Thank you for the privilege of appearing before you today. I am a legal scholar with expertise in intellectual property law. Given time constraints I am restricting my comments to the issue of transparency, which Bill C-17 presently does not address. I have two themes, each with a few specific points, that I want to touch upon. I will conclude by reading five key provisions that I think should be added to Bill C-17.

First Theme – Make evidence and regulatory work transparent

Point #1 – Amend Bill C-17 to make registration of all clinical trials, from phase 1 to phase 4, and other investigational studies, and reporting of study results mandatory for all "new drugs" and new indications for existing drugs that are submitted for regulatory approval, whether approval is ultimately granted or not.

Point #2 – Empower the Minister of Health to disclose "clinical study reports". Access to clinical study reports and the data they contain can be critical to understanding the quality of the evidence behind a given drug. A study published just last week in the British Medical Journal, comparing clinical study reports with information provided by journal publications and trial registries regarding duloxetine, a commonly prescribed treatment for major depressive disorder in Canada, concluded that "clinical study reports contain extensive data on major harms that were unavailable" from other sources. The optimal procedures for sharing clinical study reports are the subject of live debate. For that reason, defining the procedures by which clinical study reports should be made available by way of regulations is appropriate. But vesting the Minister with the authority to make them available is critical.

Point #3 – Require the Minister to publicly report all of its decisions, including product approvals, refusals, product suspensions and recalls, and the reasons behind those decisions. Patients, physicians, researchers, drug manufacturers, and other regulators would benefit from knowing how the regulator is interpreting the evidence it has on hand. In time, this will improve the quality of the regulator's decisions and Canadians' confidence in them.

Point #4 – Attach real penalties to non-compliance with transparency requirements. Despite clear penalties, backed by the force of law, in other countries like the United States, compliance has been less than adequate. According to one study ~78% of trials registered on Clinicaltrials.gov failed to provide results within the statutory 1-year timeframe. I therefore suggest a modified enforcement strategy. As in the US, Bill C-17 should make failure to comply with registration and results reporting subject to monetary fines. However, Bill C-17 should also tie results reporting to market authorization. Bill C-17 already includes an amendment to the Food and Drugs Act that would require manufacturers to comply with any terms or conditions attached to their market authorization. This power should not be used only on occasion. Rather, that new power should be used in every single drug approval where results reporting is, at the time of market authorization, still incomplete. Where the regulator rejects a drug or new indication and the results reporting requirement has not been fulfilled within six months, manufacturers should incur an additional monetary fine.

Second Theme – Make it absolutely clear that transparency trumps commercial claims

Point #1 – Section 5(6) of Bill C-17 proposes a modification to section 30(3) of the current Food and Drugs Act. The proposed change opens the door to limiting the powers contained in the Food and Drugs Act in order to implement trade agreement articles relating to intellectual property. This proposed amendment should be deleted from Bill C-17. The federal government's responsibility to protect the welfare of Canadians should not be reduced by trade objectives.

Point #2 – Claims by manufacturers that certain information is proprietary, that is, confidential business information or trade secrets, has long been the central barrier to greater transparency. However, consistent with its international obligations, Canada's Food and Drug Regulations already protect data against unfair commercial use, providing eight years of data exclusivity to innovative drugs on top of any available patent protection. Nevertheless, it is received wisdom within Health Canada that information about drug safety and effectiveness cannot be disclosed. Consequently, Bill C-17 must make it plain that the regulator has the power to disclose that information. People have given up their bodies, and taken on serious, even life-threatening risks, to help generate that information. It is not for the companies to own in secret. The regulator must be free to publicly disclose it.

Proposed Amendments: Provisions to Add to Bill C-17

To conclude, here are five provisions that should be added to Bill C-17.

Study Registration

1. (1) All clinical trials and other investigational studies involving a therapeutic product shall be registered on a publicly accessible, searchable database such as Clinicaltrials.gov, before participant recruitment begins, in accordance with the regulations.

(2) The Minister shall not issue a market authorization in respect of a therapeutic product unless any clinical trials and other investigational studies involving said therapeutic product were registered in accordance with sub-section (1), whether or not said clinical trials and other investigational studies were carried out in Canada.

Results Reporting

2. (1) All clinical trials and other investigational studies involving a therapeutic product shall report the results thereof on a publicly accessible, searchable database such as Clinicaltrials.gov within one year of the completion of trial or study, in accordance with the regulations.

(2) Where the results of one or more completed clinical trials or investigational studies associated with a therapeutic product have not been reported in accordance with subsection (1) prior to market authorization, the Minister shall require, as a condition of market authorization that such results be reported in accordance with subsection (1) within six months of the date of market authorization.

(3) In the event that a therapeutic product is not granted a market authorization by the Minister, the manufacturer shall report the results of all clinical trials and investigational studies in accordance with subsection (1) within six months of the date of the Minister's decision not to grant market authorization.

Clinical Study Reports

3. The Minister may publicly disclose clinical study reports in accordance with the regulations.

Transparent Decision-Making

4. The Minister shall disclose in a publicly accessible, searchable database information about therapeutic product authorizations, including any terms or conditions associated with a therapeutic product authorization, indication changes, refusals, suspensions and recalls, and the reasons for each such decision.

Disclosure of Safety and Effectiveness Information

5. (1) The Minister, in fulfilling sections 1 through 4, shall publicly disclose information regarding the safety and effectiveness of a therapeutic product, including adverse drug reactions, which it receives from manufacturers, health care institutions and other persons.

(2) Information referred to in subsection (1) shall not be used by a manufacturer for unfair commercial purposes as described by the regulations.