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DENATURALIZING TRANSPARENCY IN DRUG REGULATION

*Matthew Herder**

In the arena of pharmaceutical drug regulation, transparency is the favoured focus of many current policy initiatives. Transparency is predominantly understood in terms of information disclosure. Requirements to register clinical trials, publish summary results, share clinical trial data, and disclose physician-industry relationships as well as rationales behind regulatory decision making are each predicated upon this idea that imparting information will both inform and deter unwanted behaviours. In this paper, I argue that understanding transparency *qua* disclosure has clear limitations and suggest transparency can and should serve an

Dans le domaine de la réglementation des produits pharmaceutiques, les plus récentes initiatives politiques mettent l'accent sur la transparence. Par transparence on entend principalement la divulgation de l'information. Les obligations d'enregistrer les essais cliniques, de publier les résultats sommaires, de partager les données d'essais cliniques et de divulguer les relations entre les médecins et l'industrie ainsi que les raisons qui sous-tendent les décisions concernant la réglementation reposent tous sur l'idée que la divulgation sert à influencer et prévenir les comportements non désirés. Dans le présent article, j'expose les limites du fait d'inter-

* JSM, LL.M.; Assistant Professor, Faculties of Medicine and Law, Health Law Institute, Dalhousie University. E-mail: matthew.herder@dal.ca. This paper derives from a closely related research project investigating the prospect of implementing "physician sunshine payment" legislation in Canada, funded by Dalhousie University's Health Law Institute. Through that work I became curious about the history of drug regulation in Canada. Similarly, research assistance provided by Kate Archibald under that parallel project helped inspire the present work. I thus owe the Health Law Institute and Kate Archibald alike for motivating the present paper. I should also note that putting together the many twists and turns in the legislative history described here would have taken far more time if not for the timely assistance of David Michels, one of the Dalhousie Schulich School of Law's very capable research librarians. Finally, I am especially grateful for feedback from several colleagues, including Joanna Erdman, Claire Mummé, Kelly Holloway, James Baxter, Elaine Gibson, Jonathan Shapiro, and Stephen Coughlan, as well as three anonymous reviewers, which significantly strengthened this work. The author has no conflict of interest.

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additional function – namely, of enabling standard setting through a more participatory, public model of drug regulation. I turn to the history of Canadian drug regulation to demonstrate that such an alternative conception of transparency – transparency *qua* standard construction – is in fact possible. I document the regulator's extensive use of publicity practices to develop standards for assessing drug adulteration through the early years of Canadian drug regulation, from 1887 to 1920 when hundreds of analytical bulletins were publicly disseminated. I also show how, from the 1920s onwards, this participatory, public transparency transmogrified into a form of closed, insider transparency as the regulator constituted a collaborative relationship with industry. Given this shift, I suggest that an alternative conception of transparency is not only possible but also increasingly needed, and then begin to sketch how tying transparency to a revitalized concept of fraud in drug research and development might activate that participatory, public regulatory work.

prêter la transparence uniquement en termes de la divulgation et affirme que la transparence non seulement peut mais devrait remplir un objectif complémentaire, soit de permettre l'établissement de normes par le biais d'un modèle public et participatif de la réglementation des produits pharmaceutiques. Mon analyse de l'histoire de la réglementation des produits pharmaceutiques au Canada montre qu'une telle conception de la transparence – c'est-à-dire la réglementation définie comme la construction de normes – est possible. Je documente l'emploi considérable par l'organisme réglementaire de pratiques publicitaires pour établir des normes concernant le frelatage des médicaments dans les premières années de la réglementation des produits pharmaceutiques au Canada, notamment entre 1887 et 1920 lorsque des centaines de bulletins comprenant des analyses de recherches ont été diffusés. Je montre également qu'à partir des années 1920, cette conception de la transparence publique et participative se convertit en une forme de transparence fermée au public, mais accessible aux initiés, alors que l'organisme réglementaire entamait une relation collaborative avec l'industrie pharmaceutique. Je suggère qu'il est non seulement possible mais de plus en plus nécessaire de concevoir la transparence sous un nouveau jour. Enfin, j'esquisse une idée pour mettre en marche des initiatives réglementaires plus participatives et publiques en arrimant la transparence à une notion redéfinie de fraude dans le contexte de la recherche et le développement des produits pharmaceutiques.

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INTRODUCTION: A CONCEPTUAL CONTRIBUTION

Transparency is the watchword of those presently agitating for reform in pharmaceutical drug regulation. The current system lacks transparency so we need more of it in order to ensure patients are informed and not unnecessarily exposed to risks, and to honour research participants' prior contributions to pharmaceutical knowledge production.¹ Amongst critics of the current system, disclosure of more information is almost unanimously seen as the remedy.

The specifics of how to create transparency vary. Several jurisdictions require the registration of clinical trials and summary results disclosure.² In light of the shortcomings of registration and results disclosure, others advocate for opening up "clinical study reports" or even anonymized patient-level clinical trial data to independent scrutiny.³ Still others would require enhanced transparency in regulatory decision making,⁴ or disclosure

¹ See e.g. Peter Doshi, Tom Jefferson & Chris Del Mar, "The Imperative to Share Clinical Study Reports: Recommendations from the Tamiflu Experience" (2012) 9:4 PLoS Med e1001201; Peter C Gøtzsche, "Why We Need Easy Access to All Data from All Clinical Trials and How to Accomplish It", online: (2011) 12 Trials 249 <www.trialsjournal.com/content/12/1/249> [Gøtzsche, "Easy Access"].

² *Food and Drug Administration Amendments Act of 2007*, Pub L No 110-85, § 801, 121 Stat 823 at 904-22 [FDAAA 2007]; EC, *Communication from the Commission regarding the guideline on the data fields contained in the clinical trials database provided for in Article 11 of Directive 2001/20/EC to be included in the database on medicinal products provided for in Article 57 of Regulation (EC) No 726/2004*, [2008] OJ C 168/3 (2008).

³ Doshi, Jefferson & Del Mar, *supra* note 1; Gøtzsche, "Easy Access", *supra* note 1; Peter C Gøtzsche & Anders W Jorgensen, "Opening Up Data at the European Medicines Agency" (2011) 342:7808 *Brit Med J* 1184; Daniel Strech & Jasper Littmann, "Lack of Proportionality: Seven Specifications of Public Interest That Override Post-Approval Commercial Interests on Limited Access to Clinical Data", online: (2012) 13 Trials 100 <www.trialsjournal.com/content/13/1/100>; Trish Groves & Fiona Godlee, "The European Medicines Agency's Plans for Sharing Data from Clinical Trials" (2013) 346:7907 *Brit Med J* 8; Marc A Rodwin and John D Abramson, "Clinical Trial Data as a Public Good" (2012) 308:9 *JAMA* 871.

⁴ Matthew Herder, "Toward a Jurisprudence of Drug Regulation" (2014) 42:2 *JL Med & Ethics* 244 [Herder, "Toward a Jurisprudence"]; Roojin Habibi & Joel Lexchin, "Quality and Quantity of Information in Summary Basis of Decision

of physician-industry relationships.⁵ Despite their diversity, together these calls and actions cast a strong impression: that the time for greater transparency (read: disclosure of information) in the domain of prescription medicines is here and now. The impression is that we have reached a transparency tipping point, in the face of which manufacturers and their proprietary claims to the information in question – be it as “trade secrets,” “confidential business information,” or some other form of intellectual property – may finally concede defeat.

I aim to complicate that tidy impression of transparency in two fundamental ways. First, I want to denaturalize the idea that transparency in the context of drug regulation is best understood as a policy of disclosure. Rather than resort to abstraction, I turn to the history of Canadian federal drug regulation to denaturalize transparency *qua* disclosure. Historically, transparency, or – to use the term previously in use – publicity, was anchored in legislative prohibitions on the adulteration of consumer products, including drugs. Disclosure was part of publicity’s purpose. But publicity and the practices that Canada’s early regulatory institution adopted under it also served a critical standard-setting function. Through the regulator’s public dissemination of hundreds of bulletins between 1887 and 1920 that disclosed the institution’s analysis of thousands of samples of foods, fertilizers, alcoholic beverages, and supposed therapeutic drugs, standards for what was and was not an adulterated product were constructed. Transparency so purposed actually enhanced, rather than undermined, the regulator’s legitimacy.

Second, in the process of outing transparency’s more complicated purpose under Canada’s first federal food and drug laws, I trace a shift in the

Documents Issued by Health Canada” (2014) 9:3 PLoS One e92038; Giovanni Tafuri et al, “Disclosure of Grounds of European Withdrawn and Refused Applications: A Step Forward on Regulatory Transparency” (2013) 75:4 Br J Clin Pharmacol 1149; Lisa M Schwartz & Steven Woloshin, “Lost in Transmission: FDA Drug Information That Never Reaches Clinicians,” (2009) 361:18 New Eng J Med 1717.

⁵ See *Patient Protection and Affordable Care Act*, Pub L No 111-148, § 6002, 124 Stat 119 at 689 (2010) (codified as 42 USC § 1320a-7h) [*Physician Payment Sunshine Act*]. For a helpful summary of the *Physician Payment Sunshine Act*, *ibid*, as well as comparable statutes in several US states, see Igor Gorlach & Genevieve Pham-Kanter, “Brightening Up: The Effect of the Physician Payment Sunshine Act on Existing Regulation of Pharmaceutical Marketing” (2013) 41:1 JL Med & Ethics 315.

Canadian regulator's commitment to transparency. I show that the participatory *public transparency* that characterized the regulator almost from its inception in 1874 until approximately 1920, when the first federal Department of Health was formed, transmogrified into a kind of closed *insider transparency* as the regulator constituted a collaborative relationship with industry from the 1920s onwards. I show, in other words, that the public transparency for which many now agitate actually once was; moreover, the present absence of public transparency has nearly century-old roots in Canada.

The conceptual contribution I make in this paper – about drug transparency's very meaning and past practices – has significant present-day policy implications. Drug regulators today face a crisis of capacity and legitimacy in large part due to the close-knit and closed relationship they have ostensibly struck with industry.⁶ In order for regulators to fulfill their regulatory mandate and regain legitimacy, transparency's purpose needs to be about more than disclosure of information. I think transparency should also be about inviting a broader range of actors into the regulatory fold to help construct and in turn enforce new standards of drug fraud during drug research and development. However, detailing exactly how this worked in the past and how it should work in the future is beyond the scope of this work.

The paper proceeds in two primary parts, Part I and Part II, bookended by this introduction and a conclusion. In Part I, I summarize the key reasons why calls for greater transparency are now commonplace and illustrate how the policy reforms that have been put into place or proposed in response are grounded, first and foremost, in the goal of information disclosure. I conclude Part I by highlighting the limitations of disclosure and arguing for an alternate conception of transparency. Part II is historical: I trace the evolution of Canada's first federal food and drug laws, the institutional machinery that evolved to administer them, and the factors both inside and outside the institution that shaped and reshaped the regulator's commitment to transparency over time – all with an eye to showing that another understanding of transparency, namely of transparency as a means of standard making, is not only possible but increasingly needed.

⁶ See generally, Mary E Wiktorowicz, "Emergent Patterns in the Regulation of Pharmaceuticals: Institutions and Interests in the United States, Canada, Britain, and France" (2003) 28:4 J Health Pol Pol'y & L 615.

I. CONTEMPORARY DRUG DISCLOSURE DISCOURSES

A. *The appearance of a problem: Select data points*

There is a vast literature regarding the lack of transparency in drug research and development (R&D), regulation, and marketing. The following three data points provide an introduction to that literature.

First, the published scientific literature is often a poor representation of what is actually known about a given drug. There are two principal factors behind this. Journals have, for decades, had a publication bias against publishing negative findings.⁷ Meanwhile, drug manufacturers have tendencies to selectively report the studies they sponsor, suppress results they do not like, or falsify research findings altogether.⁸ The result is that about half

⁷ Kay Dickersin, “The Existence of Publication Bias and Risk Factors for Its Occurrence” (1990) 263:10 JAMA 1385; Philippa J Easterbrook et al, “Publication Bias in Clinical Research” (1991) 337:8746 Lancet 867; Kerry Dwan et al, “Systematic Review of the Empirical Evidence of Study Publication Bias and Outcome Reporting Bias” (2008) 3:8 PLoS ONE e3081. It is important to note that there are an increasing number of journals that publish so-called negative results.

⁸ An-Wen Chan A et al, “Empirical Evidence for Selective Reporting of Outcomes in Randomized Trials: Comparison of Protocols to Published Articles” (2004) 291:20 JAMA 2457; Peter C Gøtzsche, “Methodology and Overt and Hidden Bias in Reports of 196 Double-Blind Trials of Nonsteroidal Anti-inflammatory Drugs in Rheumatoid Arthritis” (1989) 10:1 Control Clin Trials 31; David Gunnell, Julia Saperia & Deborah Ashby, “Selective Serotonin Reuptake Inhibitors (SSRIs) and Suicide in Adults: Meta-Analysis of Drug Company Data from Placebo Controlled, Randomised Controlled Trials Submitted to the MHRA’s Safety Review” (2005) 330:7488 Brit Med J 385; Jon N Jureidini, Leemon B McHenry & Peter R Mansfield, “Clinical Trials and Drug Promotion: Selective Reporting of Study 329” (2008) 20:1 Int J Risk Saf Med 73; Irving Kirsch et al, “Initial Severity and Antidepressant Benefits: A Meta-Analysis of Data Submitted to the Food and Drug Administration” (2008) 5:2 PLoS Med 0260; Hans Melander et al, “Evidence B(i)ased Medicine – Selective Reporting From Studies Sponsored by Pharmaceutical Industry: Review of Studies in New Drug Applications” (2003) 326:7400 BMJ 1171; Bina Rawal & Bryan R Deane, “Clinical Trial Transparency: An Assessment of the Disclosure of Results of Company-Sponsored Trials Associated with New Medicines Approved Recently in Europe” (2014) 30:3 Curr Med Res Opin 395; Kristin Rising, Peter Bacchetti & Lisa Bero, “Reporting Bias in Drug Trials Submitted to the Food and Drug Administration: Review of Publication and Presentation”

of the research conducted with any given drug is not publicly available, and what is available is twice as likely to reflect positively on the drug.⁹ Consequently, evidence-based prescribing based on the published medical literature alone is not possible.

Second, the medical profession has lost its claim to an independent voice. Interactions with industry and/or direct involvement in drug R&D and marketing campaigns are pervasive. Industry capture has happened by diverse means. Some are predicated on “gift relationships,” for example, where “sales reps” from the pharmaceutical companies visit practising physicians with “free” drug samples, branded paraphernalia, and other gifts.¹⁰ By the 1990s, it was estimated that 85-90% of Canadian physicians were being visited by drug sales reps every other week.¹¹ The goal of these overtures by the pharmaceutical companies is to coax physicians’ prescribing practices towards their company’s products. Sales reps are known to de-emphasize or omit important safety information relating to their product.¹² Other drug

(2008) 5:11 PLoS Med 1561; F Song et al, “Dissemination and Publication of Research Findings: An Updated Review of Related Biases” (2010) 14:8 Health Technol Assess iii; Erick H Turner et al, “Selective Publication of Antidepressant Trials and Its Influence on Apparent Efficacy” (2008) 358:3 New Eng J Med 252; Craig J Whittington et al, “Selective Serotonin Reuptake Inhibitors in Childhood Depression: Systematic Review of Published versus Unpublished Data” (2004) 363:9418 Lancet 1341.

⁹ Ben Goldacre, “Health care’s trick coin”, *New York Times* (1 February 2013), online: NYT <www.nytimes.com/2013/02/02/opinion/health-cares-trick-coin.html>.

¹⁰ Michael J Oldani, “Thick Prescriptions: Toward an Interpretation of Pharmaceutical Sales Practices” (2004) 18:3 Med Anthropol Q 325. Pharmaceutical companies spend more money on sales reps (and the gifts such as drug samples that accompany their visits to physicians) than any other expenditure, including clinical trials. *Ibid* at 329, citing Joel Lexchin, *The Real Pushers: A Critical Analysis of the Canadian Drug Industry* (Vancouver: New Star Books, 1984), ch 8 [Lexchin, *The Real Pushers*].

¹¹ Joel Lexchin, “What Information Do Physicians Receive from Pharmaceutical Representatives?” (1997) 43:1 Can Fam Physician 941 at 941.

¹² See *ibid* at 942; Barbara Mintzes et al, “Pharmaceutical Sales Representatives and Patient Safety: A Comparative Prospective Study of Information Quality in Canada, France and the United States” (2013) 28:10 J Gen Intern Med 1368; Ashley Wazana, “Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?” (2000) 283:3 JAMA 373; Michael G Ziegler, Pauline Lew

company tactics involve paying physicians to do specific forms of work, for example enlisting them to help market such therapies to their physician peers, through practices including “seed trials,”¹³ “speaker bureaus,”¹⁴ and lending their names to “ghostwritten” articles.¹⁵ All of these practices ratcheted up in the second half of the twentieth century, but only began to attract sustained scrutiny in the 1990s. Despite numerous studies showing how such relationships appear to distort the evidentiary record,¹⁶ most of them are ongoing in some form. Given how pervasive these interactions have become, and the disproportionate influence that is consequently enjoyed by industry, some suggest the medical profession itself has been corrupted.¹⁷

& Brian C Singer, “The Accuracy of Drug Information from Pharmaceutical Sales Representatives” (1995) 273:16 JAMA 1296.

- ¹³ Kevin P Hill et al, “The ADVANTAGE Seeding Trial: A Review of Internal Documents” (2008) 149:4 *Ann Intern Med* 251; David A Kessler et al, “Therapeutic-Class Wars: Drug Promotion in a Competitive Marketplace” (1994) 331:20 *New Eng J Med* 1350; Samuel D Krumholz, David S Egilman & Joseph S Ross, “Study of Neurontin: Titrate to Effect, Profile of Safety (STEPS) Trial: A Narrative Account of a Gabapentin Seeding Trial” (2011) 171:12 *Arch Intern Med* 1100; Harold C Sox & Drummond Rennie, “Seeding Trials: Just Say ‘No’” (2008) 149:4 *Ann Intern Med* 279.
- ¹⁴ Marcia M Boumil et al, “Pharmaceutical Speakers’ Bureaus, Academic Freedom, and the Management of Promotional Speaking at Academic Medical Centers” (2012) 40:2 *JL Med & Ethics* 311; Lynette Reid & Matthew Herder, “The Speakers’ Bureau System: A Form of Peer Selling” (2013) 7:2 *Open Med* e31.
- ¹⁵ Joseph S Ross et al, “Guest Authorship and Ghostwriting in Publications Related to Rofecoxib: A Case Study of Industry Documents from Rofecoxib Litigation” (2008) 299:15 *JAMA* 1800; Peter C Gøtzsche et al, “Ghost Authorship in Industry-Initiated Randomised Trials” (2007) 4:1 *PLoS Med* 0047; Peter C Gøtzsche et al, “What Should Be Done to Tackle Ghostwriting in the Medical Literature?” (2009) 6:2: *PLoS Med* 0122; Sergio Sismondo, “Ghost Management: How Much of the Medical Literature Is Shaped behind the Scenes by the Pharmaceutical Industry?” (2007) 4:9 *PLoS Med* 1429; “Ghostwriting: The Dirty Little Secret of Medical Publishing that Just Got Bigger”, Editorial (2009) 6:9 *PLoS Med* 1.
- ¹⁶ Henry Thomas Stelfox et al, “Conflict of Interest in the Debate over Calcium-Channel Antagonists” (1998) 338:2 *New Eng J Med* 101.
- ¹⁷ Sergio Sismondo, “Key Opinion Leaders and the Corruption of Medical Knowledge: What the Sunshine Act Will and Won’t Cast Light On” (2013) 41:3 *JL Med & Ethics* 635.

Third, over time regulators too have proven susceptible to industry capture. For example, *ex post facto* analyses of problematic regulatory decisions have revealed that regulators have at times turned a blind eye towards conflicts of interest amongst their advisory committee members.¹⁸ Sociological accounts of regulatory work moreover suggest that the overarching approach to assessing safety and efficacy has been shaped by commercial interests.¹⁹ A number of commentators have argued that the present level of industry capture and related risk of regulatory failure is attributable to a structural conflict of interest: since the late 1980s, drug regulators' operations have become increasingly dependent upon "user fees" they collect from the very manufacturers they regulate.²⁰ Organizationally, regulators'

¹⁸ See e.g. John Abraham & Julie Sheppard, "Complacent and Conflicting Scientific Expertise in British and American Drug Regulation: Clinical Risk Assessment of Triazolam" (1999) 29:6 Soc Stud Sci 803 at 828-31. Also, several news reports document instances where advisory committees, replete with conflicts of interest, played a key role in getting a drug to market: Gardiner Harris & Alex Berenson, "10 voters on panel backing pain pills had industry ties", *New York Times* (25 February 2005), online: NYT <www.nytimes.com/2005/02/25/politics/25fda.html>; David Willman, "The new FDA: How a new policy led to seven deadly drugs", *Los Angeles Times* (20 December 2000), online: LAT <www.latimes.com/nation/la-122001fda-story.html>. Further, a study published in 2006 by Peter Lurie and colleagues found that in a sample of 221 FDA advisory committee meetings (spanning 16 different committees), at least one committee member disclosed a conflict of interest in 73% of the meetings yet only 1% of such members recused themselves from the committee. See Peter Lurie et al, "Financial Conflict of Interest Disclosure and Voting Patterns at Food and Drug Administration Drug Advisory Committee Meetings" (2006) 295:16 JAMA 1921. While such conflicts have not translated into an observable skewing of committee voting patterns, their presence in select cases has been conspicuous.

¹⁹ See John Abraham & Courtney Davis, "Drug Evaluation and the Permissive Principle: Continuities and Contradictions between Standards and Practices in Antidepressant Regulation" (2009) 39:4 Soc Stud Sci 569. Abraham and Davis further suggest that regulators' receptivity to commercial interests, driven in part by political influence, has coloured the thresholds that regulators apply to a given drug, institutionalizing a "permissive" (rather than "precautionary") approach to regulation (*ibid* at 571, 573).

²⁰ Jerry Avorn, "Paying for Drug Approvals – Who's Using Whom?" (2007) 356:17 New Eng. J Med 1697; Joel Lexchin, "Harmony in Drug Regulation, but Who's Calling the Tune? An Examination of Regulatory Harmonization in Health Canada" (2012) 42:1 Int J Health Serv 119; Joel Lexchin, "Relationship between Pharmaceutical Company User Fees and Drug Approvals in Canada

financial dependence upon firms has softened regulatory action, even introducing commercial norms in some jurisdictions such that regulators are left to “compete for business” from firms.²¹ On a more human level, regulatory officials have grown accustomed to regular, interpersonal interactions with company representatives, running the risk of engendering a shared stake in a given drug application and diminished critical distance.²²

B. Policy responses

In response to a growing list of troubling cases where important drug information was suppressed or manipulated, reckless marketing tactics were deployed, and/or conflicts of interest figured in poor decision making, several transparency measures have been put in place or are in the offing. They vary: some focus on the evidence base behind drugs, whereas others zero in on the relationships between the actors involved, be they those between physicians and manufacturers or at the regulatory interface.

The US was first to move, establishing the first set of clinical trial registration requirements in 1997, and codifying them in law.²³ Trial investigators and firms largely ignored the law for the first several years following its coming into force.²⁴ Nevertheless, an important precedent was set. Medical journals aligned with the law in 2004, making publication contingent on clinical trial registration.²⁵ In 2007, the US clinical trial registration requirements were expanded, backed with stronger penalties.²⁶ Under US federal law, summaries of trial results must also be disclosed within a specified

and Australia: A Hypothesis-Generating Study” (2006) 40:12 *Ann Pharmacother* 2216.

