May 22, 2016

Resource Management and Operations Directorate
Health Canada
5th Floor, Room 545
Address Locator 20051
Graham Spry Building
250 Lanark Avenue
Ottawa, Ontario
K1A 0K9
Email: rmod_stakeholders-intervenants_dgro@hc-sc.gc.ca
Phone: 613-219-1574

RE: comments on Health Canada Draft Guidance Document, "Disclosure of Confidential Business Information under Paragraph 21.1(3)(c) of the Food and Drugs Act" dated March 10, 2016

Dear Sir or Madam:

We are writing as clinicians and researchers with an interest in access to clinical trial data to express our concerns about the broad interpretation of confidential business information in this guidance document. Inadequate public access to medication safety and efficacy information poses a threat to quality of care and patient and public health. The impediments to information access that are described in this guidance document are unacceptable from a clinical care and medical research perspective.

We do not accept Health Canada's view that information about a drug's safety or effectiveness falls within the scope of "confidential business information" (CBI). We urge Health Canada to immediately exclude drug safety and effectiveness information from the scope of CBI as a matter of practice as well as draft regulations to that same effect in an expedited manner. The fundamental flaws in Health Canada's Draft Guidance that we outline below are in addition to this problematic approach regarding the scope of CBI.

Below, we quote several of the most problematic sections in the Draft Guidance, followed by our comments.

> 3.1.ii: Consistent with the objectives of the Protecting Canadians from Unsafe Drugs Act, information disclosed under this authority should contribute to improving the health of Canadians. Requests for disclosure under this authority should clearly define how the purpose relates to this objective and include a formal plan to use the information to advance knowledge, including making results publicly available.

The requirement for a "formal" plan will exclude the vast majority of physicians who want to examine the original data pertaining to a drug to help guide their prescribing.

> 3.1.iii: Use of this authority should be necessary to achieve the purpose for which the information is requested. A decision on whether or not to disclose CBI will include consideration of whether or not all other possible sources of the information, including from the originator of the information, have been exhausted. Only information that is directly related to the purpose set out in the request should be considered for disclosure.

The suggestion that physicians or other requestors interested in obtaining data must first try "all other possible sources of the information" prior to requesting data from Health Canada makes it likely that there could be lengthy delays between the time a requestor is first interested in data and the time to submit a request to Health Canada. Researchers will be less likely to take advantage of this provision if they must first embark on a potentially months or years long process of trying to negotiate access to clinical trial data from a drug manufacturer. We further believe that a requirement of having to negotiate with the company owning the data may discourage researchers from even attempting to get the data in the first place given that companies typically regard this information as CBI. Finally, this provision ignores the point that what is available in Clinical Study Reports is often different or more complete than what is in registries or published articles.

Perhaps most importantly, without knowing the precise data in Health Canada's possession, it is impossible to know what information to request and to know that one has obtained the same information from another source, such as directly from a manufacturer.

> 3.1.iv: Information disclosed under this authority should be kept confidential and used only for non-commercial purposes. Prior to disclosure, Health Canada requires that potential recipients of CBI sign a legally binding agreement to maintain confidentiality, except as permitted by specific exclusions. Requesters are also required to confirm that the information will not be used for commercial purposes, and to report any activities that could result in a conflict of interest. These requirements are not intended to prevent publication of the results of analyses of the disclosed information.

The requirement to sign a confidentiality agreement for the data that mandates that the data be kept confidential may preclude data recipients from being able to publish their re-analysis of the data in many scientific journals, which now require the raw data to be made available. This includes journals such as the PLOS journals and the BMJ. The higher the journal's impact factor, the more likely it is to have this requirement. Publication in higher impact journals not only lends more credibility to the data but also increases the dissemination of the information.

> 3.2: Record of contribution to improving the health and/or safety of Canadians in an area relevant to the subject of the request. Publications and research projects related to health and safety issues other than the subject of the request may be taken into account in assessing a request.

The requirement of a "record of contribution to improving the health and/or safety of Canadians in an area relevant to the subject of the request" can be read as precluding early career researchers and clinicians from applying. In fact, the research community benefits from nurturing the involvement of these people as it can lay the ground work for a continuing career in research.

> 3.3: Public exposure to a therapeutic product is generally required in order for CBI related to the product to be used for protecting or promoting human health or the safety of the public. Consequently, Health Canada expects that requests for disclosure will relate to CBI obtained in the course of its regulatory activities to evaluate and monitor the safety, efficacy and quality of therapeutic products for use in Canada.

