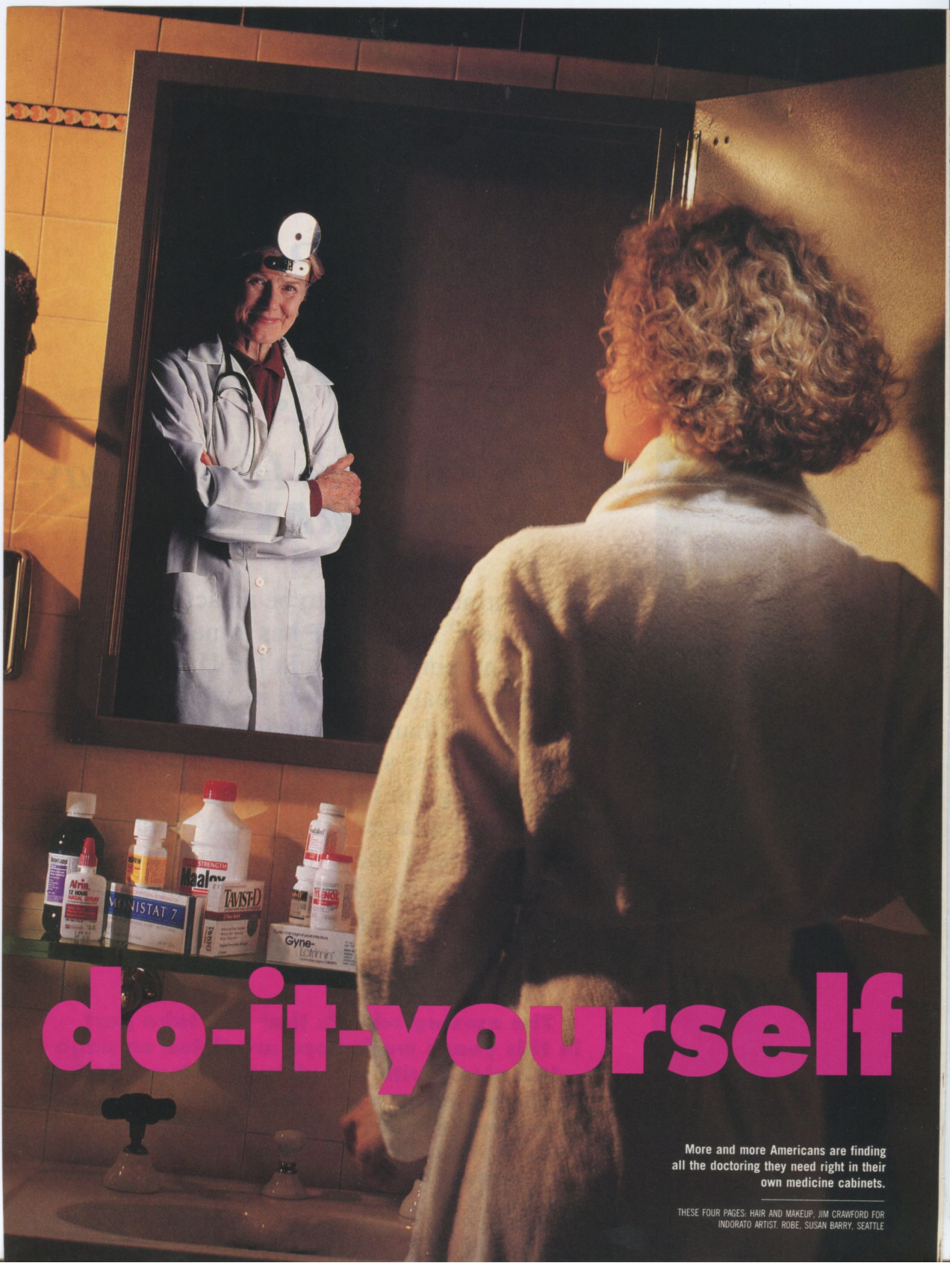


do-it-yourself

More and more Americans are finding all the doctoring they need right in their own medicine cabinets.

