FDA Successes Shouldn't Be Shortchanged

Despite Misleading Ad Campaigns and Intensive Lobbying, the Public Is Skeptical of Efforts to Weaken Safety Standards

By Rep. Henry Waxman

When I was first elected to Congress in 1974, a birth control device called the Dalkon Shield had just been introduced. The manufacturer hailed this intrauterine device, or IUD, as a safe and reliable alternative to oral contraceptives.

But the company simply had not conducted the research necessary to establish its safety. Nor did the Food and Drug Administration have the legal authority to review such medical devices before they were marketed. The result was senseless tragedy.

Twenty women died in the United States due to septic abortions caused by the Dalkon Shield. Hundreds of women became sterile, and many required hysterectomies. Countless miscarriages, infections, and reproductive disorders resulted from its use.

Congress responded by enacting the Medical Device Amendments of 1976, which authorized the FDA to review the safety and effectiveness of medical devices like the Dalkon Shield.

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Twenty years later, the deaths and suffering of the Dalkon Shield's victims have dropped from the headlines and, to a regrettable extent, from Congressional memory. The FDA has been so successful in protecting us from such medical disasters that some have been lulled into thinking we can dismantle the agency.

Last year, critics and think tanks funded by the tobacco and pharmaceutical industries lambasted the FDA as a bureaucratic "job killer." They accused the agency of killing thousands of Americans by delaying access to innovative drugs and medical devices. Their ghastly scare ads featured coffins and tombstones of the agency's alleged victims.

One year later, these shrill condemnations of the FDA sound dubious. Despite intensive lobbying and misleading ad campaigns, industry-inspired FDA "reform" bills in the 104th Congress failed to reach the floor of either the House or the Senate. The assault on the agency continues, but last year's events raise a simple question about FDA "reform": Why did it fail?

Why FDA "Deregulation" Failed

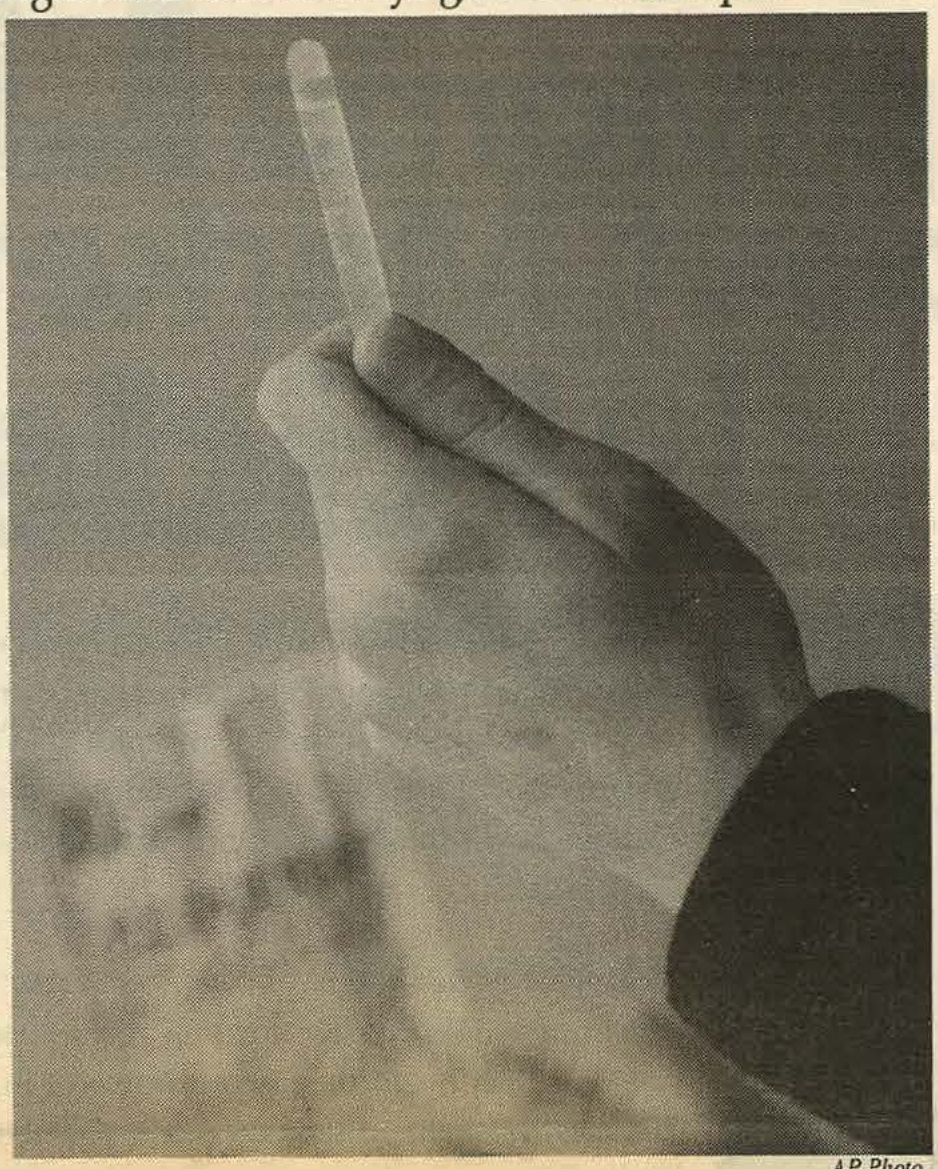
I can think of two reasons for this failure. First, the American public is justifiably skeptical of any effort to weaken the standards which assure that our food is safe and our medicines are safe and effective. They understand the FDA's critical role in upholding these standards, and 80 percent of Americans polled believe the FDA does a good job protecting the public.