²¹ L McGoe & E Jackson, “Seroxat and the Suppression of Clinical Trial Data: Regulatory Failure and the Uses of Legal Ambiguity” (2009) 35:2 *J Med Ethics* 107 at 110.

²² Herder, “Toward a Jurisprudence”, *supra* note 4 at 256.

²³ *Food and Drug Administration Modernization Act of 1997*, Pub L No 105-115, § 113, 111 Stat 2296 at 2310.

²⁴ Kay Dickersin & Drummond Rennie, “The Evolution of Trial Registries and Their Use to Assess the Clinical Trial Enterprise” (2012) 307:17 *JAMA* 1861.

²⁵ *Ibid.*

²⁶ *FDAAA 2007*, *supra* note 2.

timeframe. Other jurisdictions have or are considering similar registration and results reporting requirements.²⁷ Compliance with clinical trial registration and results reporting requirements has been modest, however.²⁸ Further, no evidence exists of penalties for non-compliance being enforced.²⁹

Calls for open access to (de-identified) patient-level clinical trial data (usually in the form of “clinical study reports”) have followed, most recently, from the US Institute of Medicine.³⁰ When the European Medicine

²⁷ For an overview, see Trudo Lemmens & Candice Telfer, “Access to Information and the Right to Health: The Human Rights Case for Clinical Trials Transparency” (2012) 38:1 Am J L & Med 63.

²⁸ See Olga Kirillova, “Results and Outcome Reporting in ClinicalTrials.gov, What Makes It Happen?” (2012) 7:6 PLoS ONE e37847; Michael R Law, Yuko Kawasumi & Steven G Morgan, “Despite Law, Fewer Than One in Eight Completed Studies of Drugs and Biologics Are Reported on Time on ClinicalTrials.gov” (2011) 30:12 Health Aff 2338; Andrew P Prayle, Matthew N Hurley & Alan R Smyth, “Compliance with Mandatory Reporting of Clinical Trial Results on ClinicalTrials.gov: Cross Sectional Study” (2012) 344:7838 Brit Med J 15; Deborah A Zarin, Tony Tse & Nicholas C Ide, “Trial Registration at ClinicalTrials.gov between May and October 2005” (2005) 353:26 New Eng J Med 2779.

²⁹ Ed Silverman, “What happens when results data from clinical trials goes missing?”, *Wall Street Journal* (5 December 2014) B2 (“[t]he NIH, for instance, can withhold grant money, while the FDA can levy a \$10,000-a-day civil penalty for trials that aren’t registered or results that aren’t reported. Yet both the NIH and FDA acknowledge they have never gone to the mat” at B2).

³⁰ Institute of Medicine of the National Academies, *Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk* (Washington, DC: The National Academies Press, forthcoming 2015), online (draft): NAP <http://books.nap.edu/openbook.php?record_id=18998>. See also Emma Maund et al, “Benefits and Harms in Clinical Trials of Duloxetine for Treatment of Major Depressive Disorder: Comparison of Clinical Study Reports, Trial Registries, and Publications” (2014) 348 Brit Med J g3510 at 5-6; Peter Doshi & Tom Jefferson, “The First 2 Years of the European Medicines Agency’s Policy on Access to Documents: Secret No Longer” (2013) 173:5 JAMA Intern Med 380; Peter Doshi & Tom Jefferson, “Clinical Study Reports of Randomised Controlled Trials: An Exploratory Review of Previously Confidential Industry Reports” (2013) 3:2 BMJ Open e002496; Hans-Georg Eichler et al, “Open Clinical Trial Data for All? A View from Regulators” (2012) 9:4 PLoS Med e1001202 [Eichler et al, “Open Clinical Trial Data”]; Gøtzsche, “Easy Access”, *supra* note 1; Andreas Lundh, Lasse T Krogsbøll & Peter C Gøtzsche, “Access to Data in Industry-Sponsored Trials”, Letter (2011) 378:9808 Lancet 1995; Vinay Rathi et al,

Agency moved towards doing so, it triggered a temporary injunction.³¹ The injunction was subsequently overturned,³² but the European regulator then did an about-face (and later waffled) on its commitment to transparency.³³ The European Parliament has also voted in favour of making clinical study reports available for all drugs approved in the future (excluding any already on the market).³⁴ It is unclear whether other jurisdictions will follow suit. Meanwhile, select drug manufacturers are making some clinical trial data available on their own terms.³⁵

A second wave of transparency initiatives has been more focused upon two sets of actors involved in interpreting the evidence associated with

“Sharing of Clinical Trial Data among Trialists: A Cross Sectional Survey” (2012) 345:7884 *Brit Med J* 17; Rodwin & Abramson, *supra* note 3.

³¹ *AbbVie Inc and AbbVie Ltd v European Medicines Agency*, T-44/13, Order of the President of the General Court, 25 April 2013 (unpublished; available on CURIA, online: European Court of Justice <<http://curia.europa.eu/juris/liste.jsf?num=T-44%252F13>>).

³² *European Medicines Agency (EMA) v AbbVie Inc and AbbVie Ltd*, C-389/13, Order of the Vice President of the Court, 28 November 2013, [2013] ECR I (forthcoming), online: EUR-Lex <<http://curia.europa.eu/juris/celex.jsf?celex=62013CO0389>>; *European Medicines Agency (EMA) v InterMune UK Ltd*, C-390/13, Order of the Vice-President of the Court, 28 November 2013, [2013] ECR I (forthcoming), online: EUR-Lex <<http://curia.europa.eu/juris/celex.jsf?celex=62013CO0390>>. See also Jim Murray, “AbbVie Withdraw Case against European Medicines Agency” (16 April 2014), *BMJ Blogs*, online: <<http://blogs.bmj.com/bmj/2014/04/16/jim-murray-abbvie-withdraw-case-against-european-medicines-agency/>>.

³³ Matthew Herder, “Government Regulators Must Steward Drug Transparency”, *Opinion* (2014) 20:8 *Nat Med* 806 [Herder, “Government Regulators”]. See also Tom Jefferson, Peter Doshi & Trudo Lemmens, “EMA’s Data Sharing Policy – Towards Peeping Tom Based Medicine?” (22 May 2014), *BMJ Blogs*, online: <<http://blogs.bmj.com/bmj/2014/05/22/tom-jefferson-et-al-emas-data-sharing-policy-towards-peeping-tom-based-medicine/>>.

³⁴ See EC, *Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC*, [2014] OJ, L 158/1.

³⁵ See Peter Doshi, “From Promises to Policies: Is Big Pharma Delivering on Transparency?” (2014) 348 *Brit Med J* g1615; Perry Nisen & Frank Rockhold, “Access to Patient-Level Data from GlaxoSmithKline Clinical Trials” (2013) 369:5 *New Eng J Med* 475; Zosia Kmietowicz, “Johnson & Johnson Appoints

drugs: physicians and regulators. With regard to the former, journals have long encouraged disclosure of conflicts of interest by researchers, including physicians; publication in most medical journals is now contingent on doing so.³⁶ Similar to clinical trial registration and results reporting, consistency, compliance, and enforcement of disclosure have proven to be ongoing challenges.³⁷ Given, however, that physicians' conflicts of interest have figured prominently in several instances of drug manufacturer wrongdoing,³⁸ not to mention that they have influenced research in problematic ways,³⁹ the US Congress bolstered journals' efforts in 2010 by passing the *Physician Payment Sunshine Act*.⁴⁰ This legislation requires manufacturers to submit

Yale Project Team To Run Data Sharing Scheme", News (2014) 348 Brit Med J g1361.

³⁶ See Catherine D DeAngelis, Phil B Fontanarosa & Annette Flanagan, "Reporting Financial Conflicts of Interest and Relationships between Investigators and Research Sponsors", Editorial (2001) 286:1 JAMA 89; Jared A Blum et al, "Requirements and Definitions in Conflict of Interest Policies of Medical Journals" (2009) 302:20 JAMA 2230 at 2231.

³⁷ See Blum et al, *ibid*; Jeffrey M Drazen et al, "Uniform Format for Disclosure of Competing Interests in ICMJE Journals" (2009) 361:19 New Eng J Med 1896; Jeffrey M Drazen et al, "Toward More Uniform Conflict Disclosures: The Updated ICMJE Conflict of Interest Reporting Form" (2010) 363:2 New Eng J M 188; Sheldon Krimsky & LS Rothenberg, "Conflict of Interest Policies in Science and Medical Journals: Editorial Practices and Author Disclosures" (2001) 7:2 Sci Eng Ethics 205; George Loewenstein, Sunita Sah & Daylian M Cain, "The Unintended Consequences of Conflict of Interest Disclosure" (2012) 307:7 JAMA 669; A Rowan-Legg et al, "A Comparison of Journal Instructions Regarding Institutional Review Board Approval and Conflict-of-Interest Disclosure between 1995 and 2005" (2009) 35:1 J Med Ethics 74.

³⁸ See e.g. Navindra Persaud, "Questionable Content of an Industry-Supported Medical School Lecture Series: A Case Study" (2014) 40:6 J Med Ethics 414; Henry Thomas Stelfox et al, "Conflict of Interest in the Debate over Calcium-Channel Antagonists" (1998) 338:2 New Eng J Med 101. In addition to the scholarly literature on the topic, the journalist organization ProPublica provides a number of resources surrounding physician-industry relationships. See "Dollars for Doctors: How Industry Money Reaches Physicians", online: ProPublica <www.propublica.org/series/dollars-for-docs>.

³⁹ Justin E Bekelman, Yan Li & Cry P Gross, "Scope and Impact of Financial Conflicts of Interest in Biomedical Research: A Systematic Review" (2003) 289:4 JAMA 454.

⁴⁰ *Supra* note 5.

information about all financial payments and transfers of value (in excess of \$10) made to physicians.⁴¹ The information is made publicly available on a website curated by government, with the idea of enabling “patients to make better informed decisions when choosing health care professionals” and “deter[ring] inappropriate financial relationships.”⁴²

Finally, jurisdictions have, to different degrees, sought to enhance the transparency of regulatory decision making, including with regard to regulators’ evaluations of safety and efficacy, the lines of reasoning applied, and the decision-making processes followed. The European Medicines Agency (EMA) has been the most progressive amongst the major regulators, publishing not only its positive decisions (i.e. drug approvals) but also its negative decisions (i.e. drug refusals).⁴³ Other jurisdictions are currently contemplating similar action or already have other measures in place.⁴⁴ However, the utility of such efforts, even those of the EMA, have been severely limited in terms of adding value to the information that is already in the public domain⁴⁵ or of informing physicians and patients,⁴⁶ much less in its capacity to foster a genuine culture of openness within regulatory institutions.

⁴¹ *Ibid*, § 6002 at 696 (codified as amended at 42 USC § 1320a-7h (e)(10)(B)(i)).

⁴² 78 Fed Reg 9457 (2013) at 9520 (Table 7) (to be codified at 42 CFR Parts 402 and 403) [“Final Rule”].

⁴³ For the policy instrument guiding this practice, see European Medicines Agency, *Procedural Advice on Publication of Information on Negative Opinions and Refusals of Marketing Authorization Applications for Human Medicinal Products*, Doc No EMA/599941/2012 (2 May 2013), online: EMA <www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004188.pdf>. See also Tafuri et al, *supra* note 4.

⁴⁴ See generally Herder, “Toward a Jurisprudence”, *supra* note 4.

⁴⁵ See Corrado Barbui, Cinzia Baschiroto & Andrea Cipriani, “EMA Must Improve the Quality of Its Clinical Trial Reports” (2011) 342:d2291 *Brit Med J* 1; Health Canada, *Results of the Evaluation of Phase I of the Summary Basis of Decision Project* (29 January 2010), online: HC <www.hc-sc.gc.ca/dhp-mps/pubs/drug-medic/sbd_er_smd-eng.php>.

⁴⁶ See Habibi & Lexchin, *supra* note 4; Schwartz & Woloshin, *supra* note 4.

C. Internal and external critiques of transparency qua disclosure

At bottom, each of the above measures emphasizes the importance of transparency in terms of *disclosure*. The underlying idea in each case is that greater disclosure will slow or stop nefarious behaviour and remedy information asymmetries between manufacturers, physicians, independent researchers, and the public at large. Understanding transparency's purpose in terms of disclosure, however, is vulnerable to both internal and external critique.

The internal critique is simply that disclosure tends not to work in practice. Part of the problem is execution. As noted above, each transparency initiative enacted to date has, to a greater or lesser extent, suffered from a lack of enforcement (as in the case of clinical trial results reporting) or attention to detail (e.g. published regulatory decisions). The other aspect of this internal critique relates to unintended consequences. For example, disclosure of clinical trial data has the *capacity* to remedy information asymmetries and thus to inform, say, physicians and patients. *But it may not*: users may be unable to discriminate between relevant and non-relevant information in the event that *too much* information is disclosed.⁴⁷ Likewise, conflict-of-interest disclosure may promote healthy skepticism amongst readers of a scientific study. *But it may not*: conflict-of-interest disclosure has been shown to have paradoxical effects, leading readers to trust someone more, not less, once they have "come clean."⁴⁸ That is, disclosure may normalize rather than undermine the behaviour in question. Publishing a set of written reasons may reveal how and why a regulator arrived at a particular decision. *But it may not*: under the guise of transparency and access to information, governmental agencies have developed "informal methods of resistance" – keeping fewer written records, omitting dissenting opinions, and so forth – thereby rendering transparency more akin to theatre than truth.⁴⁹ In short, transparency, as a policy of disclosure, can have unintended consequences and fundamentally depends on the institutions charged with delivering it – the same institutions that, as I will show in Part II below, have become

⁴⁷ See Schwartz & Woloshin, *ibid.*

⁴⁸ Daylian M Cain, George Loewenstein & Don A Moore, "The Dirt on Coming Clean: Perverse Effects of Disclosing Conflicts of Interest" (2005) 34:1 J Legal Stud 1 at 5-6.

⁴⁹ See Alasdair Roberts, "Dashed Expectations: Governmental Adaptation to Transparency Rules" in Christopher Hood & David Heald, eds, *Transparency: The Key to Better Governance?* (New York: Oxford University Press, 2006) 107.

deeply accustomed to norms of non-disclosure, or what I refer to as “insider transparency.”

An external critique of transparency *qua* disclosure is also possible: even if disclosure works, it will not solve the fundamental problem, namely of constructing, improving, and ultimately enforcing *standards* in drug R&D and regulatory evaluation. One way of illustrating the external critique is to think about the criteria of safety and effectiveness⁵⁰ that a regulator applies in deciding whether to approve a drug for sale on the market. If the regulator does not have all the available information about a drug, it is impossible to make that determination. But even when the regulator has all of it, whether the drug is safe and effective *enough* often remains open to interpretation and subject to value judgments.⁵¹ A regulator, deceived by a company about a given drug’s safety profile, might make the wrong decision by approving that drug. Yet even if that problem is corrected and the regulator is instead fully apprised of the drug’s safety risks, it might still be justified in approving the drug, for instance, where there is no therapeutic option for that patient population and thus a higher level of risk is considered acceptable. The point I am making is not that we do not need all of the information to be disclosed – we do. The point, rather, is that critical interpretive work will remain in all but the marginal cases where disclosure of a drug’s complete safety and effectiveness profile renders the interpretation unequivocal by any standard.

⁵⁰ In the literature, these criteria are typically referred to as safety and efficacy (not effectiveness) because clinical trials are thought to provide evidence of a drug’s efficacy in rigidly controlled circumstances for a carefully defined patient population. Evidence of effectiveness in the “real world,” when the drug is consumed by persons who may not meet the specific inclusion criteria of the trial or adhere to the treatment regimen, is by definition lacking at the stage of regulatory approval. Nevertheless, Canada’s *Food and Drug Regulations* require “substantial evidence of the clinical effectiveness of the new drug for the purpose and under the conditions of use recommended” in order to receive regulatory approval, and there is increasing emphasis in the literature on the need to continue gathering post-market-approval information about the safety and effectiveness of drugs. See *Food and Drug Regulations*, CRC, c 870, s C.08.002(2)(h); Hans-Georg Eichler et al, “Bridging the Efficacy-Effectiveness Gap: A Regulator’s Perspective on Addressing Variability of Drug Response” (2011) 10:7 *Nat Rev Drug Discov* 495. Consistent with the language of Canada’s regulations and the calls in the literature to address the “efficacy-effectiveness gap,” I have opted to use the term “effectiveness” in this paper.

⁵¹ See Herder, “Toward a Jurisprudence”, *supra* note 4.

Two trends in current drug R&D underscore this point. First, drug manufacturers are increasingly focused on treatments for diseases of rare incidence (in Europe, the threshold is five or fewer people per 10,000, whereas in the US the disease must affect fewer than 200,000 people).⁵² Roughly a third of all drug approvals in the US now meet that definition.⁵³ Because such drugs target diseases that are rare, clinical studies of the safety and effectiveness of orphan drugs are, as a rule, smaller than studies of interventions for more common conditions. Due to the small number of patients typically involved in orphan drug studies, it also may not be feasible to adhere to blinding and randomization procedures in a study's design. Departing from the accepted standards of sample size, study duration, blinding, and randomization may, in other words, be necessary in orphan drug R&D. But how much of a departure should be acceptable is open to question.⁵⁴ Standards for orphan drug R&D and regulatory evaluation are thus needed.

The second trend, which overlaps with the first, surrounds the pursuit of "personalized medicine," i.e. efforts to stratify patient populations based upon genomic and epigenomic information in order to make more finely tuned treatment decisions.⁵⁵ This often works by pairing a diagnostic test (for instance, for the presence of a particular genetic mutation) with a therapeutic agent. The monoclonal antibody treatment for breast cancer, trastuzumab (Herceptin®), is perhaps one of the best-known examples of a personalized medicine.⁵⁶ Trastuzumab is indicated for the 25-30% of breast

⁵² For an overview of this area of drug R&D as well as orphan drug policies, see Matthew Herder, "When Everyone Is an Orphan: Against Adopting a U.S.-Styled Orphan Drug Policy in Canada" (2013) 20:4 Account Res 227 [Herder, "Orphan"].

⁵³ See Timothy R Coté, Kui Xu & Anne R Pariser, "Accelerating Orphan Drug Development" (2010) 9:12 Nat Rev Drug Discov 901; Olivier Wellman-Labadie & Youwen Zhou, "The US Orphan Drug Act: Rare Disease Research Stimulator or Commercial Opportunity?" (2010) 95:2-3 Health Policy 216.

⁵⁴ See Aaron S Kesselheim, Jessica A Myers & Jerry Avorn, "Characteristics of Clinical Trials to Support Approval of Orphan vs Nonorphan Drugs for Cancer" (2011) 305:22 JAMA 2320 at 2325.

⁵⁵ For a discussion of how orphan drugs and personalized medicines overlap, see Herder, "Orphan," *supra* note 52 at 243-46.

⁵⁶ See Malorye Allison, "Is Personalized Medicine Finally Arriving?" (2008) 26:5 Nat Biotechnol 509 at 509.

cancer patients with a mutation in a gene called “HER2/neu,”⁵⁷ so treatment access is tied to positive testing for the mutation in question. Yet, scientific knowledge about the significance of this mutation, the drug’s mechanism of action, and the etiology of breast cancer continues to evolve.⁵⁸ It is not obvious what degree of knowledge should suffice for regulatory approval of this and other personalized medicines. Other examples show that personalized medicines are clearly testing regulators’ capacity. In the absence of clear standards, regulators are arriving at conflicting decisions about the same drug based on the same data.⁵⁹

Orphan drugs and personalized medicines are two examples that speak to a need for scientific standards; however, other kinds of standards pertaining to drug R&D are needed and in flux as well. Consider conflicts of interest stemming from physician-industry relationships. The standard has been, for some time, to disclose such relationships in scientific publications and other academic venues.⁶⁰ Disclosure has become how conflicts are to be managed rather than other strategies, such as avoidance of the conflict in the first place. Yet, information asymmetries between, on the one hand, drug manufacturers and physician “opinion leaders” they enlist to promote their products and, on the other hand, prescribing physicians and members of the public, have tended to persist.⁶¹ Accordingly, closing that information gap

⁵⁷ Charles L Vogel et al, “Efficacy and Safety of Trastuzumab as a Single Agent in First-Line Treatment of *HER2*-Overexpressing Metastatic Breast Cancer” (2002) 20:3 *J Clin Oncol* 719.

⁵⁸ For instance, after analyzing genetic and epigenetic data from hundreds of patients, a large network of scientists recently suggested that all breast cancers could be subdivided into four main types. See The Cancer Genome Atlas Network, “Comprehensive Molecular Portraits of Human Breast Tumours” (2012) 490:7418 *Nature* 61.

⁵⁹ In a remarkable example, the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) approved and rejected, respectively, the drug panitumumab (Vectibix®) for the treatment of colorectal cancer. But subsequently, as an editorial in *Nature Biotechnology* pointed out, each regulator reversed course: the EMA “gave the green light for the same mAb with a diagnostic test for mutations in the *KRAS* gene, whereas the FDA rejected it,” leading the journal to ask, “What is going on?” See “Looking Forward, Looking Back”, Editorial (2008) 26:5 *Nat Biotechnol* 475.

⁶⁰ See Part I.B, above.

⁶¹ The clearest example may be that of OxyContin. See Joel Lexchin & Jillian Clare Kohler, “The Danger of Imperfect Regulation: OxyContin Use in the

became a major impetus for the newly enacted *Physician Payment Sunshine Act* in the US.⁶² However, in choosing to cast the legislation's purpose in terms of disclosure and deterrence,⁶³ an opportunity was missed to use this transparency initiative to inculcate new standards, for instance, of avoidance of conflicts of interest.

Taken together, the internal and external critiques suggest that transparency's purpose needs to be about more than information disclosure. It needs

United States and Canada" (2011) 23:4 Int J Risk Saf Med 233; Art Van Zee, "The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy" (2009) 99:2 Am J Public Health 221; US, General Accounting Office, *OxyContin Abuse and Diversion and Efforts to Address the Problem* (GAO-04-110) (Washington, DC: United States General Accounting Office, 2003) at 21-25.

⁶² Statements made by US Senators when the bill was introduced in the US Congress support this claim. Senator Charles Grassley, for example, noted during Senate Proceeding and Debates of the first session of the 111st Congress on 22 January 2009 that the *Physician Payment Sunshine Act*, *supra* note 5, was introduced as a result of various investigations that are "troubling and reveal significant undisclosed financial ties between physicians and industry" and described these relationships as "pervasive." See US, *Cong Rec*, daily ed, vol 155, no 13, at S787 (Statements on Introduced Bills and Joint Resolutions) (22 January 2009) (Rep Grassley).

⁶³ There is no mention within the four corners of the *Physician Payment Sunshine Act* of aims other than to make information regarding the financial relationships between the medical products industry and physicians and teaching hospitals within the US more publicly available. However, the "Final Rule" (promulgated by the Department of Health and Human Services, CMS, and passed 28 February 2013), which sets out rules and regulations, provides further insight into the purpose of the *Act*:

Increased transparency regarding the extent and nature of relationships between physicians, teaching hospitals, and industry manufacturers will *permit patients to make better informed decisions when choosing health care professionals and making treatment decisions*, and *deter inappropriate financial relationships* which can sometimes lead to increased health care costs. Additionally, increased transparency about the owners and investors in GPOs will *allow purchasers to make better informed decisions and identify potential conflicts of interest with ordering physicians*.

