

# MAKE NO MISTAKE!



## *Medical Errors Can Be Deadly Serious*

*By Tamar Nordenberg*

Two months after a double bypass heart operation that was supposed to save his life, comedian and former Saturday Night Live cast member Dana Carvey got some disheartening news: the cardiac surgeon had bypassed the wrong artery. It took another emergency operation to clear the blockage that was threatening to kill the 45-year-old funnyman and father of two young kids.

Responding to a \$7.5 million lawsuit Carvey brought against him, the surgeon said he'd made an honest mistake because Carvey's artery was unusually situated in his heart. But Carvey didn't see it that way: "It's like removing the wrong kidney. It's that big a mistake," the entertainer told *People* magazine.

Based on a recent report on medical mistakes from the National Academy of Sciences' Institute of Medicine, Carvey might fairly be characterized as one of the lucky survivors. In its report, *To Err Is Human: Building a Safer Health System*, the IOM estimates that 44,000 to 98,000 Americans die each year not from the medical conditions they

edge. People in the hospital are just a small proportion of those at risk. Doctors' offices, clinics, and outpatient surgical centers treat thousands of patients each day; retail pharmacies fill countless prescriptions; and nursing homes and other institutional settings serve vulnerable patient populations.

Despite the recent focus on the IOM statistics, experts assure that the health system in the United States is safe. But its safety record is a far cry from the enviable record of the similarly complex aviation industry, which is being held up as an example for the medical world. A person would have to fly nonstop for 438 years before expecting to be in-

tive, to how they'll be used in the real world."

### Medication Mistakes

Even the seemingly simple process of giving a patient medicine—the right drug, in the right dose, to the right patient, at the right time—is, in reality, teeming with opportunities for error. The IOM estimates that preventable medication errors result in more than 7,000 deaths each year in hospitals alone, and tens of thousands more in outpatient facilities. (See "Most-Made Mistakes" on page 18.)

Name confusion is among the most common causes of drug-related errors,

## Medical errors have been ranked as the eighth leading cause of death among Americans.

checked in with, but from preventable medical errors.

A medical error, under the report's definition, could mean a health-care provider chose an inappropriate method of care, such as giving a patient a certain asthma drug without knowing that he or she was allergic to it. Or it could mean the health provider chose the right course of care but carried it out incorrectly, such as intending to infuse a patient with diluted potassium chloride—a potassium supplement—but inadvertently giving the patient a concentrated, lethal overdose.

The Institute of Medicine (IOM) estimates that fully half of adverse reactions to medicines are the result of medical errors. Other adverse reactions—those that are unexpected and not preventable—are not considered errors. (See "When Is a Medical Product Too Risky?" in the September-October 1999 *FDA Consumer*.)

The statistics in the IOM report, which were based on two large studies, suggest that medical errors are the eighth leading cause of death among Americans, with error-caused deaths each year in hospitals alone exceeding those from motor vehicle accidents (43,458), breast cancer (42,297), or AIDS (16,516).

But the numbers in the report don't tell the whole story, its authors acknowl-

ed in a deadly airplane crash, based on recent airline accident statistics. That, IOM says, places health-care at least a decade behind aviation in safeguarding consumers' lives and health.

The report is a self-described "call to action" for the health-care system. "Whether a person is sick or just trying to stay healthy, he or she should not have to worry about being harmed by the health system itself," its authors say.

In response to IOM's call, President Clinton has proposed a plan to halve the number of medical errors over five years. "If we do the right things," President Clinton said while announcing the White House plan, "we can dramatically reduce the times when the wrong drug is dispensed, a blood transfusion is mismatched, or a surgery goes awry."

Clinton's plan includes the creation of a new Center for Quality Improvement in Patient Safety, with a \$20 million budget, and the installation of patient safety programs to reduce medical errors in each of the 6,000 hospitals participating in Medicare.

