A Matter of Life And Death

Have you lost a loved one to breast cancer recently? If so, you probably wished with all your heart that your sister, mother, or wife had detected it earlier. Perhaps they would have – if the device that clinicians are calling "one of the most effective weapons against breast cancer" hadn't been banned from the US market by the FDA.

The Sensor Pad, developed in Decatur, Illinois, is simply two sealed plastic sheets with lubricant in between. When a woman or her doctor places the pad over her breast, friction is reduced, making lump detection easier. The FDA has refused to approve this simple medical device for over a decade, even though the product is sold in Japan, Singapore, Korea, and most West European countries. The reason? The FDA wants this $7 device to go through the same testing procedures that it demands for expensive pharmaceuticals. After such testing, the FDA will take up to six years to decide whether or not the device should be approved. Because drug manufacturers are required to spend much more time and money getting US approvals than offshore ones, Americans get new, life-saving drugs and devices years later than citizens of other countries – if they get them *at all*.

Sometimes this delay protects us from side effects not readily detected in animal studies. The sedative thalidomide, for example, was marketed in Europe for several years while awaiting FDA approval. In the early 1960's, the sensitivity of an unborn child to the deforming effects of drugs was not widely appreciated, so doctors began prescribing thalidomide to pregnant women. Consequently, approximately 12,000 European children were born with deformed limbs. Few American babies were affected because only a few test samples had been distributed in this country. The FDA physician who had delayed its approval was given a Presidential Award.

Paying With Our Lives

Encouraged by this feedback, the FDA began to require even more studies. Testing and approval took even longer, especially when compared with countries like Great Britain where there were no immediate changes in the way new drugs were processed. While the British continued to enjoy many new drugs to treat their illnesses, only half of these were available to Americans, and only after many more years of waiting. One of these new drugs denied to Americans was propranolol, the first Beta-blocker to be used extensively to treat angina and hypertension.

Approximately 10,000 Americans died needlessly *every year* for the three years it was against the law for their doctors to treat them with propranolol. Propranolol was finally approved in the US for minor uses in 1968, but was only approved in 1973 and 1976 for angina and hypertension respectively. The regulatory delay of this single drug may have been responsible for the death of more Americans than all other deaths from drugs *in this century*. Even so, the FDA came under severe criticism by Congress for "premature" approval of this valuable drug! Former FDA Commissioner Alexander Schmidt noted that ". . . rarely, if ever, has Congress held a hearing to look into the failure of FDA to approve a new entity; but it has held hundreds of hearings alleging that the FDA. has done something wrong by approving a drug . . . ." The "drug lag," he claimed, could only "be remedied by Congressional and public recognition that the *failure* to approve an important new drug can be as detrimental to the public health as the approval of a potentially bad drug."

The "Drug Lag"

Just how detrimental is the drug lag to public health? *Conservative* estimates of needless deaths to the "drug lag" are tens, perhaps hundreds of thousands of innocent Americans *every year*. Many more people die from the FDA's delay than are saved by waiting to see if people from other countries experience side effects from new drugs. Perhaps a loved one *you've* lost is among them.

While any harm from drugs is undesirable, we must recognize that no drug is safe for everyone. People die every year from drug allergies or idiosyncratic reactions which cannot be predicted with state-of-the-art expertise. Whenever we take drugs, we must weigh the risks and the potential benefits, just as we weigh the substantial risks and benefits of driving an automobile. By demanding that the FDA protect us from drugs that have *any* side effects, we deprive ourselves of drugs that save hundreds of thousands of lives.

Ironically, FDA regulations sometimes force people to choose between legal, but toxic, drugs and safer ones from the black market. One San Francisco physician actually encouraged his patients to take the unapproved AIDS therapy DDI, instead of the FDA-approved DDC. The less toxic DDI was developed to replace DDC, but the delays caused by FDA regulations made it unavailable for many years. In desperation, AIDS patients began purchasing the safer substance from illegal buyers' clubs, which provide unapproved medications for the terminally ill. Many people are still forced to get their medicine on the black market because of the drug lag caused by the FDA.

In 1988, AIDS patients convinced FDA commissioner Frank Young to let them import drugs marketed overseas for their own personal use. Theoretically, any US citizen can now order personal supplies this way. However, current FDA administrators are attempting to close this life-saving loophole.

At least cancer and AIDS victims can purchase new medicines somewhere. Diseases that affect only a few are seldom researched, since the staggering development costs imposed by FDA regulations can never be recovered.

Censoring Health Claims

Claims for unpatentable products, such as vitamins and mineral regimens, are likewise too expensive to recover the cost of FDA approval. For example, Vitamin C manufacturers still cannot tell the public about the published scientific papers attesting to its cardio-protective effects. Furthermore, the FDA prosecutes companies that try to share information on new uses of marketed products without going through another time-consuming and expensive approval process. For almost a decade after a definitive scientific study, the FDA forbade aspirin manufacturers to tell the public that their product could reduce heart attacks by over 40%. Since heart disease is the #1 killer in the US, many thousands of Americans each year are needlessly sentenced to death by regulation.

If aspirin had to undergo the rigorous testing that today's FDA demands, it would never be marketed. Thankfully, aspirin's benefits were well-established before the FDA had the power to suppress it.

Perhaps the most heart-wrenching victims of the FDA's refusal to permit truthful claims for unpatentable products are children born with spina bifida. Because vitamin companies are not allowed to advertise how folic acid supplementation reduces the risk of birth defects, approximately 2500 children are born each year with spina bifida and many more are aborted. Since the benefits of folic acid have been known for well over a decade, this single regulatory decision has harmed more children than thalidomide, the greatest drug tragedy of the 20th Century. How would you feel if your child was needlessly handicapped by such over-zealous regulation?

Not satisfied with its usual "gag order" on information distribution, the FDA actually ordered one US company to destroy all its cookbooks and literature about stevia, an herb used as a sweetener. Certainly something is seriously wrong with the FDA when it resorts to "book burnings" reminiscent of Communist dictatorships.

Between 1989 and 1990, two private organizations, the American Heart Association and the HeartCorps Magazine, provided consumers with "heart-smart" guidelines for food. The American College of Nutrition gave its endorsement to certain brands of vegetable oils, and a calcium-supplemented orange juice was endorsed by the American Medical Women's Association. The FDA took legal action against these organizations to keep its monopoly on health claims – even health claims made for foods!