

Remember thalidomide

Letter to the Editor

By Barbara Mintzes

It is an extraordinary triumph of spin over substance that an announcement of new legislation that dramatically reduces requirements for drug approval is called getting tough on consumer safety (Ottawa Gets Tough On Consumer Safety - April 8).

Our current system of drug regulation, brought in after the thalidomide disaster, requires evidence of a minimum of safety and effectiveness for market approval. Effectiveness evidence was the real innovation brought in after thalidomide. The reasoning was that because a medicine could cause unpredictable, horrific harm, no exposure was worth risking unless there were tangible benefits. The government's proposal for progressive licensing reverses this approach. The idea is to first bring "promising" new drugs onto the market and then watch how they do.

In other words, expose Canadians first, then count the corpses. There are problems with the current drug approval system. Companies don't have to show that a new drug is any better than existing treatments. Often effectiveness is so limited it may not make a real difference to a person's life. Companies can selectively publish only the studies that make their drug look best. Blindly speeding new drugs to market won't fix these problems. An open, accountable regulatory system will. This is what should be on the table, not "progressive" licensing.

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