America is in pain—and being killed by its painkillers.

It starts with drugs such as OxyContin, Percocet, and Vicodin—prescription narcotics that can make days bearable if you are recovering from surgery or suffering from cancer. But they can be as addictive as heroin and are rife with deadly side effects.

Use of those and other opioids has skyrocketed in recent years. Prescriptions have climbed 300 percent in the past decade, and Vicodin and other drugs containing the narcotic hydrocodone are now the most commonly prescribed medications in the U.S. With that increased use have come increased deaths: 46 people per day, or almost 17,000 people per year, die from overdoses of the drugs. That’s up more than 400 percent from 1999. And for every death, more than 30 people are admitted to the emergency room because of opioid complications.

With numbers like that, you would think that the Food and Drug Administration would do all it could to reverse the trend. But against the recommendation of its own panel of expert advisers, last December the agency approved Zohydro ER, a long-acting version of hydrocodone. “We think the benefits of the drug outweigh its risks,” says Douglas Throckmorton, M.D., who oversees regulation of drugs for the FDA. He says that Zohydro ER offers an option to some people in pain, and that the FDA has taken steps to make all opioids safer by, for example, requiring stronger warnings on drug labels. The FDA says it will also keep a close eye on how Zohydro ER is used in the marketplace.

But attorneys general from 28 states have asked the FDA to reconsider its decision because the drug offers no clear advantages over others already on the market and its potency makes it a target for misuse and abuse. And more than a dozen Republican and Democratic members of Congress have signed a bill that would ban Zohydro ER.

Opioids aren’t the only painkillers that pose serious risks. Almost as dangerous is a medication renowned for its safety: acetaminophen (Tylenol and generic). Almost 80,000 people per year are treated in emergency rooms because they have taken too much of it, and the drug is now the most common cause of liver failure in this country.

Though some of those tragedies stem from abuse, many are accidental. It’s not just that people are careless. Advice to “take only as directed” doesn’t cut it when the advice is confusing and conflicting. And with acetaminophen, the advice is exactly that. For example, the FDA has lowered the maximum per-pill dose of prescription acetaminophen, but it hasn’t taken the same step for over-the-counter products. And OTC drugmakers have wildly different notions of what people can take: Some labels advise taking no more than 1,000 milligrams of acetaminophen daily; others set the limit almost four times as high.

And with acetaminophen, accidentally taking too much is all too easy. That’s because it’s the most common drug in the U.S., found as an ingredient in more than 600 OTC and prescription medications, including allergy aids, cough and cold remedies, fever reducers, pain relievers, and sleep aids.

“All of this doesn’t mean that everyone should avoid opioids and acetaminophen altogether,” says Marvin M. Lipman, M.D., chief medical adviser for Consumer Reports. “But it does mean that the FDA should fulfill its role to protect consumers by taking strong steps to reduce the dangers, starting by reconsidering its approval of Zohydro ER.
and finally establishing consistent standards for acetaminophen.

It also means you need to know the risks, not only of opioids and acetaminophen but also of drugs such as ibuprofen (Advil and generic), naproxen (Aleve and generic), and Celebrex. That last drug, now prescribed only under its brand name, should be available in the next year or so as a lower-cost generic called celecoxib. But like its non-prescription cousins, it poses serious risks to your heart and stomach when taken regularly, as millions of Americans do.

"Pain drugs can be as bad as the pain itself," Lipman says. "So you need to know when they are really needed and how to use them safely."

**OPINIONS**

**Deadly misconceptions**

One of the biggest misconceptions people have about opioids is that the risks apply to other people, not themselves. But the "typical" victim of overdose might not be whom you think. About 60 percent of overdoses occur in people prescribed the drugs by a single physician, not in those who "doctor shopped" or got them on the black market. And a third of those were taking a low dose.