For its part, the Food and Drug Administration will take a "much-enhanced" role in error prevention, says Janet Woodcock, M.D., the head of FDA's Center for Drug Evaluation and Research. "We'll be taking a much harder look at medical products—beyond just whether they're safe and effec-

says Peter Honig, M.D., an FDA expert on drug risk-assessment. A recent example: the sound-alike names for the antiepileptic drug Lamictal and the anti-fungal drug Lamisil. The volume of dispensing errors involving these two drugs prompted the manufacturer of Lamictal, Glaxo Wellcome Inc. of Research Triangle Park, N.C., to launch a campaign warning pharmacists of the potential confusion. The possible consequences of prescribing the wrong drug are grave: Epileptic patients receiving the anti-fungal drug Lamisil by mistake could experience continuous seizures. Patients erroneously receiving the antiepileptic drug Lamictal might experience a serious rash, blood pressure changes, or other side effects.

Errors also have occurred in prescribing the arthritis drug Celebrex, the anti-convulsant Cerebyx, and the antidepressant Celexa. There have been well over 100 reports of confusion among the three drugs, none of which has resulted in serious harm to a patient.

In one case, a physician wrote a prescription for "Celexa 200 mg." Since the antidepressant drug is available in only 20 and 40 milligram doses, the doctor was called, and he corrected his prescription to the intended Celebrex 200 mg. In response to such reports, the co-marketers of Celebrex, G.D. Searle & Co., Chicago, Ill., and Pfizer Inc., New

York, have undertaken an educational ad campaign to alert health professionals to the possible mix-ups.

Under FDA's authority to regulate drug labeling, the agency's new Office of Postmarketing Drug Risk Assessment evaluates medicines' brand names in an attempt to avoid sound-alike and look-alike names. If FDA considers the name of a new medical product to be potentially confusing to health professionals, the agency works with the drug company to change the product's name. FDA is developing new standards to prevent such name mix-ups, as well as to prevent confusion between similar-looking drug packaging.

Also, the agency is developing new label standards to highlight common interactions between drugs so that doctors

are less likely to mistakenly prescribe dangerous combinations. And even after a drug is approved, FDA monitors its use to see if unexpected adverse events occur and whether any labeling changes are required to help avoid medication mishaps.

So where does FDA's responsibility end and the health professionals' judgment take over? "FDA must do everything within its authority to maximize the likelihood that approved products will be used correctly in the real world," says Honig. But, he notes, "We don't regulate the practice of medicine, such as the sloppy handwriting when prescribing a drug."

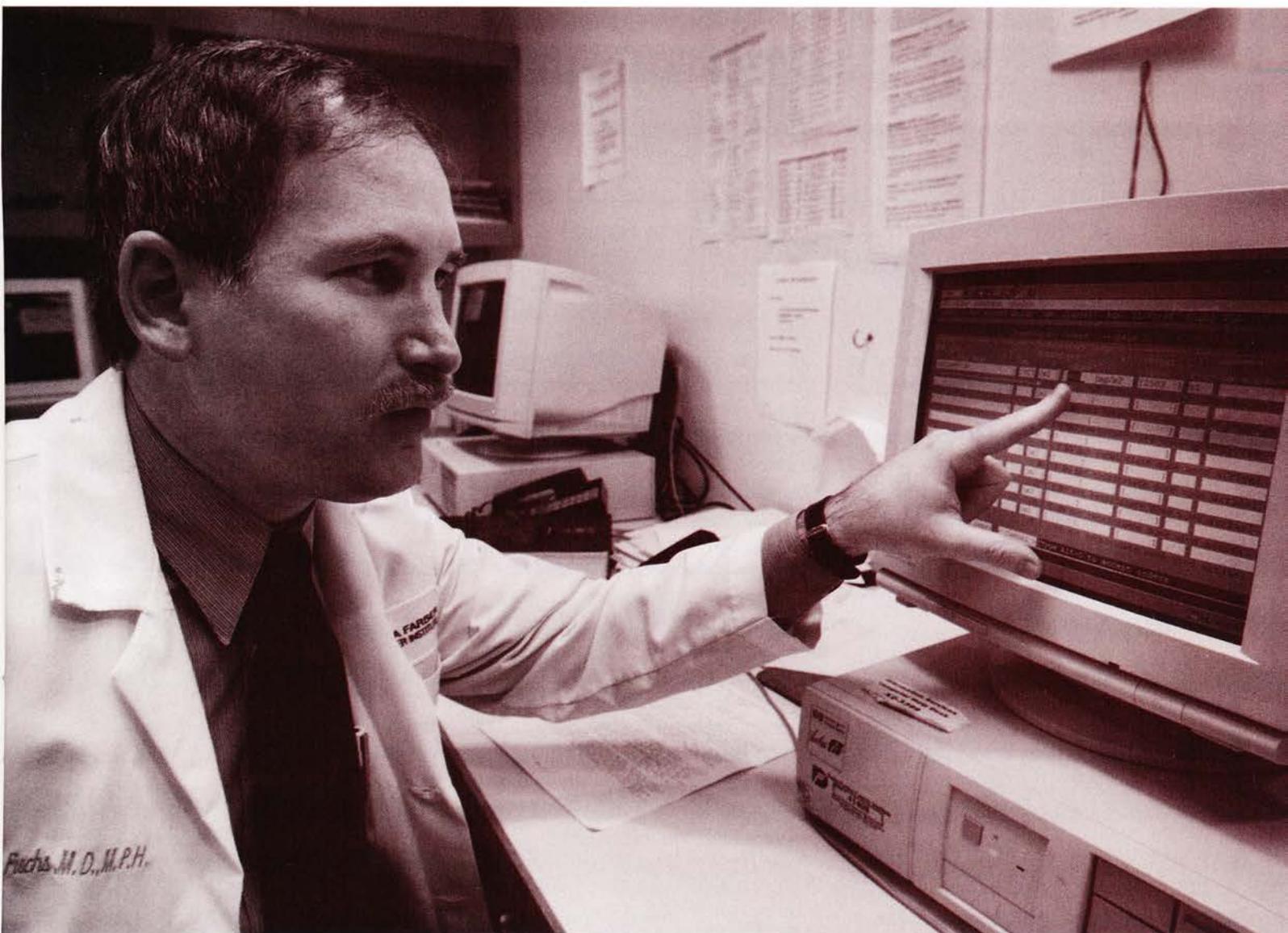
The real-world practice of medicine occurs within an intricate system, says Woodcock. "It's that complexity," she

