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WELL; A Cure That Can Be Worse Than the Illness

By JANE E. BRODY

<u>Antibiotics</u> are important drugs, often restoring health and even saving lives. But like all drugs, they can have unwanted and serious side effects, some of which may not become apparent until many thousands of patients have been treated.

Such is the case with an important class of antibiotics known as fluoroquinolones. The best known are Cipro (ciprofloxacin), Levaquin (levofloxacin) and Avelox (moxifloxacin). In 2010, Levaquin was the best-selling antibiotic in the United States.

But by last year it was also the subject of more than 2,000 lawsuits from patients who had suffered severe reactions after taking it.

Part of the problem is that fluoroquinolones are often inappropriately prescribed. Instead of being reserved for use against serious, perhaps life-threatening bacterial infections like hospital-acquired pneumonia, these antibiotics are frequently prescribed for sinusitis, bronchitis, earaches and other ailments that may resolve on their own or can be treated with less potent drugs or nondrug remedies - or are caused by viruses, which are not susceptible to antibiotics.

In an interview, Mahyar Etminan, a pharmacological epidemiologist at the University of British Columbia, said the drugs were overused "by lazy doctors who are trying to kill a fly with an automatic weapon."

Dr. Etminan directed a study published in April in The Journal of the American Medical Association showing that the risk of suffering a potentially blinding <u>retinal detachment</u> was <u>nearly fivefold higher among current users of fluoroquinolones</u>, compared with nonusers. In another study submitted for publication, he documented a significantly increased risk of <u>acute kidney failure among users of these drugs</u>.

The conditions Dr. Etminan has studied are relatively easy to research because they result in hospitalizations with diagnoses that are computerized and tracked in databases. Far more challenging to study are the array of diffuse, confusing symptoms suffered by fluoroquinolone users like Lloyd Balch, a 33-year-old Manhattan resident and Web site manager for City College of New York.

In an interview, Mr. Balch said he was healthy until April 20, when a <u>fever</u> and cough prompted him to see a doctor. Nothing was heard through a stethoscope, but a chest <u>X-ray</u> indicated a mild case of <u>pneumonia</u>, and he was given Levaquin. Although he had heard of problems with Levaquin and asked the doctor if he might take a different antibiotic, he was told Levaquin was the drug he needed.

After just one dose, he developed widespread pain and weakness. He called to report this reaction, but was told to take the next dose. But the next pill, he said, "eviscerated" him, causing pain in all his joints and <u>vision problems</u>.

Debilitating Side Effects

In addition to being unable to walk uphill, climb stairs or see clearly, his symptoms included <u>dry eyes</u>, mouth and skin; ringing in his ears; <u>delayed urination</u>; uncontrollable shaking; burning pain in his eyes and feet; occasional tingling in his hands and feet; <u>heart palpitations</u>; and muscle spasms in his back and around his eyes. Though Mr. Balch's reaction is unusual, doctors who have studied the side effects of fluoroquinolones say others have suffered similar symptoms.

Three and a half months after he took that second pill, these symptoms persist, and none of the many doctors of different specialties he has consulted has been able to help. Mr. Balch is now working with a physical therapist, but in a phone consultation with Dr. David Flockhart, an expert in fluoroquinolone side effects at the Indiana University School of Medicine, he was told it could take a year for his symptoms to resolve, if they ever do disappear completely.

Guidelines by the American Thoracic Society state that fluoroquinolones should not be used as a first-line treatment for community-acquired pneumonia; it recommends that doxycycline or a macrolide be tried first. Mr. Balch didn't know this, or he might have fought harder to get a different antibiotic.

Adverse reactions to fluoroquinolones may occur almost anywhere in the body. In addition to occasional unwanted effects on the musculoskeletal, visual and renal systems, the drugs in rare cases can seriously injure the central nervous system (causing "brain fog," depression, hallucinations and psystem (reactions), the heart, liver, skin (painful, disfiguring rashes and phototoxicity), the gastrointestinal system (nausea and diarrhea), hearing and blood sugar metabolism.

The rising use of these potent drugs has also been blamed for increases in two very serious, hard-to-treat infections: antibiotic-resistant Staphylococcus aureus (known as <u>MRSA</u>) and severe diarrhea caused by Clostridium difficile. One study found that <u>fluoroquinolones were responsible for 55 percent of C. difficile infections</u> at one hospital in Quebec.

Fluoroquinolones carry a "black box" warning mandated by the Food and Drug Administration that tells doctors of the link to <u>tendinitis</u> and tendon rupture and, more recently, about the drugs' ability to block neuromuscular activity. But consumers don't see these highlighted alerts, and patients are rarely informed of the risks by prescribing doctors. Mr. Balch said he was never told about the black-box warnings.

Lack of Long-Term Studies

No one knows how often serious adverse reactions occur. The F.D.A.'s reporting system for adverse effects is believed to capture only about 10 percent of them. Complicating the problem is that, unlike retinal detachments that were linked only to current or very recent use of a fluoroquinolone, the drugs' adverse effects on other systems can show up weeks or months after the treatment ends; in such cases, patients' symptoms may never be associated with prior fluoroquinolone therapy.

No long-term studies have been done among former users of these antibiotics. <u>Fibromyalgia</u>-like symptoms have been associated with fluoroquinolones, and some experts suggest that some cases of fibromyalgia may result from treatment with a fluoroquinolone.

A half-dozen fluoroquinolones have been taken off the market because of unjustifiable risks of adverse effects. Those that remain are undeniably important drugs, when used appropriately. But doctors at the Centers for Disease Control and Prevention have expressed concern that too often fluoroquinolones are prescribed unnecessarily as a "one size fits all" remedy without considering their suitability for different patients.

Experts caution against giving these drugs to certain patients who face higher than average risks of bad reactions - children under age 18, adults over 60, and pregnant and nursing women - unless there is no effective alternative. The risk of adverse effects is also higher among people with <u>liver disease</u> and those taking corticosteroids or nonsteroidal anti-inflammatory drugs.

When an antibiotic is prescribed, it is wise to ask what the drug is and whether it is necessary, what side effects to be alert for, whether there are effective alternatives, when to expect the diagnosed condition to resolve, and when to call if something unexpected happens or recovery seems delayed.

At the same time, when an antibiotic is appropriately prescribed, it is extremely important to take the full prescription as directed and not to stop treatment when the patient simply begins to feel better.

This is a more complete version of the story than the one that appeared in print.

DRAWING (DRAWING BY YVETTA FEDOROVA)

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