Used properly, opioids can ease severe short-term pain from, say, surgery or a broken bone, and manage chronic pain from an illness such as cancer. But people run into trouble when they inadvertently misuse the drugs—combining them with alcohol or other drugs (such as sleeping pills), taking them in too high a dose or for too long, or using them while driving or in other situations when they need to be alert.

Ideally, health care professionals should act as gatekeepers, prescribing painkillers only when they're appropriate and monitoring patients for side effects. But that's not always done, says Richard Blondell, M.D., director of the National Center for Addiction Training at the State University of New York in Buffalo, N.Y. "No doubt, the public needs to be better educated about the risks," Blondell says. "But ultimately this epidemic starts with the doctor's prescription pad."

The general public and health care providers harbor outdated and dangerous notions about opioids. Below are three of the biggest misconceptions and the facts you need to know to stay safe:

**Misconception: Opioids work well for chronic pain.** An estimated 90 percent of people suffering long-term pain wind up being prescribed an opioid despite little evidence that the drugs help much or are safe when used long-term. "But we do know that the higher the dose and the longer you take it, the greater your risk," says Gary Franklin, M.D., research professor of environmental and occupational health sciences at the University of Washington in Seattle. People who take opioids for more than a few weeks often develop tolerance, so they require higher doses, which in turn breeds dependence. And although higher doses can ease pain, they commonly cause nausea and constipation, disrupt your immune system and sex life, and leave you feeling too fuzzy-headed to participate in things such as physical activity that can speed your recovery. And in a cruel twist, the drugs can make some people more sensitive to pain.

**The safer approach.** For certain types of pain—including nerve pain, migraines, and fibromyalgia—other prescription medications usually work better than opioids. For other types of chronic pain, ask your doctor about trying OTC drugs such as acetaminophen, ibuprofen, and naproxen before prescription drugs. Non-drug measures such as exercise, massage, behavioral therapy, and acupuncture might also help. If you have chronic pain that hasn't responded to other treatment, opioids may be an option. But your doctor should prescribe the lowest effective dose for the shortest possible time and monitor you for side effects.

**Misconception: Opioids are not addictive when used to treat pain.** "That's what I and a lot of other doctors learned in medical school," Blondell says. "But we now know that's just not true." Somewhere between 5 percent and 25 percent of people who use prescription pain pills long term get addicted. Fewer women are dependent on prescription painkillers than men, but they may become dependent more quickly and are more likely to doctor shop.

**The safer approach.** Chronic pain often waxes and wanes. If you and your doctor feel you need an opioid, reserve it for flares-ups. If you take it for more than a few weeks, your doctor should advise you about early signs of addiction, including unusual moodiness, cravings, temper flares-ups, and taking unnecessary risks.

**Misconception: Extended-release versions are safer.** Opioids such as hydrocodone (Exalgo), oxycodone (Oxycodone and generic), morphine (Avinza, MS Contin, and generic), and the newly approved Zohydro ER stay in the body longer and are usually stronger than short-acting forms. They should be reserved for patients who need round-the-clock relief. But doctors sometimes prescribe them for convenience—patients need to take fewer pills—and because they believe that long acting drugs are less likely to cause a drug "high" and lead to addiction. But there's no evidence those drugs work better or are safer than short-acting ones. And people dependent on opioids seek out the higher potency of long-acting versions.

**The safer approach.** It's usually best to start with a short-acting opioid. Because

---

**It's easy to overdose on acetaminophen**

Acetaminophen is in many products, making it easy to get more than the 4,000 milligrams per day linked to liver damage and the 3,250-milligram daily maximum we recommend.

- **Tylenol Extra Strength**
  - Contains 500 milligrams of acetaminophen per pill.
  - Directions: Take no more than six pills in 24 hours.
  - Maximum Daily Dose: 3,000 milligrams.

- **NyQuil Cold & Flu**
  - Contains 325 milligrams of acetaminophen per pill (plus dextromethorphan and doxylamine for cold and flu symptoms).
  - Directions: Take no more than eight pills in 24 hours.
  - Maximum Daily Dose: 2,600 milligrams.