THESE FOUR PAGES: HAIR AND MAKEUP, JIM CRAWFORD FOR INDORATO ARTIST. ROBE, SUSAN BARRY, SEATTLE

Gyne-Lotrimin, a treatment for vaginal yeast infections that had always been sold by prescription only, suddenly appeared on drugstore shelves in February 1991, available to all for $17.50. Its arrival was a coup for the manufacturer, Schering-Plough HealthCare Products, and a blessing for sufferers who were now free to treat themselves for that all-too-familiar itching and burning sensation without the hassle and expense of seeing a doctor. Gyne-Lotrimin's appearance was quickly followed by the antihistamines Tavist-1 and Tavist-D, and the anti-inflammation treatment 1 percent hydrocortisone. Since 1980, more than 200 prescription drugs have become available without prescriptions. And many more are on the way, to the delight of a growing self-care movement that has captivated American consumers, especially women, who buy 60 percent of the drugs in the U.S.

What exactly does this expanding medical self-care market consist of? At its broadest, it is everything from computer software and health and nutrition publications to vitamins, herbal treatments and over-the-counter drugs. The movement began during the 1970s, when the baby boomers' search for a healthier lifestyle catapulted vitamin wholesale revenues from $200 million in 1970 to $1.2 billion by the end of that decade. Now the demand for self-care products has moved beyond those that simply maintain good health to ones that actually cure illness. Currently, Americans treat up to 90 percent of their health complaints without seeing a doctor at all.

As a result of these shifting attitudes, there have been sweeping changes in the availability of medications without prescription. In 1990, Americans spent $11.3 billion—an average of $0.12 per person per day—on more than 125,000 over-the-counter medications, and 400 of these products involve dosages or ingredients that

BY JOHN SEDGWICK

PHOTOGRAPHS BY MAX AGUILERA-HELLWEG

medicine

The booming self-care market makes health care cheaper and more accessible.

But is all of this good for us?

were not available without a prescription just 15 years ago. There's been a similar expansion in the market for home tests. Women spent approximately $160 million on 15 million home pregnancy tests in 1991. If they had gone to a gynecologist—at an average visit price of $82—the tests would have cost an extra $1.07 billion. It is this price differential that is creating the demand for change. Nonprescription drugs are far more economical than their prescription counterparts. In 1989, the cost of the average prescription medicine was $16.31, and the cost of a physician's visit was $38.80 more; the cost of the typical over-the-counter product, by contrast, was just $3.80.

To the public, the question of which drugs come by prescription and which ones don't is, as Churchill once said of Russia, a riddle wrapped in a mystery inside an enigma. But one thing is clear: Amid all the competing interests in the high-stakes world of pharmaceuticals, noble sentiment alone does little to place a product like Gyne-Lotrimin on the open pharmacy shelves. More than anything else, it takes a strong commitment from a drug manufacturer. These days, companies have a powerful incentive to make that commitment, since there is a lot of money to be made in bringing prescription drugs to the public over the counter, a maneuver called by the industry an Rx-to-OTC switch. "It's a big market," says Hemant Shah, an industry analyst. "And it's going to continue to grow."

In one study, women were actually better than their physicians at diagnosing their own yeast infections.

The Rx-to-OTC market was born in the mid-1970s, when an FDA panel's recommendation to switch three nighttime sleep aids from prescription-only unleashed a flurry of interest in switched drugs. Of the 10 top-selling OTC drugs introduced since then by the nation's 14 biggest pharmaceuticals companies (see chart on page 124), nine are switched products. The tenth, the number-five seller Motrin IB, is a switch in all but name (its prescription counterpart is simply called Motrin). Furthermore, even though only 30 percent of the OTC brands put forward since 1975 started out as prescription drugs, they account for almost 80 percent of the companies' total OTC sales. By contrast, completely new products made up 70 percent of the total, yet garnered only 20 percent of sales.

