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Potency and Power: Estrogen, Cosmetics, and Labeling in Canadian Regulatory Practices, 1939–1953

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Abstract

Building on a rich body of feminist scholarship on estrogen, this account interrogates how potent estrogenic cosmetics and consumer product labels emerged together, through the regulatory practices of scientists and lawyers, in mid-century Canada. Composed from archival and other primary sources, the story traces the development of Canada's first cosmetic regulations – which applied only to cosmetic products containing estrogens. In 1944, "sex hormones" had been the first substances for which the Department of National Health and Welfare adopted labels in lieu of dose or potency standards under the Food and Drugs Act. With dose-response thresholds thus written out of the Sex Hormone Regulations, in 1949, regulators devised a new type of consumer product label that warned women to use estrogenic cosmetic products "with care". Further regulatory amendments in 1950 appeared, on their face, to require positive proof of safety for estrogenic cosmetics. However, through varied administrative and enforcement practices that hinged upon "directions for use" in product labels, National Health officials quietly reintroduced dose-response logics back into estrogen regulation. As legal technologies for disciplining women consumers to regulate their own exposures, product labels were becoming instrumental. With labeling, estrogen catalyzed an early example of risk regulation in Canada.

Introduction

Today, endocrine disruption is a well-established phenomenon. The fact that

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industrial chemicals could disrupt endocrine systems of humans and wildlife burst into popular consciousness in the mid-1990s, with the publication of *Our Stolen Future* (Colborn, Dumanoski, & Myers, 1996). In translating the science to public audiences, researchers and activists have often leveraged the fact that these endocrine-disrupting chemicals can participate in humans' and animals' hormonal systems, including by mimicking estrogen in bodies.¹ Some scholars have critiqued the repronormative, heterosexist, transphobic, or ableist discourses that infuse these translations, which reinforce sex panics about disruption of normative bodies (Ah-King & Hayward, 2014; Di Chiro, 2010; O'Laughlin, 2016; Scott, 2009). Others have explored chemical and multispecies productions of sex, gender, and sexuality (Fausto-Stirling, 2000; Haraway, 2012; Hayward, 2014), and celebrated the queer intimacies and pleasures of hormone disruption (Chen, 2012; Pollock, 2016; Preciado, 2013). Without mongering these fears or indulging these pleasures, it can now be said that these molecules can change fetal development; impact fertility, metabolism, and behaviour; and cause cancer.²

In Canada, one of the first endocrine disruptors to be industrially produced was estrogen. More particularly, the interwar years saw the manufacture and marketing of estrogenic preparations made of estrone, estradiol, equilin, equilenin, or stilboestrol (or DES). Scholars have examined endocrine disruption in ways that refuse to separate the "natural" from the "cultural." For example, Nancy Langston (2010) has traced a history of endocrine disruption through the synthetic estrogen DES. Working within a material-semiotic tradition, Celia Roberts (2007) has troubled distinctions between "natural" sex hormones and "synthetic" industrial chemicals (see also Haraway, 2012). Following that tradition, this article holds hormones firmly together with (other) industrially produced endocrine-disrupting chemicals; as compounds with particular historical, political, and industrial trajectories, these are nonetheless all estrogenic substances.

Critically, whether "natural" or "synthetic," estrogenic compounds regularly resist conventional dose-response logics (Vandenberg et al., 2012; Bergman, Heindel, Jobling, Kidd, Zoeller, & World Health Organization, 2013). Conventionally, the greater the dose of a substance given to an organism, the greater the physiological response—a relationship, in pharmacology, referred to as *potency*. As scientists now know, estrogenic substances can upset the old toxicological truism that "the dose makes the poison." Some cause adverse effects at low doses, and indeed can have relatively greater toxicity at low doses than at high doses. These findings have major implications for chemical regulation, as it

implies that there is no safe threshold for exposure to estrogenic chemicals (Scott, 2015).

In pharmacology in the 1940s, however, the conventional paradigm ruled supreme. As elsewhere, Canadian laboratory scientists, pharmacists, and clinicians shaped their research, compounding, and prescription practices around concepts of dose and dosage.³ Ideas about potency routinely structured determinations, by Department of National Health officials,⁴ of whether and what amount of a substance was safe. Yet, despite their centrality to biomedical discourses, dose-response logics were not stable or unified in regulatory spheres. As explored here in the context of estrogen regulation in Canada, dose-response (or potency) limits were not legally prescribed: they were never "written into" rules or regulations. Indeed, National Health explicitly rejected the adoption in law of any dose-response limit or thresholds. Instead, dose-response limits were performed by regulators in informal, fluid, and sometimes contradictory practices. Crucially, at the core of these practices was product labeling. This article argues that estrogen, cosmetics, and product labeling were co-produced in mid-century Canada (Jasanoff, 2004).

Law's imbrication with matter has recently been taken up in sociolegal and critical legal studies. However, few legal historians have situated their work within in the material turn—whether in new materialisms, relational materialism (Mol, 2013), material feminisms (Alaimo & Hekman, 2008), or other such frameworks that center the interaction of matter and meaning. Identifying "law" and the "material world" as distinct analytical realms admittedly performs "precisely the kind of ontological partition... that we are purporting to refute" (Johnson, 2018, p. 7). Nonetheless, legal historians who embrace materiality aim to move away from law-as-discourse, separate from its (socio)material "contexts" (Johnson, 2015; Tomlins, 2016). In this spirit, my article conjoins legal history with an STS-inflected praxiological approach to ontological enactment (Mol, 2002). Contributing to interdisciplinary conversations in sociolegal studies, legal history, and STS, and using archival material not previously addressed by historians, the story told here provides an empirical case of how regulatory practices perform sociomaterial realities, and how law is enacted by sociomateriality.

My account is woven with two main evidentiary threads. First, I draw on archival evidence of the development of the Sex Hormone Regulations, and a Department of Justice file examining the constitutionality of a statutory provision on cosmetic licensing. Second, I trace the legislative evolution of that provision and the

regulatory evolution and enforcement of the Sex Hormone Regulations, specifically its labeling requirements. Intertwined, too, are contemporaneous accounts by National Health officials, scientific studies on estrogen creams, the Delaney Committee's 1952 study on chemicals in cosmetics, and newspaper ads. Informed throughout by historiographies of estrogen in its multiple materializations, 8 this story adds understanding of relations between estrogen, cosmetics, and labeling to a rich body of feminist scholarship on sex hormones.9 The initial part of this account describes the first cosmetics regulation in Canadian history, which applied only to products containing sex hormones. In lieu of any dose or potency standards for estrogens, regulators instead devised novel labels warning women to use these products "with care." Soon, however, the Department of National Health would conclude that greater direction was required. In the second section, this story recounts how further amendments to these regulations, in 1950, introduced new labeling rules unique to estrogenic cosmetics. Under these rules, women were instructed, for the first time in Canadian history, to use consumer products "only as directed" on a label. In variable administrative practices related to labeling, officials negotiated the content of these usage directions. In this way, National Health quietly reintroduced dose-response logics back into estrogen regulation. The conclusion summarizes these historical events, considering their stakes and continued implications.

Enacting Cosmetics and Gender through a "Use with Care" Label, 1939–1949

To appreciate how potent estrogenic cosmetics and powerful labeling techniques emerged together, Canada's Sex Hormone Regulations provide a revealing starting point. First enacted in 1944, these regulations purported to standardize biological drugs (Tessaro, 2018). Efforts to standardize hormones and other biological drugs were increasingly pursued by laboratory scientists and pharmaceutical manufacturers in the interwar period, and chemical synthesis of biological drugs had arguably "dissolved the boundaries between natural and artificial substances" (von Schwerin, Stoff, & Wahrig, 2013, p. 29). Yet, despite this lack of essential difference, "biologicals were often more complex, more difficult to handle, and less standardized than the chemical drugs" (Gaudillière, 2005, p. 606), with multiple physiological effects both desired and harmful (von Schwerin, Stoff, & Wahrig, 2013). Rather than see these as side effects, biologics are better understood as ontologically precarious. Their precariousness arises from their "historical construction as both natural and artificial objects" (von Schwerin, Stoff, & Wahriq, 2013, p. 29), as their "naturalness" made them

culturally desirable and pharmaceutically promising, yet difficult to produce and control. In the early 1940s, the task of stabilizing estrogenic biologics, and converting them to drugs, commonly fell to standardized bioassays (Gaudillière, 2010; Oudshoorn, 1994).

