

HEALTH

Long waits for new medicines

By Larry Lucas

Have you had to wait a long time in a doctor's office when you were sick? Did it seem as if you'd never get the help you needed? Did you feel frustrated or angry?

If so, you have some idea of how people waiting for new medicines to be developed feel. Their wait is not a matter of minutes and hours, but of years. It takes 15 years to develop a new medicine and win the approval of the Food and Drug Administration (FDA). That's twice as long as it took in the 1960s.

Why the long wait? Part of it is unavoidable. It takes a long time to turn a discovery into a safe and effective medicine, and many tests must be performed. But part of the reason for the long wait has to do with red tape. Other countries have found ways to cut the red tape of drug regulation, which means that many medicines are available overseas before patients here can get them. Last year, for example, FDA approved 28 new drugs — 18 of which were approved in other countries first.

Some patients, fed up with the FDA's slow pace, have gone

abroad to get medicines, or imported them. But not everyone can afford to do this — especially since many insurance plans only cover medicines that have been approved by FDA. In order to be fair to all patients, we have to change the system — not find ways to get around it.

Fortunately, Congress is considering a bill that would help change the system by cutting red tape and reducing paperwork. For example, applications for new drug approvals can run to 100,000 pages or more. Imagine how long it takes for companies to compile those pages and for reviewers to sift through them. Then imagine that you're sick and waiting for the new medicine that's the subject of the application. This mountain of paperwork could be cut down to size if companies were allowed to submit reports of their testing — instead of all the data generated. When you do your income tax, you file a report — or tax return — to the IRS. You don't send in all your canceled checks, receipts, pay stubs, etc. You save them, in case the IRS decides to audit you. If the IRS followed the same system as



LARRY LUCAS

the FDA, it could take years to get a tax refund. And, for people who are ill, new medicines are a lot more important. Listen to what some of the patients in the FDA's waiting room are saying.

• Lora Lagree, a cancer survivor and founder of a support group for breast cancer patients in Kansas wrote in the March 27, 1995 issue of The Manhattan Mercury that "reform is needed for an agency that has often kept life-saving innovations buried in a bureaucratic abyss."

• Howard Thiel suffered from a rare disease until his life was "transformed" by a new medicine. He blames "bureaucratic foot dragging by FDA" for preventing some
(See Medicines, Page 16)

Consider vaccination for yellow fever when traveling

HOUSTON — If your overseas travel will take you to Africa, South America or Central America, vaccination for yellow fever may be recommended — or even required.

In parts of those regions, mosquitoes transmit the disease between non-human primates such as monkeys. If human beings appear, they, too, can become part of the cycle of the disease, said Dr. James H. Runnels of the Travel Medicine Service at Baylor College of Medicine in Houston.

"Yellow fever transmission has been greatly reduced in the urban areas of affected countries," Runnels said, "through isolation of infected individuals and the destruction of mosquito breeding areas. But many countries require proof of yellow-fever vaccination for entry."

In outlying areas, vaccination is especially important, he said.

Yellow fever gets its name from the jaundice, or yellow skin and eyes, that results from liver-cell invasion.

Eighty to 90 percent of yellow-fever infection produce only mild illness, which is often not even suspected of being yellow fever. The other 10 to 20 percent are more severe, and 20 to 50 percent of the severe cases are fatal.

The mild form includes headache, fever, malaise, nausea and vomiting, Runnels said. With the severe form, these symptoms come on very rapidly, accompanied by severe pain throughout the body, extreme prostration and bleeding from the mucous membranes into the skin.

The only treatment is hospitalization and supportive care.

The live yellow-fever vaccine is very safe, effective and well tolerated, Runnels said. It lasts at least 10 years and can be taken by most people.

Those who should not take the vaccine without first consulting a physician are pregnant women, infants younger than nine months, people with compromised immune systems and people allergic to eggs.

Tips on health & nutrition

RESTAURANT-GOERS CAN EAT HEART-HEALTHY WITH PLANNING

Restaurant-goers can make healthy food choices with a little planning, says nutritionists at the DeBakey Heart Center at Baylor College of Medicine in Houston.

"Most Americans realize the importance of lowering the amount of fat and cholesterol in their diet but forgo healthy meals when they eat out," said Lynne Scott, director of the heart center's Diet Modification Clinic and an assistant professor of medicine at Baylor.

Scott is co-author of "The Living Heart Guide to Eating Out," a pocket-size reference guide that lists 160 tips on choosing low-fat, low-sodium foods when eating in restaurants. The guide also offers some planning-ahead advice to diners:

* Plan ahead for fat consumption. Choose lower-fat foods for other meals and snacks on days when dining out.

* Do not skip meals in anticipation of eating out. You will be hungrier and more apt to overeat.

"BROWN BAGGING" AT LUNCHTIME

For many busy people, "brown bagging" at lunchtime is the best way to ensure proper nutrition.

"Make wise food choices and plan ahead," said Mary Pat Bolton, a nutritionist at the Behavioral Medicine Research Center at Baylor College of

Medicine in Houston. "If you pack your own lunch, chances are you won't go for quick, high-fat snacks like corn chips and soda."

Bolton recommends some fast, healthy lunch and snack ideas:

* Plain yogurt with fruit, honey and raisins.

* Low-fat popcorn

* Cheese and whole-grain crackers

* Whole grain breads, pita pockets, or bagel sandwiches made with chicken, tuna, or lean luncheon meats and mustard.

* Pasta or leafy salad with low-fat dressing

* A frozen entree like pasta, vegetables, and chicken.

TEENAGERS: "VEGGING OUT" MORE THAN ELIMINATING RED MEAT

Parents, be forewarned. Teenagers who decide to "go green" with their diet may not realize there is more to being vegetarian than simply eliminating a food group, say nutritionists at the USDA's Children's Nutrition Research Center at Baylor College of Medicine in Houston.

"A nutritional, well-balanced vegetarian diet must be well-planned," said Janice Stuff, a research dietitian at Baylor. "Haphazard eating habits can rob teenagers of valuable nutrients."

Teens need to get adequate amounts of protein, iron, calcium, and vitamin B12 during these

body-building years. According to Stuff, a teen needs 1 gram of protein daily for each 2.2 pounds of body weight. "A 120-pound teen on a semi-vegetarian diet could meet daily protein needs with two 3-ounce servings of chicken or fish, one 8-ounce glass of milk, and one egg," she said.

FOLIC ACID: Evidence that folic acid helps prevent many types of birth defects continues to come in from studies around the world.

According to an article in the January, 1996 issue of CRN News, a publication of the Council of Responsible Nutrition, researchers in Ireland found that the risk of babies being born with Spina Bifida, or other neural tube birth defects was linked to the folate levels in the mothers' red blood cells. This is one of the more recent studies done over several years. It points up the importance of encouraging increased folate consumption by fortifying flour or other food staples with folic acid.

(Folic acid is a B vitamin that can be found naturally in green leafy vegetables and other foods.)

CANCER AND VIRUSES: There is increasing recognition of the link between some viruses and various forms of cancer. An article in the January, 1996 issue of the UT Lifetime Health Letter, a publication of the University of Texas Houston Health Center, notes that while viruses may not cause cancers, they can lower the body's immunity to many diseases, including some forms of cancer.

For example, HIV, the virus that causes AIDS, is known to lower immunity to certain cancers. Other viruses such as those which cause genital warts have associations with cancer. Besides dampening the natural

(See Health, Page 16)

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