UNEXPECTED BAD EFFECTS

Thalidomide

Thalidomide is an especially chilling example of a new medical treatment that did more harm than good.[1] This sleeping pill was introduced in the late 1950s as an apparently safer alternative to the barbiturates that were regularly prescribed at that time; unlike barbiturates, overdoses of thalidomide did not lead to coma. Thalidomide was especially recommended for pregnant women, in whom it was also used to relieve morning sickness.

Then, at the beginning of the 1960s, obstetricians began to see a sharp increase in cases of severely malformed arms and legs in newborn babies. This previously rare condition results in such extremely shortened limbs that the hands and feet seem to arise directly from the body. Doctors in Germany and Australia linked these infant malformations with the fact that the mothers had taken thalidomide in early pregnancy.[2]

A TRAGIC EPIDEMIC OF BLINDNESS IN BABIES

'In the period immediately after World War II, many new treatments were introduced to improve the outlook for prematurely-born babies. Over the next few years it became painfully clear that a number of changes in caretaking practices had produced completely unexpected harmful effects. The most notable of these tragic clinical experiences was an "epidemic" of blindness, retrolental fibroplasia, in the years 1942-54. The disorder was found to be associated with the way in which supplemental oxygen had come to be used in the management of incompletely developed newborn babies. The twelve-year struggle to halt the outbreak provided a sobering demonstration of the need for planned evaluation of all medical innovations before they are accepted for general use.'

Silverman WA. Human experimentation: a guided step into the unknown. Oxford: Oxford University Press; 1985. p. viii.

At the end of 1961, the manufacturer withdrew thalidomide. Many years later, after public campaigns and legal action, the victims began to receive compensation. The toll of these devastating abnormalities was immense – across the 46 or so countries where thalidomide was prescribed (in some countries even sold over the counter), thousands of babies were affected. The thalidomide tragedy stunned doctors, the pharmaceutical industry, and patients, and led to a worldwide overhaul of the process of drug development and licensing.[3]

Vioxx

Although drug-testing regulations have been tightened up considerably, even with the very best drug-testing practices there can be no absolute guarantee of safety. Non-steroidal anti-inflammatory drugs (NSAIDs) provide a good illustration of why vigilance in relation to drugs is needed. NSAIDs are commonly used to relieve pain and reduce inflammation in various conditions (for example, arthritis), and also to lower temperature in patients with a fever. The 'traditional' NSAIDs include many drugs that are available over the counter such as aspirin and ibuprofen. Among their side-effects, they are well known for causing irritation of the stomach and gut, leading to dyspepsia ('indigestion') and sometimes bleeding and even gastric (stomach) ulcers. Consequently, there was good reason for drug companies to see if they could develop NSAIDs that did not cause these complications.

Rofecoxib (best known by the marketing name of Vioxx, but also marketed as Ceoxx, and Ceeoxx) was introduced in 1999 as a supposedly safer alternative to the older compounds. It was soon widely prescribed. Little more than five years later Vioxx was withdrawn from the market by the manufacturer because of an increased risk of cardiovascular complications such as heart attack and stroke. So what happened?

Vioxx was approved by the US Food and Drug Administration (FDA) in 1999 for the 'relief of the signs and symptoms of osteoarthritis, for the management of acute pain in adults, and for the treatment of menstrual symptoms [that is, period pains]'. It was later approved for relief of the signs and symptoms of