Despite widespread reliance by scientists and manufacturers on standardized tests to materialize hormones, in Canada in 1944, National Health resisted endorsing conventional standardization methods for estrogenic substances such as estrone, estradiol benzoate, and stilboestrol. Senior departmental officials rebuffed efforts by Canadian physicians and pharmacists to ensure that the new Sex Hormone Regulations would prescribe standardized bioassay methods for measuring and materializing the potency of estrogens. Relatedly, National Health also refused to regulate standard doses of estrogenic preparations, though the efficacy and safety of estrogens were widely conceived as a matter of dose (Krieger et al., 2005; Langston, 2010; Sengoopta, 2006; Watkins, 2007). Instead, National Health delegated to pharmaceutical manufacturers the power to set doses of estrogenic drugs (Tessaro, 2018). In lieu of potency or dose standards, the regulations adopted "special" labeling provisions (Curran, 1953, p. 185). These rules required labels to supply information on their bioassay methods and to caution women to consult physicians (PC 1944-3721, p. 2292). Enacted with variable potencies and unfixed doses, its safety and predictability ensured not by standards but by labels, estrogen was materialized by Canadian regulators in 1944 as simultaneously safe and potent (Tessaro, 2018). With these techniques, National Health regulators rendered safe doses of estrogenic substances imperceptible (Murphy, 2006).

When the 1944 Sex Hormone Regulations were enacted, Canada lacked statutory power to regulate cosmetics. Six years earlier, American federal law had been extended to cover cosmetics (Food, Drug, and Cosmetic Act, 1938). In reaction, early in 1939, the Canadian Parliament hastily considered amendments to the Food and Drugs Act. A new definition of drug made cosmetics a class of drug and the term *cosmetic* was defined. Furthermore, the bill empowered the government to license cosmetics manufacturers. The bill passed and while much of it was proclaimed into force that summer, the cosmetics provisions were not (Proclamation, July 22, 1939). Implying that masculine war efforts trumped feminine beauty products, Linton Davidson, a food and drug analyst and informal chronicler of the Department of National Health's history, argued that World War II caused the government to postpone enacting the cosmetic provisions (Davidson, 1949b). Yet during the war, the use and sale of cosmetics exploded,

as women turned to performances of femininity to demonstrate their commitment to the war effort (Black, 2004; McEuen, 2011; Peiss, 1998). In fact, the better explanation for the delay is that, before the bill passed, there were murmurs that its cosmetic provisions may not be constitutionally valid; indeed, in a separate account, Davidson (1949a) admitted that "questions of validity loomed" (p. 81) over the bill.

By that summer, hormonal cosmetics were offered for sale in Canada. 14 Their potency conjured from estrone, estradiol, equilin, equilenin, and DES, these products comprised estrogens whipped into creams or mixed into oils. When marketing these lotions, the cosmetics industry stirred up a toxic blend of gender, age, and class directives, in a semiotic mixture infused with racial hierarchy. Advertisers bonded estrogenic creams to biomedical discourses in which menopause, and women's aging, were beginning to be framed as pathological (Bell, 1987, 1995; McCrea, 1983; Li, 2003b; Mire, 2014). Elizabeth Watkins (2007) shows in her history of hormone replacement therapy that, as cosmetics firms in the interwar period increasingly promoted the notion that youth and beauty were synonymous, their "ads imparted a clear message: use of estrogen-containing creams would make a woman's skin look younger" (pp. 84-85). Just as white, middle- and upper-class women sought hormone replacement therapy to relieve menopausal discomfort (Watkins, 2007), estrogenic cosmetics, sold in Eaton's and other high-end department stores as expensive luxury face creams, were likewise targeted at and favored by privileged female consumers. The main promoter of hormone creams was cosmetics guru Helena Rubinstein, whose products were among the most expensive on the market (McEuen, 2011). 15 Luxury hormone creams not only offered women youth and beauty but, inevitably, they also implied whiteness. As Kyla Schuller (2018) shows, the very idea of proper gendering is part of a racialized project of ranking populations. In the interwar period, the emerging mainstream cosmetics industry in the United States had been quick to commodify whiteness (Schuller, 2009; Black, 2004). 16 During World War II, estrogenic cosmetics fell in step with shifting criteria of female beauty when, as war created and deepened racial hierarchies in the US, a "genuinely 'feminine' face was dictated by racial meanings and age," and the "women considered most likely to possess or have the ability to create one were middleclass housewives" (McEuen, 2011, p. 6).

As parliamentarians were publicly debating the cosmetics bill, National Health officials were privately deliberating whether to investigate estrogenic breast enhancement creams. In March 1939, Davidson brought his supervisor's attention

to an advertisement for S-8 Brand of Hormone Preparations, represented as "restoring the breasts to the graceful contours and firmness of youth" (Figure 1). Declaring a shapely bust to be the "essence of womanly beauty" and describing a Greco-Roman bust carved in gleaming white marble as the "most envied feminine form in the world," the ad discursively links hormones, gender, and racial superiority. Characterizing the breast cream as a cosmetic not a drug—which landed it outside National Health's jurisdiction—Davidson nonetheless proposed investigatory efforts. But with the bill's passage still pending, Assistant Chief Dominion Analyst Aime Valin directed Davidson to take "no action for present" (Figure 2).



Figure 1. Advertisement for S-8 Brand of Hormone Preparations, 1 March 1939. Library and Archives Canada, RG 29, volume 258, file number 347-1-6 (Part 2), reproduction copy number e-01195705.

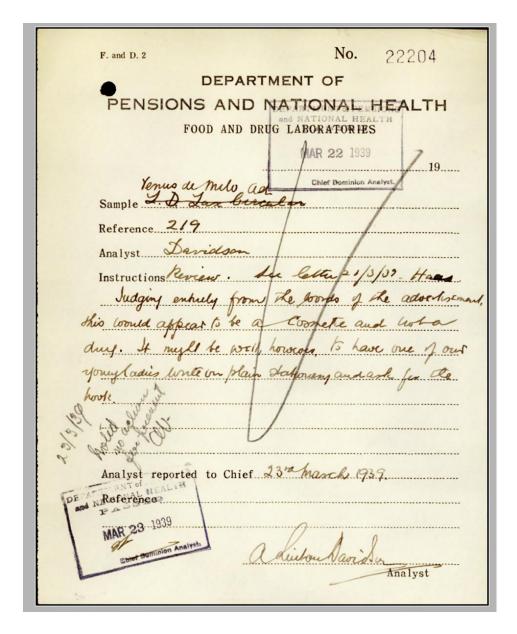


Figure 2. Analyst report to Assistant Chief Dominion Analyst, 23 March 1939. Library and Archives Canada, RG 29, volume 258, file number 347-1-6 (Part 2), reproduction copy number e-011195705.

Estrogenic creams were not supported by scientific studies demonstrating their safety. There was a paucity of evidence about to what extent topically applied estrogen was absorbed into blood streams and circulated through bodies, although some researchers attempted to assess systemic effects. For example, in a 1938 study, researchers examined creams containing androgens or estrogens (Moore, Lamar & Beck, 1938). Using a low dose, they found these hormones were easily absorbed through animals' skin, and that estrogenic face cream "sold commercially and recommended for the removal of wrinkles from normal women

has decided internal effects when applied daily on the skin of experimental animals" (Moore, Lamar & Beck, 1938, p. 14). Concluding that the creams posed hazards to women, they urged further study. Yet over the next decade, such studies would be sparse, and cosmetic companies' enthusiasm for estrogen ever more abundant.

Neither the US Food and Drug Administration (FDA) nor the American Medical Association (AMA) harbored positive feelings towards estrogenic creams. To the contrary, in the late 1930s, there was "a strong bias by the US medical profession against the over-counter sales" of estrogenic cosmetics (Mock, 1951, p. 870). Concerned about carcinogenicity, the AMA campaigned against the creams. After it published an editorial critical of Endocreme ("Endocreme," 1938), the manufacturer sued the AMA in defamation. Supportive of the AMA's position, the FDA supplied expert evidence, but the Federal Court rejected it, holding that the animal studies relied on by FDA witnesses to claim that estrogens were carcinogenic were insufficient to prove a likelihood of cancer in women. Langston (2010) finds that, as a result of the court's decision, the FDA backed down from enforcement activities to control these creams. Taking a longer view, the FDA regained its zeal by the late 1940s and early 1950s, when it targeted estrogenic creams with misbranding prosecutions (Bennett, 2020).¹⁷

In Canada, after the Second World War, National Health began preparing to regulate cosmetics, an effort led by its Food and Drugs Division. When, late in 1945, the division informed industry of its plans, the Toilet Goods Manufacturers' Association responded with a lawyer's opinion that the statutory provision empowering cosmetic licensing was unconstitutional. A Department of Justice lawyer confirmed this opinion. In Elmer Driedger's view, the licensing provision was of doubtful validity. With Driedger's assistance, in 1946 the Food and Drugs Division prepared new statutory language on cosmetics. Pivoting away from licensing, the bill proposed to prohibit the sale of injurious cosmetics and to require manufacturers to register cosmetics with information about their ingredients, and created a suite of regulatory powers. The deputy ministers of National Health and Justice approved the bill. However, Brooke Claxton, the minister of National Health and Welfare, belatedly intervened. Anxious that the registration requirements may prove contentious, Claxton's intervention killed the cosmetics amendments.

