Washington State Regulations Governing Endocrine-Disrupting Chemicals:

Current Limitations and Potential Improvements

by

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ABSTRACT

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Endocrine disruptors (EDs) are a large and pervasive group of manufactured chemicals that are prevalent in the environment and in our bodies, and that are currently underregulated. Though the outcomes of exposure to these chemicals vary, scientific techniques for observing and predicting their effects are shared in common. The most recent, substantial regulation related to EDs in Washington, the Children's Safe Products Act (CSPA), was passed in 2008. Since then, both scientific understanding and public awareness of EDs has increased dramatically. Based upon what we know now, and on novel regulatory approaches employed in the EU, this research sought to identify limitations hindering current and proposed future policies, and suggestions for how future policies could be improved, based upon scientific advances and areas of agreement among stakeholders. Through qualitative policy analysis and stakeholder interviews, this research determined that scientific uncertainty and the lack of political will, defensible data, and funding were the main impediments to current policy improvements in Washington State. This thesis recommends that future policy be enacted that employs improvement in modeling technology to predict the toxicity of chemicals prior to their use, and that Washington State follow the momentum produced by CSPA, by expanding the products regulated by the act, basing the regulation on chemical class rather than individual chemical, and designating the authority for chemical regulation to the Department of Ecology.

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This thesis is dedicated to the memory of Lorrie Brown.

1. Introduction

Human beings are exposed to hundreds of endocrine-disrupting chemicals on a daily basis, and man-made endocrine-disrupting chemicals can now be found in nearly every environment on earth (Khetan, 2014). As a class of chemicals, they alter brain development and decrease intelligence (Schug, Blawas, Gray, Heindel, & Lawler, 2015), alter thyroid maintenance, promoting obesity (Heindel, Newbold & Schug, 2015), and alter the development of reproductive organs and decrease fertility of humans and animals worldwide (Kabir, Rahman, & Rahman, 2015; Knez, 2013).

Unfortunately, endocrine disruptors are one of many poorly understood and under-regulated classes of chemicals or materials whose recent increase in prevalence threaten the sanctity of life on earth (Bergman et al., 2013). While we have dealt with these threats in the past, as demonstrated in the case of lead, developing threats such as nanometals, microplastics, and pharmaceuticals lack coherent regulation (Trujillo, 2016; Vasquez, Lambrianides, Schneider, Kümmerer, & Fatta-Kassinos, 2014).

While the most egregious endocrine-disrupting chemicals, including heavy metals, DDT, and polychlorinated biphenyls (PCBs) are now largely regulated, they persist in the environment alongside hundreds of other chemicals that threaten to increase morbidity on a global scale (Khetan, 2014; Ma et al., 2015; Rasmussen et al., 2015; Tanabe, 2002). Many of these persistent organic pollutants (POPs), once released into the environment, can continue to accumulate in animals and sediments for years or even decades after production has ceased. Because the threat posed by many endocrine disruptors is persistent, accumulating in body fat and continuing to exert endocrine-disrupting effects,

the question of regulation impacts not just the present, but the future health of people and the environment.

Washington is one of the states leading the charge on endocrine disruptor legislation within the United States. Several high-profile Washington State laws have, in recent years, found themselves translated to federal regulations (Food and Drug Administration, 2012; Children's Safe Products Act, 2008; Consumer Product Safety Improvement Act, 2008; Safe Baby Bottle Act, 2010). If we could understand how the policy in Washington has developed, and what issues are holding back its further development, that knowledge could be used to streamline the production of protective policies within Washington and within the United States as a whole. Furthermore, that information could be used to provide insight and guidance for the regulation of other emerging threats.

1.1 Lead as an example of the case for regulation

The regulation of lead in modern times represents a basic case study that demonstrates the value of and potential for future regulation (Khetan, 2014). While endocrine disruptors are a relatively unknown class of chemicals, knowledge of their impacts seem to be following a similar path as the knowledge of the dangers of lead. Similarly, lead's use in industry and the resulting political issues that occurred in the pursuit of regulation closely reflect the debate surrounding endocrine disruptors today. The current state of lead regulation presents a well-regulated end-state for endocrine-disrupting chemicals (Bridbord & Hanson, 2009; Muennig, 2009).

Lead has been recognized as a toxin for millennia, and has been indisputably proven as such in modern times. Reference to the dangers of lead date back as far as ancient

Rome. As research on lead has become more and more precise, with larger studies and more accurate measurements, the impact of lead exposure on childhood development has consistently been shown to be more devastating than previously thought (Grandjean, 2010). Recent tests have shown that there is no minimum threshold for exposure to lead, and that any exposure leads to decrease in intelligence, and associated behavioral issues (Pichery et al., 2011; Vorvolakos, Arseniou, & Samakouri, 2016).

While the dangers of lead were being explored by physicians, the benefits of lead were being explored by engineers. Since Roman times, lead has consistently proved acutely useful, due to its ubiquity and unique physical properties. Lead's easy malleability and relative robustness led to millennia of its use as pipe material in water infrastructure (Delile, Blichert-Toft, Goiran, Keay, & Albarède, 2014). Since the advent of circuitry, lead has been a crucial component in electronics manufacturing (Almeida, Madureira, Bonilla, & Giannetti, 2013). Lead has also found uses in house paint, as a gasoline additive, and in wheel and fishing weights (Kristensen, 2015; Levallois et al., 2014)

Studies tying the hazard of lead to economic and social costs have led to regulation, and kick-started the process of identifying reasonable substitutes; however it has not always been a simple process (Bridbord & Hanson, 2009). The staggering lifetime costs of contemporary lead exposure have recently been documented, and make a strong economic argument for immediate and thorough exposure mitigation (Muennig, 2009; Pichery et al., 2011). Minimizing lead exposure and identifying non-toxic substitutes for lead have become crucial elements of state, federal, and international policy (Davies et al., 2009; State of Washington Office of the Governor, 2016).

Many of the uses of lead were without substitute upon introduction and, despite our best efforts, some remain that way. While lead pipes have largely been replaced by copper and plastic pipes, these materials have their own drawbacks, including the potential for endocrine disruption (Skjevrak, 2003). While lead in solder has been restricted in the European Union since 2006, many of the beneficial properties of lead in solder have not been emulated, and exceptions to the ban still allow for the use of lead in applications where no suitable substitutes exist (Menon, George, Osterman, & Pecht, 2015).

The case of lead resembles closely that of endocrine disruptors in general. Many endocrine disruptors were assumed to be entirely benign when first put into production at the turn of the 20th century, and demonstrate properties that had and still have no direct substitute. As their impacts were being explored by biologists and physicians, new permutations with new properties were being produced and put into widespread use (Khetan, 2014). As their effects have become more apparent, certain endocrine disruptors produced in the high volumes or causing self-evident impacts have been regulated at the federal or state level. These chemicals continue to enter the environment even after the end of their production due to dissemination from legacy sources (Wattigney, Irvin-Barnwell, Pavuk, & Ragin-Wilson, 2015). Many endocrine disruptors with and without robust bodies of research surrounding their effects have been replaced due to consumer pressure (Baluka & Rumbeiha, 2016). However, many more remain in use due to a lack of a known substitute and a general lack of consideration.

