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By Michael O. Schroeder | Staff Writer

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Americans are taking more medications than ever before.

Nearly 60 to 70 percent of us take at least one prescribed drug, depending upon the estimate; for many it amounts to a fistful, potpourri of pills per day. Meanwhile, new drug approvals have reached a 19-year high. It's a mark cheered notably for the swift minting of medications to tackle so-called "orphan diseases," rare conditions for which few or no treatment options exist. But critics say an expedited drug approval process is opening the door for riskier drugs – including many not proven to provide unique benefits over drugs already on the market.

Even as an opioid overdose crisis sweeps the country, another ubiquitous, insidious danger is hidden from view. There's no formal process for quantifying injuries, hospitalizations or even deaths caused by therapeutic drug use – which excludes overdose or misuse. "Risk management begins with measuring things accurately, so you know what the threats are and the ones where you should be paying attention," says Thomas J. Moore, senior scientist for drug safety and policy at the Institute for Safe Medication Practices. But he notes that there's no system in place or accepted methodology for developing these tallies for prescription drugs, unlike with overdoses. Health providers and consumers are encouraged to report adverse drug reactions to the Food and Drug Administration, and the agency can issue safety communications, require drug label warnings and pull drugs from the market, among other risk management measures. But the FDA says it's unable to use the incomplete adverse event reporting data to quantify overall deaths that result from therapeutic drug use.

The difficulty involved in trying to estimate the toll, however, hasn't stopped Moore and other researchers from seeking to quantify how many people die annually from taking prescribed drugs – often by closely evaluating hospital admission studies. Estimates dating back nearly two decades put the number at 100,000 or more deaths annually, which includes a study published in the Journal of the American Medical Association in 1998 that projected 106,000 deaths. A more recent analysis estimates 128,000 Americans die each year as a result of taking medications as prescribed – or nearly five times the number of people killed by overdosing on prescription painkillers and heroin.

“By far the greatest number of [prescription drug-related] hospitalizations and deaths occur from drugs that are prescribed properly by physicians and taken as directed,” says Donald Light, a medical and economic sociologist and lead author of a 2013 paper that detailed the estimate, entitled “Institutional Corruption of Pharmaceuticals and the Myth of Safe and Effective Drugs.” “About 2,460 people per week are estimated to die from drugs that were properly prescribed, and that’s based on detailed chart reviews of hospitalized patients,” says Light, who is a professor of comparative health policy at Rowan University School of Osteopathic Medicine in Stratford, New Jersey. The estimate, which didn’t include those who died as a result of prescribing errors, overdose and self-medication, would make taking properly prescribed drugs the fourth leading cause of death in the U.S.

For those taking them, prescription drugs can provide myriad benefits from treating infections that could be potentially life-threatening to preventing stroke or helping manage a chronic condition. And frequently any side effects experienced are relatively minor. However, depending upon the analysis, adverse drug reactions are estimated to result in approximately 1.5 to 2.7 million hospitalizations each year. And though following a doctor's orders and medication labeling instructions can reduce harms associated with taking prescription drugs, simply taking prescribed drugs as directed can expose a person to significant risk.

“Most people who are harmed by prescription drugs [are] taking the drug as prescribed,” says Dr. Michael Carome, director of the Health Research Group at the consumer watchdog Public Citizen. Even the best projections of medication-related death and injury are likely underestimates of the harm inflicted, he says, since often these adverse events may be errantly attributed to another cause, like a patient's underlying condition.

Conversely, one difficulty in understanding the potential harm a medication may cause is that even hindsight isn’t always 20/20. It can be hard to discern the role a specific drug played when a patient develops a new health problem – particularly if a patient has multiple health conditions and is on numerous medications. “Some cases are really easy to determine; some get very difficult to determine,” Moore says.

But while complexities present challenges to pinpointing the number, Carome says population growth and aging are likely to further increase injuries and deaths resulting from taking prescription medications. “As people get older they tend to have more illnesses, and they end up taking more prescriptions,” he says, which can increase the chances drugs will interact in a dangerous way. In addition, kidney and liver function can decline with age, making it harder to metabolize drugs – thus increasing the risk of side effects.

And even a single drug taken in isolation has the potential to cause serious harm. “There’s no such thing as a risk-free drug,” he says.

For all the hoopla that may surround certain new drugs, it’s also during the time shortly after drugs are approved when safety issues often become apparent. “We have what’s called a seven-year drug rule,” Carome explains. Within the first seven years after a drug is approved, it's common for safety warnings – including the FDA’s strongest, the “black box" warning – to

come to light, Carome says. And it's within the same period, he adds, that drugs are often withdrawn from the market because of serious safety concerns.