At the end of 1946, Minister Claxton moved to National Defense. National Health was soon moving forward again on the cosmetics file. Researching what it could

not yet lawfully regulate, the department created a cosmetics section within Laboratory Services and appointed a cosmetics analyst.²² Of course, cosmetics were just one part of the department's growing capacities; in April 1949, the Food and Drug Regulations were thoroughly overhauled (PC 1949-1536; Davidson, 1949a). Concurrently, Canada finally enacted the 1939 statutory amendments regarding cosmetics (except for the constitutionally dubious licensing provision), thereby making cosmetics a class of drugs (Proclamation, April 5, 1949). Cosmetics could now be specifically governed through regulations.

However, the only type of cosmetics that Canada then chose to regulate were products containing sex hormones (PC 1949-1536, pp. 945-947). In 1949 no cosmetics were made with androgens, gonadotrophins, or progesterone—no testosterone tonic, no gonadotrophic gloss. Only estrogen, that spring of youthful, reproductive femininity, had infiltrated cosmetics. Thus, Canada's first cosmetics regulation really applied only to products containing estrogens. Driedger had no difficulty with representing cosmetics as a subclass of drugs. Robert Curran, in contrast, overtly disparaged this legislative decision. As National Health's in-house lawyer, Curran's public disdain for the Canadian government's approach is jarring. When the amendments came into effect in 1949, he wrote an article for a mainly American audience that mocked the Canadian legislation in (cis)sexist terms:

Notwithstanding the opinion of a great constitutional lawyer of long ago that "Parliament can do anything except change a man into a woman or a woman into a man," it would have been preferable if cosmetics and devices were treated as individual subjects in the legislation, rather than to distort the ordinary meaning of a drug by including in it things which common sense rejects from it (Curran, 1949, p. 411).

In this less than subtle rhetoric, Curran advanced gendered distinctions between cosmetics and drugs. Admitting that cosmetics contained medicinal ingredients, he nevertheless reckoned that cosmetics were "not expected to contain a high degree or medication nor are extensive therapeutic claims likely to be made for them" (Curran, 1949, p. 411). For Curran, the boundary was clear: "the borderline between cosmetics and drugs, of course, rests upon the claims which are made" (1952, p. 718; see also Curran, 1953). Moreover, "puffery" need not be discouraged. After all, the public would not be deceived by exaggerated or false claims, as nobody really thought that cosmetics would do "what Nature has failed to do" (Curran, 1952, p. 718).

No substance challenged such rigid distinctions more than estrogen. As will be seen, some estrogenic "cosmetics" were more potent than estrogenic "drugs." Ads for Premarin, marketed as a drug for menopause, and for Helena Rubinstein's cream, marketed as a cosmetic, made similar claims: youthful beauty, reproductive femininity, reinvigorated vitality, and happier husbands (see figures below).

Faced with estrogen's multiple materializations, and with government lawyers' diverse depictions, how, then, did National Health decide to regulate estrogenic cosmetics? As in 1944, when it had devised a "caution label" for estrogenic drugs, in April 1949, the department once again turned to labels in lieu of standards, licensing, or registration. The Sex Hormone Regulations were amended to prohibit the sale of cosmetic products containing sex hormones, unless a label bore the statement "This preparation contains a potent sex hormone. Use with care" (PC 1949-1536, section 02.0009).

Canadians had never previously been directed, by a label, to use a consumer product with care. In the 1940s, in Canada as in the US, food and drugs were required to bear labels stating what a product was. Such labels impliedly represented that the product met legally prescribed standards of quality and identity, exposing companies to misbranding or adulteration prosecutions if the product did not "measure up" to regulated recipes. National Health's innovation for estrogenic cosmetics enlisted labels to govern women's behavior, deflecting responsibility away from government and industry. For these gendered products, safety would no longer be built into the product by requiring manufacturers to follow a standardized recipe set out in pharmacopoeia or regulations. With labels, women were made responsible for ensuring their own safety, by attending carefully to how they used cosmetics.

This differential regulatory treatment reflected and reproduced gendered norms about women and bodies. Estrogens were acknowledged to be potent, yet these "naturally occurring" womanly substances were branded as "essentially safe." ²³ Cosmetics were brushed off as figuratively and materially superficial; as Curran intimated, women used cosmetics to deceive. Deceptive women could be compelled to take responsibility for avoiding the hazards occasioned by their guile. Further, regulating through labels strengthened the notion that topical cosmetics, used to cleanse or alter bodies' external surfaces, were less harmful than drugs administered parenterally or orally, thus reinforcing bodies as

impermeable, bounded, autonomous (but see Alaimo, 2010).

Shaped by this gendered script, estrogen was prepared to act up. As enacted by Canadian regulators in 1944, estrogens were already ontologically precarious—natural and synthetic, desirable and harmful, potent and safe. Once materialized as an everyday cosmetic, estrogen became even more resistant to traditional regulatory controls. Fed by regulators' reluctance to control cosmetics, fueled by stereotypes about gender, sexuality, age, and class, estrogen materially provoked the injunction to "use with care." Rules had engendered estrogenic potency, and now estrogen was potentiating gendered rules.

Resurrecting Dose-Response Logics in Estrogen Regulation through Labeling Practices, 1950–1953

One year after introducing "use with care" labels, Canada would again amend the Sex Hormone Regulations. True to pattern, National Health devised another novel form of label, continuing the turn toward delegating responsibility for safety to women consumers. In the process, estrogen and labels would become ever more entangled.

The amendment, made in 1950, abandoned "use with care" labels for estrogenic cosmetics. Instead, any cosmetic product "containing a sex hormone purporting to have oestrogenic properties" was now prohibited from sale—unless it was "demonstrated to be free from systemic effect from sex hormones," and unless new labeling requirements were met (PC 1950-2084, section C.02.010). Labels would now be required to state, "Use only as directed," and relatedly, companies would be required to include "directions for use" with estrogenic cosmetics (PC 1950-2084, sections C.02.010(a)(v) and C.02.010(b)(ii)).²⁴

The new legal test demanding that estrogenic cosmetics be proven "free from systemic effect" was laudable. It reflected ongoing medical concern about the carcinogenic hazards of topical estrogen. Importantly, this test did not necessarily depend on dose-response reasoning or evidence. To the contrary, with ahistorical reference here to a modern-day concept, this test appeared to set a highly "precautionary" standard. Rather than setting a toxicological threshold, on paper, the law demanded positive proof of safety.

In practices, however, the poison remained in the dose. National Health's scientists were devoted to toxicology's monotonic curves, measuring and materializing sex hormones through dose-response calculations. Despite this, as

mentioned, back in 1944, the department had declined to set dose ranges or potency standards for estrogenic substances in the Sex Hormone Regulations. Consequently, National Health scientists lacked any regulatory incentive to test the physiological effects of estrogenic drugs. Having eschewed standards, National Health was unable, by 1949, to perceive either a "safe" or "hazardous" dose of estrogen. What amount of estrogen in an oral, parenteral, or topical preparation was safe? Which estrogenic cosmetics were "free of systemic effect"? National Health did not know. Dose had been left to manufacturers and dosage left to clinicians. Once statutorily empowered to regulate cosmetics, National Health had to face up to dose. How would the department determine what dose—what amount—of estrogenic potency in a cosmetic was safe?

This question was complicated by the obvious fact that face cream did not come packaged in "doses." Even had National Health been monitoring the effects of estrogen preparations in cold laboratories with standardized bioassays and rodents, moving into the comfortable homes of middle-class, middle-aged women, estrogen and bodies met in ways less precise. In that creamy form, estrogen was slippery. ²⁵ Performed as predictably potent in mass-produced pills and medically supervised injections, in quotidian beauty regimens, estrogen became less knowable. How much cream a woman applied before going to bed, or when starting her day in the morning, was not determined quantitatively or mechanically, but through sensory and affective practices. How much cream does it take to make your skin *feel* softer, smoother, firmer? A dry winter's wind, a poor night's sleep, a husband's bad mood—all caused one's relations with cream to change. When these practices changed, so did estrogen's effects. In its cohabitation with wealthy women and their skin, estrogen enacted an ambiguous toxicity.