1.2 Issues related to recognizing and regulating endocrine disruptors

Endocrine disruptors are present in many of the products we use on a daily basis, including those we eat and drink from and those we trust to clean our hands (Khetan, 2014). Perhaps the most widely recognized endocrine disruptor of the twenty-first century is bisphenol A, or BPA, a manufacturing additive that makes plastics less brittle, continually leaches from resultant products during normal use, and mimics the hormone estrogen when ingested (Michałowicz, 2014). BPA remains a common ingredient in canned food liners, and is frequently found in the foods contained therein, even after rinsing (Lorber et al., 2015). Triclosan has regularly been added to soaps as an antimicrobial agent. While it has been found to be inefficient in that role and has been found to cause endocrine disruption, it continues to be used in that context (Giuliano & Rybak, 2015; Wang & Tian, 2015).

While some endocrine disruptors are used in critical applications where practical substitutes do not exist, many are employed to little practical benefit, despite the presence of viable, non-toxic alternatives, in the name of marginal cost-savings. BPA is present in almost all thermal receipt paper, in the form of a dust which easily sloughs from the paper and sticks to fingers (Björnsdotter, de Boer, & Ballesteros-Gómez, 2017). Recent public and regulatory pressures have led to the removal of BPA from this application. While known, safer alternatives, such as a vitamin-C-based mixture, exist, the BPA in these applications is frequently substituted instead with chemical analogues that also demonstrate endocrine-disrupting properties due to reasons of cost (Björnsdotter, Jonker, Legradi, Kool, & Ballesteros-Gómez, 2017).

Endocrine disruption's mode of action is well-understood and endocrine disruptors' effects are predictable. For the past three decades, the science of endocrine disruption has become more and more sophisticated, as possible pathways for disruption have been enumerated and explored (Yang, Kim, Weon, & Seo, 2015). Tests in yeasts and higher animals have provided consistent methods for detection. As more chemicals have been evaluated for their endocrine-disrupting properties, computer models have become adept at predicting endocrine-disrupting potential based upon chemical structure (Wilson et al., 2016).

However, because endocrine disruptors do not act in the same manner as traditional toxins, and because their effects are so dispersed, their dangers are not easily quantifiable and are thus difficult to definitively communicate. Because the indirect, time-delayed mode of action specific to developing organisms was so at odds with the focus of traditional toxicology, endocrine disruption was not commonly defined or recognized until the 1990s (Colborn, vom Saal, & Soto, 1993). While the effects of certain endocrine disruptors have been quantified, because we are exposed to such a variety of endocrine disruptors simultaneously, and because of the great time delay involved in many of the most detrimental outcomes, it is difficult to concretely associate real-world impacts with a single chemical (Woodruff, Carlson, Schwartz, & Giudice, 2008). Furthermore, certain endocrine disruptors have recently been shown to produce not only delayed effects, but effects on the offspring of exposed individuals (Manikkam et al., 2013; Skinner, 2014). While these impacts are observable in controlled laboratory settings and have been observed in the high-profile case of diethylstilbestrol* (Nilsson & Skinner, 2015), it is

*Diethylstilbestrol, or DES, is a chemical closely related to BPA that was prescribed to pregnant women in the 1960s as an anti-nausea medication. Exposure to DES *in utero* was found to cause birth defects.

unlikely that these same effects can ever be conclusively demonstrated in humans for most endocrine disruptors.

In addition to issues faced in demonstrating the effects of endocrine disruptors, one primary obstacle to comprehensively demonstrating the adverse effects of endocrine disruptors is the great range of impacts they may have, and the variance therein. The impacts of a single chemical can vary greatly, due to the non-linear relationship between dose and effect (Vandenberg & Bowler, 2014), the specific window of exposure (Burggren & Mueller, 2015; Fudvoye et al., 2014), and the broad range of interaction effects produced by the presence of other endocrine disruptors (Kortenkamp, 2014). These wide-ranging issues preclude accurate assessment of the risks borne by exposure to the vast majority of endocrine disruptors; making regulation that much more difficult in jurisdictions, such as Washington State, where risk characterization is an expected element of regulatory debate.

As a result, endocrine disruptor policy in Washington State is an inefficient patchwork that fails to limit human and environmental exposure to many known and suspected endocrine disruptors. While BPA has been banned from baby dishware and sports bottles in Washington State, closely related chemicals that serve the same purpose in manufacturing and have the same effect in the body have largely taken its place (Liao & Kannan, 2013; Rochester & Bolden, 2015). While the recent Children's Safe Products Act implicitly considers endocrine disruption as an adverse outcome, it only requires the reporting of chemical concentration, and does not in itself regulate endocrine disruptors on the basis of that criteria.

1.3 Qualitative policy analysis of endocrine disruptor regulation in Washington State

This thesis attempts to answer the question: What are the current limitations to Washington State endocrine disruptor policy, and how could state endocrine disruptor policy be improved through consideration of advances in the science and of the evolving policy landscape at home and abroad?

Formulating a comprehensive approach to this question required gathering insight from the scientific and political communities surrounding the issue and reflecting the broader interests of Washington State and its residents. In order to provide a framework for local discussion of the issue and to predicate more fine-grained analysis in the future, I adopted a qualitative policy analysis lens. Using this framework, I performed a case-study of the history and trajectory of endocrine-disruptor policy in Washington State, involving a comprehensive policy document review, as well as an international policy and state-of-the-science review. Significant open questions and potential future directions highlighted by these reviews were used to produce a series of questions that served as the basis for a series of open-ended stakeholder interviews that attempted to evaluate all salient perspectives on the issue. Finally, the interviews were coded based upon the same identified concerns and others that were suggested by the interview process, and results were compared and contrasted to highlight both politically feasible paths forward and more fundamental issues of contention amongst stakeholders.

The results of this research revealed that further regulation of endocrine disruptors is limited by the high degree of scientific uncertainty, the lack of available data, the potential of incurring regrettable substitutions, and a general lack of funding and political

will. While recent scientific advances have made inroads by reducing uncertainty and streamlining the data collection and evaluation process, the nature of endocrine disruption as a mechanism prohibits risk assessment, and thus inhibits the traditional legislative assessment process. Nonetheless, existing endocrine disruptor regulations pave the way for both subtle and fundamental improvements in regulation, and efforts by state agencies, industries and advocacy groups promise to improve chemical management through non-regulatory means.

To communicate the nature and significance of these findings, I begin by providing background information related to the characteristic effects that define endocrine disruptors, their history of production and use, and extant policy approaches employed in Washington, the United States, and internationally. I then critically review the state of the science to highlight disagreements and uncertainties that may impact regulation, and models of science-policy interaction to aid in identifying feasible future policies. I then describe in detail my methodology and the results of my research before discussing the implications thereof, and providing recommendations for Washington State policy and future research.