"Final Rule", *supra* note 42 at 9458-59 [emphasis added].

to serve a standard-setting function as well.⁶⁴ Transparency, understood as part of a standard-setting process of drug safety, effectiveness, or even conflicts-of-interest management, can serve a larger purpose: that of limiting consumer deception. Current drug R&D and regulation has become accustomed to consumer deception; a great deal of information is kept in confidence between regulator and drug manufacturers. Independent researchers, civil society groups, and ultimately health care consumers need access to the information to help build new standards that better hold regulators and manufacturers to account.⁶⁵ And, as I detail next in Part II, we need to look no further than the history of Canadian drug regulation to see that a conception of transparency *qua* standard construction is possible.

II. A HISTORY OF FEDERAL DRUG REGULATION IN CANADA

The tale I tell about regulating drugs and the “proprietary medicines”⁶⁶ trade of centuries past in this part of the paper is meant first to out transparency’s standard-setting function, and second to show how transparency

⁶⁴ It is important to acknowledge that there has been an ongoing discussion in the transparency literature around standard setting. However, that discussion is focused on standards about *how* to disclose information. For instance, there is a lively debate about what procedures should be in place to ensure that research participants’ privacy is not violated when individual patient-level data is disclosed. See e.g. Peter Doshi, Steven N Goodman & John PA Ioannidis, “Raw Data from Clinical Trials: Within Reach?” (2013) 34:12 Trends Pharmacol Sci 645. I would characterize that discussion as being about “process standard setting”. In contrast, the purpose of transparency that I am interested in here is on “substantive standard setting” – that is, transparency that aims to encourage actors to engage questions of what is safe, what is effective, and, as I will explain in Part II.F, what constitutes drug fraud.

⁶⁵ See Trudo Lemmens, “Pharmaceutical Knowledge Governance: A Human Rights Perspective” (2013) 41:1 JL Med & Ethics 163 at 175.

⁶⁶ Historically, the term “proprietary medicines” was used somewhat interchangeably with the term “patent medicines.” In law, these terms can overlap (a patent is a form of intellectual property and thus can be termed proprietary), but do not always: a medicine need not be patented to be proprietary; it could also be proprietary in the sense that it is kept confidential, which in law, may be protected as a trade secret. For the sake of simplicity I will generally use the broader term “proprietary medicines” throughout this paper. The remaining references to “patent medicines” denote medicines that have, in fact, been the subject of a patent.

shifted over time owing to factors within and outside of Canada's regulatory institution. My focus throughout this historical account is on drugs,⁶⁷ although the evolving legislative framework has at times ensnared other goods, including food, alcoholic beverages, and even fertilizers. Statutes and subordinate legislation provide the connecting thread in the history that follows. On top of the evolving Canadian legislative framework, I layer changes in the institutional machinery charged with administering the various laws enacted in Canada,⁶⁸ the pharmaceutical sciences, "drug houses,"⁶⁹ the medical and pharmacy professions, and intellectual property law. Each layer carries its own extensive literature, to which I cannot do justice here. Nevertheless, it is essential to integrate them into this account, if only piecemeal, in order to begin to understand the story behind the evolving legislative framework and transparency in federal drug regulation.

The story that I describe starts in the nineteenth century with the onset of federal regulation and effectively stops in 1951, when Canada first required evidence of safety *before* a new drug could be marketed.⁷⁰ It stops there because the model of transparency by then in fashion – what I will call "transparency within" the regulator-industry relationship or "insider

⁶⁷ I use the term "drugs" generously to capture both products of the past that were (falsely) characterized as therapeutic and products of today, whether pharmacological or biological in nature, and whether therapeutic, diagnostic, or both, in intended use.

⁶⁸ Significantly, much of the institutional layer of this story derives from first-hand accounts offered by members of the regulatory body, including A Linton Davidson (Assistant to the Director, Food and Drug Division), LI Pugsley (Deputy Director General, Food and Drug Directorate), and Robert E Curran (Legal Adviser, Department of National Health and Welfare). See A Linton Davidson, *The Genesis and Growth of Food and Drug Administration in Canada* (Ottawa: Ministry of National Health and Welfare, 1949); LI Pugsley, "The Administration and Development of Federal Statutes on Foods and Drugs in Canada" (1967) 23 Med Serv J Can 387; Robert Emmet Curran, *Canada's Food and Drug Laws* (Chicago: Commerce Clearing House, Food and Drug Law Institute Series, 1953) [Curran, *Canada's Food and Drug Laws*]; RE Curran, "Canada's Food and Drugs Act" (1946) 1:4 Food Drug Cosmet Law Q 492 [Curran, "Canada's FDA"].

⁶⁹ As will become apparent, the entities involved in manufacturing and selling drugs are diverse and changed substantially over time. They range from the apothecaries who were common in the seventeenth and eighteenth centuries to more modern multinational drug firms.

⁷⁰ *Food and Drug Regulations*, SOR/51-423, s C.01.301.

transparency” – essentially continues to this day. Despite the more recent advent of “access to information” laws, the subsequent years have marked a period of entrenchment, of deepening confidentiality between the regulator and industry, as I detail in the final sections of Part II. Against this endpoint, many now agitate for reform. Building upon the analysis in Part I, I close Part II by arguing that transparency reforms should be motivated not just by the goal of information disclosure, but also by the idea that transparency is a means to engage outsiders in an ongoing project of standard construction – a model of participatory, public drug regulation that I suggest below once was. That story is largely lost to present-day transparency discourse, and so I surface it here.

A. Prologue: Drug regulation circa confederation

Prior to Confederation, the manufacture, sale, and consumption of drugs occurred largely in a legal vacuum⁷¹ but amidst growing interprofessional tension between pharmacists (known also as “druggists”) and physicians in competition with one another as well as with wholesalers, large grocers, and small retailers (or “apothecaries”) – all in the business of selling drugs. Physicians and pharmacists agreed in principle that the industry needed regulation,⁷² but as historians have shown, each profession wanted to control the drug supply itself in order to subjugate the other.⁷³ Prominent physicians and pharmacists penned editorials in the *Canadian Medical Journal* and *Canadian Pharmaceutical Journal* attacking the other profession, impugning each other’s financial motives, questioning the other’s command of pharmaceutical science, and presenting themselves as the rightful steward

⁷¹ Canada East (later Ontario) enacted legislation governing the sale of poisons in 1859, which Canada West (later Québec) subsequently adopted as well. However, according to historian RJ Clark, “the original intent was to prevent trappers from using poisons in hunting animals” (RJ Clark “Professional Aspirations and the Limits of Occupational Autonomy: The Case of Pharmacy in Nineteenth-Century Ontario” (1991) 8:1 *Can Bull Med Hist* 43 at 49). Moreover, although the statutes’ provisions sought to limit druggists’ ability to dispense drugs, in practice it “had ‘little effect’” (*ibid*, citing “Pharmaceutical Legislation” (1869) 2 *Can Pharm J* 148 at 148).

⁷² Daniel J Malleck “Professionalism and the Boundaries of Control: Pharmacists, Physicians and Dangerous Substances in Canada, 1840-1908” (2004) 48:2 *Med Hist* 175 at 189 [Malleck, “Boundaries of Control”].

⁷³ *Ibid*; see also Clark, *supra* note 71.

of public safety.⁷⁴ This interprofessional contest also played out in provincial legislatures⁷⁵ as pharmacists and physicians alike pushed for provincial sanction of professional self-regulation and, with it, dominion over drugs, especially dangerous proprietary medicines.

Major changes in pharmaceutical production and distribution during the 1800s were the substrate for this interprofessional contest. In the sixteenth and seventeenth centuries, the drugs identified in most pharmacopoeias were isolated from plants rather than being derived through chemical techniques.⁷⁶ By the early to mid-nineteenth century, newer drugs such as morphine and quinine began to be extracted and synthesized “using the latest chemical techniques.”⁷⁷ At that time, “most doctors did their own dispensing. At best, druggists supplied the raw medicinal goods.”⁷⁸ Demand for druggists soon grew, especially in urban areas, given the ease of accessing druggists relative to physicians.⁷⁹ Yet, the parallel industrialization of drug production complicated druggists’ ascendancy in the marketplace. While aspiring to grow their own businesses, druggists competed with an emerging breed of drug “wholesalers,” who were able to produce and promote proprietary medicines on a larger scale than individual druggists or small retailers.⁸⁰ Indeed, a majority of the “founding members of the Toronto Chemists’ and Druggists’ Association, which ultimately became the Ontario College of Pharmacy” were trained pharmacists turned influential wholesalers.⁸¹ EB Shuttleworth is exemplary. Once a manager of a subsidiary of Northrop & Lyman, Canada’s “largest drug manufacturing and wholesale company”⁸² during this period, Shuttleworth went on to become the first

⁷⁴ *Ibid* at 53-56; Malleck, “Boundaries of Control”, *supra* note 72 at 182-84, 188 et passim.

⁷⁵ Clark, *supra* note 71 at 55-56; Malleck, “Boundaries of Control”, *supra* note 72 at 179-81.

⁷⁶ Ernst W Stieb, “A Professional Keeping Shop: The Nineteenth-Century Apothecary” (1985) 22 *Material Culture Review* 1 at 5.

⁷⁷ *Ibid.*

⁷⁸ Clark, *supra* note 71 at 45.

⁷⁹ *Ibid* at 45, 47.

⁸⁰ *Ibid* at 47.

⁸¹ *Ibid.*

⁸² *Ibid.*

editor of the *Canadian Pharmaceutical Journal* (launched in 1868), played a key role in forming the Ontario College of Pharmacy (after the passage of the Ontario *Pharmacy Act* in 1871), and founded a company under his own name in 1879.⁸³

In 1867, Ontario (or, as it was previously known, “Canada West”) lacked any legislation pertaining to medicinal drugs.⁸⁴ That very year, though, physicians pronounced their goal of requiring all apothecaries and druggists in the province to meet certain qualifications, which they, the medical profession, would oversee.⁸⁵ This galvanized the elite druggists-turned-wholesalers into action. By 1871, they had secured legislation to legitimize the profession: Ontario’s *Pharmacy Act*, the first of its kind in the country.⁸⁶ But in seeking self-governance, the druggist profession agreed to a glaring gap in their governing legislation: physicians and proprietary medicine manufacturers lacking retail operations (i.e. wholesalers) were essentially exempt from the *Pharmacy Act*.⁸⁷ The pages of the *Canadian Pharmaceutical Journal* suggest that at least some druggists favoured a statute-based system of registration, requiring proprietary medicine manufacturers to “register their formulae with the projected College of Pharmacy.”⁸⁸ Had it survived the legislative process, such a system would have pre-dated by decades the similar mechanism that was eventually enacted by the federal government.⁸⁹ However, the key wholesalers behind the law likely disfavoured oversight by registration due to the business constraints it would impose. Meanwhile, until amendments were made to the Ontario legislation in 1884,⁹⁰ physicians

⁸³ Attesting to the evolving nature of drug manufacturers, Joel Lexchin describes the company that Shuttlesworth founded as the first domestically owned drug company. See Lexchin, *The Real Pushers*, *supra* note 10 at 31.

⁸⁴ Recall that Canada West did have a statute governing the sale of poisons intended for use in hunting. See Clark, *supra* note 71 at 49.

⁸⁵ *Ibid.*

⁸⁶ Malleck, “Boundaries of Control”, *supra* note 72 at 178.

⁸⁷ *Ibid* at 185.

⁸⁸ Clark, *supra* note 71 at 48.

⁸⁹ See Part II.C, below.

⁹⁰ Amendments made to the *Pharmacy Act* in 1884 imposed registration requirements upon physicians in order to dispense drugs (Clark, *supra* note 71 at 56).

were able to “dispense and sell drugs with impunity not only in their offices, but also in their own drugstores.”⁹¹

In Québec (or “Canada East”), legislation restricting the sale of drugs had been in place since 1864; however, the legislation gave oversight authority to the medical profession, not pharmacists.⁹² Under Québec’s amended *Medical Act*, the College of Physicians and Surgeons was given the authority to license pharmacists, and the College crafted “specific educational requirements” for pharmacists.⁹³ Not until 1875, when the Pharmaceutical Association of the Province of Quebec successfully lobbied for amendment of its own legitimating statute, were druggists able to claw back control over their training.⁹⁴

Fighting between the two professions continued through the late nineteenth century, precipitating amendments to the Ontario and Québec statutes as well as other provincial statutes that followed. Much of the fight centred on the authority to write prescriptions – a power that neither profession ever exclusively won under the early provincial laws⁹⁵ – and its pecuniary implications.⁹⁶ Skeptical of each profession’s motivations, an anti-monopoly sentiment developed in the legislatures,⁹⁷ ironically opening a space for corporate actors to grow and eventually usurp control of the trade.⁹⁸ Provincial, profession-based regulation of drugs thus became increasingly inadequate in the face of a growing interprovincial and even international drug trade, especially of proprietary medicines, with a grim public health impact as a result.

⁹¹ *Ibid* at 54.

⁹² Malleck traces this back to efforts by a prominent Montréal physician named Archibald Hall, who in 1842 began proposing bills to regulate apothecaries and pharmacists. See Malleck, “Boundaries of Control”, *supra* note 72 at 179.

⁹³ *Ibid*.

⁹⁴ *Ibid* at 178, n 17; *Quebec Pharmacy Act*, SQ 1875, c 37.

⁹⁵ Clark, *supra* note 71 at 53-54.

⁹⁶ Malleck, “Boundaries of Control”, *supra* note 72 at 182-84; Clark, *supra* note 71 at 53.

⁹⁷ Malleck, “Boundaries of Control”, *supra* note 72 at 185.

⁹⁸ As detailed below, drug manufacturers grew in size and power through the twentieth century, effectively relegating physicians and pharmacists to the demand side of the pharmaceutical supply chain.

B. First forays into federal regulation in the late nineteenth century

Members of Parliament were moved to regulate drugs in 1874,⁹⁹ preceding similar legislation in the US by more than a quarter century.¹⁰⁰ According to historians, the legislation, known as the *Inland Revenue Act*, was principally motivated by a growing temperance movement.¹⁰¹ Styled closely after legislation passed by Britain in 1872, the *Act* formally captured drink, food, and drugs, and rendered the act of adulteration and the sale or offer of sale of all three goods in adulterated form a criminal offence.¹⁰²

In practice, the *Inland Revenue Act*'s provisions were brought to bear only on one category of goods during its first eight years of operation: food.¹⁰³ Part of the problem lay in the fact that the legislation did not define what an adulterated drug was, whereas adulterated liquor, food, and drink were each given statutory meaning.¹⁰⁴ This reflected the state of pharmacological sciences at the time. Although some basic standards for drugs existed, many of these standards conflicted or were in the process of being developed, as were the analytical techniques to assess a drug's consistency with any applicable standard. Thus, while the *Inland Revenue Act* created an inspectorate to enforce penalties for adulterating articles or selling the

⁹⁹ *An Act to impose License Duties on Compounders of Spirits; and to amend the "Act Respecting Inland Revenue" and to prevent the Adulteration of Food, Drink and Drugs*, SC 1874, c 8 [*Inland Revenue Act*].

¹⁰⁰ *Pure Food and Drugs Act*, Pub L 59-384, 34 Stat 768 (1906).

¹⁰¹ Petitions signed by hundreds, if not thousands, of Canadians imploring Members of Parliament to curb liquor consumption by the populace were frequently read in the House of Commons in the lead-up to the enactment of the *Inland Revenue Act*. See Dan Malleck, "Pure Drugs and Professional Druggists: Food and Drug Laws in Canada, 1870s-1908" (2006) 48:3 *Pharm Hist* 103 at 104 [Malleck, "Pure Drugs"]; Ernst W Stieb & Elizabeth J Quance, "Drug Adulteration: Detection and Control in Canada" (1972) 14:1 *Pharm Hist* 18 at 18.

¹⁰² *Inland Revenue Act*, *supra* note 99, ss 22-24.

¹⁰³ Malleck, "Pure Drugs", *supra* note 101 at 104 explains that one out of the 170 samples analyzed in the first year of the statute's operation was found to be liquor, but no further samples of liquor were analyzed until 1885.

¹⁰⁴ A drug was defined broadly to include "all articles used for curative or medicinal purposes." However, there was no definition provided for an "adulterated drug." See *Inland Revenue Act*, *supra* note 99, s 1.

same,¹⁰⁵ the inspectorate was not initially in a position to perform this function for drugs.¹⁰⁶

The absence of legislative standards made another feature of the legislation – a public reporting requirement – critical. The *Inland Revenue Act* mandated that the Minister of Inland Revenue lay “before Parliament” on an annual basis the “number of articles of food, drink, or drugs analyzed” and to “specify the nature and kind of adulterations detected in such articles.”¹⁰⁷ Without settled standards for evaluating adulteration, the public reporting requirement would serve as a mechanism to help construct standards for drugs, as well as other goods encompassed by the legislation, over time.¹⁰⁸ It also signalled an important commitment to inform the wider public about adulterated goods.

¹⁰⁵ By 1876, four analysts, located in Toronto, Montréal, Québec City, and Halifax, were tasked with analyzing samples seized by Inland Revenue officers in the different regions. Malleck, “Pure Drugs”, *supra* note 101 at 105.

¹⁰⁶ It is not clear that the inspectorate was fulfilling its mandate in respect of other goods, either, during these initial years. The Commissioner of Inland Revenue reported analysts’ findings to the House of Commons, and taken at face value these reports suggested the legislation was working: the proportion of adulterated articles diminished each year following the adoption of the *Inland Revenue Act*. Analyzed more carefully, however, the data were skewed by disproportionate testing of milk, the purity of which increased much more over the years than did that of other goods. See Malleck, “Pure Drugs”, *supra* note 101 at 105-06. Analysts’ reports were not used to convict a single person within the timeframe because, since the analysts lacked training for what they were mandated to do, criminal conviction on the basis of their reports seemed doubtful. *Ibid* at 106.

¹⁰⁷ Section 16 of the legislation read:

Every analyst appointed under this Act shall report quarterly to the Department of Inland Revenue the number of articles of food, drink or drugs analyzed by him under this Act during the foregoing quarter, and shall specify the nature and kind of adulterations detected in such articles of food, drink or drugs; *and all such reports or a synopsis of them shall be printed and laid before Parliament as an appendix to the annual report of the Minister of Inland Revenue.*

Inland Revenue Act, *supra* note 99, s 16 [emphasis added].

¹⁰⁸ Pugsley, *supra* note 68 at 397.

The absence of any enforcement of the *Inland Revenue Act* in respect of drugs helped precipitate the passage of the *Adulteration Act* in 1884.¹⁰⁹ The new legislation specified what was to be deemed an adulterated drug: namely, drugs that differed from standards set out by the British or US *Pharmacopeia* or from “other standard work on *materia medica*,” as well as drugs whose “strength or purity” was “below the professed standard under which it is sold or offered or exposed for sale.”¹¹⁰ With those (nascent) standards in hand,¹¹¹ the legislation refined its focus on adulteration, distinguishing between adulteration that resulted in harm to health and adulteration of a purely commercial character (i.e., that did not result in harm to health).¹¹²

The concern that the public might be deceived by industry practices found greater expression in the 1884 enactment and ensuing amendments. By 1885, the statute expanded its penalties to include a new penalty for false labelling of food and drugs.¹¹³ Further, the public reporting requirement was amended. Not only did the “nature and kind” of adulterations have to be

¹⁰⁹ *An Act to amend and to consolidate as amended the several Acts respecting the Adulteration of Food and Drugs*, SC 1884, c 34 [*Adulteration Act, 1884*]. Members of Parliament raised the issue of enforcement on more than one occasion prior to the enactment of the *Adulteration Act, 1884*. See e.g. *Debates of the Senate*, 5th Parl, 1st Sess, No 1 (1 May 1883) at 364-67.

¹¹⁰ *Adulteration Act, 1884*, *supra* note 109, ss 2(a)(1)-(3), respectively. Pugsley, *supra* note 68 at 399, explains that the British and US pharmacopeia standards were at times inconsistent, therefore an amendment was passed in 1899 giving priority to the British standard unless a “foreign pharmacopoeia” (in the words of the amendment) was plainly labelled on the drug in question. See *An Act further to amend the Adulteration Act*, SC 1899, c 26, s 1(f).

¹¹¹ The standardization of drugs was, at this time and for several years to come, a work in progress. See e.g. Kara W Swanson, “Food and Drug Law as Intellectual Property Law: Historical Reflections” [2011] *Wis L Rev* 331 at 346-47 (describing the development of the US pharmacopoeia).

¹¹² *Adulteration Act, 1884*, *supra* note 109, ss 26(a)-(b), respectively. The former resulted in a maximum fine of \$50 for a first offence whereas the latter, if not injurious to health, incurred a maximum penalty of \$30 for a first offence. In contrast to the 1874 statute, neither species of adulteration carried imprisonment as a potential penalty. The latter offence animated the first constitutional challenge to the legislation in the 1930s: *Standard Sausage v Lee*, [1933] 4 DLR 501, [1934] 1 WWR 81.

¹¹³ *An Act respecting the Adulteration of Food, Drugs and Agricultural Fertilizers*, SC 1885, c 67, s 25 [*Adulteration Act, 1885*].

presented to Parliament, but also the “names of vendors or persons ... and of the manufacturers when known.”¹¹⁴ According to A Linton Davidson, a future member of the department charged with administering Canada’s food and drug laws, this revised public reporting requirement was intended to “bring upon culprits a sense of shame and thus lead them to amend their evil ways” without the government having to prosecute alleged violations of the *Act* in Court.¹¹⁵ An 1890 amendment explicitly articulated the provision’s purpose in more principled terms: analyses of articles were to be “printed and published *for the information of the public*,” while giving the Minister discretion about when and in what manner such reports were to be made available.¹¹⁶

The *Adulteration Act* also added to the institutional machinery behind the legislation. Under the 1874 statute, four “local analysts” (stationed in Halifax, Montréal, Toronto, and Québec City) were responsible for all of the analytical work, relaying their results to the Commissioner of Inland Revenue in Ottawa for potential prosecution in cases of suspected adulteration.¹¹⁷ However, the quality of the local analysts’ work was generally poor and could not support prosecution in Court.¹¹⁸ To counter this capacity problem, the 1884 statute created a new position, the Chief Analyst, charged with developing quality standards for foods and drugs, establishing new analytical techniques for assessing potentially adulterated products, and re-examining ambiguous findings from the local analysts’ laboratories.¹¹⁹

¹¹⁴ *Ibid*, s 13.

¹¹⁵ Davidson, *supra* note 68 at 23.

¹¹⁶ *An Act further to amend the Adulteration Act, chapter one hundred and seven of the Revised Statutes*, SC 1890, c 26, s 5 [emphasis added].

¹¹⁷ Four additional analysts were appointed to Saint John (1879), London (1882), Ottawa (1884), and Winnipeg (also 1884). See Pugsley, *supra* note 68 at 393. The term “local analyst” is borrowed from Davidson, *supra* note 68.

¹¹⁸ Davidson, *supra* note 68 at 7.

¹¹⁹ *Adulteration Act, 1884, supra* note 109, s 3; see also Malleck, “Pure Drugs”, *supra* note 101 at 107. In addition, Pugsley, *supra* note 68 at 397, describes another attempt to improve the calibre of the analytical work: an amendment in 1888 prescribed analytical methods and set out qualifications for analysts under the Act. See *An Act to amend “The Adulteration Act,” chapter one hundred and seven of the Revised Statutes of Canada*, SC 1888, c 24. These quality control challenges foreshadowed the consolidation of all the analytical work in Ottawa shortly after the turn of the twentieth century. See Pugsley, *supra* note 68 at 399.