Advising on this question was the responsibility of Dr. Leonard Pugsley. The department's only endocrinologist, Pugsley had done doctoral studies at McGill University (Pugsley, 1932), supervised by the acclaimed biochemist Dr. James Collip. Collip had extracted and isolated the human and equine estrogens comprising the menopause drugs Emmenin and Premarin, backed by Canadian pharmaceutical firm Ayerst, McKenna & Harrison, Ltd.²⁶ By 1947 Pugsley had become the chief of Laboratory Services at National Health. He also continued to research bioassay methods for and physiological effects of sex hormones (Davidson, 1949, pp. 92-94; "Reports to the Reader," 1951).²⁷ As Langston (2010) shows, Pugsley's research was quietly influential, leading National Health—and eventually the FDA—to end the use of DES in chicken feed.²⁸ With hormonal

cosmetics, however, Pugsley would take his cues from US companies and regulators.

In a 1951 article that simultaneously highlighted and obscured National Health's practices, Pugsley described the 1950 amendments to the Sex Hormone Regulations. Explaining that National Health had thought it advisable to "limit the amount" of estrogen in cosmetics, he wrote that the department had nonetheless decided against *legally* prescribing an upper potency limit, because a limit "would tend to indicate approval and freedom from any undesirable side effects" at lower potencies (Pugsley, 1951, p. 536). Yet his article also repeatedly claimed that an "upper limit" had been *administratively* adopted (Pugsley, 1951, p. 536). This inconsistency attracts legal scrutiny, as it suggests that the department was doing precisely what it had decided *not* to authorize in law.

The internal inconsistency becomes less confusing when one recalls that Pugsley's article was aimed at an American audience. Pugsley was seeking to reassure readers that Canadian regulatory practices for estrogen were not so far removed from American ones. But American practices for estrogenic cosmetics were also legally oblique. The FDA had no authority to set potency limits for estrogenic cosmetics. Instead, it attempted indirectly to stipulate upper potency limits, through the specter of misbranding prosecutions or, relatedly, by threatening to deem higher potency creams to be drugs and to regulate them as such. While the legal source of the FDA's estrogenic potency limits was murky, the material source of the FDA's "rule" was not. The rule was born of and enmeshed within the products of Helena Rubinstein. In the 1940s, Helena Rubinstein packaged her "Estrogenic Hormone Cream" in jars advertised as containing one month's supply. Such ads implied how *much* cream should be used (Figures 3, 4). Part of a strategy to paint its products as scientific and therapeutic (Watkins, 2007), the marketing tactic made cream seem like medicine and amount like dosage, aiming to persuade women to buy and use a jar every month. By 1949 the FDA effectively took the position that existing products of Helena Rubinstein (and other reputable firms) reflected permissible potency and dose. To limit daily exposure, the FDA seems to "have settled on 10,000 International Units (IU) of oestrogens per ounce as an acceptable amount for hormone creams, as long as the amount used was no greater than 2 ounces per month" (Bennett, 2020; see also Mock, 1951).29

FINEST LASTS LONGER THE



never knew a cream could do so much

"I don't mind admitting it. I was skeptical. I just couldn't bring myself to believe that a cream could make me, or anyone, actually look younger. But I was wrong! Helena Rubinstein's Estrogenic Hormone Cream has brought new beauty to my complexion by retarding the effect of aging!"

Helena Rubinstein's Estrogenic Hormone Cream

Helena Rubinstein, having convinced herself of the value of hormones; as an important aid to beauty, presents her Estrogenie Hormone Cream. Its formula has been compounded under the close; personal supervision of this great beauty authority and contains estrogenic hormones-the equivalent of a substance, plentiful in the young, but which decreases with the years. Result? A scientific preparation that will help you achieve beauty for your skin by retarding the effects of aging. 30-Night Supply.

> HELENA RUBINSTEIN 126 BLOOR ST. W. - MI. 7755

Figure 3. Helena Rubinstein advertisement, Toronto Daily Star, 6 April 1945. "A scientific preparation that will help you achieve beauty for your skin by retarding the effects of aging. 30-Night Supply." Reproduced with permission of the copyright owner. Further reproduction prohibited without permission.



Figure 4. Helena Rubinstein advertisement, *Toronto Daily Star*, 17 October 1947. "Estrogenic Hormone Cream – Contains natural hormones which your skin absorbs. Result? You look younger! Use it for one month. See the change. 4.50." Reproduced with permission of the copyright owner. Further reproduction prohibited without permission.

In Canada, rather than a murkily authorized limit of 10,000 IU per ounce, the 1950 regulatory amendments required estrogenic cosmetics be demonstrated to be

"free from systemic effect." As noted, this test seems highly precautionary. How was this test squared with Pugsley's claim that National Health had adopted an upper potency limit for estrogenic cosmetics?

The answer lay in labeling practices. As mentioned, under the 1950 regulations, to be sold as a cosmetic, not only did a preparation need be proven free of systemic effect but its label had to state "Use only as directed" and to provide "directions for use." These labeling techniques were the means through which dose-response considerations, erased from the Sex Hormone Regulations in 1944, were smuggled back into estrogen regulation in 1950. The regulations did not articulate what "directions for use" were required. Rather, when requiring manufacturers to give usage directions, National Health inspectors could try to force firms to stipulate the *amount* of cream that women should use on a monthly basis. If that amount of cream contained less than a certain potency, National Health could deem the product to have no systemic effect and it could be legally sold as a cosmetic. In this way, the reintroduction of dose-response logics to estrogen regulation in Canada was implicit and discretionary.

Pugsley's article painted National Health's new labeling approach as deriving from a "ruling on potency," claiming that "an administrative ruling has been made on an upper limit of potency for one month's supply" (1951, p. 536). Yet no ruling, in any adjudicative or administrative law sense, had ever been made.³⁰ Recall that Pugsley was translating the Canadian approach to his American audience. US lawyers, consumer groups, and industry representatives were accustomed to the administrative rulings issued by the FDA under the 1938 Food, Drug, and Cosmetic Act. By contrast, the Canadian statutory scheme did not delegate power to National Health to issue administrative rulings. Nevertheless, this story stays with Pugsley's phrase "administrative ruling." In many respects, it perfectly apprehends a "way of regulating" (Gaudillière & Hess, 2013) emerging within National Health by the 1950s. Capturing a move away from legally codified standards in legislation or regulation, and towards more discretionary and individualized obligations, administrative ruling reflects the processual dynamic in this way of regulating. While rules codify a fixed and stable interpretation, intended to apply generally, "ruling" instead evokes more fluid regulatory interventions, tailored to individual cases.

Three episodes in the early 1950s reveal how instances of "administrative ruling" by National Health officials, centered on labeling, reintroduced dose-response logics to estrogen regulation. In doing so, these officials performed highly variable

enactments of dose-response relationships. The earliest example, in 1950, was spurred by newspaper ads for five different estrogenic breast creams. National Health's Inspection Services asked J. T. Thompson, the department's cosmetics lead, whether the creams had systemic effects. Thompson reported back with a specific enactment of a dose-response relationship. He started with the intended physiological response—growth of mammary tissue—and then worked backward to judge what amount would achieve this response. In his view, the requisite dose would be so high as to cause systemic effects. This approach conveniently allowed Thomson to take a hands-off approach:

I don't think bust development creams should be classed as cosmetics or USED except under medical supervision. To be effective, the dosage must be heavy, and I should think some degree of systemic effect would be unavoidable. Enough at least to put the preparations out of the cosmetic class. Having thus politely washed my hands of them, I get out from under!³²

However, in a separate report to Inspection Services, Pugsley disagreed that these five creams had systemic effects. While he acknowledged that they would cause growth in mammary tissue, rather than ask what dose would cause this response, Pugsley argued that breast tissue growth was inherently cosmetic: "I would say this is an effect on local tissue and not necessarily systemic action." Pugsley's enactment of weak protection was entangled with his strong commitment to labeling. Even though the creams were each advertised at 30,000 IU of potency—three times stronger than what the FDA typically tolerated for cosmetics—he felt label directions with a thirty-day limit would suffice. Of note, these five highly potent creams were already sold in a thirty-day supply. Thus, if National Health wished to limit women's exposure to only 10,000 IU per month, its inspectors would need to direct US firms to shrink the physical size of packages sold in Canada. Neutered by Pugsley's advice, National Health inspectors predictably took no action. 4

National Health's most protracted investigation of estrogenic cosmetics, pursued from its Vancouver office in 1952, provides a second example of how dose was enacted through labeling practices. Inspector E. L. Devlin was trying to bring Venus Products—which sold a breast cream called Formula V7, advertised with a pseudoscientific booklet—into compliance with the Sex Hormone Regulations. In a long letter to Venus, setting out regulatory requirements and explaining the potential carcinogenic hazards of estrogens, Devlin performed a subtly different variant of dose-response. He advised that, given estrogen's effects on breast tissue, one must assume that applying Formula V7 to breasts would affect "the

body hormone balance" such that the cream must be "regarded as having systemic effects." He therefore deemed Formula V7 to be a drug (though, at 6,000 IU, it was one-fifth the potency of the five creams earlier deemed to be cosmetics). As a drug, Formula V7 would need to comply with the drug labeling rule in section C.02.007 of the regulations, and, in Devlin's view, the label would need to state "what amount is to be used over a 30 day period."35