In an era of eroding trust in our public institutions, this is a remarkable vote of confidence. Virtually no one genuinely believes that the FDA's standards are capriciously imposed by sinister bureaucrats. In reality, they are sometimes the only positive consequence of terrible, often tragic, experiences with dangerous drugs, tainted food, and defective devices: thalidomide, the Dalkon Shield, the Shiley heart valve, DES, fatally misprescribed antiarrythmic drugs, inaccurate mammograms, faulty pacemaker leads, silicone breast implants, e. coli contaminated food...and the list goes on and on.

Second, last year's bills were not truly "reforms." They were industry-motivated FDA "deregulation" bills aimed at loosening standards and weakening crucial statutory guarantees of safety, effectiveness, and quality. Among the most reckless changes were proposals to:

- Privatize FDA approvals, with reviewers paid directly by companies for approvals of the riskiest devices and drugs, undercutting the integrity of the review process with financial conflicts of interest;
- Permit companies to make major changes in the manufacturing of drugs at any time and simply notify the FDA after the fact. But minor alterations in the way the anti-epilepsy drug carbamezepine, for example, is made could lead to a loss of efficacy, toxicity, and seizures;
- Allow companies to freely promote unapproved drug uses. Yet drugs approved for one purpose can have dangerous or even fatal effects when used for other, unapproved uses. Some dermatologists, for example, use deadly botulism toxin for the unapproved use of removing cosmetically "unsightly" wrinkles. For other, more reasonable unapproved uses, doctors and patients already receive state-of-the-art information from dozens of sources more interested in accuracy than market share.

In a particularly distasteful wrinkle, these proponents also ran countless television and print ads wrapping their deregulatory agenda in the flattering mantle of "patient" interests. In reality, the Patients' Coalition — a broad-based, independent group of patient voluntary organizations, including the American Foundation for AIDS Research, the Alzheimer's Association, the American Cancer Society, the Consumers Union, the National Organization for Rare Disorders, and the American Public Health Association — was sharply critical of last year's FDA deregulation bills.



AP Photo

Speculoscopy, a medical procedure used by gynecologists during cancer examinations, utilizes a new medical device, a special light bar, to illuminate the cervix.

FDA Reform? First, Do No Harm

Instead, the Patients' Coalition has consistently asked Congress and the FDA to adopt thoughtful, patient-oriented reforms that would improve the agency's performance — largely without any legislation whatsoever.

These patient-oriented proposals are precisely where we should start in the 105th Congress. Instead of putting the deregulatory cart before the horse, we should review the FDA's recent performance and ask ourselves whether radical deregulation is necessary. There is ample evidence that, while not perfect, the FDA has already been overtaken by dramatic changes.

Unless Congress can move quickly to correct the FDA's fiscal 1998 budget, all of the agency's recent accomplishments may be undone.

The desperate need for new treatments for AIDS, cancer, Alzheimer's, and other life-threatening diseases has forced the FDA to reinvent the drug-approval process. A decade of eroding FDA budgets in the 1980s was reversed by the Prescription Drug User Fee Act of 1992 (PDUFA), which has spurred drug approvals to new records.

Most recently, Vice President Al Gore's aggressive reinventing government initiative has led to dozens of major changes in the FDA's regulations and policies, applauded by industries and patients alike.

Compare the following factual accomplishments and reforms with the preceding list of radical FDA deregulation proposals. Which agenda best serves the health of Americans?

- In 1996, the FDA approved a record 53 new molecular entities — drugs that have never been marketed in the US before. That is nearly twice as many as the year before. Moreover, the median time for approval of these new drugs was 14.3 months, less than half the time it took in the 1980s.
- In cooperation with food industries, the FDA has launched a $24 million food safety initiative with the CDC, USDA, and EPA. The initiative will combat outbreaks of e. coli and salmonella through rigorous inspections, surveillance, and education.
- In cooperation with the drug industry, consumer labeling on prescription drugs and over-the-counter drugs will be vastly improved. Labels will be easier to understand and more legible, and will help reduce the $20 billion in hospitalizations, illnesses, and deaths resulting every year from drug misuse or adverse reactions.