In 1887 the Chief Analyst began publishing bulletins disclosing the administration's analytical findings and naming the manufacturers and vendors involved,¹²⁰ a practice that would continue for more than thirty years.¹²¹ This practice helped realize the public reporting requirement's promise. Over time, the bulletins contributed significantly to the development of drug standards, as well as standards for other goods encompassed by the legislation.¹²² On the scientific strength of these bulletins, analysts were invited to help develop standards for professional associations abroad,¹²³ and according to Davidson, the standards that the bulletins helped cultivate would effectively become the first *Food and Drug Regulations* under the 1920 *Food and Drugs Act*.¹²⁴ Moreover, bulletins provided a measure of transparency about the bureaucracy's analytical work directly to the public. Through the 1890s and early 1900s, the department's findings were frequently reported in the popular press, and there was a sense that "[t]he public were relying more and more upon the publication of standards and bulletins as guides."¹²⁵ (See Table 1 for a summary of institutional changes 1875-1945 and the number of bulletins disseminated under the first four Chief Analysts.)

¹²⁰ It is not clear on what authority the Chief Analyst undertook this activity. Commentators suggest that the Chief Analyst did not begin publishing bulletins on his own initiative. For instance, Davidson, writing in 1949, stated that "the Chief Analyst *was authorized* to make special surveys and to publish the results in bulletins ... with all details" (Davidson, *supra* note 68 at 24 [emphasis added]). Similarly, in 1967, Pugsley, *supra* note 68 at 397, wrote that "the Chief Analyst *obtained authority* to make special surveys and to publish the results in bulletins" [emphasis added]. Yet, I have not been able to identify any primary source (whether in legislation, regulations, or Order in Council) that supports these claims.

¹²¹ There are conflicting claims about the duration of this practice. Pugsley, *supra* note 68 at 397, suggested that the onset of publishing bulletins "was the beginning of an activity which is followed by food and drug control officers even today, in a modified form." In contrast, Davidson, *supra* note 68 at 56, remarked that the practice of publishing names halted in 1920, highlighting the fact that manufacturers had long fought this administrative practice. As detailed below, my research indicates the latter account is more accurate.

¹²² Davidson, *supra* note 68 at 24.

¹²³ *Ibid* at 24, 39-40.

¹²⁴ *Ibid* at 55.

¹²⁵ *Ibid*.

TABLE 1. THE INSTITUTIONAL DEVELOPMENT OF CANADA'S DEPARTMENT OF HEALTH: 1875-1945

Time-frame	Statutes in Force	Chief Analyst	Institutional Organization		# Bulletins (# Drug Bulletins)
			Ottawa	Local	
1875-1884	<i>Inland Revenue Act</i>	N/A	N/A	• 4 “local analysts” stationed in Halifax, Montréal, Toronto, and Québec (1 per location)	N/A
1884-1886	<i>Adulteration Act</i>	H Sugden Evans	• Chief Analyst	• 8 local analysts stationed in NS, NB, Québec, Montréal, Kingston, Toronto (2), and Manitoba	N/A
1887-1907	<i>Adulteration Act</i>	Thomas Macfarlane	<ul style="list-style-type: none"> • Chief Analyst • Assistant Chief Analyst • “Public analysts” (3 by 1889) 	<ul style="list-style-type: none"> • Use of local analysts gradually diminished c. 1900 • 10 part-time ex officio “inspectors” by 1905 (1 added in 1906) 	144 (16)
1907-1922	<i>Adulteration Act</i> (1907-1920) <i>Proprietary or Patent Medicine Act</i> (1908—) <i>Food and Drugs Act</i> (1920—)	Anthony McGill	<ul style="list-style-type: none"> • Chief Analyst (referred to as Chief Dominion Analyst post-1920) • Assistant Chief Analyst • Public analysts (5 by 1908, reduced to 3 during WWII); referred to as “Dominion Analysts” post-1920 • Mr. A Lemoine, one of the public analysts, given responsibility for all of the work 	<ul style="list-style-type: none"> • 3 Branch Laboratories set up in 1913 (Halifax, Winnipeg, and Vancouver) • 4th Branch Laboratory set up in 1921 (Montréal) • 8 professional staff per Branch Laboratory (1 “analyst-in-charge” and 1 assistant chemist per Branch) • Country divided into 25 “inspection districts” in 1918 and several 	296 (52)

Table 1, continued

Time-frame	Statutes in Force	Chief Analyst	Institutional Organization		# Bulletins (# Drug Bulletins)
			Ottawa	Local	
1907-1922 (cont'd)			under the <i>Proprietary or Patent Medicine Act</i> , 1908-1915 • Advisory Board, comprised of Chief Dominion Analyst, 2 physicians, and 2 pharmacists created in 1919 under the amended <i>Proprietary or Patent Medicine Act</i>	full-time inspectors appointed 1919-1920	
1923-1945	<i>Food and Drugs Act</i>	Harry M Lancaster	• Chief Dominion Analyst • Assistant Chief Dominion Analyst • Chemist • 6 Assistant Chemists • 2 Junior Chemists • 1 full-time Inspector	• 5th Branch Laboratory set up in 1927 (Toronto)	0

Sources: A Linton Davidson, *The Genesis and Growth of Food and Drug Administration in Canada* (Ottawa: Ministry of National Health and Welfare, 1949); LI Pugsley, “The Administration and Development of Federal Statutes on Foods and Drugs in Canada” (1967) 23 Med Serv J Can 387.

Amidst these advances an important gap remained: the 1884 legislation explicitly exempted secret “proprietary medicines” and medicines that were “the subject of a patent in force, and ... supplied in the state required by the specification of the patent” from the scope of articles that could be deemed adulterated.¹²⁶ The rationale for this change is not obvious from debates in Parliament. Though little scrutiny of drugs initially took place, the 1874 *Inland Revenue Act* seemingly applied to proprietary medicines by broadly defining drugs as “all articles used for curative or medicinal purposes.”¹²⁷ With standards now codified in the 1884 law, perhaps Members of Parliament were sympathetic to proprietary medicine sellers’ interest in having their remedies remain secret.¹²⁸ Attempts to regulate the sale of proprietary medicines through provincial pharmacy legislation met strong

¹²⁶ *Adulteration Act, 1884*, *supra* note 109, s 2(c)(2). The latter exception for patented medicines perhaps reflects a perceived overlap between, on the one hand, the object of the *Adulteration Act, 1884* (as well as later food and drug laws) – i.e. to prevent consumer deception in the form of, for instance, adulterated drugs – and, on the other hand, patent law, which in theory requires patent-holders to detail their invention in return for a legal monopoly. In this sense, there is a broad parallel between intellectual property law and drug regulation. Patent law’s specification requirement is motivated by a goal of transparency just as drug regulation, in penalizing adulteration, aims to curb the absence of transparency.

¹²⁷ *Inland Revenue Act*, *supra* note 99, s 1.

¹²⁸ It is worth noting that the first Chief Analyst, Henry Sugden Evans, argued in his report to Parliament that proprietary medicines should not be excluded from the *Adulteration Act*, but to no avail. In his report, Evans stated emphatically:

[N]o more pernicious class of goods is to be met with on the markets, [buoying] up by false representations the failing strength of the really afflicted, exciting fears and anticipations of evil in the minds of the hale though weak minded, and robbing the poor of his hard earned savings ... Instead of “patent medicines” and proprietary nostrums being exempted, they should be most vigorously dealt with under this Act....

Parliament, “Appendix A: The Inspection of Food and Drugs” by HS Evans (in “Report on Adulteration of Food, being Supplement No III to the Report of the Department of Inland Revenue 1885”) in *Sessional Papers*, No 5 (1886) at 11, cited in Malleck, “Pure Drugs”, *supra* note 101 at 107-08.

resistance during the same period.¹²⁹ However, controversy surrounding the three-hundred-year-old trade, which had always been predicated on secrecy, was nearing its apogee.

C. Responding to the proprietary medicine crisis at the turn of the twentieth century

The history of “proprietary medicines,” which are sometimes described in the literature interchangeably as “patent medicines” or, more colourfully, as “nostrums” and “elixirs,” dates back at least to the early 1600s in England.¹³⁰ The first such medicine known to have been advertised for sale in the Americas was Anthony Daffy’s *Elixir Salutis*. According to the *Boston News-Letter* of 4 October 1708, a half-pint of this British-born concoction could be purchased for four shillings, six-pence¹³¹ and was an effective cure against a slew of ills common in the seventeenth and eighteenth centuries.¹³² Beyond the tonic effect of the distilled alcohol the elixir contained,¹³³ it was

¹²⁹ Malleck attributes this resistance to governments’ commitment to “*laissez-faire* economics” at that time as well as to the proprietary medicine sellers’ alliance with newspapers, which relied heavily on advertising revenues from those in the trade. See Malleck, “Boundaries of Control”, *supra* note 72 at 185, 193; Malleck, “Pure Drugs”, *supra* note 101 at 110ff. See also Clark, *supra* note 71 at 48.

¹³⁰ James Harvey Young, *The Toadstool Millionaires: A Social History of Patent Medicines in America before Federal Regulation* (Princeton, NJ: Princeton University Press, 1961) at 3.

¹³¹ *Ibid* at 7.

¹³² Daffy’s elixir was touted as being effective against any number of ills common in the seventeenth and eighteenth centuries, including:

gout, ... the stone and gravel in the reins, ulceration in the kidneys or mouth of the bladder, languishing and melancholy, shortness of breath, colic, griping in the guts, the ptissic ... , green-sickness, surfeits, scurvy and dropsy, coughs, wheezings, consumptions and agues, mother and spleen, fits of the mother, and rickets”

David Boyd Haycock & Patrick Wallis, “Introduction” in David Boyd Haycock & Patrick Wallis, eds, *Quackery and Commerce in Seventeenth-Century London: The Proprietary Medicine Business of Anthony Daffy* (2005) 25 *Med Hist Suppl* 1 at 32-33.

¹³³ Recipes for the elixir refer to various forms of alcohol, including aqua vitae, proof spirits, and brandy (*ibid* at 30).

not known whether this pioneering product had any effect upon those who consumed it. Anecdotes to the contrary were either just that – consumers’ perceptions of medicinal benefit more accurately attributable to the simple passage of time and the human body’s own healing powers – or worse: (false) testimonials paid for by the drug’s promoter, printed in pamphlets, newspapers, even literary works.

Anthony Daffy’s product nevertheless proved highly profitable. Sales in Britain and New England were only a small part of an extensive distribution network, global in scope, with agents operating in Europe, North America, the West Indies, and East Asia.¹³⁴ Elixirs bearing Daffy’s name remained in commercial production as late as 1910.¹³⁵

By the time of Canadian confederation, many had followed Anthony Daffy’s lead. As noted above, Canada’s largest proprietary medicine maker, Northrop & Lyman, was founded in 1854. Scores of secret medicines had entered the market in the seventeenth, eighteenth, and nineteenth centuries; though few enjoyed the level of success of Daffy’s elixir, the vast majority copied Daffy’s business model of aspiring to absolute secrecy regarding recipes, admixed with considerable advertising.¹³⁶ By 1905, some 28,000 patent medicines were on the US market¹³⁷ and, unlike Daffy himself, who was a shoemaker by trade,¹³⁸ many physicians and pharmacists had even become part of the proprietary medicine trade.¹³⁹

As the realization grew that these secret recipes offered no remedy at all, or worse, could cause harm, physicians’ affiliations with the trade

¹³⁴ *Ibid* at 21.

¹³⁵ *Ibid* at 29.

¹³⁶ The success of Daffy’s product appears to have been owed to his business acumen, an intercontinental trust-based distribution network, his ability to keep the elixir’s recipe secret from his competitors, and substantial advertising. Unlike the campaign of most patent medicines, however, it was only *after* his *Elixir Salutis* had a strong foothold in the marketplace that Daffy began to promote his product by the printed word. See *ibid* at 36.

¹³⁷ Young, *supra* note 130 at 109-10.

¹³⁸ Haycock & Wallis, *supra* note 132 at 3.

¹³⁹ See Stamatia Tina Piper, *The Emergence of a Medical Exception from Patentability in the 20th Century* (DPhil Thesis, University of Oxford, 2008) [unpublished].

began to carry reputational costs amongst their peers.¹⁴⁰ In this way, the growing “patent medicine crisis” contributed to the professionalization of medicine.¹⁴¹ The inaugural *Code of Ethics* adopted by the Canadian Medical Association in 1868 forbade physicians from ever engaging in patenting, and sought to dissuade salesmanship by painting the “promising [of] radical cures” and the publishing of testimonials as “derogatory to the dignity of the profession.”¹⁴² Articles in Canadian medical journals decrying the proprietary medicine trade appeared from at least 1892 onwards.¹⁴³ And, although the *Code of Ethics* was a voluntary measure, physicians who continued to engage in the business faced charges of “professional misconduct” before provincial regulatory bodies.¹⁴⁴

¹⁴⁰ See *Re Crichton* (1906), 13 OLR 271, 8 OWR 841 (Div Ct).

¹⁴¹ See generally Piper, *supra* note 139.

¹⁴² Listed amongst the “duties of physicians to each other, and to the profession at large” was the following:

Equally derogatory to professional character is it for a physician to hold a patent for any surgical instrument or medicine; or to dispense a secret *nostrum*, whether it be the composition or exclusive property of himself or of others. For, if such a nostrum be of real efficacy, any concealment regarding it is inconsistent with beneficence and professional liberality; and if mystery alone gives it value and importance, such craft implies either disgraceful ignorance or fraudulent avarice. It is also reprehensible for physicians to give certificates attesting the efficacy of patent or secret medicines, or in any way to promote the use of them.

Canadian Medical Association, *Code of Ethics*, 1868, part 1, art 1.4 (transcribed from the original by A Keith W Brownell & Elizabeth Brownell, April 2001), online: CMA <www.royalcollege.ca/portal/page/portal/rc/common/documents/bioethics/primers/medical_ethics/CMACodeofEthics1868.pdf> [*CMA Code of Ethics*].

¹⁴³ See RG Guest, “The Development of Patent Medicine Legislation” (1966) 8:9 *Appl Ther* 786 at 787-88; see also Pugsley, *supra* note 68 at 400, describing concerns among physicians in the 1870s.

¹⁴⁴ In the earliest Canadian case, where Dr. Alexander Crichton was found to have distributed circulars promoting “Grippura” as a cure for grippa and influenza, an Ontario Court noted:

There is no doubt that this man has grievously offended against [physicians’] conventional rules, well recognized, though it may be not forming a written code, which obtains among the members of every learned and honourable profession. In two

In contrast, pharmacists' professionalization in the latter part of the nineteenth century was tied to their claim of expertise in drug compounding and dispensing, including dangerous proprietary medicines, and paralleled physicians' move away from those activities.¹⁴⁵ Pharmacists thus did not oppose the sale of proprietary medicines per se, provided dispensing remained under their primary control.¹⁴⁶ Pharmacists supported stronger regulation of proprietary medicines but failed on several occasions to achieve it under provincial laws.¹⁴⁷

Only after proprietary medicines received critical attention in the popular press around the turn of the twentieth century were federal legislators finally motivated to rethink the *Adulteration Act*'s omission of such dubious remedies from the legislation's ambit. In the US, two journalistic series, published in the *Ladies Home Journal* and *Colliers* respectively,¹⁴⁸ proved

respects he has violated proper decorum – modesty and propriety have been forgotten in his self-advertising and discreditable proclamation; and he has, in the second place, kept to himself and for himself this apparently valuable remedy, and has not made known the formula, in order that its benefits may be shared in by the profession and the public.

...

... The vendor of patent medicines and proprietary remedies might puff their uses and publish their testimonials and tout for customers, but not the physicians.

Re Crichton, *supra* note 140 at 284-85. See also *Hunt v College of Physicians & Surgeons of Saskatchewan*, 20 Sask LR 305, [1925] 4 DLR 834 (Sask KB); *Re Hett and the College of Physicians and Surgeons of Ontario*, [1937] OR 582, [1937] 3 DLR 687 (Ont CA).

¹⁴⁵ Clark, *supra* note 71 at 48-49.

¹⁴⁶ Those who failed to secure the necessary permission to sell drugs encompassed by provincial pharmacy legislation were prosecuted. See *R v Simpson*, 27 OR 603, [1896] OJ No 178 (QL) (Ont HC); see also *McGibbon v JP Lawrason Co*, 13 OWR 1168, [1909] OJ No 761 (QL) (Ont HC).

¹⁴⁷ See generally Clark, *supra* note 71; Malleck, "Boundaries of Control", *supra* note 72.

¹⁴⁸ See Guest, *supra* note 143 at 786. As well, the 1908 publication of "Secret Remedies: What They Cost and What They Contain" by the British Medical Association appears to have attracted public attention in Canada. See Davidson, *supra* note 68 at 50, 100 (n 17 of ch 7).

instrumental in finally provoking Congress to pass the *Pure Food and Drug Act* in 1906, following hundreds of failed legislative proposals to establish a general framework for food and drugs.¹⁴⁹ In Canada, with the *Adulteration Act* already in place, legislators developed a separate statute to address the problem of proprietary medicines in particular.

Despite its more targeted focus, passing Canada's proprietary medicines law was also a struggle. In 1904 the Senate was petitioned for information regarding patent medicines, which precipitated an investigation by the Inland Revenue Laboratory. However, the investigation yielded little useful information, "as the task of analyzing a considerable number of compounds without having any idea of their composition was a formidable one."¹⁵⁰ The issue was raised in a House of Commons Committee in 1905¹⁵¹ but the discussion stalled. The following year a report prepared by AE DuBerger on the proprietary medicine trade was presented to the House of Commons, recommending that legislation governing the sale, manufacturing, and advertising of proprietary medicines be enacted.¹⁵² In 1907 a bill to that effect was introduced into Parliament but failed to progress through further readings.¹⁵³ Finally, in 1908 the *Proprietary Medicine Act* was introduced and enacted.¹⁵⁴

¹⁴⁹ According to one source, 190 legislative proposals relating to food and drugs were introduced in Congress between 1879 and 1906 but only eight of the proposals were enacted. See CC Regier, "The Struggle for Federal Food and Drugs Legislation" (1933) 1:1 *Law & Contemp Probs* 3 at 3-4.

¹⁵⁰ Guest, *supra* note 143 at 788.

¹⁵¹ *Ibid.*

¹⁵² See Malleck, "Pure Drugs", *supra* note 101 at 112.

¹⁵³ Guest, *supra* note 143 at 788, explains the inaction as follows:

[I]t was found difficult to enact legislation that would at the same time safeguard the public and not commit injustice to business interests, and the measure was withdrawn. One wonders just how much pressure was brought to bear by the proprietary manufacturers Evidently it was greater than the public demand for legislation to protect itself.

¹⁵⁴ *An Act respecting Proprietary or Patent Medicines*, SC 1908, c 56 [*Proprietary Medicine Act, 1908*]. It is worth noting that the law did not require a medicine to be patented in order to come within the definition of a "proprietary or patent medicine". See *ibid.*, s 2(b).

The issue of transparency lay behind these twists and turns. The report submitted to the House of Commons by DuBerger, a trained chemist and practising pharmacist, clearly documented the need to protect the public against “‘quack’ nostrums.”¹⁵⁵ He equally stressed that some “patent medicines ‘possess real merits and their formulae are the fruit of long work and often the result of several years of experience and observation.’”¹⁵⁶ In DuBerger’s view, publishing the formulae of such medicines would “‘favour indelicacy and abuses on the part of unscrupulous persons,’ and would be ‘unfair.’”¹⁵⁷ According to historian Dan Malleck, this accounts for why the 1907 bill failed in the House. Requiring publication of a proprietary medicine’s formula on its label went too far and attracted strong critique from well-reputed pharmacists.¹⁵⁸ To secure support from this key interest group, the level of transparency needed to be reduced. Only on the basis of its tempered level of transparency did the subsequent 1908 bill pass.

The key provisions of the *Proprietary Medicine Act, 1908* worked as follows. First, the law defined proprietary or patent medicines as any medicine that was not listed on any of the recognized pharmacopoeias, or “upon which is not printed in a conspicuous manner ... the true formula or list of medicinal ingredients” of the putative remedy.¹⁵⁹ In other words, the law captured all those patented and/or secret remedies that were not considered “drugs” within the meaning of the existing *Adulteration Act* of 1884. Second, manufacturers, importers, and agents of such remedies were required to “procure annually from the Minister of Inland Revenue a numbered certificate of registration” by furnishing the Minister with a list of medicines to be manufactured, imported, and sold.¹⁶⁰ Third, once registered, all proprietary or patent medicines were required to be explicitly labelled as such, with the manufacturer’s name and registration number displayed

¹⁵⁵ Malleck, “Pure Drugs”, *supra* note 101 at 112.

¹⁵⁶ *Ibid*, citing DuBerger’s report to the House of Commons: Parliament, “Return to an Order of the House of Commons, dated April 23, 1906, for a Copy of the Report of A. E. DuBerger, on the Drug and Proprietary Medicine Trade of Canada” by AE DuBerger in *Sessional Papers*, No 125 (1906) at 22.

¹⁵⁷ *Ibid*.

¹⁵⁸ Malleck, “Pure Drugs”, *supra* note 101 at 113.

¹⁵⁹ *Proprietary Medicine Act, 1908*, *supra* note 154, s 2(b).

¹⁶⁰ *Ibid*, s 3.

in “conspicuous characters.”¹⁶¹ Fourth, proprietary medicines could not be sold if they contained (a) cocaine or (b) alcohol without “sufficient medication to prevent its use as an alcoholic beverage,” nor if they (c) failed to conspicuously identify on their label the presence of any of the 34 drugs listed in a schedule to the legislation. However, this last prohibition was subject to an important exception: the scheduled drugs *could* be included in the medicine’s ingredients if the medicine’s formula had been made known to the Minister – *but not the wider public* – and determined not to be dangerous to health through the registration process.¹⁶²

The *Proprietary Medicine Act* had its shortcomings. There was no provision pertaining to advertising of proprietary medicines,¹⁶³ which continued to fuel popular demand. As foreshadowed by DuBerger’s report, proprietary medicine manufacturers also did not have to reveal with any degree of precision the composition of their wares to the Minister, much less the public at large. Rather, they only had to reveal “the proportion of [the scheduled drug] contained in the mixture and dose”¹⁶⁴ and the basic presence thereof on the label¹⁶⁵ to the Minister and the public, respectively. Moreover, the *Proprietary Medicine Act* lacked a provision analogous to section 13 of the *Adulteration Act*, which required the Minister to report to Parliament annually regarding its analytical findings.¹⁶⁶

This bifurcation in approach between, on the one hand, a publicly transparent analysis of those drugs falling within the meaning of the *Adulteration Act* and, on the other, non-transparent registrations of proprietary medicines set up a choice for drug regulation in the not-too distant future. Which model – of *transparency without*, i.e. to the broader Canadian public, versus *transparency within*, i.e. confined to the regulator and the regulated – should those charged with regulating drugs, in general, adopt? Responsibility for administering both the *Adulteration Act* (and later the *Food and Drugs Act*)

¹⁶¹ *Ibid*, s 4.

¹⁶² *Ibid*, s 7(c).

¹⁶³ Pugsley, *supra* note 68 at 401.

¹⁶⁴ *Proprietary Medicine Act, 1908, supra* note 154, s 7(c).

¹⁶⁵ Guest, *supra* note 143 at 788.