Without doubt, Devlin's precautionary interpretation of the regulations was legally wrong, though it exemplifies how distinctions between cosmetics and drugs were enacted in practice. Based on his view that Formula V7 had systemic effects, Devlin properly concluded that it was a drug not a cosmetic; however, Devlin was wrong to understand that the regulations' drug labeling rule required any "directions for use."36 Regardless of the fact that National Health had no authority to impose directions for use upon drugs, firms that hawked hormones were often agreeable to directing women on how to use their products. In this case, Venus complied with Devlin's (erroneous) advice, promising to label its jars with the weight, a statement that the cream contained 6,000 IU of estrogenic substance per ounce, and a direction to use not more than 1 and 2/3 ounces each month.³⁷ Indeed, Venus had pronounced numerous directions in an insert in its advertising booklet, many of which were outrageous and drew startling associations between Formula V7 and cancer. For example, the insert advised that while "Formula V7 is not intended for the discovery of existing cysts but if its use is instrumental in doing so, then it may be considered an additional though unintentional benefit." When Devlin told Venus to remove the insert, the company argued that it was just an "amplification" of the directions for use already required by law.38

Leveraging power through labels, National Health inspectors were enacting dose controls that the department had rejected when originally preparing the 1944 Sex Hormone Regulations. Seizing upon a labeling rule for cosmetics, infusing it in practice with dose-response considerations, shifting those considerations towards substances deemed drugs, inspectors resurrected dose and reinserted it into the regulatory regime. Admittedly, reigning in a local cosmetics company dabbling in quackery was not the same as interfering in innovations of major pharmaceutical firms. Power was material. Yet estrogen, too, was powerful, triggering National Health officials to re-embrace dose-response logics previously eschewed.

Devlin wrapped up his compliance efforts with Venus in May 1952. A few weeks later, a select US congressional committee, known as the Delaney Committee,

released its final report on chemicals in cosmetics. This report followed two years of high-profile hearings, chaired by Congressman James Delaney, to study chemicals in foods and cosmetics. Endocrinologists and dermatologists had testified on potential hazards of estrogenic creams. Some witnesses had equivocated;³⁹ others had clearly expressed the view that these creams could be carcinogenic and hazardous.⁴⁰ Almost all had testified that hazard was a matter of dose. As the products were sold as both night and day creams, the report observed that women could be "covered by these substances 24 hours of every day" (House of Representatives, 1952, p. 613). The report also expressed concern that estrogenic creams, if applied in "sufficient quantity," may cause "undesirable physiological changes" (House of Representatives, 1952, pp. 613-614). However, the committee ultimately recommended only that more research "would be desirable" (House of Representatives, 1952, p. 614).

Only a few researchers would take up this invitation. One study found that, even at small doses, estrogenic creams caused systemic effects—namely, endometrial hyperplasia—if applied over a long period (Goldberg & Harris, 1952). Another found the creams did not induce any clinically observable changes to the appearance of facial skin (Behrman, 1954). Overall, this small body of research indicated that estrogenic creams were not just harmful but useless. Regardless, some commentators parroted industry's position: there was "a consensus of opinion amongst experienced observers that cosmetic hormone creams with a maximum potency of 10,000 IU per ounce (31 g.) of vehicle, if used in the manner by the informed manufacturer, are free from systemic effects" (Peck & Klarmann, as cited in Bennett, 2020).

Faced with a substance that could not easily be pinned down, National Health entrenched its reliance on labels as a regulatory strategy. A third example shows how, by 1953, informal potency limits on labels had become so routinized that, provided a product included suitable directions for use, inspectors could overlook unsubstantiated and misleading advertising claims. When regional inspectors internally raised questions about an ad for Lady Esther Hormone Cream, which boasted of the cream's high potency and ability to "renew the beautifying effects of your own waning hormone supply" (Figure 6), the chief of Inspection Services quickly advised that the claims were "within the realm of permitted cosmetic puffery." Labeled at 10,000 IU and marketed as thirty days' supply, this product exemplified compliance with the unwritten rules characterizing administrative ruling. Yet such ads exploited women's fear of aging and "preyed on women's economic and emotional dependence on men," raising the scenario "of a husband

fleeing his wife's wrinkled skin and finding comfort in the arms of a smoother-skinned woman" (Watkins, 2007, p. 87). However, National Health inspectors had no power, and perhaps no inclination, to find any "objectionable greasiness" in the advertisements warning middle-aged women that, if they did not use potent estrogenic creams, they would lose their husbands.⁴²

Before starting your hand through massage may bring their existence nand through massage may bring their existence to light in either dormant or growing state. If such cysts do exist, early discovery is of paramount importance, particularly should they prove to be malignant. If cysts are discovered or suspected, consult your physician at once. If they are not malignant, removal is a simple matter. If they should prove to be malignant. Formula V7 Treatments Please read carefully these pertinent facts and suggestions matter. If they should prove to be malignant, then prompt treatment may well save untold suffering. There is nothing in Formula V7 that will cause cysts or to start existing cysts growing. Do not waste Formula V7. Use only sufficient to permit smooth frictionless massage. A little experimentation will indicate the proper amount. Formula V7 is not intended for the discovery Use Formula V7 regularly every day if possible. of existing cysts but if its use is instrumental The most convenient time to take your Formula V7 treatment is on retiring. While not essential, in doing so, then it may be considered as an additional though unintentional benefit. it is desirable to take your treatment in a prone In rare instances a person may be allergic to a substance. Should an allergy to the use of Formula V7 manifest itself which is highly position. Lie flat on the back preferably without a pillow. Apply sufficient Formula V7 to each breast to allow smooth easy massage. RELAX and allow your thoughts to dwell on pleasant subjects. Anxiety, worry or unpleasant thoughts tend to neutralize the effect of the treatment. improbable if you can use cosmetics, then reduce the amount and the frequency of use. This will almost certainly overcome this rare problem but if reaction continues, we suggest that you do not persist in its use any more than you would Massage with light pressure from 3 to 5 minutes using movements upward and toward the persist in eating a food or using any other product to which your system is allergic. nipples. You may give yourself the treatment but more effective results may accrue if you have it done for you as it permits you to relax more Overnight results from Formula V7 should not be expected. While results in some cases have completely. been remarkable, ordinarily continued treatment Be gentle in your treatment at all times. Ordinarily the breast is not subjected to touch is required to correct a condition that has probably existed for some considerable time. Except in the more difficult and unusual cases, to any great extent other than by the pressure of garments or the body in sleep. Some women rarely ever touch their breasts with the bare hands. Bathing is done with a cloth and drying definite improvement is apparent before the first jar of Formula V7 has been finished. hands. Bathing is done with a cloth and drying with a heavy towel. Cysts have been known to grow in the breast to a size apparent to the eye before discovery, the existence of which could have been revealed at an early stage by direct contact of the bare hand. Existing cysts in the breast may lie dormant for long periods and then suddenly commence to grow. Contact of the bare Venus Products Ltd. 1043 West Broadway VANCOUVER CANADA

Figure 5. Venus Products' advertising booklet insert for Formula V7, March 1952. Library and Archives Canada, RG29, volume 259, file number 347-1-6 (Part 4), reproduction copy number I-115336.



Figure 6. Lady Esther Advertisement, *London Free Press*, 26 October 1953. "Stay Lovely... Stay Loved... with Lady Esther Natural Estrogenic Hormone Cream." Library and Archives Canada, RG 29, volume 259, file number 347-1-6 (Part 4), reproduction copy number I-115336.



A Frank Statement about Estrogenic Hormones by Helena Rubinstein

"Estrogenic Hormones are the most effective agents yet discovered for helping

yet discovered for helping women to look younger." Thelieve, with all my bear, that Estrogenic hormous can make you look younger. While adding scientish after carried out relumative portions with Estrogenic Hormous Cocum, More than 90 years ago I started applying homous cream to say own skin. Since then have observed the effect on thousands of their women. All this time, too, Lhave keep toward my own laboratories.

Dramatic Proof

We, now have dramatic proof that Estrogenie Hormones can often bring about a decided improvement in the appearance of dry, oldish akin. One of the many imporant tests which have contributed to this proof took place recordly at a leading university in New England. 1. The hands of twenty-five women between the ages of 53 and 53 were placed under scientific observation for six months. 2. Two different ecounts were modeled.

Estrogenic Hormones. The other did not The creams looked islanical. Even the doctor making the study did not know which hand received the Estrogenic Hormone Cream

- At the end of 6 months, the doctors former their conclusion: "The skin of the left hands (with one or two exceptions) looked faller, less wrighted, more youthful."
- It was then learned by the experi-menting doctors, that Estrogenic Hor-mone Cream was the one which had been used on these younger-looking left hunds!