2. Background

Endocrine disruptors represent an emerging hazard that *will* become more regulated as time goes on, and for that reason, it is worthwhile to search for presently feasible fixes to bypass that regulation process. While the precise definition of endocrine disruptor may remain somewhat unclear, many chemicals in widespread use today fulfill even the most conservative requirements. Regardless of precisely what definition is used, a wide variety of chemicals alter the normal, beneficial function of the endocrine system and lead to negative health outcomes for humans and animals at all stages of development (Bergman et al., 2013; Groshart & Okkerman, 2000; TEDX, 2017). For these reasons, a systematic review of state policies relating to this class of chemicals is warranted. I begin by describing the basic tenets of endocrine disruptors. I then review established approaches to toxics policy, and evaluate their efficacy based upon established criteria. Finally, I review external influences on Washington State policy, along with past and current policies to establish to state of endocrine disruption regulation and to establish a framework for future policy recommendations.

2.1 Definition

There exist today several different definitions of endocrine disruptor that differ in subtle but significant ways. Perhaps the broadest definition was proposed by the U.S. EPA (1997), for which an endocrine disruptor is an “exogenous agent that [interferes] with the synthesis, secretion, transport, binding, action, or elimination of natural hormones in the body that are responsible for the maintenance of homeostasis, reproduction, development, and/or behavior.” The operative word “interferes” here is open to interpretation. The WHO presented a slightly more concrete definition of

endocrine disruptor: “an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations” (Damstra et al., 2002). “Adverse health effects” indicates that the outcome must be negative, rather than simply different, as could be interpreted in the EPA definition. Further, this definition applies to humans and animals alike, and puts greater emphasis on transgenerational effects. The WHO also distinguishes between known and potential endocrine disruptors, clarifying that the latter “might be expected to lead to endocrine disruption” (Damstra et al., 2002). Most recently, the European Food Safety Authority distinguished endocrine disruptors as a sub-class of the larger body of "endocrine active substances," with the latter encompassing "any chemical that can interact directly or indirectly with the endocrine system, and subsequently result in an effect on the endocrine system, target organs and tissues," with the further classification as an endocrine disruptor depending upon "the type of effect, the dose and the background physiological situation" (Barlow et al., 2010). While there exist other definitions of endocrine disruptors, the main points of contention seem centered around the qualitative nature of their impact. This definitional debate is further explored in the literature review.

It is also important to bear in mind that the delineation of “endocrine disruptor” characterizes chemicals by their mode of action, rather than their precise endpoint*. What is clear in the above definitions, and as will become clear with further examples, is that these chemicals are classed together through their mechanism. It is this characteristic that makes them more difficult to coherently regulate; changes in developmental stage,

*For example, if one was diagnosed with breast cancer following chronic exposure to BPA, cancer would be considered the *endpoint*, and endocrine disruption the *mode of action*.

exposure level, and simultaneous exposures will radically alter the impact of the same basic mechanical alteration (Burggren & Mueller, 2015; Fudvoye et al., 2014; Kortenkamp, 2014; Vandenberg & Bowler, 2014). To understand this, it is important to understand the role of the endocrine system with the body.

2.2 Human effects of endocrine disruptors characterized by life stage

The endocrine system acts as a signaling pathway wherein the movement and varying concentrations of hormones alter the development and day-to-day operation of other organ systems. During periods of growth, such as the perinatal period & puberty, the endocrine system guides the development and refinement of the various organs of the body (Khetan, 2014). During periods of relative stasis, the endocrine system regulates the normal functioning of those same organ systems. Disruption of the endocrine system during different periods of the life cycle manifest in different ways.

Many endocrine-disrupting chemicals have only had their impacts directly demonstrated in animal studies. While broad predictions of population-level effects can be made based upon animal studies, and while population-level statistics can be recorded that support those studies, it remains very difficult to conclusively link a certain chemical with population-level outcomes, for the reasons cited above and due to legal and moral objections against direct human testing (Bergman et al., 2013).For example, it is difficult to conclusively demonstrate an association between fetal endocrine disruptor exposure and adult male semen quality because there are so few cohorts “with stored blood samples from mothers during pregnancy and with offspring of sufficient age to perform follow-up studies. Therefore… one of the core elements of the endocrine disruptor hypothesis has remained untested for almost 20 years” (Vested et al., 2014**).** The same

applies to any effects that are only demonstrated in offspring or grandchildren of the exposed.

The endocrine system is most sensitive to disruption during fetal development and during the first year of life (Palanza et al., 2016). While organs are developing from previously undifferentiated cells, the exact nature of their development is heavily dependent on hormones. Alterations to the signals that cells and organs receive at this time can take several different forms. In the case of the sexual organs, perinatal endocrine disruption has been associated with physical malformation; incompletely formed uteruses, and undescended testes and hypospadias, or more generally leading to reduced sperm count and viability, menstrual irregularity, or simply reduced fertility (Costa et al. 2014; Knez, 2013; Vested et al., 2014). Effects on the thyroid lead to hyperthyroidism and obesity (Gutleb et al., 2016; Heindel et al., 2015). Neurodevelopment of the brain is altered, altering brain function and leading to decreased intelligence and behavioral disorders such as autism (Schug et al., 2015). In addition to these immediately apparent changes, subtler structural changes to these systems can also occur, that manifest as cancers and chronic diseases much later in life (Gibson & Saunders, 2014; Hu et al., 2016; Knower et al., 2014; Rezg et al., 2014; Soto et al., 2013).

Much of the same is true during puberty, although the subtler physical changes lead to similar, subtler maldevelopments (Fudvoye et al., 2014). This difference persists, and is described in the concept of “body burden” (Huang et al., 2014). In effect, younger people are more sensitive to endocrine disruptors because their bodies require proportionally more food and water, etc. in order to maintain growth. Further, children metabolize faster than adults and are thus more frequently exposed to acute doses of endocrine disruptors

present in the environment. While near puberty the visibly altered outcomes may be more of degree than of kind (e.g., earlier onset of puberty), exposures at this period often take the form of delayed effects as described above.

During periods of relative stasis, namely post-puberty, endocrine disruptors primarily act as agonists (Fudvoye et al., 2014; Rezg et al., 2014). During these periods or life, hormones typically regulate the body, and ensure the stability and maintenance of existing systems. While during periods of development, issues are primarily associated with acute doses of endocrine disruptors that alter development, chronic exposure during adulthood stresses the target organ, potentially limiting its ability to operate beneficially and contributing to premature failure.

It has recently been demonstrated that exposure to certain endocrine disruptors can alter gene expression in subsequent generations, leading to effects of exposure that may only manifest in the grandchildren of those exposed (Manikkam et al., 2013; Rissman & Adli, 2014; Skinner, 2014). These transgenerational epigenetic impacts may mean that the effects of exposure to certain endocrine disruptors may not manifest until the grandchildren of the exposed individuals are born, perhaps not until decades later.

2.3 Salient characteristics of known endocrine disruptors

Perhaps the most infamous endocrine disruptor, beyond heavy metals such as arsenic and lead, is the pesticide DDT, the subject of Rachel Carson's *Silent Spring* (1962) and a catalyst for the environmental movement of the 1960s and 1970s. The additive Bisphenol A, or BPA, is nearly as well known today for its ubiquity in consumer products and its

insidious association with breast cancer, among other endpoints (LaKind & Naiman, 2015).

