes commit suicide regardless of treatment.

The FDA and the manufacturer denied any

link between Prozac and suicide. They discounted a 1990 article in the *American Journal of Psychiatry* describing cases of "intense violent suicidal preoccupation after 2 to 7 weeks of fluoxetine [Prozac] treatment."<sup>23</sup> Fifteen years later, on July 1, 2005, the FDA finally warned that "adults being treated with antidepressant medicines, particularly those being treated for depression, should be watched closely for worsening of depression and for increased suicidal thinking or behavior."<sup>24</sup>

The problems with Prozac and Vioxx have received lots of press coverage. One drug that has garnered far less attention is salmeterol. It is one of the most popular prescription asthma medications in the world, found in asthma inhalers such as Advair and Serevent. Although salmeterol has been on the market since 1994, it wasn't until May 2006 that the FDA required the manufacturer "to alert health-care professionals and patients that these medicines may increase the chance of severe asthma episodes, and death when those episodes occur." An analysis published in the *Annals of Internal Medicine* reported that "salmeterol may be responsible for approximately 4,000 of the 5,000 asthma-related deaths that occur in the United States each year."<sup>25</sup> People who use salmeterol for first-line asthma treatment should never stop this drug on their own, but they should check with their physicians to find out more about this controversial issue. Unfortunately, the lesson from these drug disasters is that you have to be extremely vigilant. Doctors

rely on the FDA for crucial drug advice. But the feds count on drug companies to supply them with this information. This is like asking the fox to guard the chickens. What's more, once the FDA has approved a medication, the agency may feel a sense of responsibility for it. Admitting that a drug is causing problems, or even killing people, is tough.

## BALANCING BENEFITS AGAINST RISKS

The whole point of this book is to help you and your physician weigh the benefits, risks, and costs of various treatments. Choosing the best approach to any given problem depends upon a variety of factors.

A life-threatening condition like cancer justifies drugs that are extremely expensive and highly toxic. But for less dangerous conditions, most people might prefer to start treatment with inexpensive, safer remedies. Just as a family on a tight budget may choose a car based on price and fuel efficiency, an individual without prescription drug insurance might want to consider inexpensive home remedies, over-the-counter treatments, or prescription drugs that are economical. Even folks with insurance may want to control their costs and minimize their risks.

**“ I assumed toenail fungus was a fact of life for me. It had spread to five or six toenails when I finally saw a dermatologist. The prescribed**

**treatment was costly, and after it began, the dermatologist told me the odds of reinfection after treatment were around 50 percent.**

**I had a nightmare reaction to the pills a week later. I was in remote Finland, of all unlikely places, when I developed hives and severe itching. After 24 hours of nonstop nonsleep itching, I got through to my doctor and was told to stop taking the pills.**

**When I got home, I decided to try the vinegar treatment. I applied a drop of distilled white vinegar to my toenails with a cotton swab each time I got out of the shower. As the nails grew out, the fungus was completely gone, along with slight traces of athlete's foot.**

**Cost: Under \$2 over 9 months**

**Side effects: None**

**Effectiveness: 100 percent (or 200 percent if you include the athlete's foot)”**

How do you know what treatment is best for your condition? Most people assume that doctors have a sophisticated system for selecting the most appropriate medication for their patients. Someday that may be true, especially when genetic testing leads to targeted therapy. But as things currently stand, doctors frequently work by trial and error. They may prescribe a blood pressure medicine and ask you to come back in several weeks to see whether it is doing the job or whether you have experienced intolerable side effects.

In a sense, each prescription is an experiment. Some people may find that Zolofit is

miraculous in its ability to relieve depression and allow them to function normally. Others may discover that Zoloft makes them anxious and dizzy, gives them diarrhea and insomnia, or ruins their love life. Because of this incredible variation in individual reactions, doctors cannot predict ahead of time how any given person will respond.

As a result, you'll do better if you are actively involved in this process. No one else can know how you are feeling. The most prescribed drug in the United States is one for pain. Nearly 100 million prescriptions are filled annually for the combination of hydrocodone and acetaminophen. But no one can assess your pain except you. Treatments to alleviate anxiety, depression, and insomnia are also best evaluated by the patient. But even conditions like high blood pressure, diabetes, elevated cholesterol, and thyroid imbalance require you to monitor your progress and give your doctor honest feedback.