Yes, we now have proof that these Estrogenic Hormone preparations can safely give women younger-looking skin.

Important to Women Over 35 If you are over 35, then you must realize that your skin is steadily loting its youth giving

Estrogenic Hormone; are natural substances. And they really work in a very simple way. When gently masseed into your skie, they make your under-skin fill out. This in turn stretches the enter-skin. When this happens, tiny lines become less visible. Your skin, as the doctors reported, looks "fuller, less excitabled, more youtful."

Works in Two Ways

My Eurogenic Hormone Cream works in two ways to help your skin look more youthful, It works from widen ... as your skin almorlus the natural estrogenic hormones. And it works from without ... as its rich emollicuts smooth away dryness, help you recapeure that young look.

But these admirable results don't happen our night. Even though women tell me they not an improvement after only one carb. always active them to rey out my Estrogenia Horinone Cream and Oil for at least 3 months.

But even at the end of 30 days, I um sure you will note a real change — a younger-looking skin.

A Thrilling Experience

A THIRING Experience

If you are over \$\tilde{S}\$ it is a thrilling experience when you begin to look younger.
Compliments come your 'I'h hat
have you been doing to yourself?" ask
your friends, You yourself brighter,
your friends, You yourself brighter,
your friends, You yourself brighter,
you have a new assurance. A new
poise, Your husband look at you with
new interest. Life suddenly seems more
exciting.

80.312



FOR A LIMITED TIME

Figure 7. Helena Rubinstein advertisement, Toronto Daily Star, 6 February 1952. "Your husband looks at you with new interest." Reproduced with permission of the copyright owner. Further reproduction prohibited without permission.

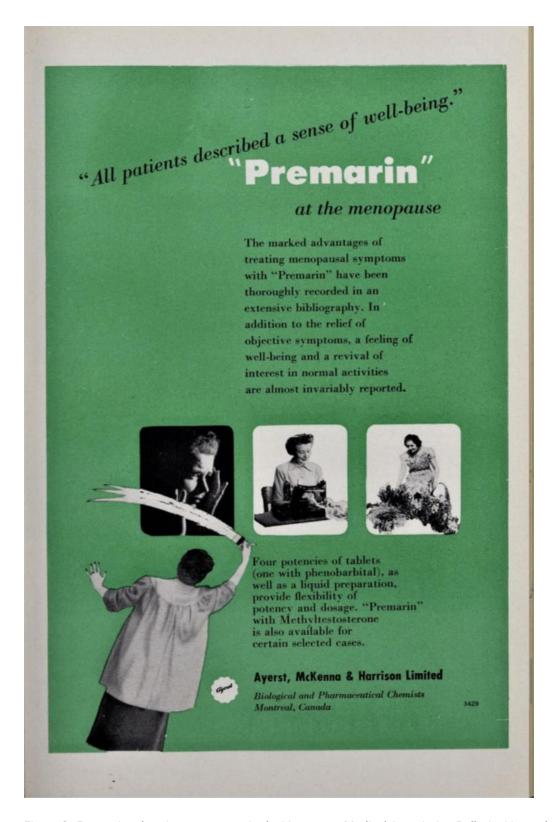


Figure 8. Premarin advertisement, 1951, in the Vancouver Medical Association Bulletin, November 1951. (History of Nursing in Pacific Canada, UBC Open Collections, retrieved from https://open.library.ubc.ca/collections/historyofnursinginpacificcanada).

Concluding Thoughts: Law in Estrogen, Estrogen in Cosmetics, Cosmetics through Labels

Law is still "commonly seen as a discourse, something that is distinct from, yet gives meaning to, things in the 'real world'" (Johnson, 2015, pp. 409-410). However, careful readings of historical evidence can fracture this boundary, revealing law's material formations and matter's legal forms. Holding together matter and law—or, shrinking the distance between the onto-epistemological and the political that this equation solidifies, holding together potency and power⁴³—can subvert insistent representations of toxicity as "wayward particles behaving badly" (Liboiron, Tironi, & Calvillo, 2018, p. 333). Instead, toxicity can be interrogated as ways in which "forms of life and their constituent relations, from the scale of cells to cultures, are enabled, constrained, and extinguished within broader power systems" (Liboiron et al., 2018, p. 336).

In exploring the historicity of estrogen as a legal phenomenon, and the historicity of labeling as an estrogenic phenomenon, this account has interrogated how estrogenic realities were enacted with regulatory powers, techniques, and practices in Canada in the mid-twentieth century. Materialized through regulation as potent and ineffective, hazardous and safe, natural and an artifice, systemic and cosmetic, estrogen was a provocation to regulators (Roberts, 2007). Perceiving toxicity through monotonic dose-response curves, and facing potent substances that were associated with cancer and reproductive effects, in the early 1940s, the Department of National Health nonetheless decided to let the pharmaceutical industry decide in what doses and potencies estrogen should be made and sold. In so doing, conventional dose-response thresholds were written out of regulations under the Food and Drugs Act, making it largely impossible to perceive a "safe dose" of estrogen (Murphy, 2006). In this way, estrogen came to matter in midcentury Canada.

Thus materialized, estrogen bit back, catalyzing new labeling practices. When National Health decided later that decade to regulate estrogenic cosmetics, but was unable to rely on regulatory experience with dose thresholds or potency standards for parenteral or oral estrogen, its officials subtly reintroduced doseresponse logics to topical estrogen. They did so by effectively enacting "potency limits," through novel labels that directed women how to use these products—first by suggesting "care" should be used, and later by providing direction on how much cream to use in a given period. These labeling practices were not uniform, however, nor were the dose-response logics that they perpetuated. This account has showed how variable labeling practices enacted different ontologies of

potency. Departmental inspectors, tasked with scrutinizing ads to identify non-compliance and on alert for misleading representations, were suspicious of overblown claims made for these creams and inclined to assume adverse effects, working backwards from this assumption of hazard to promote safer doses through use directions. The chief of National Health's Laboratory Services, by contrast, trained as an endocrinologist, open to hormonal drugs and skeptical of unproven hazards, acted from an assumption of safety. Pugsley viewed labels less as a means to guarantee safety—which was presumed—and more as a performance of regulatory oversight. Ultimately, these practices reacted to and reproduced estrogens' precarious ontologies through regulatory techniques and material technologies of labeling. For regulating ambiguously potent substances marketed to women, labels were becoming instrumental.

In this entanglement of law, toxicity, and gender, estrogen was not the only phenomenon being naturalized. Menopausal women were also constructed with estrogen (Bell, 1987; McCrea, 1983). Estrogen was performed, in regulatory practices, as malleable, superficial, deceptive, temperamental. In regulating cosmetic estrogen with labels rather than standards, National Health sought to "standardize" the consumption behavior of menopausal women construed to possess those very same features.

As artefacts of gendered regulatory strategies for estrogen, product labels have a troubled history. In Canada, labeling techniques emerged as a means by which industry and government regulators could evade responsibility for potency, dose, and safety of estrogenic substances, as product labels delegated responsibility for "safe dosing" of potentially harmful substances to feminized consumers. Moreover, this delegation of responsibility was never about arming women with information about hazards that they could rely upon to make informed "choices." Rather, direction for use labels evolved in response to estrogenic substances that had been "standardized" with variable potencies and unfixed doses. Far from transparency, such labels maintained the imperceptibility of estrogenic hazard. Thoroughly naturalized, today, as a gendered technique of green governmentality or of precautionary consumption for toxic consumer products (MacKendrick 2018; Scott, Haw, & Lee, 2017), warning and direction labels first emerged with estrogen. In Canada, estrogens were the first substances for which labels were used in lieu of standards, initially for drugs, then for cosmetics. Labels allowed regulators to require that potent ingredients be identified in consumer products and to discipline women to regulate their own exposure by following directions. Such labels made it explicit, for the first time, that women would need to govern

themselves accordingly.44

In this respect, National Health's potent mixture of labels and "administrative ruling" to apprehend and mitigate the hazards of estrogen should be understood as an early example of risk regulation in Canadian law. The deployment of usage directions performed estrogen as a risk to be managed, rather than as a hazard to be avoided. This mode of governance kept dose-response considerations, limits, or thresholds "off the books"; rather than codified in statutes or regulations, potency limits were enacted more ambiguously in fluid administrative practices. Materialized in these practices, potency becomes an assemblage of social, material, and legal relations that are enabled and circumscribed through product labels. Returning to the old toxicological truism, perhaps there is another critique available, one that moves us beyond simple condemnation of reliance on conventional monotonic dose-response curves for endocrine disrupting chemicals. What if we started with the proposition that—at least in some times, at least in some places—the dose really does make the poison? If the dose makes the poison, then what makes the dose?