Endocrine disruptors represent a threat to the health of the environment and human beings alike, and in a large variety of ways, many of which are only now becoming well-understood. Many steps go into producing an accurate estimate of the risks of any given chemical, some of which cannot be taken with our current knowledge (Bergman, 2013). In contradistinction to traditional chemicals considered in toxicology, the manner in which the endocrine system operates leads to a nonlinear relationship between dose and response (Vandenberg & Bowler, 2014). Because much of the exposure to endocrine disruptors comes from non-point sources (Tijani et al., 2013), their movement through the environment must be modeled and tested. Even if all of these characteristics were evaluated in isolation, the interaction effects of multiple endocrine disruptors on the endocrine system are effectively unpredictable, rendering the real-world evaluation of risk unattainable (Kortenkamp, 2014).

In order to fully evaluate the risk of an endocrine disruptor in isolation, a series of functional questions must be answered. Endocrine disruptors have historically been classed and researched based upon the specific hormone which they disrupt, with much of the research focusing on estrogen and testosterone (Bergman, 2013). Once the specific hormone that is impacted is identified, it must next be determined the mode of action of disruption, be it altering the “synthesis, secretion, transport, binding, action, or elimination” of the hormone (U.S. EPA, 1997). Once the affected hormone and mode of action are identified, the dose-response relationship still needs to be determined.

Endocrine disruptors, depending on their mode of action, frequently subvert the idea that “the dose makes the poison.” Hormones do not exert linear effects; in practice, the lack of a hormone might inhibit a certain response, a small dose might prompt that same response, and a larger dose might overwhelm the system, and have the same effect as no dose at all (Vandenberg & Bowler, 2014). This inverted-U relationship, or non-monotonic dose-response relationship, undermines the established scientific understanding, and was largely responsible for the delayed acknowledgement of the issue posed by endocrine-disrupting chemicals.

The definition of endocrine disruptor encompasses a wide variety of chemicals, many of which act in very different ways. A large subset of endocrine disruptors is specifically designed to move rapidly through our environment and accumulate in body tissues (Faure & Lefevere, 1998). Certain pesticides, for example, are designed to move through the water column, integrate into plant and pest tissues, and persist throughout at least a whole growing season. The same attributes that make them effective in disrupting pests leads them to accumulate in the environment and in humans and other animals. Persistence in the environment leads to chronic exposure for organisms in that environment (Faure & Lefevere, 1998). Persistence in body tissue, or bioaccumulation, may manifest as chronic exposure or as acute exposure (Wang et al., 2015). Certain other endocrine disruptors present a threat not due to their persistence, but due to their ubiquity. For example, BPA degrades quickly in the environment and is quickly metabolized, but because of its presence in so many products that humans handle and directly ingest every day, the majority of people are chronically exposed to it (LaKind & Naiman, 2015).

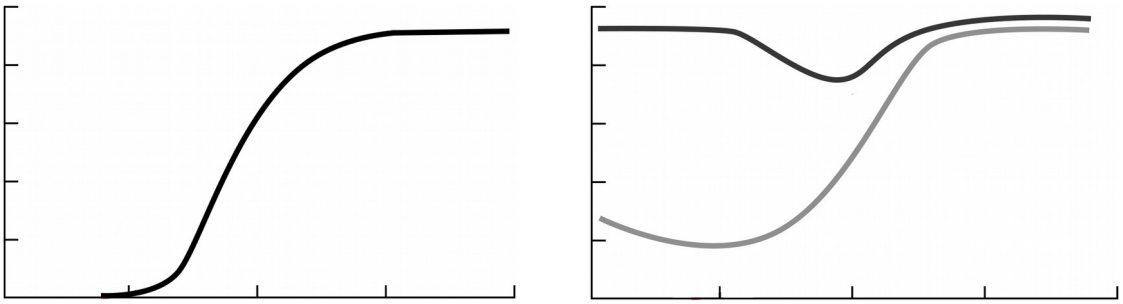

Figure 1: Monotonic and non-monotonic dose-response curves: These graphs represent an organism's response to the presence of a chemical. The x-axis represents the dose of the chemical, and the y-axis represents the degree of organism response. Traditional toxicology assumes a continuous increase until saturation, as illustrated by the black curve on the left. Non-monotonic curves can take many forms, for instance an inverted *U* shape, indicated by gray curves on the right, which may be caused, for example, by two contradictory monotonic curves. (Adapted from UNEP/WHO, 2013)

Even if the direct mode of action and source and magnitude of exposure are known for any given chemical, to precisely predict its impact on individuals requires analyzing the combined effect of multiple simultaneous endocrine disruptors (Kortenkamp, 2014; Trasande et al., 2016). While one chemical may act to mimic estrogen, another may act to inhibit estrogen receptors. Their effects may magnify each other or cancel each other out, and that relationship may itself be non-monotonic, producing different synergistic effects as the concentration of one or both of the endocrine disruptors changes. To account for the combined effect of the total range of endocrine disruptors in the environment would require the production of an increasingly complex model. Considering the uncertainties present in the preceding steps, this holistic modeling is currently unattainable.

2.4 Historical context of endocrine disruptor proliferation and knowledge

While the endocrine system has always been altered by the environment, the nature and magnitude of exposure changed upon the advent of the chemical revolution. Many natural chemicals impact and alter the expression of the endocrine system to some degree, such as phytoestrogens, plant-based chemicals that mimic estrogen (Sirotkin &

Harrath, 2014). However, many manufactured chemicals are more resistant to degradation, are more potent, and are more liable to bioaccumulate than naturally-occurring endocrine active substances. The proliferation of hydrocarbons as a resource for chemical manufacturing led to a chemical revolution that is ongoing, and has continued to accelerate. Every year, thousands of novel chemicals enter into commerce, without requirement that they be tested for their unintended effects (U.S. EPA, 2017).

Not only do there exist uncertainties relating to the effects of these chemicals, but also uncertainties as to precisely which chemicals are in use and at what concentrations. In the United States, there exists no requirement that the precise use of chemicals be reported, much less the magnitude; thus, it is difficult to rank chemicals in terms of their ubiquity, and to make informed decisions as to which are most imminently in need of evaluation.

The increase in the production and distribution of endocrine disruptors, and the recent recognition of their far-reaching effects, has prompted an increase in the variety and sophistication of tests for endocrine disruption. Before the mode of action of endocrine disruption was well-understood, most chemicals were tested for safety via administration in large doses to adult organisms (Shukla et al., 2010). As our understanding of the endocrine system developed, it was discovered that the effects of endocrine disruptors often did not reflect the typical dose-response curve, and thus the limited data points evaluated in traditional toxicological tests frequently failed to correctly predict effects. Further, in testing only adult organisms, reproductive and developmental effects were not tested for and thus not acknowledged. Essentially, toxicology considered cancer as the result of acute chemical exposure, failing to encompass the most serious impacts of endocrine disruptors (Buonsante, 2014).

