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Clinical Drug Trials Are Heavily Influenced by Drug Companies

What is this research about?

Before drugs can be sold in Canada, the Food and Drugs Act and Regulations require that they go through a series of clinical trials. The goal of these trials is to prove that the drugs work and are also safe. Canada, in particular, is an attractive place to conduct clinical trials. The country is known for its public Medicare system, large numbers of highly trained scientists, high quality data, and its lower costs compared to the US. More than 80 percent of clinical drug trials in Canada, however, are funded by the pharmaceutical industry. What impact do private interests have on the process by which drugs are approved and brought to the public?

What did the researcher do?

Joel Lexchin, a Professor at York University in Toronto, looked at the overall state of clinical trials in Canada. He analyzed how the interplay between public and private interests may affect clinical trials.

What did the researcher find?

The researcher found that the desire to make a profit is having an influence on all aspects of clinical trials. He also found an unwillingness on the part of Health Canada to assert the interests of the public. For example, the Therapeutic Products Programme (TPP) – the branch of Health Canada that approves drugs – used to have a default time of 60 days to review applications for clinical trials. But it has decreased this time by half. (Initially, it proposed changing the time to 48 hours.) This decision helps the pharmaceutical industry, but not the public. It also goes against the mandate of the TPP – now known as the Therapeutic Products Directorate (TPD). The nominal goal of the TPD was to ensure that Canadians had access to safe and effective drugs.

Canada has taken up nearly all of the guidelines of the International Conference on Harmonization (ICH). The ICH works to standardize the procedures for clinical trials and bring countries into harmony. But research has shown that the pharmaceutical industry tends to set the agenda for the ICH. And there seems to have been no analysis of the impact that this will have on the Canadian regulatory system.

As of 2002, Canada has no system for inspecting Research Ethics Boards (REBs), which have to

What you need to know:

Despite its stated interest in openness and transparency, Health Canada continues to deny the public access to information about clinical trials. It is also moving at a snail's pace in developing a policy on clinical trials registration. Health Canada seems to be putting the drug industry's needs ahead of the public good.

approve all clinical trials. Members of publicly based REBs, in hospitals and universities, have worried about the relationship between these boards and the drug industry. In recent years, many companies have moved their trials out of these public settings and into private, "for-profit" REBs. It has been argued that these "for-profit" boards, because they depend on the pharmaceutical industry for their revenue, might be reluctant to decide against denying approval for clinical trials.

Commercial interests also have an impact on recruiting patients for clinical trials and the running of these trials. It is in the industry's interests to test drugs on people for whom it is easiest to see the benefits. Health Canada, however, hasn't challenged this situation. Its guidelines on who should and shouldn't be included in clinical trials are non-mandatory. Evidence shows a lack of monitoring by Health Canada – and a lack of concern about regulations being violated. Commercial factors, in general, are taking a greater role in clinical research. One example of this trend is the rise of Contract Research Organizations (CROs). CROs are private companies, hired by pharmaceutical companies to coordinate and run clinical trials. Unlike academic researchers, CROs have no inherent interest in the data they collect. As a result, they are much more willing to keep their results secret. Also, although information on all trials must be filed when drug companies seek approval for new drugs, Health Canada views this data as private property. It doesn't make data available for the public or the review of independent scientists. There has been a push for clinical trials to be registered in online, publicly accessibly databases. Health Canada began discussions about developing clinical trial registries in 2005 but hasn't yet reached any decision.

How can you use this research?

This research may be of interest to policymakers, researchers, and health professionals with an interest in the role that the pharmaceutical industry plays in clinical trials for drugs. If Health Canada is still committed to the public health, it may wish to examine the extent to which it favours business interests over those of the public.

About the Researcher

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