If a certain medicine gives you a rash or makes you dizzy, don't just put up with it. Let your doctor know that it may be time to move on and try another option. Clear communication is essential for assessing whether the medicine is doing what it should and whether any side effects that crop up are too difficult to tolerate. According to one study, if patients tell their doctors about drug side effects and if the doctors are attentive and adjust the treatment, many harmful reactions can be avoided. The investigators concluded that nearly 8 million adverse events could be prevented "if patients

and their physicians communicated better and if physicians acted more reliably to address medication symptoms."<sup>26</sup>

***“Some time ago, I saw my doctor because of generalized but constant muscle pain unrelated to physical activity. I hurt all over, especially in my calves. Pain remedies had no noticeable effect.***

***I really felt I would be an invalid by age 60 if things continued as they were. My doctor did all sorts of tests, including blood work and x-rays, but found nothing definitive. I was in good health though I felt miserable!***

***He chalked it up to old age (56) and the beginnings of arthritis. I asked him specifically if it could be due to the Lipitor he had prescribed shortly before all this started. He said no, because my liver function tests were normal. It was easy for him to say, but I was finding it difficult to get through a normal day.***

***I then tried going off the Lipitor, and the pain went away! When I started it again, the pain came back, 2 days later. The doctor switched me to Zocor, but I had the same symptoms.”***

We have heard from hundreds of people who have experienced severe, sometimes debilitating muscle pains associated with statin cholesterol-lowering drugs, such as Crestor (rosuvastatin), Lescol (fluvastatin), Lipitor (atorvastatin), Mevacor (lovastatin), Pravachol (pravastatin), and Zocor (simvastatin). Even when blood tests do not show any abnormali-

ties, people can experience muscle or joint pain as well as weakness. Others have reported neuropathy (nerve damage), memory problems, and sexual difficulties. It would be easy for a physician to chalk up such symptoms to “aging.” But you don’t have to accept that explanation if it doesn’t feel right. You need to listen to your body and pay attention when it complains. If lowering your cholesterol means that you can no longer exercise or enjoy an active social life because of pain, it’s time to consider some other way to reduce the risk of heart disease.

As crucial as it is to keep track of your progress and report possible side effects to your doctor when you are taking prescription drugs, it is just as important, if not more so, to keep tabs on how you are doing if you are using over-the-counter medications, dietary supplements, or home remedies. Drugs such as Advil and Motrin IB (ibuprofen) and Aleve (naproxen) may carry risks similar to those of their prescription formulations, even though the dosage may be lower. Bleeding gastrointestinal ulcers are a potential complication that puts tens of thousands of people in the hospital each year.

Even natural products like turmeric, the yellow spice in curry powder and yellow mustard, may hold unexpected dangers. Many people have reported their success using turmeric or its active component, curcumin, to relieve arthritis pain or psoriasis. But we have also heard from some who have experienced severe rash and itching, elevated liver enzymes,

and even a potentially life-threatening interaction with warfarin (Coumadin).

**“ I started taking turmeric after reading that it could help my psoriasis, but I developed a severe rash. I stopped using it last week. The rash is still with me, but my biggest concern developed today.**

**I went for a routine blood test, necessary because I use Coumadin due to a prior lung embolism. My doctor called me 3 hours later to tell me that the number, which should have been between 2 and 3, was at an extremely thin level of 13. I was told to come in immediately for a vitamin K shot. I think your readers should know about this type of reaction.”**

Even though turmeric is a natural product commonly used in Indian food, its safety must not be taken for granted. When used as a botanical medicine, it should be treated with the same respect that other drugs get. That goes for any other herb, dietary supplement, or home remedy as well. Because there is always the potential for dangerous interactions between herbs, dietary supplements, and medications, it is essential that you consult a knowledgeable physician before considering any of these approaches.