Awareness of these other modes of action were publicly acknowledged in the latter half of the 20th century, and inspired more targeted testing methods. Perhaps the most critical demonstration of endocrine-disrupting effects was the rash of birth defects caused by diethylstilbestrol, a drug with endocrine-disrupting properties prescribed to cure morning sickness in pregnant women (Troisi et al., 2016). Following these revelations, the sophistication and variety of testing methods increased, leading to the adoption of studies on pregnant organisms, and multigenerational studies. Recent moral objections to live animal testing have led to the production of increasingly sophisticated testing methods involving single-celled organisms or computer models, which allow for precise demonstration or prediction of the effect that a chemical will have on the endocrine system, from which the broader impacts can be synthesized (Doke & Dhawale, 2015).

Increasingly sophisticated models of environmental chemical movement have been developed, paralleling the development of these internal tests and predictive models (Khetan, 2014). These tests allow for increasingly sophisticated predictions of the impact of the environmental release of endocrine disruptors, in addition to exploring how endocrine disruptors enter and move within living beings.

While these tests and models focus on chemicals in their known form, equally important is an understanding of the degradation pathways of these chemicals. Frequently, the chemical constituents that endocrine disruptors degrade into in the natural environment have endocrine-disrupting properties of their own (Makarova et al., 2016). Thus, effective evaluation of the impacts of the release of an endocrine disruptor into the environment are incomplete without an understanding of their iterative reduction to benign components.

While degradation models will allow us to better understand the movement and effects of currently produced chemicals, it also allows us to predict the impact of future chemicals, which is something that has been incorporated into the recent field of green chemistry (Schug et al., 2013). “Green chemistry” refers to a process of chemicals development, wherein the chemicals, before mass manufacture, are tested for both their beneficial characteristics and their potential to cause unwanted outcomes including endocrine disruption. This typically involves predictive modeling, wherein a chemical is tested to see if it shares characteristics with known endocrine-disrupting chemicals. Green chemistry may also involve early and formalized tests for endocrine disruption, often in the form of simple yeast assays.

Green chemistry is often employed in a process of “alternatives assessment,” wherein a product manufacturer who recognizes the potential hazard of a certain chemical searches for a less hazardous alternative. In this approach, relative hazard is considered alongside differences in cost and effectiveness.

2.5 Justification for review of Washington State endocrine disruptor policy

Despite and because of the current limitations to the study of endocrine disruptors, a systematic review of endocrine disruptor policy in Washington state is merited. Assuming business as usual, even as tests for endocrine disruption become more sophisticated, the lag between production and policy adoption means that it will be a decade or more before extant approaches are adopted into law. Furthermore, endocrine-disrupting chemicals, as a classification, reflect other chemical and material classes that pose similar health and environmental hazards. The history and potential regulatory responses to the issue of

endocrine disruption may be useful in formulating policy responses to these analogous issues.

The primary issue worth exploring in the context of endocrine disruptor policy is the temporal disconnect between the time in which a hazard is first established and the time in which a corresponding risk is concretely established. Because many of the advances in testing procedures are still in development, it is unlikely that the risk posed by any endocrine disruptor will be evaluable for many years to come. Further, the sheer proliferation of endocrine-disrupting chemicals and their synergistic effects make it unlikely that their true risk can ever be precisely established. Nonetheless, recent legislation has demonstrated that there is popular support for improved and proactive regulation, and has begun to evaluate endocrine disruptors from a hazard-based approach.

To understand this phenomenon, it is worth fully exploring the context of current policy, to form as coherent a picture as possible. To understand the limitations and opportunities of state-level policy, both federal policy and local policies should be reviewed. To see how future policies should be broached and couched, this thesis reviews historical Washington State regulations and proposed regulations, attempting to evaluate the conditions that led to their success or failure. To bolster this work, this study collects a variety of stakeholder perspectives, to qualify the results and to address questions of political feasibility.

This work is designed to find resonance with and application in other geographies and other disciplines. While every state is different, other states can nonetheless learn from the example of Washington State, and aide in their own paths forward. Several other states have already addressed the issue of endocrine disruptors, or have adopted policies

analogous to those discussed in this work. Interstate collaboration surrounding this issue exists amongst a handful of states, but approaches to regulation are infrequently unified.

Different classes of chemicals or materials have and will proceed through similar science-policy arcs, and a clear examination of the typical characteristic of these arcs could be rewarded by streamlining the process in future conflicts. Prior to endocrine disruptors, heavy metals and carcinogens have followed a similar arc and have begun to reach a regulatory equilibrium that serves as a model for the end-goal for endocrine disruptor regulation. There are similar narratives developing in regards to microplastics, nanometals, and pharmaceuticals, material and chemical classes that face unique scientific challenges to understanding and political challenges to regulation, but which broadly speaking could be compared to endocrine disruptors. By explaining the historical struggle for endocrine disruptor regulation and the potential thereof going forward, it is my hope that the struggles surrounding these other classes can be streamlined, and their regulation can more quickly reflect our understanding of their dangers.

2.6 Established approaches to toxics policy

Within the sphere of public policy, there are many alternate approaches to chemical regulation that may produce comparable regulatory ends. As with all policy issues, each approach faces its own set of barriers to implementation, and each approach favors the resulting certainty of a certain variable or variables while allowing the others to alter in order to compensate. For example, while a tax may allow legislators to carefully control the cost of certain chemicals, it provides no direct control over the volume of chemicals purchased. Thus, the choice of regulatory approach is carefully tied to questions of

political practicality and political vision. Table one, below, illustrates the seven most common regulatory approaches to chemical management, as identified in the literature.

Table 1: Policy mechanisms applicable to endocrine-disrupting chemicals

Policy Mechanism	**Description**	**Explicit Goal**
Ban	Cessation of production, distribution, sale, etc.	Remove chemical from commerce/environment
Environmental Quality Standard	Point-source regulation of soil, water, airborne chem. concentration	Limit pollution rate (typically in accordance with external goals)
License	Require chemical producers/importers to seek explicit permission to produce/import chemicals	Demarcate chemical producers/importers
Permit	Distribute rights to limited amount of chemical production/import over a specified time period	Delimit chemical proliferation (and fund remediation)
Tax	Add surcharge to chemical production/import/distribution process	Increase cost of chemical use (and fund remediation)
Reporting Requirement	Require retailers to publicly test for and indicate chemical presence/concentration	Increase consumer awareness/empower decision-making
Labeling Requirement	Require indication of chemical presence/concentration on retail products	Increase consumer awareness/empower decision-making

While there is debate over which criteria impact the success or failure of policy (discussed further in the literature review), Eisner (2007) provides a comprehensive list of criteria that may impact the feasibility of environmental legislation, several of which

can be readily assessed for existing policy alternatives: “certainty of results;” “cost,” either to the public or the government; “corrigibility,” or ease of alteration in the face of changing knowledge or norms; “timeliness” of expected outcomes; and “compatibility with normative values.” In addition to these, Eisner delineates three further criteria which are highly context dependent: “administrative feasibility;” “robustness” in the face of varying circumstances; “dynamic efficiency,” or the effect of the regulation on innovation within the affected field; and “public acceptance.” While administrative feasibility can be assessed for certain policy mechanisms based upon existing regulations, the latter three are either too context sensitive to be generalized. The table below illustrates how chemical management policy mechanisms compare in terms of Eisner’s metrics.