- **Walgreens Pain Reliever PM**
  - Contains 500 milligrams of acetaminophen per pill (plus diphenhydramine as a sleep aid).
  - Directions: Take two pills at bedtime.
  - Maximum Daily Dose: 1,000 milligrams.

**TOTAL acetaminophen within a 24-hour period: 6,600 mg**
Rates of opioid sales and overdose deaths, United States, 1999–2011

<table>
<thead>
<tr>
<th>Year</th>
<th>Opioid sales</th>
<th>Opioid deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td>1999</td>
<td>3.1</td>
<td>0.6</td>
</tr>
<tr>
<td>2003</td>
<td>7.8</td>
<td>1.0</td>
</tr>
<tr>
<td>2007</td>
<td>8.0</td>
<td>1.5</td>
</tr>
<tr>
<td>2011</td>
<td>7.9</td>
<td>2.0</td>
</tr>
</tbody>
</table>

(1) In kilograms per 10,000 people. (2) Per 100,000 people. Source: Centers for Disease Control and Prevention.

long-acting drugs are more likely to be stolen, misused, and abused, if your doctor prescribes one, expect careful monitoring.

**ACETAMINOPHEN**

**Dangerous doses**

When taken at recommended doses, acetaminophen is safe for pain relief for most people, even when used long term. But there's little margin for error. Exceeding the maximum recommended dose—by even a little bit—can prove toxic, especially to the liver. And as the box on the facing page shows, it's easy to do.

It has long been known that large doses of acetaminophen taken at once can be fatal. But cumulative smaller doses totaling more than 4,000 milligrams (eight 500-milligram, or “extra strength,” pills) can be just as dangerous, if not more so. People who took repeat doses of the medication—for complaints such as headaches, muscle pain, and toothaches—that put them over the maximum daily amount were more likely to have brain, kidney, and liver problems, and faced a greater risk of dying or needing a liver transplant than people who had taken a single, large overdose. That’s according to a 16-year Scottish study of people treated in the emergency room published in 2011.

That same year, the FDA tried to reduce acetaminophen poisonings by limiting the prescription products to 325 milligrams per pill. The agency noted that higher doses don’t relieve pain better and that people are more likely to overdose on them.

But the agency has not yet imposed the same limits for nonprescription products, even though they account for 80 percent of the acetaminophen taken in the U.S. No doubt, that pleased OTC drugmakers: “Extra strength” products with 500 milligrams of acetaminophen per pill are big sellers.

And because acetaminophen shows up in so many products, you need to check all drug labels for acetaminophen. Then make sure you stay below the safe upper limit when you combine the pills. And you should avoid acetaminophen altogether if you are at risk for liver disease or drink alcohol heavily, because that multiplies the dangers. If you regularly take the drug, watch for signs of liver damage, including dark urine, pale stools, upper-right abdominal pain, and a yellowish tinge to the whites of the eyes.

**Safe opioid use**

**What are opioids?** They’re the strongest pain medications, available only with a prescription. Common brand names include OxyContin, Percocet, Vicodin, and Zohydro ER. Generics include fentanyl, hydrocodone, morphine, and oxycodone.

**Read the label.** Never take more than advised, don’t take with alcohol, and don’t combine with any other drug without your doctor's OK. Most opioid deaths involve alcohol or sleeping pills.

**Get tested for sleep apnea.** If you snore loudly, get checked for the condition, because opioids can make it worse or even fatal.

Tell your doctor if you have a cold, an asthma flare-up, or bronchitis because opioids can interfere with breathing. You may need a lower dose until you recover.

Don’t drive or do anything that requires you to be fully alert, especially when you start taking an opioid or whenever you change the type or dosage.

Lock up opioids. "Keeping opioids around is like keeping a loaded gun in your medicine cabinet," says Richard Blondell, M.D., whose research shows that most teens hooked on prescription painkillers started with medication they got from their own house or from a friend.