## **SAVING MONEY, STAYING SAFE**

Skyrocketing drug costs are wrecking everyone’s budget. Ask any director of a hospital

pharmacy and she will tell you that medicines are breaking the bank. Employers are complaining, state budgets are busted, and if you have to pay for your own prescriptions, you know firsthand how costly your pills are. Even the co-pays are getting outrageously expensive. Some insurance companies and HMOs are now charging a \$40 or \$50 co-pay for brand-name prescriptions.

Generic drugs are frequently promoted as the best solution to the high cost of prescription medicines. The savings can be dramatic. For example, at the beginning of this chapter, we listed the cost of 100 pills of Valium (\$193.89). If you opted for the generic (diazepam) instead, you'd pay less than \$20. Who wouldn't choose to take advantage of this kind of a deal? After all, generics are supposed to be identical to their brand-name counterparts.

But how good are they, really? The FDA maintains that generics are excellent. And the insurance companies that have embraced generics trust the FDA to guarantee equivalency. A generic is supposed to get into the bloodstream just like the original innovator drug and work exactly the same in the body.

For decades we agreed and recommended generics. After all, the FDA has stringent guidelines for approval. But we have become concerned that certain drugs may be harder to substitute. And we have heard from hundreds of readers who have astonishing stories to share.

## Dilantin versus Phenytoin

**“My mother went on Dilantin in August 2003. In September she was admitted to a rehab hospital. Her neurologist told them to give her only Dilantin, not a generic substitute.**

**Later that month, she had four grand mal seizures and was taken to the emergency department at the hospital. When I got there she wasn't expected to make it. The ER doctor told me that he did not think my mom had even had her Dilantin the past few days because her level was so low. The next day I learned she had been given generic phenytoin instead of Dilantin for the last few days. I am convinced that is why she suffered seizures.”**

This is not the only report we have received about generic phenytoin. Other readers also have complained about having breakthrough seizures when they were switched from Dilantin to the generic. A study published in the journal *Neurology* revealed that several patients who were well controlled on Dilantin experienced seizures that required trips to the emergency room and even hospitalization after they began taking generic phenytoin.<sup>27</sup> After this study was published, the state of Minnesota reversed its rule to automatically switch patients to generic phenytoin.

Phenytoin is not the only drug that worries us. We have received many other complaints about generic drugs such as atenolol (Tenormin), fluoxetine (Prozac), omeprazole (Prilosec), and warfarin (Coumadin). Some drugs

are tricky to use. Coumadin, for example, is an anticoagulant that requires careful dosage adjustment and monitoring.

## Coumadin versus Warfarin

**“I needed surgery for a torn rotator cuff in my shoulder. Before the operation, they found my heart was in atrial fibrillation, so the surgery was postponed until my blood could be thinned to prevent blood clots forming in the heart.**

**I got a prescription for Coumadin and the pharmacist gave me the generic, warfarin. I took it for a month, but we couldn't get my blood in order. My cardiologist finally checked on exactly what pill I was taking and was shocked to see that it was a generic. He said even though it is supposed to be the same, it is not. As soon as he switched me to real Coumadin, my blood responded and I was able to have the operation.”**

Medications like Dilantin and Coumadin are known to have a “narrow therapeutic index.” In doctor-speak, that means that there’s not much room between too little drug—which undermines effectiveness—and too much drug—which puts people at risk of having a serious toxic reaction. We urge users of such medicines to consider carefully whether the potential savings they get with a generic drug is worth risking a significant health problem.

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We have been investigating issues related to generic drugs and the potential dangers of counterfeiting for years. We have interviewed people at the FDA and the USP (United States Pharmacopeia), which sets standards for all prescription and over-the-counter medicines sold in the United States. For more details on this issue and suggestions for how to deal with some of the problems that may be associated with generic substitution, please turn to Generic Drug Quandary on page 15.

## EXECUTIVE SUMMARY

By now, you should realize that FDA approval does not necessarily mean that a particular medicine will work for you or that it will be safe. Instead, you need to participate in the decision about what treatment to try and when to move on to something else. In *How to Use This Book*, on pages xvii to xviii, there is a description of how you and your doctor can see at a glance what treatments might make sense.

At the end of the book, there’s a list of drugs and remedies that our People’s Pharmacy consultants would take along if they were going to be marooned on a desert island. We hope that never happens to you, but it may give you some guidance for coping with less extreme situations.

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