"These switched products are driving the pharmaceuticals business right now," says Arthur M. Rosen, executive vice president of Sudler & Hennessey, a New York City advertising firm that handles a number of switched products. "Any drug company that doesn't have them is at a very, very serious disadvantage." Such a serious disadvantage that the mad pursuit of switched, or switchable, drugs is rearranging the industry. Several companies have merged or formed joint ventures solely to get their hands on these kinds of products. Procter & Gamble, for instance, which has already bought the makers of Vicks cough remedies and the laxative Metamucil, has recently undertaken a joint venture with Syntex Laboratories Inc. to market its Naprosyn, a pain reliever that is due to move from prescription to OTC very soon.

But drug companies can't switch a product by snapping their fingers, much as they might like. They have to persuade the FDA and ultimately the public that such a move is a good idea, an undertaking that can burn up years of effort, tens of millions of dollars and an incalculable portion of their sanity. The FDA approval process alone has cost the industry $125 million since 1975. Such a massive investment, in turn, dictates the type of prescription drugs that companies are likely to take OTC. Broadly speaking, switches are limited to drugs that address what might be called mass-market ailments, like headaches, heartburn and runny noses—instead of more specialized maladies like, say, allergic conjunctivitis—because only common afflictions will ever generate enough revenues to cover the heavy expenses. Presumably, if these costs could be reduced by a more streamlined approval process, an entire realm of more specialized products, like that allergic-conjunctivitis remedy, could be made available OTC.

A drug's patent status is another consideration. A switch to OTC can be a way of preserving the lucrative franchise of a prescription drug after its 17 years of patent protection runs out. One of the reasons prescription drugs can be so expensive is that the company is granted what amounts to a monopoly on a drug as long as its patent is good. After that, others are free to market "generic" forms at more competitive prices. An Rx-OTC switch allows the company to substitute brand loyalty, which has been created through years of use via prescription and then solidified by advertising, for patent protection, thereby extending what marketers call the product life cycle. For example, when Warner-Lambert's patent on the prescription-only antihistamine Benadryl expired in the mid-1960s, the drug's market share was hit hard by competing generics. Then, in 1985, the FDA cleared the active ingredient in Benadryl for OTC sale. After more than a decade of tough competition in the prescription-only market, the company was still able to use the goodwill associated with the

ROBE, NATORI

At-home tests can tell you if you're pregnant within a day of missing your period and only a minute after taking the test.

HOME TESTS

Today, you can find out if you're pregnant. Tomorrow, you may be able to test for the HIV virus. All in the privacy of your own home.

If the booming self-care movement aims to self-medicate, why not go all the way and self-diagnose as well? That may be possible sooner than you think. Individuals can already measure their blood sugar, find out if they are pregnant and see when they are ovulating, all in the privacy of their own homes. Ten years ago, these tests were available only in medical laboratories.

In approving home tests, safety and accuracy are the FDA's main concerns, and until recently the kits did not fare very well when they were taken out of the laboratories and placed in the hands of untrained, often anxious, consumers. Now, however, what was once a tricky and time-consuming home chemistry experiment is as simple as loading film into an automatic camera. Most pregnancy tests deliver the results in five minutes; the latest models have reduced that to one. And they can detect pregnancy within a day of a missed period. Such accuracy was not available at any price 15 years ago.

The pharmaceuticals industry has not overlooked the commercial success of such testing kits and is readying other varieties for development. First up is a cholesterol meter that would require only a drop of blood to provide a numerical cholesterol reading in one minute—something of considerable value to hypertensives as well as fitness enthusiasts. Another possibility is a test for strep throat in children. A more explosive product under consideration is a home test for HIV. The technology is available, according to Julie Zawisza, a director of the Health Industry Manufacturers Association, a trade group that represents the medical device industry. Because of the need to maintain strict privacy, home testing offers some important advantages, but it also runs up against what Zawisza terms such social considerations as the need to have a medical professional immediately available for those who test positive and the importance of revealing the results to epidemiologists who are tracking the disease.

The possibilities for home testing are enormous, in short, and so are the potential consequences for society. As screening tests become more advanced, it is possible to imagine home tests that would give a private readout of an individual's genetic dispositions—toward alcoholism, say, or gallstones. That's a thorny issue for a future FDA. But the technology is already well on its way. "All it takes for a home test is a discrete sample of the body's tissue or fluids," says Zawisza. "Beyond that, it's all packaging."