¹⁶⁶ *Adulteration Act, 1885, supra* note 113, s 13.

and the *Proprietary Medicine Act* rested, after all, with the same government officials.¹⁶⁷

As shown below, subsequent legislative changes, evolving legal norms, and institutional practices suggest that the model of *transparency within* embodied in the *Proprietary Medicine Act* won out, notwithstanding the diminishing relevance of the nostrum trade through the twentieth century. Given that outcome, the pre-market focus of the *Proprietary Medicine Act* becomes conspicuous: it was the first piece of Canadian legislation to require registration *before* market entry. In contrast, the *Adulteration Act* (and its predecessor statute of 1874) focused on adulteration (and, later, on false labelling and misbranding) *after* market entry. In the decades that followed the proprietary medicine crisis at the turn of the twentieth century, punctuated by the sulphanilamide tragedy in the late 1930s¹⁶⁸ and the thalidomide disaster in the early 1960s,¹⁶⁹ *pre-market* evaluation of a drug's safety and efficacy became all-important. And, as that shift occurred, the set of norms and practices that evolved under the 1908 *Proprietary Medicine Act* – the first form of pre-market drug regulation in Canada¹⁷⁰ – seemingly came to dominate. In hindsight, then, it appears that the *Proprietary Medicine Act* marked the start of “insider transparency” as opposed to “public transparency” in Canadian drug regulation.

¹⁶⁷ Davidson, *supra* note 68 at 51, explains that Mr [A] Lemoine, who was appointed as a public analyst under the *Adulteration Act* in 1901, initially assumed sole responsibility for the patent medicine registration process. He was “assigned the duty of examining formulae containing scheduled drugs to see whether the amounts used exceeded dosage limits fixed by medical advisers with a view to allowing manufacturers exemption from having to print the name of the scheduled drug on the labels and wrappers as required by the Act” (*ibid*). Later, others aided in this work and a “Proprietary or Patent Medicine Division” was formalized as part of the Food and Drugs Directorate under the auspices of the Department of Health, when it was created in 1919 (*ibid*).

¹⁶⁸ See Swanson, *supra* note 111 at 366.

¹⁶⁹ See Jean F Webb, “Canadian Thalidomide Experience” (1963) 89:19 Can Med Assoc J 987.

¹⁷⁰ Even though registration only required disclosure of select drugs rather than any evidence of safety or efficacy as expected under more modern drug laws, the *Proprietary Medicine Act, 1908* put the burden of proof squarely on the manufacturer to show that the provision was observed. See *Proprietary Medicine Act, 1908*, *supra* note 154, s 7(2).

D. The beginning of the end: Legislative changes 1919-1920, evolving institutional practices, and relevant shifts outside the regulator

1. The 1919 amendments to the *Proprietary Medicine Act* and the 1920 *Food and Drugs Act*

The deficiencies of the original *Proprietary Medicine Act* were plain: manufacturers had only to declare the presence and proportion of the scheduled drugs, not the precise composition of the medicine, to the bureaucracy and there was no measure to deter extravagant curative claims. These concerns were raised in the House of Commons in 1915 and “several professional associations” argued for reform in 1917.¹⁷¹

In 1919, the legislation was significantly amended.¹⁷² Amongst other changes, such as expanding “the list of dangerous drugs” and establishing “maximum dosage limits ... for a number of drugs,”¹⁷³ the scope of conduct prohibited by the legislation increased. Failing to “conspicuously” name any scheduled drugs “and the amount per dose” on drug labels was prohibited.¹⁷⁴ Further, representing that a proprietary or patent medicine was a “cure for any disease” and making “false, misleading or exaggerated claims” on the “wrapper or label, or in any advertisement” were also prohibited.¹⁷⁵

The 1919 amendments also revised the registration process and, in so doing, the explicit terms of the underlying model of transparency within the confines of the regulator-regulated relationship. Manufacturers were obliged to “furnish the Minister with a statement under oath of the quantity of ... drug or drugs [named in the Schedule to the Act] contained in such medicine,” and if such statement was “incorrect or false,” the manufacturer could incur a fine or face imprisonment.¹⁷⁶ At the same time, the 1919

¹⁷¹ Guest, *supra* note 143 at 788.

¹⁷² *An Act to amend The Proprietary or Patent Medicine Act*, SC 1919, c 66 [*Proprietary Medicine Act, 1919*].

¹⁷³ Pugsley, *supra* note 68 at 402.

¹⁷⁴ *Proprietary Medicine Act, 1919*, *supra* note 172, ss 7(1)(c)-(d).

¹⁷⁵ *Ibid*, ss 7(1)(e)-(f).

¹⁷⁶ *Proprietary Medicine Act, 1919*, *supra* note 172, s 3(2). When initially introduced, the bill required disclosure of the formula to the Minister, but the level of transparency was reduced during the legislative process. See *Debates of the*

amendments unequivocally indicated that transparency was confined to the two parties. Once statements from manufacturers about the drugs contained in their products were received, under the revised *Proprietary Medicine Act* the department was statutorily required to treat them as “confidential.”¹⁷⁷ Even though no such (explicit) obligation of confidentiality had appeared in the 1908 statute, the new language appears to have attracted no scrutiny in either the House of Commons or the Senate when the 1919 amendments were debated.

The following year, in 1920, the *Adulteration Act* was repealed and replaced with the first Canadian *Food and Drugs Act*.¹⁷⁸ Consistent with preceding legislative changes, the new statute continued to expand the scope of conduct captured. Influenced by the United States’ 1906 *Pure Food and Drugs Act*,¹⁷⁹ the 1920 Canadian statute created a new offence of “misbranding” to extend the law’s reach beyond adulteration and false labelling.¹⁸⁰ Secondly, although authority to introduce requirements through an Order in Council stemmed from the 1884 adulteration legislation,¹⁸¹ the 1920 statute “enlarged and placed on a more formal basis” this practice of regulation through delegated legislation.¹⁸² The new law significantly expanded regu-

Senate, 13th Parl, 2nd Sess (26 June 1919) at 770. *C.f.* Pugsley, *supra* note 68 at 402, stating, in error, that the formulae had to be disclosed.

¹⁷⁷ *Proprietary Medicine Act, 1919*, *supra* note 172, s 3(2).

¹⁷⁸ *Food and Drugs Act*, SC 1920, c 27 [*Food and Drugs Act, 1920*].

¹⁷⁹ Pugsley, *supra* note 68 at 404.

¹⁸⁰ According to commentators, misbranding was initially tied to foods only, but was extended to drugs by 1927. See Pugsley, *supra* note 68 at 408. In fact, the 1920 statute made misbranding of drugs an offence but failed to specify what a misbranded drug was (whereas it did define a misbranded food). See *Food and Drugs Act, 1920*, *supra* note 178, ss 5, 16. See also the Appendix, below, for the text of the provisions rendering adulteration and misbranding an offence. Note also that the misbranding offence was removed from the legislation in 1953. Compare *An Act respecting Food and Drugs Act*, RSC 1952, c 123, ss 8, 26 [*Food and Drugs Act (RSC 1952)*], with *An Act respecting Food, Drugs, Cosmetics and Therapeutic Devices*, SC 1953, c 38, s 9 [*Food, Drugs, Cosmetics and Therapeutic Devices Act, 1953*].

¹⁸¹ *Adulteration Act, 1884*, *supra* note 109, s 23.

¹⁸² Pugsley, *supra* note 68 at 405.

lation-making powers to facilitate the *Act*'s administration.¹⁸³ This power was put to immediate use in fashioning the inaugural *Food and Drug Regulations* out of the standards that had been developed, in significant part, through the public dissemination of 440 bulletins between 1887 and 1920.¹⁸⁴ The exercise of this regulation-making power would become increasingly instrumental in subsequent years, cementing the close, confidential relationship between the regulator and industry.

2. Evolving institutional practices at the Department of Health

Institutional changes with significant implications for the transparency of the bureaucracy's work to the public coincided with the repeal of the *Adulteration Act*. The 33-year-old practice of publishing the names of individuals and manufacturers suspected of adulteration in publicly available bulletins, approximately 68 of which had focused specifically on drugs,¹⁸⁵ was halted. Manufacturers and vendors had long protested this administrative practice to no avail.¹⁸⁶ However, as one official, A Linton Davidson, later explained, "[t]he new Department into whose hands control of the laboratories had passed, was not impressed with the advantages of publicity on such topics."¹⁸⁷

This "new Department" was the Department of Health, created in 1919 to assume control over the administration of the *Adulteration Act* (then still in place)¹⁸⁸ and, from 1920 onwards, the *Food and Drugs Act*. Department

¹⁸³ The *Adulteration Act*, 1884, *supra* note 109, s 23 simply gave the Governor in Council the discretion to "make such regulations as to him seem necessary for carrying the provisions of this Act into effect." In contrast, the *Food and Drugs Act*, 1920, *supra* note 178, ss 14-15 specified several specific regulation-making powers for the Governor in Council.

¹⁸⁴ Davidson, *supra* note 68 at 55-56.

¹⁸⁵ Davidson, *ibid* at 108-17, provides a list of all the bulletins pertaining to food and drugs published between 1887 and 1920.

¹⁸⁶ *Ibid* at 56. See also *ibid* at 61; Pugsley, *supra* note 68 at 403-04.

¹⁸⁷ Davidson, *supra* note 68 at 56.

¹⁸⁸ Administration of the *Adulteration Act* had been temporarily transferred from the Department of Inland Revenue to the Department of Trade and Commerce during 1918-19 (*ibid*).

officials began to highlight the importance of “cooperation” with industry, language that increasingly appeared in the decades that followed.¹⁸⁹ As early as 1928, industry began to be directly involved in crafting regulations under the *Food and Drugs Act*.¹⁹⁰

It is difficult to pinpoint *what* motivated this shift away from public transparency and *when* closed-door cooperation with industry gained favour. The process was probably gradual and attributable to a mix of factors.

Members of Parliament had, on occasion, voiced concern about the administration’s practice of naming manufacturers and vendors suspected of adulteration and false labelling.¹⁹¹ Yet, under the direction of two successive Chief Analysts, first Thomas Macfarlane and especially later under Anthony McGill, the practice of publishing bulletins with copious details linked to specific manufacturers and vendors grew steadily (see Table 1, above). When the new *Food and Drugs Act* came into force, McGill was still at the helm, though his tenure ended in 1922. Perhaps the promulgation of the first *Food and Drug Regulations* in 1920, the contents of which drew significantly from past bulletins, was perceived as diminishing the need for public dissemination of the department’s analytical work.

A second explanation derives from the source of the regulations – Cabinet – and the tradition of “administrative secrecy” wedded to Westminster parliamentary systems.¹⁹² That tradition is strong in Canada: administrative

¹⁸⁹ For example, another department official, Robert E Curran, who authored the first major text on *Canada’s Food and Drug Laws*, wrote in 1953 that the lack of Canadian jurisprudence regarding the provisions of the *Food and Drugs Act* was a testament to the close, cooperative relationship between the department and manufacturers:

The close co-operation ... which has developed between industry and the departmental officers with the infrequency with which matters are referred to courts for determination, speaks highly of the quality of the administration, and of the [administrative] interpretation that has been given to many of these difficult provisions.

Curran, *Canada’s Food and Drug Laws*, *supra* note 68 at 200.

¹⁹⁰ Davidson, *supra* note 68 at 68.

¹⁹¹ *Ibid* at 27, 61.

¹⁹² See Donald C Rowat, “How Much Administrative Secrecy?” (1965) 31:4 Canadian Journal of Economics and Political Science 479.

secrecy has long been effected through Cabinet as part and parcel of the doctrine of ministerial responsibility.¹⁹³ Administrative secrecy is, on this view, supposed to facilitate ministers' work and day-to-day policy development in lockstep with civil servants. Thus, as the source of many Orders in Council and regulatory revisions to come, it is possible that Cabinet propagated norms of secrecy from the top down.

A horizontal influence within the department was also in play. The norms of confidentiality inscribed by the amended *Proprietary Medicine Act* may have begun to bleed over into the rest of the department's work. As part of the 1919 amendments to the *Proprietary Medicine Act*, an Advisory Board to "determine the limits of dosage of scheduled drugs"¹⁹⁴ was struck, composed of the Chief Analyst, two "medical men," and two "teachers of pharmacy."¹⁹⁵ The latter were known to be tolerant of secrecy,¹⁹⁶ and, as described below, the medical profession's stance towards certain drug manufacturers was already softening. Perhaps this Advisory Board was one site in which practices beyond the administration of the *Proprietary Medicine Act* were gradually redefined.

A fourth explanation for the apparent shift may be cross-fertilization between the department and industry. During the First World War, staffing was a challenge because "the Canadian chemical industry was growing in stature and competing vigorously for the service of chemists."¹⁹⁷ In subsequent years, however, there is some evidence of a revolving door between the public and private sector. Archival documents provide the earliest indication of this; an internal memorandum appended to an organizational chart of the newly formed Department of Health identifies a person named LeSueur as being suited "better than anyone we know of" for the position of "Direc-

¹⁹³ *Ibid*; see also Richard J Bazillion, "Freedom of Information: A Canadian Dilemma" (1983) 72:288 *The Round Table* 382.

¹⁹⁴ Davidson, *supra* note 68 at 59.

¹⁹⁵ *Ibid* at 60. The wording of the legislation was more vague: the Board was to be composed of the Chief Analyst and two to four other "property qualified persons." *Proprietary Medicine Act, 1919*, *supra* note 172, s 2.

¹⁹⁶ Malleck, "Boundaries of Control", *supra* note 72 at 195.

¹⁹⁷ Davidson, *supra* note 68 at 57. At the time, industry was offering \$2,500 as annual salary whereas the government paid \$1,700 on average (*ibid*).

tor of Publicity.”¹⁹⁸ Amongst LeSueur’s qualifications was his prior experience working for the “Dupont and MacArthur interests in New York before 1914.”¹⁹⁹ The Dupont company had, at that time, recently transformed from a “family-controlled manufacturer” to a “large, vertically integrated, and centrally administered firm” that asserted tight control over trade secrets as a matter of strict company policy.²⁰⁰ Archival records show that LeSueur came to occupy the position of “Supervisor of Publicity,” and it is possible his approach to that role was influenced by his time with Dupont. Later examples of crossover between industry and civil service also exist. In 1939, Dr. GDW Cameron became the department’s Chief of the Laboratory of Hygiene (created in 1921 to, *inter alia*, inspect drug manufacturing facilities),²⁰¹ having entered the civil service from Connaught Laboratories, then a publicly owned Canadian drug company. Cameron would serve as the Deputy Minister of Health starting in 1946. That same year, the department added a position of “business manager” to relieve the Chief Dominion Analyst of the burden of managing “accounts, supplies and finance.” The person hired, Charles A Summers, “had been connected with the drug business” prior to the Second World War.²⁰² Finally, Dr. Clarence Morrell, who became Chief Dominion Analyst in 1946 after serving for years in the pharmacological laboratory of the department, evidently maintained a close relationship with drug manufacturers, given that he eventually stepped down from the Food and Drug Directorate in 1965 to join the CIBA-Geigy Ltd. board of directors.²⁰³ To the extent that these recorded examples speak to a trend, crossover between the public and private sphere may have contributed to the shift away from public transparency.

¹⁹⁸ Memorandum from Dr. DA Clark, Assistant Deputy Minister, Department of Health, to Dr. [JA] Amyot, [Deputy Minister] re “Division of Sanitary Statistics and Publicity – Dr. C. A. Hodgetts” (14 April 1920) and accompanying undated documentation, Ottawa, Library and Archives Canada (on file with author).

¹⁹⁹ *Ibid.*

²⁰⁰ See Catherine L Fisk, *Working Knowledge: Employee Innovation and the Rise of Corporate Intellectual Property, 1800-1930* (Chapel Hill, NC: University of North Carolina Press, 2009) at 196-98ff.

²⁰¹ *Ibid* at 65, 82.

²⁰² *Ibid* at 91.

²⁰³ Lexchin, *The Real Pushers*, *supra* note 10 at 66.

Fifth and finally, publicity practices may have fallen into disfavour as department officials interacted more and more regularly with their regulatory counterparts in the US. Since 1938, when the US instituted its regime of pre-market safety regulation, government officials who disclosed information that qualified as a “trade secret”²⁰⁴ or (after 1948) “confidential business information”²⁰⁵ – a designation that manufacturers claimed extended to most, if not all, of the information they shared with the regulator – were potentially subject to criminal sanction.²⁰⁶ The “food and drug men” of Canada and the US were known to congregate under the auspices of the US-based food and drug institutes through the late 1940s and ’50s.²⁰⁷ Thus, it is conceivable that US regulators, versed in the importance of confidentiality even before the 1938 criminalization of public disclosure, had begun to impress upon Canadian officials the norm of confidentiality in earlier years.

Whatever the animating factors, only traces of transparency to the wider public remained. In 1927, Davidson co-authored four surveys of “commercial pharmaceutical preparations” with the new Chief Analyst (now referred to as the Chief Dominion Analyst), Harry Lancaster. The surveys focused on *nux vomica*, belladonna root, belladonna leaves, and hydrastis – four drugs²⁰⁸ in wide use in the 1920s – and each was published in the *Canadian Medical Association Journal*.²⁰⁹ However, the surveys were brief and did

²⁰⁴ 21 USC § 331(j).

²⁰⁵ 18 USC § 1905.

²⁰⁶ As Rebecca S Eisenberg notes, it is not obvious that information about a drug’s safety and efficacy falls within these categories of trade secrets or confidential business information. Absent a duty to disclose such information, however, the safest course – in terms of liability – for regulatory officials was non-disclosure. See Rebecca S Eisenberg, “Data Secrecy in the Age of Regulatory Exclusivity” in Rochelle C Dreyfuss & Katherine J Strandburg, eds, *The Law and Theory of Trade Secrecy: A Handbook of Contemporary Research* (Cheltenham, UK: Edward Elgar Publishing, 2011) 467 at 473.

²⁰⁷ See e.g. “Meetings of Food and Drug Men” (1954) 9:6 Food Drug Cosm LJ 308; “Meetings of Food and Drug Men” (1956) 11:10 Food Drug Cosm LJ 559.

²⁰⁸ Curiously, three of the four drugs surveyed were listed as proprietary medicines under the Schedule to the *Proprietary Medicine Act, 1908*, *supra* note 154.

²⁰⁹ HM Lancaster & AL Davidson, “Commercial Pharmaceutical Preparations: 1. Nux Vomica” (1927) 17:7 Can Med Assoc J 803; HM Lancaster & AL David-

not name any manufacturers of the drugs in question, in sharp contrast to the hundreds of bulletins disseminated under Lancaster's predecessor, Anthony McGill. The annual reports published under Lancaster did not make up the difference. Rather, the reports gave "but scanty glimpses of the work done in the laboratories,"²¹⁰ for instance, by simply listing the number of samples analyzed and the percentage considered adulterated, falsely labelled, or misbranded and by providing brief, generalized synopses of the department's work on select classes of drugs in circulation.²¹¹ Whether addressed to physicians or the public more generally, no further communiqués of the department's analytical work – identifying specific samples from specific sources – were issued after the final bulletin was published in 1920.

3. Shifts in the field of pharmaceuticals, patenting practices, and the profession of medicine

Outside the regulatory institution, things were shifting as well, in the pharmaceutical business, patenting practices, and the medical profession. The pharmaceutical medicines market was becoming increasingly segmented between a small but growing number of companies thought of as "ethical manufacturers," which at the time did not trade in secret remedies, patent drugs, or utilize rash amounts of advertising to promote their products, and a slew of entities engaged in those very practices. The former, amongst which were counted many of the firms that gave rise to the "big pharmas" or "brand-name" manufacturers of today, including Eli Lilly, Merck, Smith Kline & Co., and Parke-Davis, had a direct interest in advocating for greater regulation of proprietary medicine makers, and the medical profession was

son, "Commercial Pharmaceutical Preparations: 2. Belladonna Root" (1927) 17:8 Can Med Assoc J 923; HM Lancaster & AL Davidson, "Commercial Pharmaceutical Preparations: 3. Belladonna Leaves" (1927) 17:10 (pt 1) Can Med Assoc J 1187; HM Lancaster & AL Davidson, "Commercial Pharmaceutical Preparations: 4. Hydrastis – Golden Seal" (1927) 17:11 Can Med Assoc J 1317.

²¹⁰ Davidson, *supra* note 68 at 64.

²¹¹ Davidson, *ibid* at 64-67ff (and accompanying notes for ch 9 at 101), cites several annual reports in support of this claim. See also Canada, *Report of the Work of the Department of Pensions and National Health* (Ottawa: King's Printer, 1938) at 97-108.

a powerful ally in their campaign against (unethical) secret remedies.²¹² To the extent the so-called ethical manufacturers were ever opposed to patenting (as opposed to secrecy) that opposition did not last. By 1911, for instance, Parke-Davis had successfully sought and defended its patent on human adrenaline,²¹³ generating a precedent that would forever invite human biology into the realm of patentable subject matter.²¹⁴

At the same time, within the medical profession, a more nuanced stance towards patenting was developing. Retreating from its prohibitive position, the American Medical Association passed a resolution in 1914 empowering its Board of Trustees to receive “patents for medical and surgical instruments and appliances...as trustees for the benefit of the profession and the public” provided no financial rewards accrued to the individual inventors or the association.²¹⁵ Institutions engaged in medical research and individual physicians began to carefully test the waters of patenting.²¹⁶ In 1922, the prohibition on patenting contained in the Canadian Medical Association’s *Code of Ethics* was deleted, never to return.²¹⁷

The best-known example of medical patenting from that era took place in Toronto, where Frederick Banting, John Macleod, Charles Best, and Bertram Collip devised a method of extracting insulin for the treatment of diabetes. Banting and Macleod, as physicians, were reticent to patent but recognized the importance of maintaining control over their technology to ensure safety and affordable access. The foursome thus assigned control over to the

²¹² Swanson, *supra* note 111 at 371-72, documents this alliance in the US.

²¹³ *Parke-Davis & Co v HK Mulford Co*, 189 F 95 (SD NY 1911).

²¹⁴ The lasting significance of this decision has been described in numerous articles. See e.g. Jon M Harkness, “Dicta on Adrenalin(e): Myriad Problems with Learned Hand’s Product-of-Nature Pronouncements in *Parke-Davis v Mulford*” (2011) 93:4 J Pat & Trademark Off Soc’y 363.

²¹⁵ Morris Fishbein, “Are Patents on Medicinal Discoveries and on Foods in the Public Interest?” (1937) 29:11 Ind Eng Chem 1315 at 1317.

²¹⁶ For example, on the strength of its 1914 policy, in 1918 the American Medical Association (AMA) took ownership of a patent for “thyroxin,” a hormone discovered at the Mayo Clinic. However, as explained by Swanson, *supra* note 111 at 373, the arrangement “foundered due to lack of agreement among the AMA membership about whether medical patents should be allowed at all.”

²¹⁷ Receiving remuneration for or dispensing a “secret nostrum” was still regarded as reprehensible, however. See *CMA Code of Ethics*, *supra* note 142, part B, art 1.4.

University of Toronto, a patent was filed and obtained,²¹⁸ and Banting and Macleod went on to receive the Nobel Prize in 1923. The university in turn licensed the technology on a *non-exclusive* basis to Eli Lilly, which helped scale up production of insulin at an affordable price. The story has long been heralded as an instance of responsible university-industry commercialization. Extrapolating from that example, some even advocated that the profession should use patents to manage the supply of other drugs.²¹⁹ However, as noted by historian Kara Swanson, the experience also had a lasting impact upon the business model of the ethical drug manufacturers:

[Eli Lilly] learned that developing drugs in-house, rather than negotiating licenses with doctors with ethical qualms about patents and universities committed to the public interest, would permit exclusivity, and thus monopoly pricing, for the life of a patent. The insulin model of patent control, while lauded by the [American Medical Association], could be partially replaced by federal regulation and was unsatisfactory to a key set of players in the drug marketplace, the manufacturers [once described as ethical].²²⁰

While the medical profession as a whole remained ambivalent towards patenting through the 1930s, '40s, '50s, and beyond, the so-called ethical manufacturers began to seize control of the drug supply and, coupled with further regulatory changes, they relegated physicians to the demand side of the equation.