This provision could be used to preclude release of information about products that were submitted to Health Canada but not approved. This type of information is important for two reasons: 1) a product that is denied approval may be related to a drug already on the market; 2) if the product is subsequently approved then it could be useful to know what new data became available or how data might have been interpreted differently between the two applications.

> 7: PROCESS TO REVIEW REQUESTS FOR DISCLOSURE

There is no timeline for completion of this process.

> 7: Health Canada's decision is based on a rigorous evaluation and a review process that is fair, reasonable and takes into account all relevant factors. The review process is overseen by a committee of senior Health Canada officials mandated to recommend a decision based on relevant technical and scientific expertise. The Review Committee's recommendation is considered by a senior Health Canada official, not involved in the review process, who has been designated to exercise the Minister's authority to disclose CBI under the Food and Drugs Act (section 21.1(3)(c)).

In our view it would be useful to have someone outside of Health Canada to be on the committee to review the application as this can bring a fresh set of eyes and user perspective into the decision making process.

> 7.1: Screening: Requests are reviewed to ensure that they are complete, including proof of qualifications, corporate mandate, and a project description that includes a specific purpose for seeking access to CBI. Incomplete requests will be returned to the requestor.

Health Canada should keep a public record of the time it takes to process each request, broken down by the time the request was in Health Canada's hands, for example, the time taken to evaluate a request, and the time it was in the requestor's hands, for example, the time taken to respond to a query from Health Canada regarding the specific interest of various documents among the many in Health Canada's holdings.

8: REQUIREMENTS FOR PERSONS REQUESTING DISCLOSURE OF CONFIDENTIAL BUSINESS INFORMATION UNDER PARAGRAPH 21.1(3)(C)

The amount of information that Health Canada is requesting from someone applying for the data would be very onerous for a single clinician or even a small group of researchers. This section repeats themes such as Health Canada's directive that requestors should include evidence indicating "that the requester has exhausted other sources of the information requested, including from the originator of the information." Such a requirement can take years to fulfill, and as such, is clearly incompatible with the overarching goal of protecting and promoting the health of Canadians.

The section also repeats the notion that requestors must present a "project summary that clearly indicates the purpose of the proposed disclosure and how it relates to the protection or promotion of human health or the safety of the public." Health Canada should assume clinicians and researchers that request for information on a drug's safety or effectiveness are doing so for purposes that relate to the protection and promotion of human health. A simple attestation to this effect would be sufficient, just as a simple attestation that the data are not to be used for commercial purposes. Any requirement for more details is an invitation for a debate over requestors' ulterior motives, which, whatever they are, cannot be assumed to be detectable prior to data release.

The current draft guidance is a recipe for ensuring *minimal* use of the drug data Health Canada holds. However the health of Canadians is best served by ensuring the *maximal* re-use of the data Health Canada holds on drug safety and effectiveness. As such, we urge you to dramatically redraft the guidance document along the lines we recommend above.

Sincerely,

Joel Lexchin MD
Professor, School of Health Policy and Management
York University
Emergency Department, University Health Network
Toronto Ontario

Elia Abi-Jaoude, MSc, MD, PhD(C), FRCPC
The Hospital for Sick Children
University of Toronto
Toronto Ontario

John Abramson MD, MSC
Lecturer, Dept. Health Care Policy
Harvard Medical School
Boston MA

Ken Bassett MD, PhD
Professor of Medicine
University of British Columbia

Vancouver BC

Sharon Batt PhD
Adjunct Professor, Department of Bioethics
Dalhousie University
Halifax, NS

Jonathan Beaumier BScN, RN
University of British Columbia
Vancouver BC

Alain Braillon MD, PhD
Alcohol Treatment Unit
University Hospital
Amiens France

James Brophy MD, PhD
Professor of Medicine & Epidemiology
McGill University Health Center
Montreal QC

Arthur L Caplan PhD
Drs. William F. and Virginia Connolly Mitty Professor of Bioethics
Director – Division of Medical Ethics NYU Langone Medical Center
New York City, NY

Courtney Davis PhD
Department of Social Science, Health and Medicine
King's College London
London, UK

Nihar Desai MD
Assistant Professor of Medicine
Yale University School of Medicine
New Haven CT

Peter Doshi PhD
University of Maryland School of Pharmacy
Baltimore Maryland

Carl Elliott MD PhD
Professor, Center for Bioethics
University of Minnesota
Minneapolis MN

Daniel M. Fox PhD

London UK

David Healy
Professor of Psychiatry
Hergest Unit
Bangor Wales
UK

Benji Heran
Research Manager, Vancouver Coastal Health
Richmond BC

Anne M Holbrook MD, PharmD, MSc, FRCPC
Director, Division of Clinical Pharmacology & Toxicology,
Department of Medicine, McMaster University
Hamilton Ontario