Benadryl name to push the antihistamine's annual sales from its pre-OTC $15 million to $150 million within a year of the switch.

But the FDA is the biggest roadblock to Rx-OTC possibilities. "Nobody wants an OTC thalidomide," says John T. Walden of the Non-Prescription Drug Manufacturers Association (NDMA), referring to the sedative that produced thousands of terrible birth defects in Europe in the early Sixties. Although the drug was never cleared for sale in the U.S., it is the specter of the thalidomide baby that governs the agonizingly cautious review process accorded switch candidates. This despite the fact that an OTC switch is the culmination of a lengthy process that begins with a company's data-laden application to sell a new prescription drug and continues through years of experience with thousands of patients who have used the prescription product.

The drugs that have made the Rx-OTC switch are the most thoroughly investigated of the hundreds of thousands of drugs on the market today. In the past 20 years, only two switched drugs have had to be returned to a prescription basis for safety reasons, and no deaths have resulted. The FDA has recently introduced a procedure requiring physicians to report immediately any drug-related hazard that they discover, thereby limiting any damage and making switched drugs even safer. In fact, there is ample evidence that many more drugs could be made available without jeopardizing public health. Among medicines that require prescription for sale in the U.S., 34 are sold freely in other countries.

Even with all this history behind them, Rx-OTC switches are subjected to further restrictions by the FDA. The illness the drug is designed to alleviate must be mild and easily self-diagnosable, and the treatment itself of limited duration. The recently cleared anticancer drug Taxol, for example, is never going to go OTC because cancer patients require continued monitoring by a physician. In addition, the drug—when taken as instructed—must be unlikely to produce hazardous side effects or induce addiction. The more powerful and biologically active a drug is—which means the more effective it is—the higher the odds that it will produce some sort of toxic side effect, so an antibiotic like tetracycline or a painkiller like Demerol would never be cleared for sale OTC. Finally, the product's labeling and instructions must be easy to follow.

At the extremes, the FDA policy is obviously sensible. The problems come where the dangers are slight but not totally absent. There, the FDA is all too inclined to err on the side of caution. Take the birth-control pill. Because of a list of possible side effects that is dauntingly long, the FDA has always insisted that the Pill be sold by prescription only. But its side effects are no more numerous or ominous than are those listed for aspirin, which has never required a prescription. And the Pill has long been available OTC (and without incident) in Europe and South America.

Only now is the FDA getting around to considering the question of taking the Pill OTC, and it is doing so with obvious reluctance. A long-planned preliminary "workshop" meeting of 11 interested parties in February was canceled at the last minute because, according to an FDA spokesperson, it was deemed "insufficiently inclusive." The spokesperson would not say which organizations had been left out, and at press time the meeting had not yet been rescheduled.

One cannot be too optimistic about the Pill's chances of appearing on open pharmacy shelves anytime soon, given the FDA's record with the less controversial antiyeast medication switch. If Schering-Plough hadn't been so dogged in its efforts, Gyne-Lotrimin would probably still be sold by prescription only.

TOP-SELLING NEW OTC PRODUCTS

Of the 66 over-the-counter products introduced by the nation's 14 leading manufacturers since 1975, all of the top 10 were originally available by prescription only. The combined factory sales for these 10 products in 1991 was $933 million.

BRAND	PURPOSE	DATE OF Rx-OTC SWITCH	1991 SALES
1. **Advil**	painkiller	1984	**$285** million
2. **Monistat 7**	yeast-infection medication	1991	**90** million
3. **Sudafed**	decongestant	1981	**81** million
4. **Dimetapp**	decongestant	1985	**78** million
5. **Motrin IB**	painkiller	1989	**74** million
6. **Nuprin**	painkiller	1984	**74** million
7. **Benadryl**	antihistamine	1985	**73** million
8. **Gyne-Lotrimin**	yeast-infection medication	1990	**63** million
9. **Actifed**	decongestant	1983	**61** million
10. **Afrin**	decongestant	1979	**54** million

Source: Sudler & Hennessey Consumer Group, 1992

As it was, the company's patience was sorely tested.

