Doctor Flags Dangerous Flaws In Drug Regulation

Dr. Michele Brill-Edwards is a senior physician who spent 15 years with Canada's **Health Protection Branch** (HPB). She resigned after becoming convinced that the HPB was risking thousands of lives by putting the financial interests of drug companies above the protection of the public safety.

At the "heart" of the debate are a class of best selling drugs known as calcium channel blockers. These drugs are used to treat high blood pressure, angina and heart arrhythmias. The problem in recognizing the fatal side effects of these calcium channel blockers, says Brill-Edwards, is that it is difficult for the practising physician to discern between heart attacks due to the drug, and heart attacks due to the disease itself.

Calcium channel blockers were originally approved for the treatment of heart disease, not high blood pressure. The drugs work by interfering with muscle contractions by preventing the movement of calcium across cell membranes.

By the 1990's, these drugs were overtaking the older drugs used for the treatment of high blood pressure. In a **Fifth Estate** expose aired on **CBC-TV** on February 1996, journalist **Trish Wood** put it this way: "these drugs became popular without any solid proof that they either prevented heart attacks or prolonged life, while the older therapies had a good track record."

As early as 1989, **Dr. Salim Yusef**, Head of Clinical Trials at the National Institute of Health and now the Head of Cardiology at the Hamilton General in Ontario was growing concerned about the side effects of these drugs, especially a short acting calcium channel blocker known as nifedipine. He co-authored a paper saying that there was no evidence that these drugs saved lives or prevented a new heart attack. In 1991, Yusef's second paper produced stronger evidence that linked nifedipine to an increased rate of deaths in users. His paper was all but ignored. Dr. Yusef also expressed his serious concerns to the HPB.

Then the issue came into the spotlight in 1995 when three studies were published that showed an increase death rate from the use of nifedipine. In one of these reports, **Dr. Curt Furberg** and his colleagues analyzed data from 16 studies involving more than 8,000 patients. They found that those on moderate to high doses of nifedipine had a death rate almost three times higher than patients not given the drug.

Furberg estimated that tens of thousands of patients had died from taking these drugs for treatment of high blood pressure. Furberg believes that the onus is on the industry to show the safety of the long acting calcium channel blockers which it has not yet done. A large long term study is now underway on the effects of the longer acting drugs, but results won't be in until the year 2000.

Meanwhile, in January 1996, the **Health Protection Branch** prepared a "Dear Doctor" letter to all physicians to warn of the possible dangers of calcium channel blockers, especially nifedipine and cautioned that none of them should be used as a first line of treatment for high blood pressure or angina.

At least two doctors on the expert advisory committee that wrote the letter were closely aligned to the drug companies making these drugs. **Dr. Martin Myers** was one of these. He stated that there was no good proof, only circumstantial evidence, that nifedipine was harmful. He also argued that since there is no good evidence that the longer acting drugs are harmful, it would be a great disservice to take them off the market.

Earlier in 1991, Brill-Edwards had objected to the quick approval of a new migraine drug known as Imitrex or sumatriptan. According to Brill-Edwards, the key problem is the drug can cause spasm in blood vessels leading to heart attack and stroke. Users are advised not to take the drug if they have angina or heart disease.

However, many women prescribed imitrex may be unaware they have heart disease. Imitrex may cause sudden deaths but the connection can't be made because the coroner usually doesn't know that the patient was on imitrex. In the present system, there is no accurate method in place to track these potentially lethal side effects, and this greatly concerns Brill-Edwards.

Brill-Edwards also uncovered fraud within the **Prices Review Board** (which is supposed to be a watchdog on behalf of the public). The committee used inflated prices of drugs as the standard by which to compare prices charged by the drug companies. This board is currently under review by the Auditor General of Canada.

Other senior civil servants, concerned about these serious lapses in the regulatory process have joined with Brill-Edwards to form the **Alliance for Public Accountability** . On their own time and money, over 100 civil servants have committed to working towards a safer system. The public is invited to join in their fight. (see their website, or write mbrilled@uottawa.ca fax 613-523-4244).

The cruel joke, says Brill-Edwards, is that the HPB has lax standards with respect to high risk products like blood and prescription drugs, but high standards with low risk products like herbs and supplements.

However, she notes that "there is a huge difference between a blood transfusion, taking aspirin and taking garlic capsules. The same department which apparently lacks enough personnel to adequately inspect blood centers across Canada can somehow manage to hire an army of inspectors to inspect small Canadian herbal businesses and regulate them out of existence."

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