Perhaps the most important regulatory change in this process, one initially resisted by representatives of the “Canadian Pharmaceutical Manufacturers Association” (CPMA),²²¹ was to tie access to certain drugs to a

²¹⁸ Initially, only Best (a medical student) and Collip (a biochemist) were named as the inventors. But Banting and Macleod were later added, apparently because Lilly told the University of Toronto that doing so was necessary to ensure the patent’s validity. See “Insulin”, US Patent No 1469994 (12 January 1923); Swanson, *supra* note 111 at 385, n 257.

²¹⁹ *Ibid* at 374.

²²⁰ *Ibid* at 382.

²²¹ This association has been renamed several times over its history. Originally, the Association was formed by representatives of ten pharmaceutical and toilet product companies and named the “Canadian Association of Manufacturers of Medicinal and Toilet Products.” It was renamed the CPMA in 1915, and then

physician's prescription-writing power.²²² In Canada, provincial pharmacy statutes already stipulated this, but there was a lack of uniformity, so in 1939 the provinces implored the federal government to intervene under the *Food and Drugs Act*.²²³ When the provinces reiterated their concerns about the "over-the-counter" sale of certain dangerous drugs to the general public in 1941, the federal government acted, prohibiting by Order in Council the sale of nine dangerous drugs without a physician's prescription,²²⁴ including sulphanilamide, which had precipitated the same regulatory change (and others) in the US in 1938.²²⁵

While the move represented, on its face, a limitation on the industry's freedom to operate, in effect the advent of prescriptions under federal law greatly reduced companies' marketing audience to physicians rather than the public writ large. Companies in the prescription drug business substantially changed their practices, employing an increasing number of "detail men" to promote their products to physicians.²²⁶ The medical profession meanwhile struggled to maintain its independence. The pages of the *Canadian Medical*

again in 1965 to the "Pharmaceutical Manufacturers' Association of Canada" (PMAC). Finally, in 1999 PMAC became "Canada's Research-Based Pharmaceutical Companies," styled as Rx&D. See Rx&D, "Our History", online: Rx&D <www.canadapharma.org/about-rxd/corporate-information/our-history>.

²²² Pugsley, *supra* note 68 at 412. It is worth noting that limiting access to certain drugs by requiring physician prescriptions was a justifiable policy change given growing concerns associated with excessive over-the-counter consumption. Nevertheless, the policy change had significant unintended consequences, as the pharmaceutical industry subsequently focused its marketing efforts squarely upon the medical profession.

²²³ *Ibid.*

²²⁴ PC 1941-8443, (1941) C Gaz, 1495-96 (*Food and Drugs Act*, Prescription Drugs).

²²⁵ Swanson, *supra* note 111 at 365-66.

²²⁶ Michael Oldani notes that detail men date back to the nineteenth century, while at the same time documenting companies' increasing reliance on them in recent years. See generally Michael J Oldani, "Thick Prescriptions: Toward an Interpretation of Pharmaceutical Sales Practices" (2004) 18:3 *Med Anthropol* Q 325. In a Canadian context, evidence of detail men can be found in nineteenth-century medical journals. See e.g. Malleck, "Boundaries of Control", *supra* note 72 at 189-91.

Association Journal attest to the deluge of information that physicians were now presented with and the value they sometimes placed upon the help provided by pharmaceutical company representatives to make sense of the fast-growing body of drug literature.²²⁷ Swanson succinctly summarizes the impact of these changes in the US:

As the rate at which American physicians wrote prescriptions began to skyrocket, and armies of detail men entered doctor's offices to market the new drugs, the medical profession traded a patron relationship with the "ethical" and an oppositional relationship with the proprietaries for a co-dependent relationship with Big Pharma.²²⁸

This would appear to apply equally in Canada, as members of the Canadian medical profession gradually began to align their interests with ethical manufacturers, soon to be known as "brand-name" or "innovator" companies. In 1958, the CPMA formed a "Medical Section" comprised of fifteen physicians employed full-time as medical directors within the Canadian offices of fifteen "pharmaceutical houses."²²⁹ The Medical Section's functions were, amongst others, to "assist the [CPMA] to maintain and increase the prestige of the industry with the whole medical profession"; "initiate and support clinical and pharmacological studies of general interest"; and, "[a]s necessary or as requested, to act as liaison between the [CPMA] and the Food and Drug Department in Ottawa on matters of a medical nature."²³⁰ At the time of the inception of the CPMA's Medical Section, some were ready to equate the motivations of the medical profession with those of industry, while others acknowledged there was acrimony or at least ambivalence between the two.²³¹ By the lead up to the expansion of compulsory licensing of

²²⁷ See e.g. H Clark Balmer, "Controlling the Chaos" (1961) 85:15 Can Med Assoc J 836.

²²⁸ Swanson, *supra* note 111 at 392-93.

²²⁹ TC Routley, "Panel Discussion: The Role of the Medical Section, C.Ph.M.A., in the Canadian Pharmaceutical Industry" (1958) 79:11 Can Med Assoc J 924 at 924.

²³⁰ Leighton Smith, "Organization and Aims of the Medical Section" (1958) 79:11 Can Med Assoc J 924 at 925.

²³¹ Compare Routley, *supra* note 229, with WK MacDonald, "The Medical Section of the Canadian Pharmaceutical Manufacturers Association and the Pharmaceutical Industry" (1958) 19:11 Can Med Assoc J 927 at 928.

patented drugs in 1969, however, the Canadian medical profession became brand-name companies' main ally in resisting that policy change.²³²

Softening tension and progressive alignment of physicians with (ethical) manufacturers, spawned in part by regulators' restriction of some drugs to access by prescription only, together mark a dark turn for transparency. Physicians were once amongst the most vocal critics of practices of secrecy and patenting in the nostrum trade, policing transgressions of their own as contrary to their professional ethical obligations. However, in the wake of the University of Toronto researchers' success with patenting and the growing interconnections with industry after the advent of prescription drugs in 1941, the profession's concerted resistance to intellectual property norms entirely dissipated. The profession consequently offered no challenge to the regulator's decision to do that work of vetting under a cloak of confidentiality with manufacturers.

E. Drug regulation in the mid-twentieth century and beyond: Entrenched regulator-industry confidentiality

1. The onset of pre-market assessments of "new drugs"

In 1953, the *Food and Drugs Act* was completely overhauled. Since 1920, few changes within the four corners of the statute had been made. Of particular interest, the public reporting provision contained in the original *Inland Revenue Act* of 1874 had remained intact from 1890 through 1952.²³³ Orders in Council and revisions to the 1920 *Food and Drug Regulations* had, however, wrought significant changes in the years leading up to 1953.

The changes in subordinate legislation were significant because they brought the regulator, which by 1944 had become organized as the Food

²³² Lexchin, *The Real Pushers*, *supra* note 10 at 108-11.

²³³ If anything, it had been enhanced over time. In 1952, the provision required the Chief Dominion Analyst to publish "for the information of the public" reports of "the number of articles of food and drugs analysed" and to "specify the nature and kind of adulteration detected, the nature and kind of misbranding found thereon, together with all the particulars regarding the vendors and manufacturers of such articles." See *Food and Drugs Act* (RSC 1952), *supra* note 180, s 25.

and Drug Directorate,²³⁴ into closer contact with manufacturers. For example, in 1942 an Order in Council established a “Canadian Committee on Pharmacopoeial Standards,” which, as the official LI Pugsley noted, was an “important event in the development of drug laws in Canada” as it “brought together expertise from the medical and pharmacy professions as well as from the drug manufacturers.”²³⁵ Industry thus began to have a say in the very standards to which it was held accountable under the *Food and Drugs Act*. In 1948, a system of informing industry as a whole, rather than “selected interested parties,” of proposed regulatory changes *before* they were made via “Trade Information Letters” and of soliciting feedback was implemented.²³⁶ In 1951, at the behest of, and after extensive consultations with, manufacturers, the Food and Drug Directorate published a “Guide” regarding labelling and advertising of foods and drugs, which manufacturers reportedly found “very useful.”²³⁷ Most important, a requirement to submit information regarding any “new drug” to the regulator prior to marketing for the purpose of demonstrating safety was integrated into the *Food and Drug Regulations* in 1951 (thirteen years after the US had done so in response to its sulphanilamide tragedy).²³⁸

This last change in particular signalled deeper change in the very rationale for government regulation in the sphere of drugs: a change from regula-

²³⁴ The Food and Drug Directorate combined the Food and Drug Division, the Labels and Advertising Division, and the Proprietary and Patent Medicine Division. Pugsley, *supra* note 68 at 417.

²³⁵ *Ibid* at 416. The committee continued after 1953 as the “Canadian Drug Advisory Committee” (*ibid*).

²³⁶ *Ibid* at 418.

²³⁷ *Ibid*.

²³⁸ This change built upon an earlier reorganization of the *Food and Drug Regulations*, undertaken in 1949, that segregated each type of article then regulated under the *Act* (food, drugs, vitamins, and cosmetics). The 1951 amendments requiring pre-market evaluations of “new drugs” mirrored the steps taken by the US in 1938 following the deaths of 100 persons who had consumed a “new Elixir of Sulphanilamide preparation in which diethylene glycol was used as the solvent”; no pre-market animal toxicity studies of that solvent, which proved to have fatal effects, had been undertaken. In practice, the Canadian regulator received information of “most of the new drugs prior to marketing,” as many US-based manufacturers simply sent the Canadian officials the same information that they gave to the FDA. However, prior to the 1951 amendments, there was no legislative requirement *compelling* manufacturers to do so, and in its

tion to prevent public ignorance about what drugs were and what their use could not claim to achieve to regulation in order to ensure the safety (and later the efficacy) of drugs *on the public's behalf*.²³⁹ This was necessary in the sense that drugs were far more complex by the twentieth century than in the past. As Swanson asks rhetorically regarding the drug that motivated the move to pre-market safety regulation in the US, “[e]ven if each bottle [of sulphanilamide] had been clearly labeled ‘diethethylene glycol,’ how could patients have used that information?”²⁴⁰ Yet, from the perspective of transparency, the significance of this shift in regulatory rationale could not have been starker. If the onset of post-market regulation in 1874 in Canada was about *stopping private secrecy* and the quackery that flourished because of it, then the onset of pre-market regulation in 1951 was about *expanding the shared public/private secrecy* between the regulator and all regulated manufacturers. This was the same brand of insider transparency that had been formalized in the 1919 amendments to the *Proprietary Medicine Act*.²⁴¹

Swanson has characterized the US food and drug regulatory law *qua* intellectual property law,²⁴² and the same is borne out in Canada as well. If intellectual property law is at bottom about negotiating the openness of information, then drug regulatory law clearly has an essential role to play. Drug regulation was initially designed to limit industry’s “trade secrets”; in time, an understanding between industry and regulators evolved, legitimating expectations that business information would be kept in confidence, as often seen in contemporary employer-employee relationships or, historically, under the principles of master and servant law.²⁴³

absence, there was a sense that “Canada was becoming a proving ground for foreign manufacturers to test-market their new drugs” (Pugsley, *supra* note 68 at 422).

²³⁹ This language borrows from Swanson, *supra* note 111 at 381-82, who has described the 1938 change in the US along these lines.

²⁴⁰ *Ibid* at 366.

²⁴¹ *Supra* note 172.

²⁴² See generally Swanson, *supra* note 111.

²⁴³ For a careful, historical analysis of the evolution of norms of secrecy or confidentiality in employment settings in the US, see Fisk, *supra* note 200 at 27-28, 92-105ff.

The sheer volume of information being generated by drug manufacturers (which were increasingly US-based) by the 1940s may have put an increasing premium on this norm of confidentiality. As Joel Lexchin describes, this period marked a “dramatic transformation” in the drug industry.²⁴⁴ Many Canadian firms were unable to compete with larger, foreign-owned (ethical) manufacturers,²⁴⁵ which implemented “sophisticated technological processes” to synthesize new drugs in-house, benefiting from economies of scale and increasingly open world trade markets.²⁴⁶ With vastly greater amounts of data under their control, these companies were growing accustomed to the norms of confidentiality formally institutionalized south of the border under the 1938 US law, and the body that represented their interests in Canada, the CPMA, presumably began to impress their perspective upon Canadian officials.²⁴⁷

Viewed in light of these developments, the 1953 overhaul of the *Food and Drugs Act* becomes a crystallizing moment. During Senate hearings on the proposed amendments in late 1952, the CPMA pushed to make the regulator’s obligation to safeguard the “confidential nature of information” explicit.²⁴⁸ The bureaucracy resisted, noting that “[e]very employee in the government service is required to take an oath of secrecy on taking his office” and this was deemed to be “the proper way to safeguard the interests of the manufacturer rather than by providing a penalty provision for disclosure of information.”²⁴⁹ But even in this resistance there is telling evidence of a shift in thinking: the regulator did not challenge the manufacturer’s interests in having that information kept confidential; no discussion of a

²⁴⁴ Lexchin, *The Real Pushers*, *supra* note 10 at 32.

²⁴⁵ *Ibid* (“[p]rior to World War II a significant portion of the industry had been Canadian controlled, but the postwar wave of acquisitions left only one domestically owned company of any consequence, Connaught Laboratories” at 32).

²⁴⁶ *Ibid*.

²⁴⁷ *Ibid* at 33. Over time, the CPMA (later PMAC and then Rx&D) became increasingly comprised of foreign-controlled companies. In 1961, 50 of the 57 manufacturers in PMAC were foreign owned. In 1981, 62 of 66 manufacturers in PMAC were foreign-owned (*ibid*).

²⁴⁸ Senate, Standing Committee on Public Health and Welfare, *Report of the Committee to whom was referred the Bill “J”, intituled: “An Act respecting Food, Drugs, Cosmetics and Therapeutic Devices”* (December 1952) at 18 (Chair: CJ Veniot).

²⁴⁹ *Ibid* at 71 per RE Curran.

possible countervailing duty to publicly share such information took place. In fact, when the amendments to the *Food and Drugs Act* were passed, no discussion whatsoever regarding the changes made to the public reporting provision that was part and parcel of Canadian food and drug law since 1874 occurred in the Senate (where the bill originated), during committee hearings, or the House of Commons. Yet, the public reporting provision had entirely disappeared from the four corners of the legislation.²⁵⁰ Secrecy as between regulator and regulated industry had, from a legislative drafting point of view, become *parti pris*.

Although the thalidomide disaster of the early 1960s generated further important reforms,²⁵¹ from the perspective of public transparency, the rest is essentially history. Thalidomide motivated governments and regulators in turn to require more information about the safety and efficacy of new drugs before market entry. In principle that was a laudable move. But with it, the regulator grew steadfast in its commitment of confidentiality to industry.

²⁵⁰ All that remained under the heading of “Analysis” was the following in the 1953 legislation:

23. (1) An inspector may submit any article seized by him or any sample therefrom or any sample taken by him to an analyst for analysis or examination.

(2) Where an analyst has made an analysis or examination he may issue a certificate or report setting forth the results of his examination or analysis.

See *Food, Drugs, Cosmetics and Therapeutic Devices Act, 1953*, *supra* note 180, s 23.

²⁵¹ See the discussion of changes to the statute as well as to the *Food and Drug Regulations* in Pugsley, *supra* note 68 at 438-40. Three particularly noteworthy changes are the prohibition of further sales of thalidomide, the authority to make regulations regarding the distribution of drug samples to physicians by manufacturers, and the requirement imposed upon manufacturers to submit not only safety data in respect of new drugs but also “substantial evidence of the clinical effectiveness of the new drug ... under the conditions of use recommended” (*Food and Drug Regulations, amended*, SOR/63-386, s C.08.002(2)(h)). See *An Act to amend the Food and Drugs Act*, SC 1962, c 15. As well, in 1975 the *Proprietary Medicine Act, 1908*, *supra* note 154, was repealed under *An Act to repeal the Proprietary or Patent Medicine Act and to amend the Trade Marks Act*, SC 1975, c 43, s 1.

2. A shift in Canadian patent policy and growing competition from “generics”

The discovery of antibiotics and other new drugs circa the early 1950s, and the attendant high prices of these new drugs, underscored the absence of competition in the drug business. Given the incredible demand, in the abstract, these new drugs should have motivated competition. The ethical manufacturers had, however, come to rely on patents to limit competition in the years since Eli Lilly’s experience with university-controlled insulin production.

Controversy over the high price of many drugs produced by the ethical manufacturers – almost entirely foreign-owned by the 1960s²⁵² – motivated a change in Canada’s patent laws. Though compulsory licensing was allowed under the *Patent Act* as of 1923,²⁵³ not a single application was made for a compulsory license between 1923 and 1949.²⁵⁴ In the face of considerable opposition from the CPMA (by then operating as the “Pharmaceutical Manufacturers Association of Canada” (PMAC)), the *Patent Act* was amended in 1969 to allow importation of patented drugs (as opposed to the previous, more restrictive compulsory licensing mechanism that re-

²⁵² Lexchin, *The Real Pushers*, *supra* note 10 at 33ff.

²⁵³ Scope for compulsory licensing was added to the *Patent Act* following similar changes to patent laws in Great Britain enacted in 1919, restricting patents to “process or products by process, not to the product itself.” Canada, *Report of the Commission of Inquiry on the Pharmaceutical Industry* (Ottawa: Ministry of Supply and Services Canada, 1985) at xxxiv, 1 (Chair: Harry C Eastman) [*Eastman Commission of Inquiry*]; see also *An Act to amend and consolidate the Acts relating to Patents of Invention*, SC 1923, c 23, s 17.

²⁵⁴ Lexchin, *The Real Pushers*, *supra* note 10 at 166, offers the following explanation for the lack of compulsory licenses:

The lack of applications up to this time [i.e. 1949] probably reflected the absence of any drug “winners,” that is drugs which were major advances and which forecast volume sales with record profits. But after 1949, there were significant developments in a number of therapeutic fields – antibiotics, corticosteroids and tranquillizers being three prime examples. However, from 1949 until 1966, there were only 34 applications made, an increase which the Restrictive Trade Practices Commission did not consider significant in light of the potential.

quired manufacturers to make them within Canada's borders).²⁵⁵ Compared to preceding years, a significant spike in compulsory licensing occurred thereafter; by 1983, more than 290 licences had been granted, but genuine competition was limited to a "small part of the drug market" and still largely dominated by foreign-owned companies.²⁵⁶

Regardless of its ultimate impact, the new compulsory licensing regime had immediate regulatory implications and amplified an ongoing dispute about the quality of "generic" drugs relative to the "brand-name" drugs manufactured by the ethical manufacturers. In the 1950s, '60s, and '70s the ethical manufacturers called into question the quality of generic drugs in a variety of ways, for example by distorting the findings of studies comparing the consistency of brand-name and generic versions of a drug with established pharmacopeia standards.²⁵⁷ Illustrating the close ties between the Food and Drug Directorate and industry under his direction, CA Morrell publicly stated that "he personally would always buy a brand-name drug, to ensure that he obtains the quality and efficacy guaranteed by the reputation of a well-known manufacturer."²⁵⁸ With the advent of a workable compulsory licensing mechanism in 1969, the difference in quality – or lack thereof – between brand-names and generics took on heightened significance. The regulatory question became: what evidence would generic manufacturers

²⁵⁵ *An Act to amend the Patent Act, the Trade Marks Act and the Food and Drugs Act*, SC 1969, c 49, ss 1(4), 1(6). It is worth noting that this change in the *Patent Act* in the face of opposition by PMAC has been credited to the civil service. See Lexchin, *The Real Pushers*, *supra* note 10 at 171, citing Ronald W Lang, *The Politics of Drugs: A Comparative Pressure-Group Study of the Canadian Pharmaceutical Manufacturers Association and the Association of the British Pharmaceutical Industry, 1930-1970* (Westmead: Saxon House, 1974) at 246. To the extent this is accurate, it is illustrative of the diversity in views vis-à-vis the pharmaceutical industry that exist across different governmental institutions over time. Whereas Consumer Affairs was institutionally opposed to, or steadfast in the pursuit of policy objectives in the face of criticism from PMAC, the Food and Drug Directorate had a much friendlier relationship with the industry. Indeed, consistent with the industry's goal of precluding the amendments in question, the Directorate appears to have sounded cautions about these amendments to the *Patent Act*. See Lang, *ibid.*, at 244-45ff.

²⁵⁶ Lexchin, *The Real Pushers*, *supra* note 10 at 172-73.

²⁵⁷ *Ibid.* at 65-66.

²⁵⁸ Lang, *supra* note 255 at 189, cited in Lexchin, *The Real Pushers*, *supra* note 10 at 66. Note, however, that Morrell's successor renounced this statement.

have to provide to gain market approval from the Food and Drug Directorate? With patent barriers to market entry removed, the regulator's approach to this evidentiary question would substantially mediate competition between brand-name and generic firms.

It is unclear precisely when the regulator settled its approach but at some point the Directorate determined that generic firms did not need to provide safety and efficacy data *de novo* for drugs already on the market. Rather, the regulator required generics to demonstrate that their products were "bioequivalent" to the previously approved drugs.²⁵⁹ Litigation records reveal that, as late as 1985, the regulator did not allow generics to rely on brand-name product data that had been claimed as confidential by the brand-name manufacturers.²⁶⁰ Yet, the Commission of Inquiry's report of the same year suggests the opposite practice.²⁶¹

While the regulator's approach was in flux, the brand-name firms challenged Canada's shift in patent policy and the attendant regulatory inference that generic drugs were in fact bioequivalent with their own. At first, their strategy consisted of publishing booklets and other materials that impugned the bioequivalence of generics.²⁶² As generic manufacturers became more savvy and started extracting information from the US Food and Drug Administration about brand-name drugs via freedom of information requests (filed pursuant to the US *Freedom of Information Act*, passed in 1966),²⁶³ ethical manufacturers also contested the regulator's practice in more legal terms. Brand-name manufacturers, for instance, claimed that the "product monograph," which is distributed to physicians with the drug, was confidential information and therefore generic manufacturers should not be permit-

²⁵⁹ *Eastman Commission of Inquiry*, *supra* note 253 at 5, 391-92.

²⁶⁰ In the context of an access-to-information dispute, a brand-name company referred to a letter written by a Director of the Bureau of Prescription Drugs under the HPB, in which the Director assures the President of the brand-name company that, based on a memorandum provided by legal services in 1985, information contained in an innovator's product monograph cannot be used by a generic company to demonstrate evidence of the clinical effectiveness of the generic drug. See *Glaxo Canada Inc v Canada (Minister of National Health and Welfare)* (1992), 41 CPR (3d) 176, 52 FTR 39 (FCTD) [*Glaxo Canada*].

²⁶¹ *Eastman Commission of Inquiry*, *supra* note 253 at 5, 391-92.

²⁶² Lexchin, *The Real Pushers*, *supra* note 10 at 67.

²⁶³ 5 USC § 552 (1966).

ted to rely on information within the product monograph in asserting the bioequivalence of their product.²⁶⁴

Thus, the Food and Drug Directorate (soon renamed the Health Protection Branch) became an inflection point in a highly competitive drug production environment. The federal government would later reverse its compulsory licensing policy, partially in 1987, then completely in 1993.²⁶⁵ By that time, however, competition between generic and brand-name companies was fierce, with much of the dispute centring on the norms of confidentiality surrounding data imparted to the regulator. In the final section of Part II of the paper, I detail how the regulator has, in the context of access-to-information disputes, become the mediator between generic and brand-name drug firms. And, in that capacity, advocacy for *public* transparency has been decidedly absent.