Schering-Plough first considered switching Gyne-Lotrimin more than a decade ago as it gazed covetously at Johnson & Johnson's share of the vaginal yeast treatment market: Johnson & Johnson's Monistat and Terazol controlled over three quarters, while Gyne-Lotrimin's share hovered in the single digits. If Schering-Plough could go OTC with its product, the company reasoned, perhaps it could improve those numbers. Unfortunately, the FDA had never approved any vaginal antifungal medication for OTC sale, and the agency is always loath to break new ground.

By the same token, the virgin-territory aspect was also a good reason for Schering-Plough to proceed. The company was well aware of the marketers' 65 percent rule, which states that the first product into any new market category garners 65 percent of sales. One reason that Advil outsells its fellow ibuprofen tablet Nuprin by almost four to one is that Advil beat Nuprin to market by six weeks—virtually an eternity in consumer-product marketing.

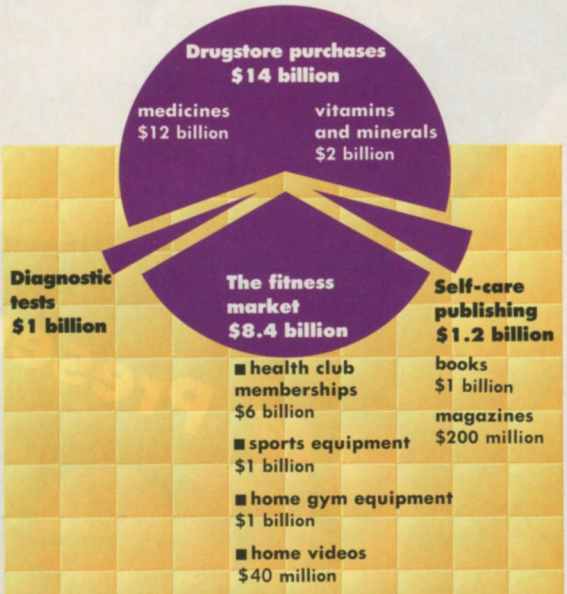
Schering-Plough made its first formal FDA application to switch Gyne-Lotrimin in 1982. True to form, the agency dismissed the petition, saying that women could not properly diagnose a yeast infection themselves. What appears to be a yeast infection can turn out to be an inflammation of the cervix, diabetes, the sexually transmitted disease trichomoniasis or a number of other afflictions, according to Joseph K. Winfield, M.D., assistant professor of obstetrics and gynecology at Howard University, who was the medical officer in charge of the Gyne-Lotrimin evaluation. Like many physicians, he was distrustful of a patient's ability to self-diagnose and choose her own medications. But the company forged ahead. It called on a number of women's groups, including the American Medical Women's Association and the Association of Professional Flight Attendants, to testify about the usefulness of having such a product available OTC. And to support its contention that the drug was safe, the company supplied reams of data from human trials.

Still, Dr. Winfield forwarded the petition with his recommendations against the switch to an advisory panel that had convened to study the matter. The panel saw the issue differently. Amid all the data, it was impressed with two pieces of information. One was a study in which women were, by a slim margin, actually better than their physicians at diagnosing their own yeast infections. The other was the company's willingness to market the product—through its advertising and its labeling—only to women who had already had a yeast infection diagnosed by a doctor and could therefore compare the new outbreak with the old one. It may also be that the presence of a number of women on the panel tipped the balance. No one at the FDA will come out and say as much, but the FDA's Paula

(continued on page 184)

THE SELF-CARE BOOM

We haven't given up on doctors, but when total spending on self-care hits $24 *billion* a year, we can't help wondering: What's up, Doc?



The first thing to note about the way money is being spent on self-care is that no matter how you look at it, self-care is not a fad. Nor is it limited to the traditional notions of medicine. In its widest definition, self-care incorporates anything that benefits your health.