says, "coupled with the limitations of humans, that makes avoiding mistakes a consuming task."

### Human Limitations

As its title—*To Err Is Human*—suggests, the IOM report supports moving away from the traditional culture of "naming, shaming, and blaming" individual health providers who make mistakes. Instead, the institute believes that preventing future errors is best achieved by designing a safer overall system.

Woodcock supports that view. Most health-care practitioners are competent professionals who are vulnerable to error simply by virtue of being human, she says. The professionalism model—"If we train people enough, they won't make a mistake, and we'll punish them



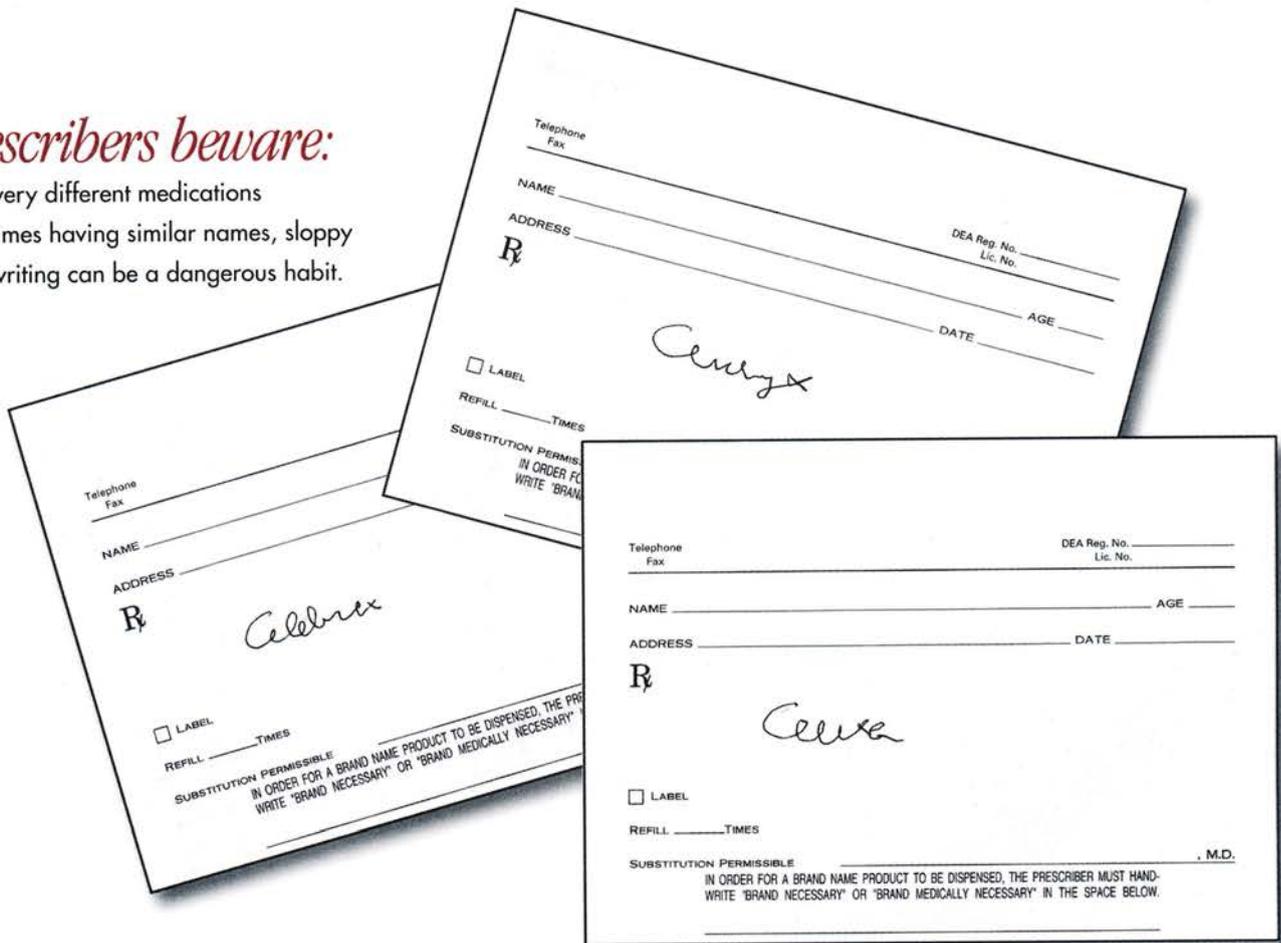
Even a simple computer system can provide a lifesaving check of doctors' prescribed treatments.

Photograph by Steven Gilbert, StudioFlex Productions.

# Name confusion is among the most common causes of drug-related errors.

## Prescribers beware:

With very different medications sometimes having similar names, sloppy handwriting can be a dangerous habit.



if they do”—has outlived its usefulness, according to Woodcock. “People have made mistakes and been drummed out of their professions. They were the ones unfortunate enough to administer the lethal dose, but the systems were not in place to adequately support them in preventing such an error.”

Some medical centers have begun using computer programs and other system supports to curtail medical mishaps by double-checking the care decisions doctors and nurses make. Even simple computer systems that use electronic prescriptions in place of handwritten ones have in some cases already paid off with substantial error reductions. (See “Lessons Learned,” on page 17.)

But systems, too, can fail, cautions Raymond L. Woosley, M.D., a professor and chairman of pharmacology at