3. Absent the public: Adversarialism under the *Access to Information Act* post 1984

Canada was slow to follow other countries in implementing an access-to-information law. Whereas the US passed its freedom-of-information law in 1966, Canada's *Access to Information Act* (*ATI Act*) came into force in 1983.²⁶⁶ The *ATI Act* entitles any person (including companies) to records held by the government *provided* the information therein is not exempt from disclosure pursuant to one or more exemptions in the statute.²⁶⁷ Information

²⁶⁴ See *Cyanamid Canada Inc v Canada (Minister of Health and Welfare)* (1992), 52 FTR 22, 41 CPR (3d) 512 (FCTD) [*Cyanamid Canada* (first instance) cited to FTR], aff'd (1992), 45 CPR (3d) 390, 9 Admin LR (2d) 161, 148 NR 147 (FCA).

²⁶⁵ See *Patent Act Amendment Act, 1992*, SC 1993, c 2 (assented to 4 February 1993). This policy change was part and parcel of a larger shift toward increasingly liberalized world trade, which imposed a number of intellectual property constraints upon signatory nations. For a summary of these various changes, see Blake, Cassels & Graydon – Food and Drug Law Group, “Developments in Canadian Law Relating to Food, Drugs, Devices, and Cosmetics as of December 1992” (1994) 49:2 Food & Drug LJ 323 at 325ff.

²⁶⁶ *Access to Information Act*, RSC 1985, c A-1 [*ATI Act*].

²⁶⁷ The main exemptions under the legislation pertain to “personal information,” “third party information,” and information concerning the “operations of government” (*ibid*, respectively ss 19, 20, 21).

considered to be “trade secrets,” “confidential information,” or information that could result in competitive harm or undermine contractual negotiations of a “third party” (in this case, a brand-name company) are each *prima facie* exempt under the *ATI Act*.²⁶⁸

Undeterred by these exemptions and already practised in seeking brand-name drug information under the US law, generic manufacturers were apparently amongst the first entities to avail themselves of the *ATI Act*.²⁶⁹ In response to generics’ requests, the Health Protection Branch proved willing to disclose a drug’s product monograph or similar information, triggering a spate of judicial review by brand-name manufacturers. Courts dispensed with brand-names’ claims of confidentiality over the product monograph on the ground that they tend to be widely distributed to health care professionals and the information they contain is also available from other sources.²⁷⁰ Over time, the judiciary refined the boundaries of the third party information exemptions and the processes to be followed when processing an access-to-information request, finally culminating in 2012 with the Supreme Court of Canada’s decision in *Merck Frosst Canada v Canada (Minister of Health)*.²⁷¹

²⁶⁸ *Ibid*, ss 20(1)(a)-(d).

²⁶⁹ For example, amongst the first reported decisions under the *ATI Act* was a case concerning a request for the notice of compliance and product monograph for apresuline tablets, marketed by CIBA-Geigy Ltd, a brand-name manufacturer. It is worth noting that the party that made the request to the Health Protection Branch is not named in the body of the court’s decision. See *CIBA-Geigy Canada Ltd v Canada (Minister of National Health and Welfare)* (1986), 11 CPR (3d) 98, 36 ACWS (2d) 358 (FCTD). Indeed, the identity of the information “requestor” is seldom transparent in the case law under the *ATI Act*. Typically, the two parties to the litigation are the brand-name manufacturer (which is the source of the information and purports to have an interest in its not being disclosed) and the Minister of National Health and Welfare. However, as illustrated in some decisions, a generic company or an individual or entity acting on such a company’s behalf is commonly behind the access-to-information request. See e.g. *Glaxo Canada*, *supra* note 260; *AstraZeneca Canada Inc v Health Canada*, 2005 FC 1451, 143 ACWS (3d) 406 [*AstraZeneca*], *aff’d* 2006 FCA 241, 149 ACWS (3d) 766.

²⁷⁰ *Cyanamid Canada Inc v Canada (Minister of National Health and Welfare)* (1992), 45 CPR (3d) 390, 9 Admin LR (2d) 161, 148 NR 147 (FCA), *aff’g* *Cyanamid Canada* (first instance), *supra* note 264; *Glaxo Canada*, *supra* note 260.

²⁷¹ 2012 SCC 3, [2012] 1 SCR 23, 342 DLR (4th) 257 [*Merck Frosst*].

What is remarkable about this body of jurisprudence is not the judiciary's interpretation of the scope of these third party information exemptions,²⁷² but rather the way in which it documents the regulator's established practice of keeping drug safety and efficacy data (that is not part and parcel of the product monograph or otherwise in the public domain) confidential. In early cases where brand-name companies attempted to retain exclusive control over the product monograph or otherwise maintain the confidentiality of certain information, they tendered into evidence letters from regulatory officials that they claimed gave them "assurances of confidentiality."²⁷³ While that manoeuvre failed in Court (in part, because the product monograph was regarded as part of the public domain)²⁷⁴ and some other forms of information have been made available in response to access-to-information requests, the regulator has consistently screened out information about clinical trials from potential disclosure, on the basis of internal "Third Party Information – Operational Guidelines."²⁷⁵ That information is essential to determining a drug's safety and efficacy. Yet, courts have "never squarely considered whether the design and results of clinical trials fall within the [ATI Act's] exemptions related to third-party information because, in several instances, ... [that information] had already been severed from the records [the regulator] chose to disclose."²⁷⁶

²⁷² It is worth noting that the judiciary has, on occasion, placed some useful limitations on the scope of these exemptions. See e.g. *AstraZeneca*, *supra* note 269 ("information which would give insight into how government carries out its approval process is not the type of information which Parliament wished to exempt from disclosure" at para 82). For a discussion of these limitations, see Matthew Herder, "Unlocking Health Canada's Cache of Trade Secrets: Mandatory Disclosure of Clinical Trial Results" (2012) 184:2 Can Med Assoc J 194 at 195-96 [Herder, "Unlocking Health Canada"].

²⁷³ See e.g. *Glaxo Canada*, *supra* note 260 at 183; *Cyanamid Canada* (first instance), *supra* note 264 at 32.

²⁷⁴ *Glaxo Canada*, *supra* note 260 at 185; *Cyanamid Canada* (first instance), *supra* note 264 at 35-36. See also Treasury Board of Canada Secretariat, *Access to Information Manual* (6 June 2014), § 11.14.3, online: TBCS <www.tbs-sct.gc.ca/atip-airpr/tools/atim-maai01-eng.asp#ftnref11-29>.

²⁷⁵ See Herder, "Unlocking Health Canada", *supra* note 272. The "Third Party Information – Operational Guidelines" have been described in several court cases; see e.g. *Merck Frosst*, *supra* note 271 at para 89.

²⁷⁶ Herder, "Unlocking Health Canada", *supra* note 272 at 196.

This pattern outs the structural shortcomings of adversarial disputes over access to information in which the regulator is pitted between brand-name companies and generics. Under section 20(6) of the *ATI Act*,²⁷⁷ the regulator has the authority to disclose third party information (save for trade secrets) where the public interest “clearly outweighs” the commercial harm that such disclosure could occasion. There is, however, no indication that the regulator has ever invoked this public interest override in support of disclosure. As a result, in the context of an access-to-information dispute, no one articulates for the court why the public interest might militate in favour of open access to safety and efficacy data. Entities other than the regulator that are potentially able to articulate such a claim also have not generally sought standing in these sorts of proceedings.²⁷⁸

The absence of such a voice shapes the proceedings. Aware that the majority of access-to-information requests emanate from generic firms eager to tap into a brand-name’s market, courts are likely to have specific harms to a business (rather than to Canadians) foremost in mind. Protecting Canadians is, the court will assume, what the regulator is tasked with. Thus, the underlying norm of the regulatory system – that confidential sharing of information between the regulated industry and regulator serves the public interest – is not critically examined. In the lone case where a private individual (not affiliated with the drug industry or the media) argued for disclosure of safety data pertaining to widely prescribed anti-hypertensive calcium channel

²⁷⁷ *Supra* note 266.

²⁷⁸ I performed a search of the Westlaw database in 2012 for judicial reviews of decisions by Health Canada under the *ATI Act*. Only two cases involving individuals (one of whom was a member of the media) were found. All of the remaining 29 cases involved pharmaceutical companies. Other access-to-information requests have been initiated by members of the medical community and other concerned citizens, but none of these applications have extended to judicial proceedings. See Matthew Herder et al, “Against Vaccine Assay Secrecy” (2015) 11:2 *Hum Vaccin Immunother* 498; Ann Silversides, “Transparency and the Drug Approval Process at Health Canada” (Fall 2005), online: Women and Health Protection <www.whp-apsf.ca/pdf/transparency.pdf>. In *Merck Frosst*, *supra* note 271, the Information Commissioner of Canada sought to apply for intervenor status before the Supreme Court of Canada. But its motion seeking an extension on the time to apply for leave to intervene was denied by Justice Deschamps. Two months prior to that motion, BIOTEC Canada was successful in its motion for intervenor status. See *Merck Frosst*, *supra* note 271, SCC Docket 33320, online: SCC <www.scc-csc.gc.ca/case-dossier/info/dock-regi-eng.aspx?cas=33320>.

blocker drugs on the basis of the public interest override, the Federal Court was highly deferential to the regulator's decision not to disclose.²⁷⁹ There was no substantive engagement by the court with the question of disclosing safety data in the public's interest. The Supreme Court's recent decision in *Merck Frosst* is symbolic of this lack of judicial engagement: Justice Cromwell gestured repeatedly to the public interest override in *obiter*, but did not cite a single example of its application.²⁸⁰

For this structural reason and others (most notably the delays involved),²⁸¹ the *ATI Act* is not a workable mechanism for achieving public transparency. Its exemptions (and Health Canada's reliance on them) instead illustrate that confidentiality has long – since roughly 1920 – been the rule within Canada's regulatory institution with respect to drug safety and effectiveness information.²⁸² In the final section of Part II, I suggest that in order to disrupt these norms and occasion a more participatory, public form of transparency, it may be necessary to redefine drug adulteration under the *Food and Drugs Act*.

F. Epilogue: De-antiquating adulteration

The inception of Canadian regulation was driven by concerns about consumable goods being adulterated, i.e. altered from what they ought to be comprised of, especially food products, but also drugs. Purification was the express goal. Adulteration attracted fines and/or imprisonment. As shown above, however, what each consumable good ought to be comprised of was far from clear at the onset of federal intervention.²⁸³ Thus, as the regulator assumed inspection and enforcement responsibilities, developing standards to inspect against was a pressing matter. Transparency, or, to use the term of that time, publicity, seems to have served that purpose. Even after basic standards were incorporated into the *Adulteration Act* in 1884, the findings of inspectors and analysts were left open to outside scrutiny through the Chief

²⁷⁹ *Rubin v Canada (Minister of Health)*, 2001 FCT 929 at para 54, 14 CPR (4th), aff'd 2003 FCA 37, 23 CPR (4th) 312, 238 FTR 159.

²⁸⁰ *Supra* note 271 at paras 75, 81, 97, 106.

²⁸¹ See Herder, "Unlocking Health Canada", *supra* note 272 at 197.

²⁸² *Ibid* at 197ff.

²⁸³ See Part II.B, above.

Analyst's annual reports to Parliament and the publication of hundreds of voluminous bulletins. Bulletins published by the Department of Inland Revenue seemingly became benchmarks for manufacturers and interested publics – from consuming citizens to fellow regulators abroad and laboratory scientists – to read, employ, and critically engage with. Print media played an important mediating role, regularly covering the Department's findings and publishing responses from affected industries.²⁸⁴ Further research is required to map this complex dialogue, including all of the actors and interests involved and the evolution of the standards that the regulator in turn applied to drugs. The fundamental point for my purposes is that the regulator's publicity practices helped to fill a critical void: the standards to be applied to evaluate potential drug adulteration. In the process, the regulator gained legitimacy, which it was frequently failing to achieve through prosecutions of alleged violations of the statute in court.²⁸⁵

Over time the legislation's adulteration provisions diminished in relevance as drugs were standardized and, according to regulatory officials, commanded manufacturer adherence.²⁸⁶ New provisions were added to the *Adulteration Act* and *Food and Drugs Act* to capture manufacturers' false claims about a drug's therapeutic properties (e.g. via false labelling) and other promotional tactics. Each statutory incarnation remained geared towards limiting consumer deception – “drug fraud,” broadly understood – about what a drug was, what it could promise to achieve, and its potential harms. (See the Appendix for a summary of these changes in the scope of drug fraud under Canada's early drug laws as compared to current legislation.) But these new provisions focused, almost exclusively,²⁸⁷ on consumer

²⁸⁴ Davidson, *supra* note 68 at 23, 27. For examples of media coverage, see “Sweetness long drawn out”, *Toronto Daily Star* (14 September 1906) 8; “Figures that tell stories: Canada drinks good coffee”, *Toronto Daily Star* (22 November 1910) 8.

²⁸⁵ Davidson, *supra* note 68 at 23.

²⁸⁶ See RE Curran, “Revision of Canadian Food and Drugs Act” (1952) 7:11 Food Drug Cosmet Law J 711 at 714-15ff.

²⁸⁷ Until the *Food and Drugs Act* was amended in 2014 (as discussed below), the main exceptions to this focus on deception during the post-market period related to making false or misleading statements about a clinical trial or to an inspector more generally, which could extend to clinical trial site inspections. See, respectively, *Food and Drug Regulations*, *supra* note 50, ss C.05.016(1) (b), C.08.018(2); *Food and Drugs Act*, RSC 1985, c F-27, s 24(1) [*Food and Drugs Act* (current)]. However, the extent to which the regulator has availed

deception in respect of drugs approved for sale on the market.²⁸⁸ Indeed, *post-market* regulation of drug fraud remains part and parcel of the regulator's mandate to this day.²⁸⁹

The onset of *pre-market* drug regulation (first under the *Proprietary Medicine Act* and subsequently under the *Food and Drugs Act*) introduced a different frame. Instead of scrutinizing drug production for potential fraud, the regulator's task was to screen for substantial evidence of a drug's safety and efficacy, i.e. to assess a drug's risks versus benefits, based on data provided by manufacturers (as opposed to drug samples and data generated by the regulator in the course of post-market inspections for suspected adulteration). Emphasis upon pre-market risk-benefit assessment grew dramatically in the wake of the thalidomide crisis – a burden the regulator bore while claiming an increasingly cooperative, confidential relationship with manufacturers.

itself of these provisions is not publicly known.

²⁸⁸ For example, the current *Food and Drugs Act* prohibits false labelling and advertising in respect of a drug. See *ibid*, s 9. As well, the regulator has taken steps to facilitate the communication of adverse drug events to health care providers and patients through its *MedEffect Canada* website. This activity is not construed as policing drug fraud, but rather as communicating drug safety information to consumers in a timely fashion. See Health Canada, "Drugs and Health Products: MedEffect Canada", online: HC <www.hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>. It is worth noting that bulletins published under Canada's early food and drug laws may appear broadly similar in function to the *MedEffect Canada* website. However, as discussed above, those bulletins served not only to inform, but also to *develop*, standards applicable to drugs. The *MedEffect Canada* website, in contrast, is designed solely to inform health care providers and patients about adverse events.

²⁸⁹ Although direct-to-consumer advertising is prohibited for prescription-only drugs in Canada, the regulator has exempted certain types of advertisements from that prohibition and delegated "actual review of ads for compliance with regulatory requirements" to "private or other agencies": Colleen M Flood, "The Evidentiary Burden for Overturning Government's Choice of Regulatory Instrument: The Case of Direct-to-Consumer Advertising of Prescription Drugs" (2010) 60:2 UTLJ 397 at 400-01. For analysis and criticism of this state of affairs, see David M Gardner, Barbara Mintzes & Aleck Ostry, "Direct-to-Consumer Prescription Drug Advertising in Canada: Permission by Default?" (2003) 169:5 Can Med Assoc J 425; Barbara Mintzes, Steve Morgan & James M Wright, "Twelve Years' Experience with Direct-to-Consumer Advertising of Prescription Drugs in Canada: A Cautionary Tale" (2009) 4:5 PLoS One e5699.

More than half a century later, the limitations of that closed model of predominantly pre-market regulation are plain. Having cultivated a relationship of “mutual dependence” with industry,²⁹⁰ the regulator has compromised its ability to act swiftly and effectively to ensure patient safety, as evidenced by, *inter alia*, delays in drug withdrawals and disclosure of adverse events.²⁹¹ The Canadian regulator also faces considerable resource challenges,²⁹² limiting the regulator’s capacity to critically assess the summary data provided by manufacturers. The increasing focus upon orphan drugs, personalized medicines, and alternative clinical research designs²⁹³ noted in Part I of this paper is likely to exacerbate these resource challenges as new targeted therapies test the limits of established regulatory standards of safety and effectiveness. Finally, manufacturers have developed increasingly sophisticated methods of skewing the evidence in respect of a drug in their favour in order to secure regulatory approval. Apart from burying negative findings, these methods include using “multiple endpoints in [a clinical trial] and select[ing] ... those that give favourable results,” carrying out “multicentre trials and select[ing] ... results from centres that are favourable,” and “conduct[ing] subgroup analyses and select[ing] ... those that are favourable.”²⁹⁴ The regulator, like systems of peer review,²⁹⁵ is unlikely to discover these methods because it is difficult, time-consuming work

²⁹⁰ Wiktorowicz, *supra* note 6 at 629.

²⁹¹ See Matthew Herder et al, “Regulating Prescription Drugs for Patient Safety: Does Bill C-17 Go Far Enough?” (2014) 186:8 Can Med Assoc J E287.

²⁹² See Wiktorowicz, *supra* note 6 at 643-44, 650 (describing the resources of Health Canada’s Therapeutic Products Division as “moderate” and linking that level of resources to the interdependent relationship that the regulator has formed with industry); Mary E Wiktorowicz et al, *Keeping an Eye on Prescription Drugs, Keeping Canadians Safe: Active Monitoring Systems for Drug Safety and Effectiveness in Canada and Internationally* (Toronto: Health Council of Canada, 2010) at 13-14, online: Government of Canada Publications <http://publications.gc.ca/collections/collection_2011/ccs-hcc/H174-21-2010-eng.pdf>. See also *supra* note 19 and accompanying text.

²⁹³ See Marc Dunoyer, “Accelerating Access to Treatments for Rare Diseases” (2011) 10:7 Nat Rev Drug Discov 475; David J Stewart, Simon N Whitney & Razelle Kurzrock, “Equipoise Lost: Ethics, Costs, and the Regulation of Cancer Clinical Research” (2010) 28:17 J Clin Oncol 2925.

²⁹⁴ Richard Smith, “Medical Journals Are an Extension of the Marketing Arm of Pharmaceutical Companies” (2005) 2:5 PLoS Med 0364 at 0365.

²⁹⁵ *Ibid.*

and often contingent upon having access to the raw individual patient-level data, which manufacturers carefully guard despite corporate commitments to transparency.²⁹⁶ The Canadian regulator typically only holds summaries of the raw data in the form of “clinical study reports.”²⁹⁷ Yet, these methods that manufacturers employ to ensure that a study’s results will be favourable by its very design effectively render the distinction between research and marketing – or, pre-market and post-market regulation – meaningless. Deception or drug fraud now transcends both.

To counter these methods and related concerns, drug regulation needs to be critically enhanced. In late 2014, Canada’s regulator secured a variety of new statutory powers, including the power to unilaterally recall drugs for reasons of patient safety and enforce conditions attached to a drug’s market authorization as well as giving the Minister of Health the discretion to disclose drug information.²⁹⁸ As well, a broad new penalty for “knowingly” making a “false or misleading statement to the Minister” or “providing him or her with false or misleading information ... in connection with any matter ... concerning a therapeutic product” was added to the legislation.²⁹⁹ These new powers and penalties are significant and welcome, particularly insofar as they assist the regulator in discharging its post-market mandate.³⁰⁰ However, in my view these amendments to the *Food and Drugs Act* inadequately address the transcendent quality of drug fraud today. The transparency-related amendments subscribe to the disclosure function of transparency, largely on a discretionary basis.³⁰¹ Given the intimacy of the regulatory in-

²⁹⁶ See e.g. Peter Doshi, “Putting GlaxoSmithKline to the Test over Paroxetine” (2013) 347:7933 *Brit Med J* f6754 at 2-3.

²⁹⁷ See Doshi, Jefferson & Del Mar, *supra* note 1, for a description of what clinical study reports encompass.

²⁹⁸ See *An Act to amend the Food and Drugs Act*, 2nd Sess, 41st Parl, 2014, ss 3-4 (assented to 6 November 2014), SC 2014, c 24 [*Food and Drugs Act, 2014*].

²⁹⁹ *Food and Drugs Act* (current), *supra* note 287, s 21.6, as amended by *Food and Drugs Act, 2014*, *supra* note 298, s 3.

³⁰⁰ Herder et al, *supra* note 291.

³⁰¹ See *Food and Drugs Act* (current), *supra* note 287, ss 21.1(2)-(3), as amended by *Food and Drugs Act, 2014*, *supra* note 298, s 3. For an analysis of the transparency provisions of the new amendments, see Matthew Herder, “The Opacity of Bill C-17’s Transparency Amendments” (23 June 2014), *Impact Ethics* (blog), online: <<http://impactethics.ca/2014/06/23/the-opacity-of-bill-c-17s-transparency-amendments/>>.

stitution with drug manufacturers, Canadian drug regulation would be better served by amendments that made transparency mandatory and directly tied such transparency obligations to a revitalized concept of drug fraud. The new penalty for providing false or misleading information extends, on its face, to both the pre-market and post-market phases of drug R&D. But the provision's focus on "false or misleading" statements or information is substantially similar to pre-existing provisions in the legislation,³⁰² and it is not clear whether such wording is broad enough to motivate the standard-setting exercise I envision. More importantly perhaps, there is no indication that the new transparency powers are intended to assist the regulator in detecting instances of potential fraud, much less how that will occur in practice.³⁰³ These recent amendments to the *Food and Drugs Act* may therefore mark a missed opportunity to enable others,³⁰⁴ outside the regulatory institution, to take up the task of constructing and enforcing new standards of drug fraud.

The history of Canadian drug regulation teaches us that not knowing what drug fraud looks like in exact terms should not be a bar to regulation. Originally, the regulator had no standards to apply for determining drug adulteration. This lack of standards compelled regulatory transparency. What does fraud in drug R&D today look like? The above examples of methods used by manufacturers to tip the design of clinical trials in their favour offer a starting point. There is also a burgeoning literature regarding scientific fraud.³⁰⁵ Its focus is on outright manipulation or falsification of

³⁰² See *supra* note 287 and references therein.

³⁰³ In a sense this lack of detail is typical. Specific details about how legislative provisions are to be operationalized are more likely to be located in regulations or institutional policies and guidelines. Nevertheless, it is noteworthy that Health Canada did not, at any stage during the legislative process, indicate that the transparency-related provisions in the proposed law were intended to help detect, deter, or prosecute potential instances of drug fraud.

³⁰⁴ Specifically, as I have argued elsewhere, I think this should require mandatory disclosure of all clinical study reports and anonymized patient-level data upon request, as well as all regulatory decisions of drugs, whether positive (i.e., drug approvals) or negative (i.e., drug refusals, abandoned drugs, and withdrawn drugs) in nature. See, respectively, Herder, "Government Regulators", *supra* note 33; Herder, "Toward a Jurisprudence", *supra* note 4.