The running and fitness "booms" of the 1970s and 1980s got the entire movement off and running. But even after the booms quieted down, *lifestyles* had changed permanently. A new way of thinking about health and healing had caught on—and for good reason. Scientists were telling us that there was a lot we could do to prevent the need for a doctor. And, as you can see from this chart, Americans took their advice to heart. We now spend some $24 billion a year on everything from in-line skates to herbal remedies to exercise videos to over-the-counter drugs to self-help books. There are even companies—Alternative Health Insurance Services in Woodland Hills, California, is one—that advertise health care plans offering coverage for chiropractic, acupuncture, naturopathy and homeopathy, in addition to more traditional treatments. Self-care is big business.

Sources: Sporting Goods Manufacturers Association; medical- and pharmaceuticals-industry analysts; SELF research

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Botstein, M.D., does admit: "As more women come into the medical profession and into this office, it is inevitable that their views have more influence." The panel voted to clear Gyne-Lotrimin for sale over the counter in June 1990. Schering-Plough received final approval from the FDA five months later, in late November.

Schering-Plough's problems were not over, however. Consumers have grown so accustomed to relying on their doctors for any "real" medication that it can be difficult to convince them of the value of a drug that no longer requires a doctor's prescription. The drug company's marketers needed to maintain the aura of the drug's prescription-only exclusivity, even as they made it available to everyone. The secret for most switched products is to make their promotions sound science-y and to direct the message to an exclusive, professional, upscale consumer group. Gyne-Lotrimin's ads featured women doctors who discussed the problem of yeast infections in unusually frank terms. In one ad the word "vaginal" was used twice, to the discomfort of the manufacturer. "We wanted to be straightforward," Frankie Cadwell, president of Schering-Plough's advertising agency, told *The Wall Street Journal*. "Women are ready to hear it."

Once the marketing campaign was in place, Schering-Plough rushed the product out to stores by overnight mail five weeks after receiving FDA clearance. Women responded with similar alacrity. By the end of 1991, Gyne-Lotrimin was reporting $63 million in annual wholesale revenues, a remarkable accomplishment given its relatively small market share when it was a prescription product. Rival Johnson & Johnson would not be left out of the action, though. When it saw that Gyne-Lotrimin was to be switched, it secured FDA permission as well, and then capitalized on the name recognition of its Monistat 7 to surpass Gyne-Lotrimin, with $90 million in annual sales. Together, the two accounted for a 50 percent jump in the vaginal yeast cream market, to

$300 million in 1991. Analysts expect that the market will reach $400 million by 1995. Clearly there were a lot of women who suffered from yeast infections who had not been served by the prescription-only system.

Given the high cost of health care today, one might think that the FDA would be under some pressure to speed up the pace of switches for financial reasons alone. After all, countries like England and Denmark have increased their switches just to keep health care costs down. In addition to being less expensive than prescription drugs, the newly available products reduce the total cost to the health care system by removing the price of a doctor's visit, to say nothing of the cost of lost work time. (Even though Gyne-Lotrimin is cheaper as an OTC product, the price is still high enough and the need great enough that antiyeast medications are some of the most frequently shoplifted items in drugstores. Market pressures, however, are starting to bring prices down. Competitors Mycelex-7 and Fem-

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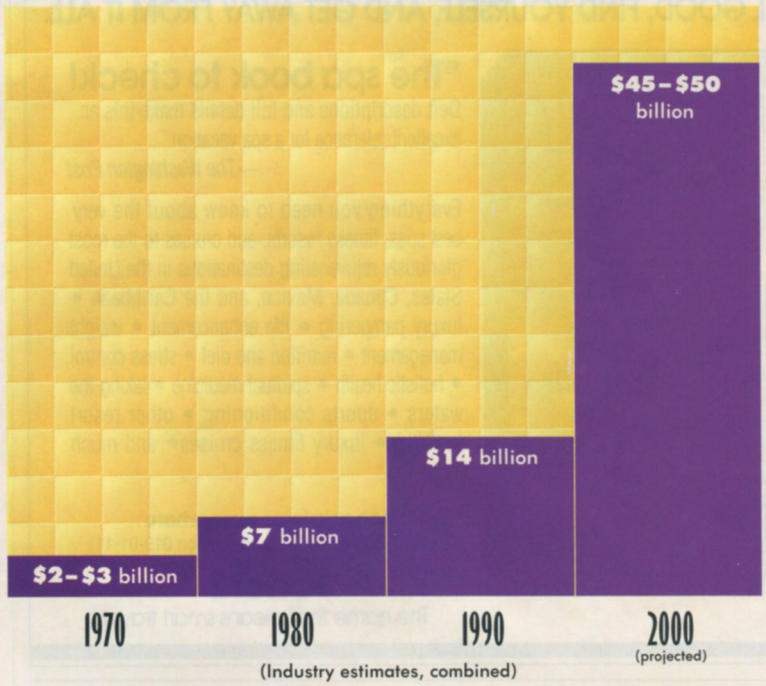
SELF-CARE SPENDING SOARS

