

This American Life
Episode #505 “Take Only As Directed”

Statement from Edwin K. Kuffner, M.D., Vice President of OTC Medical Affairs and Clinical Research at McNeil Consumer Healthcare:

We've been making Tylenol for the past fifty-four years. Every week, somewhere around fifty million Americans take acetaminophen, many on the advice of nurses, pharmacists, and doctors of all specialties. When considering the safety of Tylenol, it's important to remember that all medicines have both benefits and risks – doesn't matter whether it's an over-the-counter medicine or a prescription medicine. Taking too much of any medicine can be harmful.

When taken as directed, acetaminophen is both safe and effective. But when anyone takes an overdose, the risk can include severe liver damage, which especially when untreated can be fatal. That's why it's so important for all your listeners and anyone who takes any medicine to always read the label and follow the directions. When taken as directed, acetaminophen is one of the safest over-the-counter medicines. If anyone has any questions about any medicine they're taking, they should talk to a health care professional such as a doctor, nurse, or pharmacist.

When you consider our long history of Tylenol, it makes sense that McNeil would be active in educating people about taking medicines responsibly and specifically about the dangers of acetaminophen overdose. This is something that we do. We're committed to preventing acetaminophen overdose. Even one patient who takes an acetaminophen overdose is one too many. Our hearts go out to those who have overdosed and gotten sick and to the families and loved ones of those who have died.

When we talk about the benefits and risks of acetaminophen, you really need to consider the benefits and risks of other pain relievers and the potential consequences of switching from one pain reliever to another. Many pain relievers are available over the counter, such as ibuprofen and naproxen. These pain relievers are known as non-steroidal anti-inflammatory drugs and they also have significant risks, even when taken as directed. Research has shown that ibuprofen and other non-steroidal anti-inflammatory drugs have potentially serious risks such as gastrointestinal bleeding and kidney damage. So for many people with common conditions such as ulcers, kidney disease, heart disease, acetaminophen is often the most appropriate option for pain relief. Research has shown – and it's important for people to understand – that even if a small percentage of patients shift from acetaminophen to ibuprofen or other non-steroidal anti-inflammatory drugs, this would have an adverse impact on public health with greater numbers of deaths and hospitalizations.

The risks of acetaminophen overdose are well known. They've been known for decades. They're well-documented in the medical literature. Over the years there has been a lot of discussion and sometimes even disagreement within the medical and public health communities about how we can reduce the risk of acetaminophen overdose. As the

makers of Tylenol, obviously we've played an important role in that discussion and we've helped to really advance the medical community's understanding about the risks and benefits of acetaminophen. We've conducted a lot of research. In fact, we think our company has funded more studies on acetaminophen than any other single public or private organization. We even helped make acetaminophen one of the most studied over-the-counter medicines in the world. We're proud of the fact that we support research, including a nation-wide study that led to the FDA approving an antidote for acetaminophen overdose in 1985. This antidote has now become the standard of care for treating acetaminophen overdose in hospitals and emergency rooms across the US and this antidote has prevented tens of thousands of patients from developing liver injury and saved countless lives.

Many of our company studies have been peer reviewed and shared openly with the scientific and medical communities at meetings and through medical publications. These include more than 150 safety and efficacy studies that have demonstrated that acetaminophen is effective against many different types of pain, from headache and migraine to dental pain, to osteoarthritis, menstrual pain, and common aches and pains. We've been a leader in studying the benefit of acetaminophen in multiple different conditions, including fever. After decades of study and over half a century of use by the public and healthcare providers, Tylenol remains the most doctor-recommended brand of over the counter pain reliever. It's recommended in guidelines developed by many medical organizations and it's recognized by the FDA as a benefit to tens of millions of consumers each year.

Over the years, we've worked closely with the FDA. It's our responsibility as the manufacturer of Tylenol, to report every adverse event that we become aware of with our product. Each of our employees is required to be trained in Adverse Event Reporting. This is just part of our normal pharmacovigilance process. Over the years, we've been a leader in educating both patients and consumers as well as doctors and other healthcare professionals about the benefits and risks of acetaminophen. In fact, since Tylenol came onto the market in the 1950s, information about Tylenol has been available in the Physicians' Desk Reference and we continue to make this important information available through the PDR today.

Over the years we've evolved how we provide information to patients, consumers, and healthcare professionals. Today we have a website for physicians and other healthcare professionals. It's called tylenolprofessional.com. We provide this information so that doctors and other healthcare professionals can access information about our medicines, including patient education materials, pediatric dosing charts and, very importantly, guidelines for the management of acetaminophen overdose. We're really committed to providing patients and consumers information about acetaminophen. Recently we created the Get Relief Responsibly website and initiative. Through getreliefresponsibly.com, patients and consumers can get information to really help them use Tylenol safely. One of the features of this website is a list of common over-the-counter and prescription medicines that contain acetaminophen. Consumers can go there, they can look up all the medicines that they're taking. We hope this prevents people from taking two

acetaminophen-containing products at the same time and thereby preventing acetaminophen overdose.

Through the years, and most recently with our Get Relief Responsibly Initiative, our efforts and the efforts of multiple other stakeholders such as the FDA and the Consumer Healthcare Products Association, acetaminophen awareness messages designed to prevent acetaminophen overdose have been seen over one billion times.

How medicines are labeled is extremely important. It's important to the pharmaceutical industry. It's also important to the medical community. And opinions about medicine labels they've changed over time, as have the labels. We believe any label change should be medically accurate and it should be based on research. You need to take careful consideration as to how a new label will be understood by patients and consumers. We don't want to create confusion or unintended consequences such as a consumer potentially switching to medicines that may not be right to them or, in fact, even harmful. After careful consultation with the FDA, over the years we've made changes to the labels of Tylenol in an effort to help consumers understand how to use the medicine safely. The FDA recognizes that labels will change over time and that a label change does not mean that a prior label was inadequate. In fact, label changes are an indication that our medical understanding is evolving and that the public health system really is working. Most recently, after consulting with the FDA, we voluntarily lowered the recommended maximum daily dose of Extra Strength Tylenol to further expand the margin of safety between the recommended dose and potential overdose. There's no question that we still believe 4,000 milligrams is a safe dose. The new dosing instructions reduce the maximum daily dose from eight pills – or four grams per day – to six pills – or three grams per day – unless directed by a doctor.

We've been in discussion with the FDA as well as other makers of acetaminophen about putting an icon on all over-the-counter and prescription acetaminophen-containing medicines. Our research suggests that an icon can help patients identify acetaminophen in their medicines and that it also has the potential to help avoid overdose by preventing patients from taking multiple medicines that contain acetaminophen at the same time.

By the end of this year, we'll begin putting a message on Extra Strength Tylenol bottle caps telling consumers and patients that this product contains acetaminophen. And we're working closely with pharmacies to improve the labeling on prescription medicines that contain acetaminophen so that patients always know their medicine contains acetaminophen and that they should avoid taking multiple acetaminophen-containing medicines at the same time.