Georgetown University Medical Center. Woosley’s example: “It’s true that if you have a prescription drug with an electronic bar code on it—the right code—it can help prevent errors. But if the wrong code is on there, you may have even more errors. There will always be mistakes, though they will be different mistakes as the systems change. You’ve got to be ready to handle them.”

Despite technological advances, preventing mistakes will always depend on the vigilance of health professionals, Woosley says. Otherwise, human carelessness can render useless the very systems designed to avert mistakes. Even among pharmacies with a computer program to highlight dangerous drug interactions, according to a study published in the *Journal of the American Medical Association*, one-third of pharmacists

nevertheless continued to fill prescriptions for a known killer combination: the prescription antihistamine Seldane (terfenadine) with the antibiotic erythromycin. (Seldane has since been removed from the market.)

“The pharmacists would get the computer warnings and zip right on by them,” Woosley says. “Or they would turn off the program entirely.” Why turn off the computer program? Because, Woosley explains, it was slowing down the pharmacists when they wanted to print labels.

Health professionals “are trained to memorize everything and are rewarded for it,” says the pharmacology professor. “The medical student who says, ‘I don’t know; I’ve got to look it up’ is likely to fail an exam, yet that’s the one who is less likely to make an er-

# Lessons Learned

Nineteenth-century essayist William Ellery Channing defined error as “the discipline through which we advance.” Some medical institutions have turned tragic patient safety failures into life-saving lessons.