The amount of money Americans spend on medical self-care has quadrupled over the past 20 years, reaching $14 billion by 1990



(Industry estimates, combined)

Sources: Kline & Co., The Freedonia Group, Non-prescription Drug Manufacturers Association

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Care have begun aggressively advertising their products as cheaper than either Gyne-Lotrimin or Monistat 7.) Insurance companies would benefit as well by avoiding reimbursement for the doctor bills and the cost of the drug itself, since OTC drugs are considered discretionary and therefore not covered under any drug insurance plan. Still, the regulations governing the FDA's procedures do not permit the consideration of cost when making the decision to relicense a drug as OTC, according to Dr. Botstein.

This high-minded attitude about protecting the public's health without regard to expense, not surprisingly, has been very expensive. According to one study, American consumers saved $600 million over a two-year period after the anti-inflammation cream 0.5 percent hydrocortisone was switched in 1979. In another report, the widely publicized Tylenol tamperings in 1982 resulted in consumers' turning to the security of prescription products at a total cost of $382 million in physicians' visits, time lost from work and travel costs. It has been estimated that the existence of all OTC products, not just switches, saves American consumers $10 billion a year.

While it is probably too much to say that Americans have finally abandoned the traditional form of health care in which white-coated doctors oversee the nation's health, they are certainly demanding more choices, and the marketplace is providing them. A study in *The New England Journal of Medicine* recently estimated that in 1990, 34 percent of Americans sought out alternative forms of healing, spending some $10.3 billion on "unconventional therapies," megavitamins and various diet formulas. Ever sensitive to the public mood, Congress has set up a special office of alternative medicines in the Department of Health and Human Services to explore the effectiveness of such treatments. And the market for home computer programs that diagnose illnesses and suggest treatments has tripled in just five years. Pharmaceuticals companies and phy-

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sicians are coming to terms with these changes. It is time for the FDA to enlarge its thinking, too.

One way would be for the FDA and Congress to consider a proposal that has been put forward by the American Pharmaceutical Association (APhA). It would establish a third class for drugs that lies between the two extremes of prescription and nonprescription. This third class might serve as a kind of way station for drugs under consideration for OTC status. They would be controlled by the pharmacist, whose talents are sorely underutilized in the current drug delivery system. "The pharmacist is totally left out," says Kenneth L. Dretchen, Ph.D., professor of pharmacology at Georgetown University. "The public thinks of him as nothing more than a tablet-counter behind the glass in the back of the pharmacy." In fact, after five years of study, pharmacists have had more course work in the nature of the drugs themselves than have physicians, and they are licensed by the state. The APhA has been pushing for this legislation for almost 30 years without success.

Although such switches as Gyne-Lotrimin garnered a lot of attention, the pace of switches is not going as fast as some drug companies—and the public—might like. A recent examination by the NDMA counted 53 drugs on manufacturers' wish lists for switches, including treatments for herpes, urinary tract infections and anxiety insomnia. The NDMA reports that 22 of them are in the preliminary stages of the approval process. At the FDA, Botstein is doubtful that many will get the go-ahead any time soon. "Those numbers are greatly exaggerated," she says.

The FDA's slowness is a pity, but the general trend is unmistakable. "The FDA used to be paternalistic," says William T. Beaver, M.D., a professor of pharmacology at Georgetown University and a former consultant to the FDA. "But in the past 20 years, the agency has come to believe that people can make more rational judgments about their own health. And pretty much everybody benefits from a change like that." □