Expect regular monitoring. If you are taking the drugs for chronic pain, "your doctor should assess you at regular visits. If pain and function do not improve at least 30 percent after starting the drugs, then they probably are not working well enough to justify the risks," says Gary Franklin, M.D. Your doctor should also make sure that you take the drugs as prescribed by, for example, counting your pills.

Discard unused pills. You may be able to give them back to your pharmacy. If you can’t, the FDA says, unlike other drugs, opioids are so risky excess pills should be flushed down the toilet.

Should I ask my doctor for Celebrex?

In most cases, no—for several reasons. First, the drug, which in generic form is known as celecoxib, doesn’t ease pain from osteoarthritis better than related drugs available without a prescription, including ibuprofen (Advil and generic) and naproxen (Aleve and generic), according to our Best Buy Drugs analysis. And though some research suggests that celecoxib is less likely to cause stomach bleeding, it might be more likely than naproxen to increase the risk of heart attacks and strokes.

In addition, though celecoxib should be available next year as a generic and will eventually cost less than the brand-name original, it can take a year or more for savings to trickle down to consumers. We estimate that a year after it becomes available as a generic, celecoxib will cost about $70 per month. That’s roughly half of what brand-name Celebrex now costs—but about seven times as much as what generic ibuprofen or naproxen costs.

Because of the risks posed by those drugs, we suggest that most people with arthritis start with appropriate doses of acetaminophen, which is safer when used properly. That’s especially true for people who have a history of ulcers, bleeding, kidney disease, or any form of cardiovascular disease.

**ConsumerReports BEST BUY DRUGS**

For details on the safe use of pain medications, go to CRBestBuyDrugs.org/painpills. CR Best Buy Drugs is a free Consumer Reports project.
Got pain? Try these drugs ... and try these nondrug measures, too

For many minor ailments, an over-the-counter drug might be all you need. Acetaminophen (Tylenol and generic), aspirin, ibuprofen (Advil, Motrin IB, and generic), and naproxen (Aleve and generic) are generally safe for occasional use when used appropriately. We recommend OTC generic and store-brand versions because they are cheaper than and just as safe and effective as their brand-name versions.

Hey, FDA!

People need more protection from pain relievers

Yes, we are talking to you, FDA. The pain-reliever marketplace is confusing and even dangerous for consumers. A few steps on your part could save thousands of lives each year.

Reconsider your approval of Zohydro ER. In an 11-to-2 vote, your own advisory panel urged you to reject the drug because of its potential for abuse. And your sister agency, the national Centers for Disease Control and Prevention, says opioid addiction is a leading health care problem. Zohydro ER does not fit a pressing medical need; similar drugs are available. Addiction experts fear it will just fill a void for street narcotics. Sales of OxyContin (oxycodone) took a hit when drugmaker Purdue Pharma reformulated the pills to make it more difficult for people to crush them and snort the powder or dissolve and inject it. Zohydro ER now has no such safeguards. At least require its manufacturer, Zogenix, to make the drug difficult to abuse and require training for doctors who dispense it. And you should raise the bar for how you approve narcotic pain drugs.

Make acetaminophen standards consistent. A per-pill dose of 525 milligrams is just as effective as stronger doses, and safer. That’s the limit you set for prescription acetaminophen. So why not the same for OTC drugs, which account for 80 percent of acetaminophen use? We’d also like consistent drug labels. We found recommendations varying from 1,000 milligrams per day in some nighttime pain relievers to 3,900 milligrams in some products that combine acetaminophen with allergy drugs or cold and flu drugs. We think the labeled daily limit should be no more than 3,250 milligrams.

Consumers, you can help, too

Contact the FDA at 888-461-6332 or at druginfo@fda.hhs.gov and let it know you want stricter standards on pain pills. Have you been harmed by opioids or acetaminophen? Share your story with us at ConsumerReports.org/paindrugs. Learn about our Safe Patient Project (SafePatientProject.org), which works with advocates to make health care safer.