## Department of Veterans Affairs

The VA health-care system is held up in the Institute of Medicine’s report on medical errors as a shining success story. The VA has the largest health-care system in the country, by one estimate serving more than 3 million veterans a year at its 172 hospitals and its 1,000-plus outpatient clinics, nursing homes, counseling centers, and other health programs.

The VA counted almost 3,000 errors—some 700 deaths among them—within its health network between June 1997 and December 1998.

Among the major steps the VA has taken to improve its safety record is a new bar-coding system to prevent and track medical errors. Generally, the bar-coding system works this way: ID strips are worn by nurses and patients and attached to medications. Before giving a patient a drug, a nurse scans all three ID strips into a computer, which verifies that the drug is being given correctly and will not cause drug interactions. If the program identifies a potential problem, it flashes a warning. Otherwise, it just

keeps a record of the activity.

In a test of the bar-coding technology at two VA hospitals in Kansas, the medication error rate dropped 70 percent over a five-year period.

Other changes at VA facilities include:

- Storing concentrated potassium chloride and other such hazardous medications away from patient care areas, and
- Encouraging cooperation and a focus on correcting the system rather than placing blame on individuals unless they perform negligently or incompetently.

## Dana-Farber Cancer Institute

In November 1994, two women got poisonous doses of chemotherapy while being treated for recurrent breast cancer at the prestigious Dana-Farber Cancer Institute in Boston. Boston Globe medical reporter Betsy Lehman, age 39 at the time, died as a result of the error, and the second patient, Maureen Bateman, suffered permanent heart damage and died from cancer several months after the mistake.

Instead of prescribing the daily dose of the powerful anticancer drug cyclophosphamide to be given on each of four days, as planned, the doctor ordered the drug’s combined four-day dose so that the total was given to the patients each day.

Since the fatal miscommunication, Dana-Farber has updated its systems to avoid errors. For one thing, the institute

has installed a \$1.7 million computer system to take over many tasks. Doctors don’t hand-write prescriptions anymore, but instead fill out an electronic form with the patient’s personal information, as well as the name of the drug, the dose, and the number of days for which the medicine is to be given. The information goes into the institute’s computer system, which compares the information with upper dose limits for the drug and other pre-programmed guidelines. If the doctor seems to have made a mistake, the computer signals the error.

Secondly, a nurse checks the information in the computer before ordering the drug from the pharmacy. The pharmacist conducts yet another computerized review for potential drug interactions with other drugs, foods, or the patient’s allergies.

After being prepared at the pharmacy, the drug goes next to the nurses’ station, where two nurses check the drug’s label and the patient’s wristband to make sure the right person gets the drug.

Additionally, the cancer center began a system of non-punitive error reporting to encourage open discussion of medical mistakes. The change effectively brought about what the institute has described as a “dramatic increase” in error reporting. ■

—T.N.

ror.” Woosley hopes medical students will be taught to accept their limitations and admit their mistakes. Under the current system, however, some people call that goal pie-in-the-sky.

## Culture of Secrecy

Neonatologist Margaret Donahue, M.D., says the fear of being sued suppresses discussions about medical errors. “Even if a procedure is done with the best intention and skill, and it doesn’t turn out the way it was supposed to, the doctor often still ends up having to pay the patient a huge settlement. It’s

that culture—the feeling they’re going to lose no matter what they do—that keeps physicians closed among themselves.”

Historically, people have looked for someone to blame when medical accidents happen, according to FDA’s Woodcock. For victims and their relatives, she says, there may be some satisfaction in that. But from the perspective of fixing the problem, the secrecy that results keeps the medical community from learning what happened and how to correct the problem.

Most experts agree that mandating medical error reporting, in itself, will not

surmount the hesitancy of doctors. More than 20 states currently have mandatory reporting systems, yet state officials say that underreporting persists.

FDA, too, faces the problem of “tremendous underreporting,” according to Susan Gardner, Ph.D., deputy director of the Office of Surveillance and Biometrics in the agency’s Center for Devices and Radiological Health.