Dr. Tom Jefferson
Honorary Research Fellow
Centre for Evidence Based Medicine
Oxford UK

Amy Kapczynski JD
Professor of Law
Yale Law School
New Haven CT

Harlan Krumholz MD SM
Harold H. Hines, Jr. Professor of Medicine and Public Health
Yale University School of Medicine
New Haven CT

Kendra Lawrence RN
Drug Assessment Working Group, Therapeutics Initiative
University of British Columbia
Vancouver BC

Brenda LeFrançois PhD
Professor
Memorial University of Newfoundland
St. John's NL

Richard Lehman MD
Senior Clinical Fellow
Cochrane UK
UK

Jeanne Lenzer
Associate editor
The BMJ, USA

Yolande Lucire PhD, MBBS, DPM
Forensic & Medico-Legal Psychiatry
Sydney NSW

Noni E MacDonald MD, MSc, FRCP(C), FCAHS
Professor of Pediatrics
Dalhousie University
Division Pediatric Infectious Diseases
IWK Health Center
Halifax NS

Evan Mayo-Wilson DPhil, MPA
Assistant Scientist
Center for Clinical Trials and Evidence Synthesis
Department of Epidemiology
Johns Hopkins Bloomberg School of Public Health
Baltimore Maryland

Barbara Mintzes PhD
Senior Lecturer
Charles Perkins Centre and Faculty of Pharmacy
The University of Sydney

Dr. Vijaya Musini
Assistant Professor, Dept. of Anesthesiology, Pharmacology and Therapeutics
Manager, Drug Assessment Working Group, Therapeutics Initiative
University of British Columbia
Vancouver BC

John M. Nardo MD
Assistant Professor
Psychoanalytic Institute
Department of Psychiatry
Emory University
Atlanta GA

Meryl Nass MD
Ellsworth free medical clinic
Ellsworth ME

Manon Niquette

Professor, Département d'information et de communication
Université Laval
Researcher, ComSanté, Centre de recherche sur la communication et la santé
Laval QC

John H Noble Jr PhD
Emeritus Professor, State University of New York at Buffalo
Buffalo NY

Nancy F. Olivieri MD, FRCP(C)
Professor, Pediatrics, Medicine and Public Health Sciences,
University of Toronto
Toronto ON

Cait O'Sullivan PharmD
Clinical Pharmacist, Island Health
Researcher, Therapeutics Initiative
University of British Columbia
Vancouver BC

Thomas L. Perry MD, FRCPC
University of British Columbia Therapeutics Initiative
Faculty of Medicine
University of British Columbia
Vancouver BC

Nav Persaud MD
Assistant Professor, Department of Family and Community Medicine University of Toronto
Toronto ON

Lorri Puil MD, PhD
University of British Columbia
Vancouver BC

Melissa Raven
Postdoctoral Fellow
Critical and Ethical Mental Health research group (CEMH)
University of Adelaide
Adelaide SA

Professor Wendy Rogers BM.BS, PhD, FRACGP
Macquarie University
Sydney NSW

Joseph Ross MD MHS
Associate Professor of Medicine and Public Health

Yale University School of Medicine
New Haven CT

Udo Schuklenk PhD
Professor of Philosophy and Ontario Research Chair in Bioethics
Department of Philosophy
Queen's University
Kingston ON

Sergio Sismondo PhD
Professor, Department of Philosophy
Queen's University
Kingston ON

R. Anne Springer PhD(NURS), MN, BScN, RN (CNS)
Assistant Professor, College of Nursing
Vice-Chair University of Saskatchewan Bio-Medical Research Ethics Board
Saskatoon SK

Jean-Claude St-Onge
Retired philosophy professor

Aaron M Tejani BSc(Pharm), PharmD
Researcher
Therapeutics Initiative
University of British Columbia
Vancouver BC

David Urquhart MD, CCFP
General Practitioner/Family Physician
Kingston ON

James Wright MD
Professor
Dept. of Anesthesiology, Pharmacology & Therapeutics
University of British Columbia
Vancouver BC

Diana Zuckerman Ph.D.
President
National Center for Health Research
Washington DC

Janice Graham*, PhD
Professor
Medical Anthropology and Infectious Diseases
Faculty of Medicine, Dalhousie University
Halifax NS

Jillian Clare Kohler*, PhD
Associate Professor
Leslie Dan Faculty of Pharmacy
Munk School of Global Affairs & Dalla Lana School of Public Health
University of Toronto
Toronto ON

*Added following submission to Health Canada on May 24, 2016