Chapter 2

50,000 Cries for Help

The number of cases of FTS reported to the FDA by mid-February 2014 was around 50,000. The number is not exact, and here's why.

Working with the reports submitted to the FDA takes some thought. For instance, there is an important difference between the terms *cases* and *reports*. The sheer number of reports sent to the FDA can exaggerate the number of actual cases, or incidents, that have occurred. This is because reports may arrive from more than one source: patients, doctors, pharmacists, drug companies. Thus, several reports may be submitted regarding the same case. To avoid counting these redundant reports, we designed our search of FDA records to wean out the duplicates and provide us with a reliable number of actual cases, or incidents, of FQ toxicity reactions.

In January 2014, with the help of Paul Danese of FDAble.com, a company that obtains FDA records and conducts streamlined searches, we undertook a rigorous analysis of the records. We also dismissed cases in which an FQ was listed as a secondary cause, that is, one of several possible causes that could include other drugs or illnesses. Instead, we selected only those cases in which the FQ was the primary and therefore most probable cause of injury—so probable that it would be accepted as proof in a court of law.

Our research determined that during the fifteen-year span beginning in the fourth quarter of 1997 to the fourth quarter of 2012, 41,290 individual cases of FQ toxicity were reported to the FDA. This amounts to about 2,950 cases a year. Using this number, we can generally estimate that by the end of 2013, approximately 45,000 cases of FTS had been reported to the FDA. And by the last quarter of 2015, about 50,000.

That does not include the ten years of FQ injuries that occurred from 1987, when Cipro was approved, through the first three quarters of 1998. The numbers during this ten-year span are difficult to estimate since other FQs entered the market and some were removed because of dangerous side effects or poor sales. For this reason, let's just stick with the likely number of 50,000 cases of FTS reported to the FDA by the end of 2015, although we know that the numbers reported to the FDA are likely gross underestimates. Another group that monitors medication side effects, Dr. David Healy's RxIST.org, place the number of reactions with just Cipro at about 97,000.

The Real Number of FQ-Induced Injuries Is Far Higher

If 50,000 is the estimated number of cases of FQ injuries reported to the FDA from the fourth quarter of 1997 until the end of 2015, then this equals an average of about 2,950 cases per year. When you consider that FQs are prescribed around 30 million times annually, a few thousand cases of serious side effects per year may not seem too bad.

However, we must consider two additional factors. First, many FQ toxicities are extremely severe. Other antibiotics can cause severe reactions such as liver failure or disfiguring skin reactions, but they are very rare. Serious, disabling FQ toxic reactions are not so rare, and they are often very severe.

Second and most important, the 50,000 cases reported to the FDA are almost certainly a gross underestimate of the problem. In prior studies, experts have repeatedly found that the number of cases of medication reactions reported to the FDA represents only the tip of the iceberg. Only about 2–5 percent of adverse drug reactions from medications are reported to the FDA.[1-6] Indeed, in one large study, the percentage of reactions reported to the FDA was less than even 1 percent.[7] Some of these statistics were determined in studies undertaken by the FDA itself.[8]

Let's assume that a higher number such as 5 percent of FTS cases have been reported to the FDA. Then we must multiply the 50,000 FDA cases by a factor of twenty to get a full picture. This amounts to 1,000,000 cases of FTS, more than 55,000 a year. Even for drugs prescribed millions of times annually, this is a frighteningly high number.

Failure to Inform

Suppose you develop a bladder or sinus infection and go to your doctor. Let's say your doctor does the right thing by informing you fully, saying, "Cipro is the best drug for this problem. However, drugs like Cipro are believed to cause more than 55,000 serious, sometimes disabling, sometimes permanent reactions each year. Do you still want to take it?" Would you say, "Yes, please"? Not likely.

The problem is, it is unlikely you'd ever get an accurate description of FQ's toxicities from most doctors. Studies show that only 10–25 percent of patients receive adequate warnings from their doctors about the drugs they are prescribed. This means that 75–90 percent do not.

And if many doctors are unaware of the extent and severity of FQ reactions, how could they provide you with an adequate warning in the first place? [9–12]

Massive Overuse

The situation is made worse by the fact that FQs are frequently prescribed unnecessarily. Many people with whom I've consulted were prescribed FQs needlessly. Minor infections like bladder or sinus infections are rarely life threatening and should be treated initially not with big guns with big risks, but with safer antibiotics that are usually sufficient.

Some FQs are prescribed without any evidence that an infection exists in the first place. Remember, antibiotics are only useful for killing bacteria. They are useless against viruses, allergies, or inflammation or other causes of discomfort or pain. Years ago, I provided my expert legal opinion in a case involving a healthy, athletic, twenty-five-year-old teacher. She went to the emergency room for lower abdominal pain. The doctor, apparently in a hurry, examined her briefly, declared she *probably* had a bladder infection, and prescribed Levaquin. In fact, she had no physical symptoms of a bladder infection. She only came to the ER to be sure she didn't have an ectopic pregnancy, an early pregnancy that might have gotten stuck in her fallopian tube. She only went to the ER to be checked.

Four pills of Levaquin later, the young woman commenced a horrifyingly painful four-year journey of disability that continues today. Her urine test at the ER showed little sign of infection and the culture showed no bacteria. She showed no fever or signs of a serious infection. The doctor could have waited a couple of days, then checked her again before throwing an antibiotic as powerful as Levaquin at her. As it turned out, her bacterial culture was normal, and the prescription had been altogether unnecessary. A study of antibiotic use in hospitals has found that about one-third of antibiotics for urinary tract infections were given for too long, or without proper evaluation, or weren't necessary at all.[13]

As the most prescribed antibiotics in America, FQs get prescribed inappropriately a lot.[14] Medical associations around the globe are now calling for greater restraint in the prescribing of antibiotics, especially FQs. For example, the American Thoracic Society urges doctors to use other, safer antibiotics—Zithromax (Z-Pack) or doxycycline (a type of tetracycline), for example, for people with common types of pneumonia. FQs then can be used if these methods fail. Similarly, although doctors commonly start patients on FQs for bladder or sinus infections, other antibiotics should be considered initially because they are safer and often effective.

Strains of many kinds of bacteria now resistant to antibiotics, including FQs, are emerging at a rapid pace. Medical authorities have been calling for renewed efforts to develop a new generation of antibiotics that can protect us. This effort may work, but only if doctors are

required to prescribe these precious, lifesaving medications more appropriately than they have done with the FQs.

It is not an exaggeration to say that the development of penicillin and subsequent antibiotics are among the top achievements in the history of medicine. Because of these wonder drugs, the top causes of death in the early twentieth century, pneumonia and tuberculosis, are no longer feared. Drugs can perform miracles, and are prescribed every day in medical practice. Yet with all due respect to the good things FQs accomplish—they can indeed be lifesaving—the number and severity of FQ toxicities are unacceptable. The FQ tragedy ranks among the worst in the history of modern medicine in terms of numbers, pain, and disability, equal to or perhaps exceeding the harm caused by thalidomide or Vioxx. Unfortunately, the FQ tragedy will continue until:

> Appropriate FQ use is clearly defined and limited to serious or life-threatening medical disorders by the drug companies and FDA.
>
> Patients are fully informed about the possible toxicities of FQs before they are prescribed them by their doctors.
>
> Doctors prescribe FQs only when there is a legitimate, proven reason for their use.
>
> Doctors correctly identify FTS reactions and report them to the FDA.

The poisoning of healthy people by FQs has to stop. And as I will explain in detail later, we can start accomplishing this today.

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