Table 2: Summary of Eisner’s (2007) criteria relevant to policy choice for applicable mechanisms

Policy Mechanism	**Certainty of results**	**Cost (direct public)**	**Administrative feasibility**	**Corrigibility**	**Timeliness**	**Compatibility w/ normative values**
Ban	High	High	Low	Low	High	Low
Quality Standard	High	High	Moderate	Moderate	High	High
License	Moderate	Moderate	[unknown]	Moderate	Moderate	Moderate
Permit	High	Variable	[unknown]	Moderate	High	Moderate
Tax	Moderate	Variable	Low	Moderate	Moderate	Low
Reporting Requirement	Low	Moderate	High	High	Low	High
Labeling Requirement	Low	Moderate	Moderate	High	Low	High

2.6.1 Regulatory mechanisms

The most immediate approaches to chemical regulation involve the control of production, sale, or use of a certain chemical or chemicals (Eisner, 2007; Faure & Lefevere, 1998; Richards, 1999). If a chemical disrupts the beneficial functioning of the endocrine system, the logic goes, ensure that it does not reach our endocrine systems. While this approach may be justified in the face of a particularly deleterious chemical, the example of BPA* demonstrates the issue that substitutability presents to this approach. If we ban a single chemical, or even a class of chemicals, users will frequently substitute the most similar available chemical or class of chemicals, in order to minimize cost. While these chemicals will be likely to have the same beneficial properties, a ban alone provides no incentive for reducing the negative impacts of as-yet unregulated chemicals. From a strictly economic perspective, a ban is also inefficient in the sense that the marginal benefits of chemical use may exceed the marginal costs up to a certain threshold (Faure & Lefevere, 1998). In other words, strictly banning certain chemicals may incur a social cost greater than that of allowing their limited use.

One policy instrument that is more useful as a complement to existing legislation than as a standalone source of authority is a quality standard, which dictates a maximum acceptable concentration of a chemical in a given medium, such as soil, air, or wastewater treatment plant effluent (Faure & Lefevere, 1998). Washington State has water quality standards, regulating the concentration in public waterways of a variety of chemicals

* BPA was banned from use in sports bottles in Washington State. In its stead, many sports bottles now contain BPS, BPF, or another chemical closely related to BPA that serves the same purpose in bottle construction and has similarly deleterious effects in the human body.

including endocrine disruptors. Frequently, as in this case, acceptable concentrations are designed to limit the calculated human health risk to a certain level of adverse outcomes. However, dictating chemical policy in this indirect way makes it difficult to improve when the quality standards aren't met, because environmental pollution is often caused by a variety of dispersed sources that are difficult to regulate simultaneously, and may not be applicable direct sources of endocrine disruptor exposure, such as sports bottles or receipt paper.

For this reason, standards are often established in tandem with a licensing or permitting system (Faure & Lefevere, 1998). In this system, producers of large environmental discharges must receive a license to discharge certain chemicals, or a permit to discharge certain chemicals in certain amounts. While this can lend itself to the regulation of endocrine disruptors within environmental discharges, it could just as easily apply to the concentration of endocrine disruptors in consumer products. Polluters found to be out of compliance with the system are penalized.

If regulators wished to directly alter the demand, thus indirectly reducing the supply, of endocrine-disrupting chemicals, they could tax them (Mason, 1998). Taxes could be applied to the production, distribution, or consumption of endocrine-disrupting chemicals. In raising the cost of using specific chemicals, taxation would make preferable solutions more cost-competitive, and generally reduce the incentive to use endocrine-disrupting chemicals. However, this method leads to much more inexact outcomes than direct methods of regulation, as it is difficult to determine the relationship between cost and demand. In extreme cases, where no substitute exists, a tax may not alter the production or dissemination of a chemical at all.

As is the case with the Children's Safe Products Act (CSPA), the most relevant current regulation in Washington State, endocrine disruptors could be subject to reporting requirements. In contrast to the above-mentioned regulations, this approach requires fewer resources to implement, and is easily validated with laboratory testing. Further, because this approach does not restrict the actual concentration of any chemicals, the requirements to add a chemical to a reporting list are frequently less stringent than for a ban list. If there is reason to believe that a chemical is hazardous, but its risk cannot be quantified, collecting concentration information from producers and distributors allows for a more robust understanding of risk to be produced in the future. In practice, this approach may act as a sort of "soft ban," as it indicates to companies that these chemicals are under consideration for subsequent command-and-control regulation.

Similarly, labeling requirements could see the presence and potential impacts of endocrine disruptors reported on consumer packaging, akin to the Surgeon General's warnings on cigarette packaging. While this approach may be more amenable than command-and-control, it requires a high degree of certainty to be implemented, at which point command-and-control regulations may be preferable.

2.7 Broader policy considerations

While not reducible to a formulaic regulatory archetype, there are several more fundamental conceptual changes that could be made to the regulation of endocrine disruptors which would alter their production and distribution.

Perhaps the most important conceptual shift would be in the burden of proof, which would begin with a minimum data set requirement (Khetan, 2014). Currently, at the

federal level and by extension at the state level, when a new chemical is manufactured and enters commerce, there is no requirement that any safety testing be done on that chemical; in fact, no data about the chemical need be supplied at all. Thus, if anyone has reason to believe that a product is harmful and should be regulated (assuming that they can even identify the active chemical in the first place without being stymied by obfuscating trade secret laws), they must isolate or synthesize the chemical themselves and perform their own tests to prove harm before they have any chance of enabling regulation. In contrast to the American system, the European union requires that any chemicals manufactured in high volumes be thoroughly tested at the expense of the manufacturers. Adopting a system where the manufacturer must demonstrate the safety of their product would perhaps lead the chemical industry to adopt principles of green chemistry.

Barring the implementation of a minimum data set, and a shift in the burden of proof of safety/risk, regulators can provide other incentives and opportunities to industry members to test for hazards posed by chemicals prior to their large-scale production (Eisner, 2007). Washington State has developed programs to promote self-regulation of industry through the principles of green chemistry and alternatives assessment. These programs teach the use of existing frameworks that test for adverse outcomes throughout the process of chemical development and production, with an attempt to minimize the cost of failure if hazardous endpoints are discovered. While these programs may increase awareness, in the absence of external pressure in the form of regulation, they provide little incentive for chemical manufacturers to actually alter their processes.

2.8 Influences of agencies and extra-judicial policies on state policies

2.8.1 State Agencies

Before discussing the precise policies, it is worth considering the agencies tasked with enforcement, the differences in approach between agencies, and the differing authorities that relevant agencies wield. To that end, the agencies most frequently empowered by endocrine-disrupting legislation are the Department of Ecology (Ecology), the Department of Health (Health), and the Department of Enterprise Services (Enterprise Services).

The majority of proposed EDC legislation grants enforcement authority to Ecology, as most of the proposed legislation uses approaches that target existing areas of its authority. Nearly any command-and-control legislation falls under Ecology's purview, given its role in regulating air and water quality, and its existing role in regulating business and industry. Outreach programs sponsored by Ecology more frequently court business and industry participation than citizen participation. Judgments made within Ecology frequently accept as evidence demonstrations of hazard, even if they haven't been calculated to specific risks, and Ecology is frequently able to act on such a basis (Steward, 2016). The Department of Health, when empowered by legislation, frequently plays a complementary role to that of Ecology. While Ecology has capacity for environmental and materials testing, most biological studies are enacted by Health.