³⁰⁵ For an introduction into that cognate literature and a meta-analysis of the existing empirical evidence up to 2009, see Daniele Fanelli, "How Many Scientists Fabricate and Falsify Research? A Systematic Review and Meta-Analysis of Survey Data" (2009) 4:5 PLoS ONE e5738.

scientific data. Is that a sufficient definition? Or should it extend to research findings that have not and cannot be replicated? What about conflicts of interest amongst researchers? What work, if any, should such conflicts play in assessments for potential fraud? Not knowing the answer *a priori* to some or all of these sub-questions regarding the scope of drug fraud maps onto the history of publicizing suspected instances of drug adulteration – that approach was not simply to deter adulteration, but also to determine what it was, in dialogue with interested publics. Transparency, so understood as a means of determining what constitutes fraud in drug R&D and enlisting outsiders to help actively screen for it, holds more promise than transparency as (discretionary) disclosure *per se*. And it is needed now precisely because of the closed relationship that has evolved between the regulator and manufacturers. Independent researchers and civil society have played critical roles in discovering recent cases of what I would term drug fraud.³⁰⁶ Tying transparency to a revised prohibition on drug R&D fraud could invite more of that work, and encourage others to participate in it.³⁰⁷

Many important legal and pragmatic questions inevitably remain. First, is it possible to enshrine in law an open-ended concept of fraud, given legal restrictions against laws that are unduly vague?³⁰⁸ If not, can the regulator,

³⁰⁶ Lemmens & Telfer, *supra* note 27 at 92-94; Lemmens, *supra* note 65 at 164-65.

³⁰⁷ Interestingly, despite the explosion of literature in recent years on “participatory governance” or “collaborative governance,” I was unable to find an article in that literature focused on the drug regulation context. Key works in that literature include Archon Fung & Rebecca Abers, *Deepening Democracy: Institutional Innovations in Empowered Participatory Governance* (New York: Verso, 2003) and Archon Fung & Erik Olin Wright, “Deepening Democracy: Innovations in Empowered Participatory Governance” (2001) 29:1 *Politics & Society* 5. My working assumption is that this stems from the confidential nature of regulator-industry interaction. As I have discussed elsewhere, regulators frequently use “advisory committees” in their decision-making processes. However, I would not characterize such committees as a form of the participatory governance that I think is needed, because of the close alignment of interests between the supposed outsiders who tend to serve on these committees and the manufacturers whose drugs are under consideration. See Herder, “Toward a Jurisprudence”, *supra* note 4. The participatory, public form of transparency that I envisage here assumes a greater degree of disinterestedness on the part of the publics that I think need to be involved.

³⁰⁸ It is a principle of fundamental justice that laws that carry imprisonment as a penalty cannot be too vague, thus section 7 of the *Charter of Rights and Freedoms* potentially constrains the enactment of a provision that leaves open the

through its institutional practices, nevertheless accommodate an open-ended discussion about what ought to be considered drug fraud for the purpose of engaging outside actors in the regulatory process? Second, the willingness of outside actors, particularly independent researchers, to become involved in the project of constructing and enforcing newly developed standards of drug fraud should not be automatically assumed. As noted above, some independent researchers are already engaged and have made critical contributions to what is known about a given drug's safety and efficacy. But the question remains: will that activity scale up to the extent necessary? Do we need to encourage more independent scrutiny and, if so, how? If we rely on traditional tools such as government grants to support that work, how should we choose who those grants should go to? What trade-offs do such traditional mechanisms carry? Third, how should the work of those outside and inside regulatory institutions be intertwined? Timing is a critical issue. Most of the contemporary transparency initiatives surrounding clinical trial data (apart from registration, which is supposed to occur prospectively) require that results be reported, or patient-level data made available, *ex post facto*. If outside participation is to meaningfully inform regulatory decision making, however, earlier access may be needed. Other procedural questions also need to be answered. Can – and if so, how will – manufacturers be allowed to contest any independent analyses of data they provide to the regulator? What weight should an independent analysis of a dataset be given by the regulator? There is also considerable debate in the transparency literature regarding how best to protect research participants' privacy and ensure that choices made about knowledge sharing during the informed consent process are respected.³⁰⁹ In my view, it is likely impossible to fully guarantee anonymity when sharing clinical data. Yet, researchers and companies routinely share clinical data during drug R&D despite the privacy risks. I therefore see no principled reasons why participants would not be willing to tolerate the same kinds of risks for the purposes of independent scrutiny. Even so, designing and implementing procedures that address these privacy and other ethical concerns remains necessary.

definition of fraud. Vagueness can also arise under section 1 of the *Charter* or as a general rule of law. For a discussion of these general principles, see e.g. *R v Nova Scotia Pharmaceutical Society*, [1992] 2 SCR 606, 93 DLR (4th) 36.

³⁰⁹ Compare Doshi, Jefferson & Del Mar, *supra* note 1, with Eichler et al, "Open Clinical Trial Data", *supra* note 30.

Each of these sets of questions requires greater analysis. I have proposed the basic idea here in light of the history of Canadian drug regulation that I have sketched. On my account, transparency figured importantly in that history not only because of its deterrence-by-disclosure capability, but moreover because of the role transparency played in inviting others to be active in the project of drug regulation. Transparency was tempered in time – it disappeared, really – as the regulator began to value a cooperative relationship with industry, the model of regulation shifted towards pre-market evaluations of drug safety and efficacy, R&D became more complex, norms of confidentiality took hold, intellectual property rights proliferated, and the medical profession – once a vocal critic of secrecy – sat quiet. Perhaps a revised conception of drug fraud, recast with publicity's past purpose in mind, can throw open the work of regulatory institutions, disrupt current norms, and push transparency's promise.

CONCLUSION: TRANSPARENCY *REDUX*?

In this paper I have sought to “denaturalize” the understanding of transparency as information disclosure that pervades contemporary policy initiatives in the pharmaceutical policy arena. Through an analysis of the historical evolution of Canadian drug regulation, I have shown that transparency can also serve an important standard-setting purpose and I have argued that such an understanding of transparency should be renewed, given the closed, confidential relationship that has developed between Canada's regulatory institution and drug manufacturers, the deceptive industry practices known to be used in drug R&D, the increasing complexity of pharmaceutical interventions such as orphan drugs and personalized medicines, and norm changes in the medical profession. I have suggested that tying transparency to a revised conception of drug fraud has the potential to motivate a more participatory, public model of drug regulation that appears to have existed under Canada's first federal food and drug laws, yet eroded over time.

In fact, however, the paper's call to denaturalize transparency is misleading. Transparency has no natural state; rather, as shown by my analysis, it is socially constructed, capable of multiple meanings, and subject to change over time. That makes the concept worth holding on to, but its value will always depend on the actors involved in making transparency happen. Through a robust practice of publicizing its analytical work, Canada's drug regulator once helped to ensure public engagement in regulation; in time, as the regulator constituted a closer relationship with the industry, that mode of

public, potentially participatory transparency fell away. My novel contribution to the literature on transparency in pharmaceutical drug regulation has been to suggest that tying transparency to a revitalized conception of drug fraud could recast transparency in its historical, standard-constructing role, reinvigorating those inside the regulatory institution and welcoming others on the outside to play a stronger regulatory role.

APPENDIX.

KEY CHANGES IN THE HISTORICAL EVOLUTION OF DRUG FRAUD AND RELATED ACTIVITY, 1874-1953 VERSUS THE PRESENT.

Legislation	Type of Drug Fraud Added to Legislation	Corresponding Provision(s)
<i>Inland Revenue Act, 1874</i> <i>(An Act to impose License Duties on Compounders of Spirits; and to amend the "Act Respecting Inland Revenue" and to prevent the Adulteration of Food, Drink and Drugs, SC 1874, c 8)</i>	Adulteration	22. ... [E]very person who shall wilfully admix and every person who shall order any other person to admix any ingredient or material with any drug to adulterate the same for sale, shall, for the first offence, forfeit and pay a penalty of one hundred dollars, together with the costs attending the conviction, and for the second offence shall be guilty of a misdemeanor, and be imprisoned for a period not exceeding six calendar months with hard labor.
	Sale of adulterated articles	<p>23. Every person who shall sell or offer for sale any article of food or drink with which, to the knowledge of such person, any deleterious ingredient or material injurious to the health of persons eating or drinking such article has been mixed, and every person who shall sell as unadulterated any article of food or drink or any article commonly used in the preparation of food or drink or any drug which is adulterated, shall, for every such offence, on conviction of the same, pay a penalty of one hundred dollars, together with the costs attending such conviction; and if any person so convicted shall afterwards commit a like offence, he shall pay a penalty of two hundred dollars, and in either case the adulterated articles shall be seized as forfeited to the Crown.</p> <p>24. Any person who shall sell any article of food or drink or any drug, knowing the same to have been mixed with any other substance with intent fraudulently to increase its weight or bulk, and who shall not declare such admixture to any purchaser thereof before delivering the same, and no other, shall be deemed to have sold an adulterated ... drug ... under this Act.</p>

Appendix, continued

Legislation	Type of Drug Fraud Added to Legislation	Corresponding Provision(s)
<i>Adulteration Act, 1884</i> (An Act to amend and to consolidate as amended the several Acts respecting the Adulteration of Food and Drugs, SC 1884, c 34)	Adulteration injurious to health	26. Every person who wilfully adulterates any article of food or any drug, or orders any other person so to do, shall, on conviction, – (a) If such adulteration is deemed to be, within the meaning of this Act, injurious to health, for the first offence incur a penalty not exceeding fifty dollars or less than ten dollars together with the costs of conviction, and for each subsequent offence a penalty of not less than fifty dollars and not exceeding two hundred dollars, together with the costs of conviction.
	Adulteration not injurious to health	26. (b) If such adulteration is deemed not to be injurious to health, incur a penalty not exceeding thirty dollars, together with the costs of conviction, and for each subsequent offence a penalty not exceeding one hundred dollars and not less than fifty dollars together with the costs of conviction.
	Sale of adulterated articles that are injurious to health	27. Every person who by himself or his agent sells, offers for sale, or exposes for sale any article of food or any drug, found to be adulterated within the meaning of this Act, shall, on conviction, – (a) If such adulteration is deemed to be within the meaning of this Act injurious to health, for a first offence incur a penalty not exceeding fifty dollars, together with the costs of the conviction, and for each subsequent offence a penalty of not less than fifty or more than two hundred dollars, together with the costs of the conviction;
	Sale of adulterated articles that are not injurious to health	27. (b) If such adulteration is not deemed to be within the meaning of this Act injurious to health, incur for each such offence, a penalty of not less than five or more than fifty dollars, together with the costs of the conviction.

Appendix, continued

Legislation	Type of Drug Fraud Added to Legislation	Corresponding Provision(s)
<i>Adulteration Act, 1885</i> <i>(An Act respecting the Adulteration of Food, Drugs and Agricultural Fertilizers, SC 1885, c 67)</i>	False labelling	25. Every person who knowingly attaches to any article of food, or any drug, any label which falsely describes the article sold, or offered or exposed for sale, shall incur a penalty not exceeding one hundred dollars and not less than twenty dollars, with costs.
<i>Proprietary Medicine Act, 1908</i> <i>(An Act respecting Proprietary or Patent Medicines, SC 1908, c 56)</i>	False labelling	7. No proprietary or patent medicine shall be manufactured, imported, exposed, sold or offered for sale – ... (c) if it contains any drug which is included in the schedule to this Act but the name of which is not conspicuously printed on, and an inseparable part of, the label and wrapper of the bottle, box or other container ... [unless the manufacturer, etc.] transmit[s] to the Minister an affidavit specifying such drug and the proportion of it contained in the mixture and dose and ... it appears to the Minister that the proportion of the drug used is not dangerous to health.
<i>Proprietary Medicine Act, 1919</i> <i>(An Act to amend The Proprietary or Patent Medicine Act, SC 1919, c 66)</i>	False statements to the Minister	3. (2) Such manufacturer or agent shall, at the time of applying for the said certificate of registration, for any medicine containing any of the drugs mentioned in or added to the Schedule to this Act, furnish the Minister with a statement under oath of the quantity of such drug or drugs contained in such medicine, which statement shall be filed in the department, and shall be treated as confidential. Any person furnishing the Minister with a statement that is incorrect or false shall ... be liable for making a false or incorrect statement upon oath, [and] be liable to a penalty not exceeding one hundred dollars and costs or to imprisonment for any term not exceeding two months, and the Minister shall have power to cancel any certificate of registration that the Minister may have granted for the medicine described in such statement.

Appendix, continued

Legislation	Type of Drug Fraud Added to Legislation	Corresponding Provision(s)
<i>Proprietary Medicine Act, 1919</i> (cont'd)	False labelling as to drug amount	7. (1) No proprietary or patent medicine shall be manufactured, imported, exposed or offered for sale or sold in Canada, – ... (c) if it contains any drug which is included in the Schedule to this At the name of which and the amount per dose of which are not conspicuously printed on an inseparable part of the label and wrapper of the bottle, box or other container, or if the quantity of such drug exceeds the amount permitted by the Advisory Board;
	False labelling as to drug name	7. (1) No proprietary or patent medicine shall be manufactured, imported, exposed or offered for sale or sold in Canada, – ... (d) if it contains any drug which is included in the Schedule to this Act and the name of such drug as used on the label be not the commonly employed name of such drug;
	False advertising as a cure	7. (1) No proprietary or patent medicine shall be manufactured, imported, exposed or offered for sale or sold in Canada, – ... (e) if the article be represented as a cure for any disease;
	False advertising by exaggerated claims	7. (1) No proprietary or patent medicine shall be manufactured, imported, exposed or offered for sale or sold in Canada, – ... (f) if any false, misleading or exaggerated claims be made on the wrapper or label, or in any advertisement of the article.

Appendix, continued

Legislation	Type of Drug Fraud Added to Legislation	Corresponding Provision(s)
<i>Adulteration Act, 1915</i> <i>(An Act to amend the Adulteration Act, SC 1915, c 9)</i>	False labelling or neglect to label	37. Every person who knowingly attaches to any article of food or any drug any label which falsely describes the article sold, or offered or exposed for sale, or who neglects or refuses to label or mark any article of food or drug in accordance with the requirements of this Act, shall incur a penalty for the first offence not exceeding two hundred dollars and not less than twenty-five dollars, or two months in jail, or both, and for each subsequent offence a penalty not exceeding three hundred dollars and not less than fifty dollars, or four months in jail, or both....
<i>Food and Drugs Act, 1920</i> <i>(Food and Drugs Act, SC 1920, c 27)</i>	Sale of adulterated or misbranded articles that are injurious to health	16. (1) Every person who by himself or his agent or employee manufactures for sale, sells, offers for sale or exposes for sale, any article of food or any drug which is adulterated or misbranded, shall be guilty of an offence, and, – (a) if such adulteration is deemed to be injurious to health within the meaning of this Act, shall for a first offence be liable upon summary conviction to a fine not exceeding two hundred dollars and costs, and not less than fifty dollars and costs, or to imprisonment for any term not exceeding three months, or to both fine and imprisonment, and for each subsequent offence to a fine not exceeding five hundred dollars and costs and not less than fifty dollars and costs, or to imprisonment for any term not exceeding six months, or to both fine and imprisonment....
	Sale of adulterated or misbranded articles that are not injurious to health	16. (1) Every person who by himself or his agent or employee manufactures for sale, sells, offers for sale or exposes for sale, any article of food or any drug which is adulterated or misbranded, shall be guilty of an offence, and, – ... (b) if such adulteration is not deemed to be injurious to health within the meaning of this Act,

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Legislation	Type of Drug Fraud Added to Legislation	Corresponding Provision(s)
<i>Food and Drugs Act, 1920</i> (cont'd)		or if the article is misbranded, shall for a first offence be liable upon summary conviction to a fine not exceeding one hundred dollars and costs and not less than twenty-five dollars and costs, or to imprisonment for any term not exceeding three months, and for each subsequent offence to a fine not exceeding two hundred dollars and costs and not less than fifty dollars and costs, or to imprisonment for any term not exceeding six months, or to both fine and imprisonment.
	Refusal of access	20. If after being requested to do so by an inspector or any person who has in his possession or under his control any food or drug refuses or omits to show the inspector the place in which such articles are stored, or refuses or fails to admit the inspector into every such place, or refuses or omits to show the inspector all or any of such articles in his possession, or to permit the inspector to inspect the same, or to give any sample thereof, or to furnish the inspector with any light or assistance he requires for any of such purposes, he shall be guilty of an offence, and shall be liable, upon summary conviction, to a fine not exceeding two hundred dollars and costs, and not less than fifty dollars and costs, or to imprisonment for any term not exceeding three months, or to both fine and imprisonment.
	Possession of materials by manufacturer usable for adulteration	21. Any material found in possession of a manufacturer of food or drugs, or in any of the premises occupied by him as such, and being apparently of a kind which might be employed for purposes of adulteration and for the possession of which he is unable to account to the satisfaction of an inspector, may be seized by such inspector and a sample of such material submitted for identification to a Dominion analyst. Should the Dominion analyst's certificate prove the material to be of such a kind as might be used for purposes of adulteration,

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Legislation	Type of Drug Fraud Added to Legislation	Corresponding Provision(s)
<i>Food and Drugs Act, 1920</i> (cont'd)		the manufacturer shall be deemed wilfully to have exposed for sale adulterated food or drugs, and shall be liable, upon summary conviction, for a first offence, to a fine not exceeding two hundred dollars and costs, and not less than fifty dollars and costs, or to imprisonment for any term not exceeding three months, or to both fine and imprisonment, and for each subsequent offence to a fine not exceeding five hundred dollars and costs and not less than one hundred dollars and costs, or to imprisonment for any term not exceeding six months, or to both fine and imprisonment, and the material in question shall be forfeited to His Majesty, and may be disposed of as the minister may direct.
<i>Food and Drugs Act (RSC 1952)</i> <i>(An Act respecting Food and Drugs Act, RSC 1952, c 123)</i>	Distribution of samples	34. No person shall distribute, cause or permit to be distributed from door to door or in a public place or on a public highway or through the mail, any sample of any drug, but this section does not prevent manufacturers or wholesale dealers from distributing samples by mail or otherwise in compliance with individual requests for them, or from distributing samples to physicians, veterinary surgeons, dentists, registered nurses, hospitals, or to retail druggists for individual redistribution to adults only.
<i>Food, Drugs, Cosmetics and Therapeutic Devices Act, 1953</i> <i>(An Act respecting Food, Drugs, Cosmetics and Therapeutic Devices, SC 1953, c 38)</i>	Advertising or sale as treatment for certain diseases <i>(replacing misbranding)</i>	3. (1) No person shall advertise any food, drug, cosmetic or device to the general public as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states mentioned in Schedule A. (2) No person shall sell any food, drug, cosmetic or device (a) that is represented by label, or (b) that he advertises to the general public as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states mentioned in Schedule A.

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Legislation	Type of Drug Fraud Added to Legislation	Corresponding Provision(s)
<i>Food, Drugs, Cosmetics and Therapeutic Devices Act, 1953</i> (cont'd)	Sale of unsanitary or adulterated drugs	8. No person shall sell any drug that (a) was manufactured, prepared, preserved, packed or stored under unsanitary conditions; or (b) is adulterated.
	False labelling or advertising	9. (1) No person shall label, package, treat, process, sell or advertise any drug in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety. (2) A drug that is not labelled or packaged as required by the regulations, or is labelled or packaged contrary to the regulations, shall be deemed to be labelled or packaged contrary to subsection (1).
	Non-compliance with drug standards	10. (1) Where a standard has been prescribed for a drug, no person shall label, package, sell or advertise any substance in such a manner that is likely to be mistaken for such drug, unless the substance complies with the prescribed standard. (2) Where a standard has not been prescribed for a drug, but a standard for the drug is contained in any publication mentioned in Schedule B, no person shall label, package, sell or advertise any substance in such a manner that it is likely to be mistaken for such drug, unless the substance complies with such standard. (3) Where a standard for a drug has not been prescribed and no standard for the drug is contained in any publication mentioned in Schedule B, no person shall sell such drug unless (a) it is in accordance with the professed standard under which it is sold, and (b) it does not resemble, in a manner likely to deceive, any drug for which a standard has been prescribed or is contained in any publication mentioned in Schedule B.

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Legislation	Type of Drug Fraud Added to Legislation	Corresponding Provision(s)
<i>Food, Drugs, Cosmetics and Therapeutic Devices Act, 1953</i> (cont'd)	Manufacture under unsanitary or unsafe conditions	11. No person shall manufacture, prepare, preserve, package or store for sale any drug under unsanitary conditions. 12. No person shall sell any drug described in Schedule C or D unless the Minister has, in prescribed form an manner, indicated that the premises in which the drug was manufactured and the process and conditions of manufacture therein are suitable to ensure that the drug will not be unsafe for use. 13. No person shall sell any drug described in Schedule E unless the Minister has, in prescribed form and manner, indicated that the batch from which the drug was taken is not unsafe for use.
	Distribution of samples	14. (1) No person shall distribute or cause to be distributed any drug as a sample. (2) Subsection (1) does not apply to the distribution of samples of drugs by mail or otherwise to physicians, dentists or veterinary surgeons or to the distribution of drugs, other than those mentioned in Schedule F, to registered pharmacists for individual redistribution to adults only or to a distributor in compliance with individual requests.
<i>Food and Drugs Act (current)</i> <i>(Food and Drugs Act, RSC 1985, c F-27)</i>	Sale of unsanitary or adulterated drugs	8. No person shall sell any drug that (a) was manufactured, prepared, preserved, packaged or stored under unsanitary conditions; or (b) is adulterated.
	False labelling or advertising	9. (1) No person shall label, package, treat, process, sell or advertise any drug in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.

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Legislation	Type of Drug Fraud Added to Legislation	Corresponding Provision(s)
<i>Food and Drugs Act</i> (current) (cont'd)	Non-compliance with drug standards	<p>10. (1) Where a standard has been prescribed for a drug, no person shall label, package, sell or advertise any substance in such a manner that it is likely to be mistaken for that drug, unless the substance complies with the prescribed standard.</p> <p>(2) Where a standard has not been prescribed for a drug, but a standard for the drug is contained in any publication referred to in Schedule B, no person shall label, package, sell or advertise any substance in such a manner that it is likely to be mistaken for that drug, unless the substance complies with the standard.</p> <p>(3) Where a standard for a drug has not been prescribed and no standard for the drug is contained in any publication referred to in Schedule B, no person shall sell the drug unless</p> <p style="padding-left: 40px;">(a) it is in accordance with the professed standard under which it is sold; and</p> <p style="padding-left: 40px;">(b) it does not resemble, in a manner likely to deceive, any drug for which a standard has been prescribed or is contained in any publication referred to in Schedule B.</p>
	Manufacture under unsanitary or unsafe conditions	<p>11. No person shall manufacture, prepare, preserve, package or store for sale any drug under unsanitary conditions.</p> <p>12. No person shall sell any drug described in Schedule C or D unless the Minister has, in prescribed form and manner, indicated that the premises in which the drug was manufactured and the process and conditions of manufacture therein are suitable to ensure that the drug will not be unsafe for use.</p> <p>13. No person shall sell any drug described in Schedule E unless the Minister has, in prescribed form and manner, indicated that the batch from which the drug was taken is not unsafe for use.</p>
	Distribution of samples	14. (1) No person shall distribute or cause to be distributed any drug as a sample.

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Legislation	Type of Drug Fraud Added to Legislation	Corresponding Provision(s)
<i>Food and Drugs Act</i> (current) (cont'd)		(2) Subsection (1) does not apply to the distribution, under prescribed conditions, of samples of drugs to physicians, dentists, veterinary surgeons or pharmacists.
	False or misleading information to the Minister	26. No person shall knowingly make a false or misleading statement to the Minister – or knowingly provide him or her with false or misleading information – in connection with any matter under this Act concerning a therapeutic product.