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- The FDA implemented the popular and successful new nutrition labeling, which allows American consumers to better manage their nutrition and diets.
- A few weeks ago, the FDA's regulations for youth tobacco prevention took effect. Every year, one million American children and teenagers become regular smokers, and a third of them will die prematurely from tobacco-related diseases. In the next seven years, the FDA's efforts should cut youth smoking in half.

These reforms have or will reach into the homes of all Americans, improving their health and safety. Congress has an obligation to review and build on these successes before brushing them aside with a flurry of untested and speculative ideas, like lowering the drug efficacy standard or privatizing product reviews wholesale. In fact, there is one problem looming over both Congress and the FDA that deserves immediate, cooperative action.

User Fees: Real Reforms Cost Real Money

The Administration's proposal of $136 million in new, unauthorized FDA user fees in its fiscal 1998 budget threatens to derail collection of vital user fees already authorized by PDUFA, the 1992 user fee act. These new, phantom user fees also endanger reauthorization of PDUFA and any hope of enacting follow-on regulatory enhancements.

PDUFA has led to dramatic improvements in the speed of approval of innovative drugs and biologics. The statute requires, however, that collection of PDUFA user fees only occur if the FDA budget remains at or above a minimum baseline. Since authorization of the phantom user fees is unlikely in the extreme for the current budget cycle, the FDA budget may fall below this critical baseline.

Failure to collect the PDUFA user fees will lead inevitably to layoffs at the FDA and disastrous delays in product approvals. Patients

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in desperate need of new therapies and start-up companies relying upon timely product launches will pay the price for such a debacle.

Moreover, the FDA and the prescription drug and biotechnology trade associations have recently completed successful negotiations on a set of reforms designed to further speed the approval of new drugs. Known as "PDUFA2," these proposals promise equally important gains for patients and regulated industries alike. However, PDUFA2 can only be successfully authorized by Congress and implemented by the FDA if the agency's baseline budget is intact.

Both regulated industries and the FDA have long recognized the important "no-free-lunch" lesson from PDUFA and recently reaffirmed it in their PDUFA2 agreement. During the 1980s, the FDA was shouldered with new statutory responsibilities just as its budget began to shrink. The 1992 act enacted tough but fair targets for drug approvals, while granting the FDA the resources necessary to meet those targets.

Because of PDUFA, drug approvals have never been faster. The FDA is approving crucial breakthrough treatments,

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including two new cancer drugs and three AIDS drugs just last year, in six months or less. Studies by the General Accounting Office and others have concluded that the US approves drugs faster — and more safely — than Europe.

Unless Congress can move quickly to correct the FDA's fiscal 1998 budget, all of these accomplishments may be undone.

Is Genuine FDA Reform Possible?

Securing a stable FDA budget, ensuring reauthorization of PDUFA, and enacting PDUFA2 would be a remarkable achievement for the 105th Congress — a true trifecta of FDA reform and one requiring real compromises in Congress.