The Department of Enterprise Services, which administers state purchasing, has also been the subject agency of several laws regarding preferential purchasing of endocrine-disruptor-free products. Given the limited relevant scope of Enterprise Services'

authority, these laws are more precisely targeted and perfunctory in nature than those addressed to Health or Ecology.

Table 3: Division of departmental authority regulating endocrine-disrupting chemicals

Department:	**Approach**	**Areas of Responsibility**
Ecology	Hazard-based	Air/water quality; industry and commerce
Health	Risk-based	Human studies, health advisories
Enterprise Services	N/A	State purchasing

2.8.2 Federal and interstate policies

In order to understand the potential range of policies, and contextualize shifting policies over time, it is important to understand the shifting federal policy landscape. While much of the legislation relevant to endocrine disruptors and the media in which they may be regulated have been established since the wave of environmental legislation in the seventies or earlier, regulatory changes at the EPA, and a recent amendment to the Toxic Substances Control Act (which has yet to be enforced) have directly impacted Washington's regulatory authority.

The longest-standing federal regulation relevant to endocrine disruptors is the Federal Food, Drug, and Cosmetic Act (FFDCA), which was passed in 1938. The act regulates what can be added to and sold as food, drugs, and cosmetics. The section related to food is fairly robust, and grants the Food and Drug Administration authority to evaluate food additives. The cosmetic portion of the act, however, does not provide very stringent protections or limitations on cosmetic additives. While there have been recent pushes to

improve cosmetics regulation, including the Safe Cosmetics Act and Safe Personal Care Products Act, they have not been successful thus far.

The Clean Water Act of 1972, and the Water Quality Act of 1987 (collectively CWA) dictate and regulate acceptable levels of water pollution in the United States. Under these acts, states are allowed to set their own water quality standards above and beyond those mandated federally, under criteria deemed as or more stringent than those in the CWA.

The Toxics Substance Control Act (TSCA) of 1976 granted the EPA authority to catalogue and evaluate the safety of chemicals in commerce. The act grandfathered in all chemicals in commerce prior to its passing, granting them immunity from scrutiny via assumption of safety. While it granted the EPA authority to test the safety of new chemicals on the market, and ensured the reporting of new chemicals, it made no provisions for chemical manufacturers to report the amount of the chemical being produced, or whether it was ever commercially produced at all. Thus, while the list of chemicals regulated under TSCA grows every year, the EPA has no basis on which to determine which chemicals are actually present in commerce. While EPA has the authority to regulate all these chemicals, doing so first requires evaluating them for specific detrimental endpoints, a process requiring much more funding than the EPA has historically had access to. Thus, only the most obviously detrimental chemicals end up being regulated (Markell, 2010).

Recently, TSCA has been amended by the Chemical Safety Improvement Act (CSIA). This act allows EPA to require chemical manufacturers to perform tests on the impacts of their chemicals, but only if defensible evidence is produced to support that request. The act increases the sophistication of tests that can be used to evaluate chemical safety. It

also presses the EPA to identify the chemicals presenting the greatest hazard and evaluate them for acceptable risk level and regulate them appropriately. One of the most contentious changes to the act involves state preemption; when the EPA determines an acceptable risk level for a certain chemical going forward, states will now be preempted from substituting a more restrictive level.

2.8.3 International policies

The Registration, Evaluation, and Authorization of Chemicals (REACh) laws in the EU, established in 2007, and their subsequent analogues in non-member countries have provided a contemporary model for chemical regulation. The REACh model connects manufacturers of chemicals produced in high volumes into clearinghouses, requires those clearinghouses to produce minimum data sets for those chemicals, and then regulates the chemicals based upon the produced information. While the production of minimum data sets for high-volume chemicals hints at a potential source of chemicals data upon which to base policy in Washington, much of those data are suppressed beyond the EU in the name of trade secrecy, or available only in digest form, insufficient to provide a basis for regulation.

REACh requires chemical manufacturers to use the best available science to evaluate the safety of all widely produced chemicals in commerce. Crucially, REACh relies strongly on the precautionary principle, accepting demonstration of hazard as sufficient justification for stringent chemical regulation. Additionally, REACh is critical of animal testing, prompting the production of non-animal analogues.

Because many chemical manufacturers produce chemicals for multiple markets, REACh is likely already impacting the chemicals manufactured or imported into Washington State. As more countries adopt a REACh-like approach to chemical safety, so will the global impact of the approach. Even if chemicals with demonstrable hazard remain unregulated in Washington, many chemicals that would otherwise enter Washington waters from overseas will be prevented from doing so.

2.9 Enacted Washington State policies

Perhaps the first policy in Washington State that was written with the concept of endocrine disruptors in mind is the Chemical Action Plan, which was established by executive order. This plan prompted Ecology to produce a list of the ten chemicals or chemical classes of greatest concern, and systematically produce comprehensive statewide plans to address regulation of those chemicals. The order begins by defining persistent toxic chemicals through the example of mercury, dioxin and polychlorinated biphenyl, the latter two of which are classically understood as endocrine disruptors. It cites concern for these chemicals because they “are toxic in small amounts, remain in the environment for long periods of time, and build up in humans, fish and animals.” The first chemical class to be explored under this act were the flame retardant PBDEs. Following evaluation of PBDEs by Ecology, the 2008 session law 65 was passed greatly reducing their acceptable use within Washington. At that same time, however, Ecology transitioned from focusing on Chemical Action Plans to enforcing another law passed that year. The following table represents significant legislation related to endocrine disruptors.

Table 4: Enacted Washington State policies relating to endocrine-disrupting chemicals

2002	Exec. Order No. 02-03	Promotes Sustainable Practices by Agencies
2004	Exec. Order No. 04-01	Orders the regular production of Chemical Action Plans
2008	Wash. Sess. Laws 65	Reduces acceptable uses for polybrominated diethyl ethers (PBDEs)
2008	Wash. Sess. Laws 288	Children's Safe Products Act
2009	Wash. Sess. Laws 243	Promotes substitution of lead wheel weights
2010	Wash. Sess. Laws 140	Phases BPA out of children's food containers and sports bottles
2010	Wash. Sess. Laws 147	Phases copper out of brake pads
2014	Wash. Sess. Laws 135	Encourages state agencies to avoid purchasing PCB-containing products

The Children's Safe Product Act has become the central element of state policy related to endocrine disruptors. It allows for Ecology to require chemical manufacturers and importers to test for and report the presence and concentration of a list of chemicals that Ecology can modify at its discretion. Most crucially, the definition of relevant chemicals was open-ended both in the source of research accepted as evidence and in the endpoints considered as cause for concern. Section 70.240.010 of the revised code of Washington states the following:

> 'High priority chemical' means a chemical identified by a state agency, federal agency, or accredited research university, or other scientific evidence deemed authoritative by the department on the basis of credible scientific evidence as known to do one or more of the following:
> (a) Harm the normal development of a fetus or child or cause other developmental toxicity;
> (b) Cause cancer, genetic damage, or reproductive harm;

(c) Disrupt the endocrine system;
(d) Damage the nervous system, immune system, or organs or cause other systemic toxicity;
(e) Be persistent, bioaccumulative, and toxic; or
(f) Be very persistent and very bioaccumulative.