With growing calls by some activists and academics for more extensive consumer product labeling as a regulatory strategy to tackle exposure to toxic chemicals, such questions remain entirely relevant today. Mandatory labeling of gendered consumer products has rapidly traveled far beyond estrogenic cosmetics. A few years after the Sex Hormone Regulations first incorporated cosmetics, standalone cosmetic regulations followed (SOR/52-271). These regulations governed cosmetics not through standards, licensing, or registration, but with cautions, directions, and other labeling requirements—techniques that were introduced, in Canada, with estrogen.

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engagement with and elevation of this work.

Notes

- ¹ These chemicals were called "environmental estrogens" in the 1980s. That evocative term has fallen out of use as scientists have come to understand that endocrine-disrupting chemicals have many different and complex modes of action. In addition to estrogenic action, endocrine-disrupting chemicals can have androgenic or anti-androgenic effects. Further, they do not only mimic hormones by attaching to hormone receptors but can block receptors, among other participations in endocrinal systems. For a scientist's account summarizing the evolution of the field, see McLachlan (2016).
- ² The scientific literature on the human health effects of endocrine-disrupting chemicals is voluminous. For one authoritative summary, see Bergman, Heindel, Jobling, Kidd, Zoeller, & World Health Organization (2013).
- ³ In brief, dose is the amount of a drug that is administered at one moment in time, while dosage is the dose that is administered over a particular time period.
- ⁴ In 1944 the former Department of Pensions and National Health was split into two departments. Pensions became the responsibility of a new Department of Veterans Affairs, and a separate Department of National Health and Welfare was legislatively constituted. See An Act to establish a Department of National Health and Welfare, 1944–1945, and An Act to amend The Department of National Health and Welfare Act, 1945.
- ⁵ For examples and summaries of this scholarship, see Cloatre (2013); Cloatre & Pickersgill (2015); Cole & Bertenthal (2017); Davies (2017); Grabham (2016); Faulkner, Lange, & Lawless (2012); and Lezaun (2012).
- ⁶ The material turn has found tremendously diverse expression, including through actor-network theory, object-oriented ontology, thing theory, agential realism, posthumanism, speculative realism, non-representational theories, and material feminisms. Many of these approaches have quite different disciplinary origins, and it is not my goal in this essay to delineate or assess the various similarities or differences.
- ⁷Library and Archives Canada, Legal opinions and materials of precedential value, RG 13, vol. 2635, file no. 9-150108, "Powers to License Manufacturers of

Cosmetics / if Section 3(j) of Food & Drugs Act is Unconstitutional". This file was released in full under the *Access to Information Act* on January 29, 2018, following a statutory appeal to the federal Information Commissioner, and is on file with the author.

⁸ For the leading historiography of sex hormones, estrogenic drugs (and other technologies), and/or endocrinology in the interwar period in North America and Western European states, see Bell (1987, 1995); Oudshoorn (1994); Fausto-Stirling (2000); Seaman (2003); Li (2003a, 2003b); Gaudillière (2005, 2010); Krieger et al. (2005); Sengoopta (2006); Roberts (2007); Watkins (2007); Langston (2010); and Haraway (2012). This list excludes historiography of the contraceptive pill, introduced in the mid-1950s.

⁹ The term *sex hormones* is fraught with difficulty and has long been problematized in scientific and feminist discourses (Oudshoorn, 1994; Fausto-Sterling, 2000; Roberts, 2007). Like these authors, I adopt the term where it was used by my historical actors. Scientists and bureaucrats within National Health and on the Canadian Committee on Pharmacopoeial Standards did not always use this term. At the risk of overgeneralizing, these actors tended to speak of *sex hormones* when contemplating end-use products (including in the context of the Sex Hormone Regulations). In other contexts, such as when preparing pharmacopoeia monographs, they would speak of estrone, estradiol benzoate, stilboestrol, and so on.

¹⁰ However, as Langston (2010) shows, as early as 1939, some research into the synthetic estrogen stilboestrol (DES) had also shown that toxicity did *not* relate strictly to dose, and indeed that "low doses of DES could be more toxic than high doses" (p. 38). She argues that as "early as the 1930s...researchers knew that estrogens do not act in linear or predictable ways" (p. 38).

¹¹ In its Food, Drug, and Cosmetic Act 1938, the United States imposed requirements for pre-market regulatory approval of "new drugs." In Canada, regulatory approval for new drugs was still decades away. However, for present purposes, the point is that neither the US nor Canada required pre-market approval of cosmetics—whether through regulatory approval of new products, standardized potency test methods, prescribed "doses," or otherwise.

¹² The 1939 amendments that were brought into force addressed miscellaneous matters. Only one provision in the bill that was unrelated to cosmetics was not

proclaimed into force in August 1939; see section 4.

¹³ Other National Health officials later made the same argument; see Curran (1953) and Pugsley (1967). Privately, though, Elmer Driedger's January 29, 1946 legal opinion indicates that, before it passed, the licensing provision attracted some constitutional concern; see Library and Archives Canada, Legal opinions and materials of precedential value, RG 13, vol. 2635, file no. 9-150108, "Powers to License Manufacturers of Cosmetics / if Section 3(j) of Food & Drugs Act is Unconstitutional".

¹⁴ The earliest ad located that offered a hormone "beauty aid" product for sale was published in 1938; see "20% discount" (1938). In the US, hormonal cosmetics became available for sale at roughly the same time, at the end of the 1930s (Mock, 1951).

¹⁵ Some cheaper creams, advertised for breast enlargement rather than for facial skin, were sold in Canada through mail order. See, for example, November 7, 1950 memo from Curran to Whitmore enclosing five advertisements; Library and Archives Canada, Legal opinions and materials of precedential value, RG 13, vol. 2635, file no. 9-150108, "Powers to License Manufacturers of Cosmetics / if Section 3(j) of Food & Drugs Act is Unconstitutional".

¹⁶ In the 1930s and 1940s, production and marketing of certain other cosmetic products in the US (and likely also in Canada) drew heavily upon racism. In particular, in this period, the mainstream cosmetic industry intensified racist marketing of skin whitening products to Black Americans (and to southern Europeans and white women of Anglo-Saxon descent); see Peiss, 1998; McEuen, 2011; Mire, 2014; Hunter, 2011; Glenn, 2008. Most of these products contained ammoniated mercury, a highly toxic agent with no "safe dose." Currently in Canada, consumers continue to purchase skin-whitening products for cosmetic uses. Most of these products contain illegal toxic substances—such as mercury, hydroquinone, corticosteroids, and tretinoin—that are banned or restricted in cosmetic products in Canada and indeed in most industrialized countries; see Ghetoh and Amyot, 2016. While such products raise concerns, in a pharmacological idiom, about hazardous dose or dosage, as illegal substances they do not engage similar questions to those examined here regarding how regulators substitute labeling practices for traditional safety standards.

¹⁷ See, for example, U.S. v. 11 Jars of Female Sex Hormone Estrogenic Ointment

Cream (Case No. 2089, FDC No. 21350, Sample No. 35600—H, disposition December 11, 1946); U.S. v. 94 Jars, etc., (Case No. 3034, FDC No. 27873, Sample No. 57635—K, disposition November 17, 1949); U.S. v. 176 Jars, etc. (Case No. 2726, FDC No. 26641, Sample No. 2790—K, disposition April 5, 1949); U.S. v. 40 Cases, etc. (Case No. 4277, FDC No. 34886, Sample No. 17403—L, disposition January 14, 1954); U.S. v. 8 Jars (Case No. 4181, FDC No. 35320, Sample No. 58957—L. 30-185 M, disposition July 9, 1953); and Hormonex (FDC No. 38280, Sample No. 30-185 M, disposition September 23, 1955). These reported FDA Notices of Judgment are digitally archived by the US National Library of Medicine, at https://fdanj.nlm.nih.gov/. For discussion of some of these enforcement proceedings, see Bennett (2020).

- ¹⁸ January 22, 1946 letter from Chisholm to Varcoe, in Library and Archives Canada, Legal opinions and materials of precedential value, RG 13, vol. 2635, file no. 9-150108, "Powers to License Manufacturers of Cosmetics / if Section 3(j) of Food & Drugs Act is Unconstitutional".
- ¹⁹ January 25, 1946 memo from Driedger to Varcoe; January 29, 1946 draft letter by Driedger to Varcoe; and February 1, 1946 letter from Varcoe to Chisholm, in Library and Archives Canada, Legal opinions and materials of precedential value, RG 13, vol. 2635, file no. 9-150108, "Powers to License Manufacturers of Cosmetics / if Section 3(j) of Food & Drugs Act is Unconstitutional". The crux of Driedger's legal advice was that the licensing provision could not be constitutionally valid, under federal legislative powers, "because nothing is prohibited." In essence, National Health was precluded from licensing a substance under the criminal law power unless the licensing regime was integrated with a criminal prohibition.
- ²⁰ Driedger is a well-known figure in Canadian legal history. His influential 1983 text *The Construction of Statutes* (2nd ed.) is one of the authorities that has been most frequently by the Supreme Court of Canada. In addition to his scholarly work, his career with the Department of Justice culminated with his appointment as deputy minister.
- ²¹ May 27, 1946 letter from Curran to Varcoe, in Library and Archives Canada, Legal opinions and materials of precedential value, RG 13, vol. 2635, file no. 9-150108, "Powers to License Manufacturers of Cosmetics / if Section 3(j) of Food & Drugs Act is Unconstitutional".