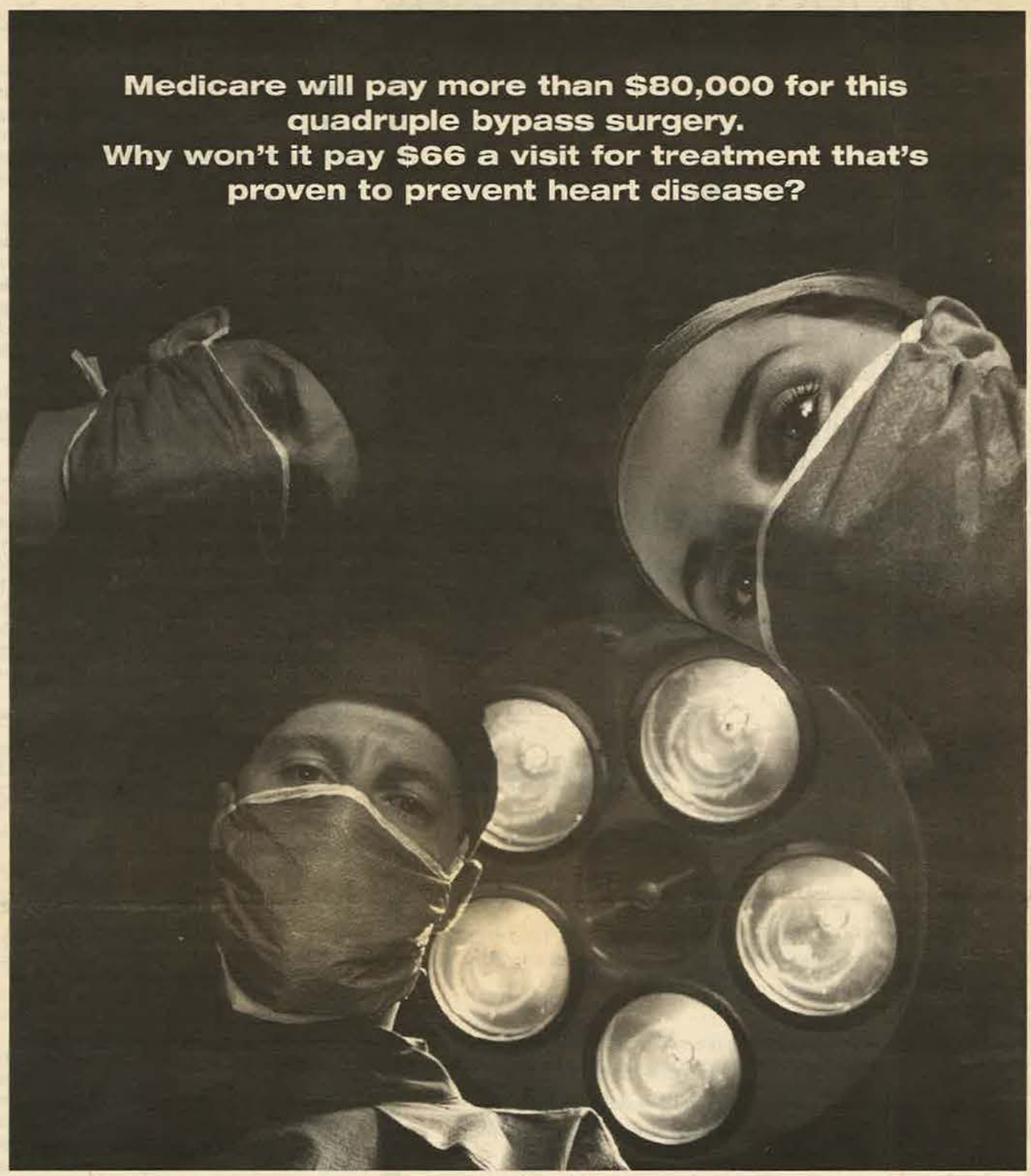
Reasonable, public-interested compromise is precisely how genuine FDA reforms have been enacted in the past. Congress has a respectable record of collaborating with the agency, patients, health care providers, and regulated industries in developing important legislation — like the landmark Kefauver-Harris amendments of 1962, the Medical Device Amendments of 1976, the Orphan Drug Act of 1983, the Hatch-Waxman Amendments of 1984, the Safe Medical Device Amendments of 1990, the Nutrition Labeling and Education Act of 1990, the Mammography Quality Standards Act of 1992, and the Prescription Drug User Fees Act of 1992.

This impressive history illustrates the rewards of strengthening the standards that protect the American public — not of launching ideological crusades against important public health agencies. Instead of indulging in fruitless rhetoric, the 105th Congress can make a valuable contribution if it focuses on concrete steps that improve the FDA and benefit patients.

With US drug approvals moving at record speeds, we should address tangible problems like reauthorizing PDUFA. With the FDA's own reinvention under way, we should give the agency the resources it needs to carry out its food safety initiative, youth tobacco prevention, and other critical public health duties.

And if legislation is necessary, we should work together to enact genuine, patient-driven reforms that enhance the health and safety of the American public.

Medicare will pay more than $80,000 for this quadruple bypass surgery.
Why won't it pay $66 a visit for treatment that's proven to prevent heart disease?



After years of high cholesterol and poor eating habits, George Anderson's arteries have become dangerously clogged. So today, surgeons are performing a quadruple bypass operation. George's medical bills for this procedure will be more than $80,000. Medicare will pay for almost all of it. Yet, it doesn't pay a penny for treatment that could have helped delay or even avoid surgery—office visits to a **Registered Dietitian** for Medical Nutrition Therapy.

Research shows that patients with heart disease and diabetes who regularly receive Medical Nutrition Therapy have a much better chance of managing their disease. They require fewer hospitalizations, surgeries, medications and have fewer complications. So, over the course of a long-term condition like George's, Medicare could save millions.

Increase coverage now, save millions later.

This year Medicare will spend $113 billion to treat patients with diabetes and heart disease. By covering office visits to R.D.s for Medical Nutrition Therapy now, the savings will offset additional costs by $26 million in just 5 years. And the savings would grow each year thereafter.

But, it's not just the money. Medical Nutrition Therapy could help millions to live longer, more productive lives with less pain and suffering.

Medical Nutrition Therapy
A Solution That Saves.

THE AMERICAN DIETETIC ASSOCIATION • THE VOICE OF NUTRITION