"We advise people not to take the drug for seven years" after approval, he says, with exceptions only for actual breakthrough drugs, which Carome contends are few and far between. Those that offer a unique breakthrough treatment compared to what's already on the market – like those that treat orphan diseases – would be one such example. But even in those instances, because of the limited safety information available, he recommends proceeding with caution.

Helen Haskell, president of the nonprofit safety organization Mothers Against Medical Error, says it's not just patients but doctors who frequently don't always have the full picture about risks of prescribed drugs. Even when that information is available, she adds, doctors aren't necessarily aware of every drug risk, given harried schedules and all there is to know in medicine. So doctors often rely on information drug reps provide, patient advocates say. And research finds that health providers routinely overstate the perceived benefits of drugs – as with medical procedures – while downplaying or not discussing harms.

Haskell's rule of thumb: If you're taking a new-to-you medication (whether newly approved or not), and you experience a new symptom, suspect the medication first. It may seem counterintuitive, and many doctors may be loath to blame the drug they prescribed for how lousy you feel, but Haskell says it's more important that patients report such symptoms, which could be side effects. Also, ask about alternatives to the medication.

While some patient advocates – as well as members of Congress – have applauded the FDA for expediting the approval process for breakthrough drug treatments, the agency has also faced sharp criticism for not doing enough to reduce the likelihood patients could be harmed by newly approved medications.

Since drug maker Merck yanked the blockbuster painkiller Vioxx (approved in 1999) in 2004 due to an increased risk of strokes and heart attacks, only a few other new drugs have been pulled from the market; that includes Abbott Laboratories' agreeing to withdraw the diet drug Meridia, approved in 1997, in 2010, after it was also found to increase the risk of strokes and heart attacks. And Carome says the agency now seems reluctant to pull new drugs off the market.

But the FDA asserts that neither in its approval process or post-marketing monitoring has it lagged on safety as it works to more quickly greenlight certain drugs.

"Today, thanks to the efforts of those across the FDA, we are delivering new, lifesaving therapies to patients faster than any other developed country and more expeditiously than ever before," FDA spokeswoman Sandy Walsh wrote in an email. "In addition, we have significantly strengthened the drug safety surveillance system in the United States, modernized drug review processes, and introduced new genomic and related sciences into the drug evaluation process."

Reward and Risk

In addition to monitoring drugs already on the market, the FDA has sought to meet demand for newer therapies to treat rare diseases, approving drugs in 2015 ranging from Orkambi – a therapy for the lung disease cystic fibrosis – to an enzyme replacement therapy called Strensiq to treat patients with infantile- and juvenile-onset hypophosphatasia, a bone disease that can be fatal.

The 45 new medicines approved by the FDA last year provide patients with important new treatment options and will play a key role in helping them live longer, healthier lives, wrote Andrew Powaleny, a spokesman for the industry trade association PhRMA, in an email. “More than a third of the new medicines approved were first-in-class treatment options – offering a completely new way to treat diseases – and nearly half were for rare conditions. Among the new medicines are innovative cancer treatments with the potential to prolong and transform patients’ lives."

However, some health experts and consumer advocates, including Carome, say that drugs approved in areas where a range of treatment options already exist – from managing diabetes to controlling cholesterol – tend to offer little or no new benefits, compared to less costly and more proven treatments already on the market, while increasing risk. “Newer patented drugs have much higher prices, and yet the vast majority of new patented drugs have been shown by independent review groups to be little or no better than older post-patent drugs that sell at generic prices,” Light adds.

But the FDA’s Deputy Center Director for Clinical Science, Dr. Robert Temple, contends that comparing effectiveness of drugs isn't always the best approach. “Some people do better on one drug than another very similar drug and you don't always know the reason,” Temple writes on the FDA’s site.

Even so, pills, like cars, can turn out to be lemons. So, experts say, don’t assume a brand-name drug is better than a less expensive generic or even that a doctor-recommended drug is necessarily the best option for you in a particular drug class.

To bone-up on drug safety information, start by going to the FDA’s website to read the drug label and see reported adverse events, and check out independent analysis on drug harms. Older adults should also consider the American Geriatrics Society Updated Beers Criteria, which identifies medications seniors should avoid or use with caution. Last updated in 2012, clinicians and pharmacists say this remains a very useful and important list for seniors when weighing drug benefits against harms. Incorporate risk comparisons in discussing drug choices and alternatives with your doctor.

As it relates to expediting the approval process for novel drug therapies, including how to treat rare conditions, the FDA remains bullish – while deflecting concerns that increasing the speed of approval increases the risk for patient harm. “Scientific research has helped us better understand the mechanisms of a disease and allow for targeted drug development. When we see signs of efficacy early on in the development process, we need to find the fastest path to get a product on the market,” Walsh says. She adds that the FDA “applies the same statutory approval standard of safety and efficacy to new drugs that we’ve always applied. Increased flexibility does not alter our fidelity to the science and our commitment to patient safety.”