- ²² March 1, 1946 letter from Curran to Driedger, in Library and Archives Canada, Legal opinions and materials of precedential value, RG 13, vol. 2635, file no. 9-150108, "Powers to License Manufacturers of Cosmetics / if Section 3(j) of Food & Drugs Act is Unconstitutional". See also Davidson, 1949a, p. 9.
- ²³ By contrast, a study published by the AMA concluded that it was "accepted that a certain amount of puffery is necessary in the field of promotional cosmetic advertising. However, some manufacturers of creams containing estrogens have made claims, either directly or by innuendo, that overstep these limits" (Behrman, 1954, p. 122).
- ²⁴ Ads for the drug Premarin, regularly deployed these two phrases throughout the 1940s and 1950s. Premarin was developed and first marketed in Canada, in the early 1940s, by the pharmaceutical firm Ayerst, McKenna & Harrison Ltd.
- ²⁵ Additionally, and critical to practices later enacted by National Health officials to put an informal "upper limit" on potency, the regulations also required a statement of the "net contents" (or weight) of an estrogenic cosmetic product; see section C.02.010(b)(iii).
- ²⁶ For studies in a material-semiotic or relational materialism tradition that attend to the "texture" of ordering practices, see, for example, Law & Lien (2012), and De Laet & Mol (2000).
- ²⁷ Pugsley published at least one study with Collip; see Collip, Pugsley, Selye, & Thompson (1934). See also Li (2003a), pp. 91–94 for information about Pugsley and fellow graduate students' experiences in Collip's lab.
- ²⁸ After joining National Health in 1939, Pugsley authored and co-authored scientific studies regarding biological assay methods for hormones; see Pugsley & Morrell (1943); Pugsley (1946); and Willis, Rampton, & Pugsley (1949).
- ²⁹ For the research on the effects of DES in chicken feed, see Bird, Pugsley, & Klotz (1947).
- ³⁰ In 1950 the FDA tried to crystallize its "rule of thumb" on the potency of estrogenic cream into a statutory rule. When the House Commerce Committee was considering amendments to make it easier to restrict the sale of prescription drugs, the FDA asked it to write into the act an "exemplary list of prescription

drugs" to guide interpretation of a new definition of prescription drugs. On the list was "Estrogenic Substances—except skin creams containing not more than 10,000 International Units of estrone, or the equivalent of other estrogens, per ounce of cream" (Dunn, 1951, p. 969). However, industry opposed this list and the Durham-Humphrey bill passed in 1951 without it (Dunn, 1951, p. 966).

- ³¹ In the context of US federal administrative law, as a general category, administrative rulings would include interpretations, opinions, orders, directives, and decisions issued by administrative agencies that have been legally empowered by legislation to make those rulings.
- ³² "Administrative ruling" also provides a convenient label not found in the historiography of Canadian public law. The legal and historical literature regarding debates, in the interwar period, over the legitimacy of delegated legislation and the emerging administrative state is massive, and I cannot rehearse it here.
- ³³ November 1950 handwritten note from Thomson to Whitmore, in Library and Archives Canada, Department of Health fonds, RG 29, "Food and drugs Articles taken from newspapers magazines & newspaper advertisements," 1949–1953, vol. 259, file no. 347-1-6 (part 4), reproduction copy no. I-115336.
- ³⁴ November 7, 1950 memo from Curran to Whitmore (with handwritten note by Pugsley), in Library and Archives Canada, Department of Health fonds, RG 29, "Food and drugs Articles taken from newspapers magazines & newspaper advertisements," 1949–1953, vol. 259, file no. 347-1-6 (part 4), reproduction copy no. I-115336. Ironically, Pugsley's formulation unintentionally implied that these five creams could not be sold as cosmetics, as preparations that did *not necessarily* cause systemic effects failed to meet the more stringent legal test of being *demonstrated to be free* from systemic effect.
- ³⁵ November 7, 1950 memo (Pugsley's handwritten note), in Library and Archives Canada, Department of Health fonds, RG 29, "Food and drugs Articles taken from newspapers magazines & newspaper advertisements," 1949–1953, vol. 259, file no. 347-1-6 (part 4), reproduction copy no. I-115336.
- ³⁶ March 21, 1952 letter from Devlin to Venus Products Ltd., in Library and Archives Canada, Department of Health fonds, RG 29, "Food and drugs Articles taken from newspapers magazines & newspaper advertisements," 1949–1953, vol. 259, file no. 347-1-6 (part 4), reproduction copy no. I-115336. Devlin also

requested various other label changes, which he asserted were required pursuant to section C.002.007.

³⁷ March 26, 1952 letter from Venus Products Ltd. to Devlin, in Library and Archives Canada, Department of Health fonds, RG 29, "Food and drugs – Articles taken from newspapers magazines & newspaper advertisements," 1949–1953, vol. 259, file no. 347-1-6 (part 4), reproduction copy no. I-115336.

³⁸ March 26, 1952 letter from Venus Products to Devlin; March 28, 1952 letter from Devlin to Venus Products; and May 16, 1952 letter from Devlin to National Health officials, in Library and Archives Canada, Department of Health fonds, RG 29, "Food and drugs – Articles taken from newspapers magazines & newspaper advertisements," 1949–1953, vol. 259, file no. 347-1-6 (part 4), reproduction copy no. I-115336. Venus Products Ltd. was remarkably candid about its reasons for wanting to retain these directions for use: "Our only hope was that in the event of cancer being discovered coincidental with the use of Formula V7 that the victim would think and do a little investigating before going off half cocked and blaming us unjustly. One claim with the publicity that would be sure to attend regardless of how unjust that claim was or whether our product was proven harmless in the highest court the results to us would be so adverse that it could well put us out of business."

³⁹ Chemicals in food products: Hearings before the House Select Committee to investigate the use of chemicals in food and cosmetics, House of Representatives, 82d Cong., 2d Sess., 583 (November 20, 1951) (testimony of Dr. Ervin Epstein, pp. 739-740); and Chemicals in food products: Hearings before the House Select Committee to investigate the use of chemicals in food and cosmetics, House of Representatives, 82d Cong., 2d Sess., 583 (November 23, 1951) (testimony of Dr. Thomas H. Sternberg, pp. 919-920).

⁴⁰ Chemicals in food products: Hearings before the House Select Committee to investigate the use of chemicals in food and cosmetics, House of Representatives, 82d Cong., 2d Sess., 583 (November 20, 1951) (testimony of Dr. H. V. Allington); and Chemicals in food products: Hearings before the House Select Committee to investigate the use of chemicals in food and cosmetics, House of Representatives, 82d Cong., 2d Sess., 583 (November 23, 1951) (testimony of Dr. Samuel Ayres).

⁴¹ October 26, 1953 memo and November 2, 1953 memo in Library and Archives Canada, Department of Health fonds, RG 29, "Food and drugs – Articles taken

from newspapers magazines & newspaper advertisements," 1949—1953, vol. 259, file no. 347-1-6 (part 4), reproduction copy no. I-115336.

⁴² In the bottom right-hand corner, Figure 6 states Lady Esther Hormone Cream had "no objectionable greasiness!"

⁴³ Originally published as *L'anomalia selvaggia*. *Saggio su potere e potenza in Baruch Spinoza*, Negri 1991/2000 identifies as "potere" and "Potenza" what in English translations of Spinoza had both been reduced to "power."

44 When it comes to changes materialized through topical estrogenic products, not everybody has been given the self-responsibilizing option of attending to their own exposures by following label directions. Transgender women and non-binary people wanting estrogen-derived effects of softer skin, less body hair, or breast enhancement often lack the option of purchasing over-the-counter products and following labeled directions. If they wish estrogen to shape their embodiments, this use is typically medicalized, supervised by a physician willing to prescribe it. While boundaries between estrogenic drugs and cosmetics were blurred in the 1940s and 1950s, for trans or genderqueer people seeking more feminine embodiments in 2020, such boundaries are rigidly enforced by law. Indeed, in this scenario, labels are disregarded, as, in many jurisdictions, estrogen must be prescribed "off-label."

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