Hospitals, nursing homes, and other facilities that use medical devices are required to report to FDA all deaths caused or possibly caused by devices. “Guess what? They don’t report,”

# “It’s unfortunate that people research buying a car better than they research health-care decisions.”

—Peter Honig, M.D., FDA risk-assessment expert

says Gardner, whose office gets only about 4,000 reports a year from the 40,000 to 50,000 facilities covered by the reporting requirement.

Gardner thinks that simply assuring facilities of confidentiality of reports could go far to increase compliance with the reporting requirement. “If you give incentives to report, they’ll report. In many cases, that might simply mean good feedback so they can improve their systems.” A published list of previously reported device problems in FDA’s database, Gardner says, would enable facilities to benchmark their own experiences. Newsletters could discuss important medical device issues. And strategies could be suggested to avoid potential pitfalls in using a medical device.

With devices, more than with drugs, it can be difficult to determine if an adverse event was a preventable error or an unexpected reaction, Gardner says. Devices sometimes require specific knowledge and training to use the product correctly.

It’s the interface between the device and the user, referred to as “human factors,” that can complicate an investigation into why something went wrong. The problem usually isn’t that the device itself broke, Gardner says, but rather that it wasn’t intuitively user-friendly, or the user didn’t have instruc-

tions on hand or didn’t know about a change in the way the device was to be used in a certain setting.

In the agency’s Center for Biologics Evaluation and Research, the lack of reporting is characterized by consumer safety officer Sharon O’Callaghan as one of the biggest problems where medical errors are concerned. She says that while manufacturers of biological products, such as blood components and vaccines, must report to FDA certain errors that occur during manufacturing, companies are not sufficiently aware of reporting requirements.

For biological products, manufacturing errors can lead to mistakes in treatment that are potentially serious and even deadly. In blood banks, for example, a blood product that is mislabeled can present a serious threat to a patient if the wrong type of blood is transfused.

“Things happen that we might not hear about,” O’Callaghan says. “We want to increase reporting so we can assess what’s happening in the industry.” To increase reporting of manufacturing glitches, the agency has proposed a rule that would increase the number of facilities that must report errors and other adverse events.

Clinton’s proposal to reduce medical errors contains a nationwide, state-based system of reporting medical errors that

would include mandatory reporting of mistakes that result in death or serious injury and voluntary reporting of other medical mistakes, including so-called “close calls” or “near misses.” Clinton also expressed support for legislation that protects provider and patient confidentiality, while safeguarding the legal remedies of those whose health is harmed.

## To Improve Is Human

Woodcock encourages consumers to help prevent errors by being vigilant about their health-care—understanding their treatment, keeping organized records of what doctors they see and what medications they take, and asking questions when things don’t seem right. For example, “If your pills look different than they have in the past, they might be the right medication, and they might not. But raise the issue.”

Honig calls consumer education the “secret weapon” in the war against medical errors. “It’s unfortunate that people research buying a car better than they research health-care decisions. They’re willing to tolerate more uncertainty with their health-care than their mode of transportation.” He encourages patients to feel comfortable asking more questions about their medical care.

With everyone from pharmaceutical manufacturers to consumers playing a role in improving the safety of the health system, Woodcock believes that the already “very safe” medical system in the United States will become even safer. “There are fixes,” she says. “We know that from other industries.”

The spotlight on the health system’s problems might be just what the system needed to transform itself, says Woodcock. After all, as the IOM report notes, “It may be part of human nature to err, but it is also part of human nature to create solutions, find better alternatives, and meet the challenges ahead.” ■

*Tamar Nordenberg is a staff writer for FDA Consumer.*

## Most-Made Mistakes

The American Hospital Association lists these as some common types of medication errors:

- **Incomplete patient information** (not knowing about patients’ allergies, other medicines they are taking, previous diagnoses, and lab results, for example)
- **Unavailable drug information** (such as lack of up-to-date warnings)
- **Miscommunication of drug orders**, which can involve poor handwriting, confusion between drugs with similar names, misuse of zeroes and decimal points, confusion of metric and other dosing units, and inappropriate abbreviations
- **Lack of appropriate labeling** as a drug is prepared and repackaged into smaller units
- **Environmental factors**, such as lighting, heat, noise, and interruptions, that can distract health professionals from their medical tasks ■

—T.N.