While these considerations leave the door open for broad reporting requirements, the law also guided Ecology to choose only fifty chemicals for the list, to reflect the initial cost estimate for the law, which was budgeted based upon an assumption of fifty chemicals. Since that time, however, Ecology has expanded and continues to expand the list to reflect other legislative concerns, and to support other agency work.

Beyond creating a reporting requirement, CSPA limited the acceptable concentration of pthalates and cadmium in children's products, although the determined values were later preempted by federal regulations allowing for slightly higher concentrations.

In general, Health works closely with Ecology in determining chemicals to regulate under CSPA, and in relation to many other policies with implications to both human and environmental health. A provision in CSPA requested the creation of an information campaign, which has been pursued by the Department of Health. While not the direct result of state policy, Health performed a multi-year, federally funded study testing for the presence and concentration of certain chemicals in various populations around Washington, including many endocrine disruptors. Unfortunately, funding was not renewed and this study has not persisted, withering one potential avenue for evaluating the efficacy of future policies.

The Department of Enterprise Services administers policies related to the chemicals present in state-funded purchases, and is authorized by the remaining listed laws, as well

as the CSPA, to alter their purchasing habits. Unsurprisingly, changes to purchasing are often accompanied by a requirement to consider relative costs as well as relative safety.

2.10 Proposed state policies

While seven bills relating to endocrine disruptors have passed into law since the beginning of the 2007-8 biennium, in that same time period about 70 more bills related to endocrine disruptors have been proposed and failed to pass. Many of these bills are replicates of the same bill, proposed and refined between legislative sessions. While lead and mercury have consistently been the subject of perennially proposed legislation, there has been a slight increase in bills targeting more exotic endocrine disruptors—benzene, bisphenol A, PCBs, flame retardants, and perfluorinated chemicals, which all impact humans by means of the endocrine system. While most of the proposed bills are targeted at negative human endpoints, many of the lead, mercury, and benzene bills are concerned with the environmental release of the chemical. Recent proposed legislation relating to flame retardants and electronics has sought to extend the reach of CSPA in a piecemeal fashion. Highly specialized legislation which would be administered by Ecology, such as the recently proposed ban of perfluorinated chemicals in food packaging, is being increasingly frequently brought before the legislature.

Table 5: List of proposed state policies related to endocrine-disrupting chemicals

Biennium	HB No.	SB No.	Title	Related to*
2017	1596		Requiring manufacturers of electronics to report the presence of high priority chemicals under the children's safe products act.	CSPA
	1744		Concerning the use of perfluorinated chemicals in food packaging.	CSPA
	1842		Taking action to address lead in drinking water at facilities frequented by children.	Pb
	1925		Taking action to address lead in drinking water in schools.	Pb
	1738		Continuing to protect water quality by aligning state brake friction material restrictions with the requirements of a similar nationwide agreement.	Cu
		5501	Concerning imposing a surtax on the possession of hazardous substances.	
		5745	Addressing contaminated drinking water stemming from the lead content in drinking water infrastructure, including pipes, connections, and fixtures.	Pb
15-16	1049	5021	Concerning cadmium in children's jewelry.	CSPA
		6042	Concerning cadmium in children's jewelry.	CSPA
	1472	5406	Concerning use of chemical action plans to require safer chemicals in Washington.	
		5056	Concerning the use of chemical action plans for recommendations of safer chemicals.	
	1984		Concerning the use of certain chemicals in food.	
	1174	5684	Concerning flame retardants.	CSPA
	1845	5577	Concerning pharmaceutical waste.	
		6540	Ensuring safe playgrounds and turf fields.	
		5829	Conducting remedial actions under the model toxics control act.	MTCA
		6131	Requiring safer chemicals in Washington.	
		6570	Prioritizing the expenditure of funds associated with the	MTCA

* *CSPA = Childrens Safe Products Act; Cu = Copper; DES = Department of Enterprise Services; Hg = Mercury; MTCA = Model Toxics Control Act; Pb = Lead; PCBs = Polychlorinated Biphenyls;*

			model toxics control act for the cleanup of toxic pollution.	
13-14	2779		Concerning the use of certain chemicals in food.	
	1294	5181	Concerning flame retardants.	CSPA
		5933	Concerning flame retardants.	CSPA
		5984	Banning certain flame retardants in children's products and residential upholstered furniture.	CSPA
		6048	Concerning flame retardants.	CSPA
		6540	Banning tris(1,3-dichloro-2-propyl)phosphate and tris(2-chloroethyl)phosphate flame retardants in children's products and residential upholstered furniture.	CSPA
		5348	Directing the department of health to review the impact of chemicals on public health.	
		6086	Reducing PCBs in Products Purchased by Agencies	PCBs
		6501	Concerning polychlorinated biphenyl(PCB)contamination in Used Oil Recycling	PCBs
11-12	1319		Regarding the safety of certain children's products.	CSPA
	2241		Reducing the introduction of lead into the aquatic environment.	Pb
	2266	6120	Concerning children's safe products.	CSPA
		6630	Concerning children's safe products.	CSPA
		2821	Concerning children's safe products.	CSPA
		6369	Protecting environmental quality and human health.	
09-10	1342		Creating a pilot program to screen children for lead poisoning.	Pb
	1345		Creating a pilot program to screen children for lead poisoning.	Pb
	1346		Concerning the labeling of lead-containing products.	Pb
	1799		Reducing the release of mercury into the environment.	Hg
	1809		Reducing the release of mercury into the environment.	Hg
	3018	6557	Limiting the use of copper and other substances in vehicle brake pads.	Cu
	2818		Reducing the environmental health impact of cleaning in state facilities.	DES
	2914		Reducing the release of mercury into the environment.	Hg
		6248	Concerning the use of bisphenol A.	BPA
	1165		Providing for the safe collection and disposal of unwanted	

			drugs from residential sources through a producer provided and funded product stewardship program.	
	1180		Regarding the use of bisphenol A.	BPA
		5813	Reducing the release of mercury into the environment.	Hg
		5977	Regarding the testing of the chemical content of products sold at retail.	CSPA
07-08	1355		Incorporating human health analysis into environmental review under chapter 43.21C RCW.	
	2166		Enacting the Washington safe cosmetics act of 2007.	CSPA
	2185		Reducing the levels of benzene in groundwater and drinking water.	Benzene
	2696		Testing for elevated levels of lead in children.	Pb
	4007		Requesting Congress and the Environmental Protection Agency to further regulate benzene.	Benzene
	1464		Reducing the environmental impact of cleaning state facilities.	DES
	1570		Authorizing a biomonitoring program.	
	1601		Creating the children's environmental health and protection advisory council.	CSPA
	1847		Providing for lead poisoning prevention education and screening.	Pb
	2143		Requiring the use of alternatives to lead wheel weights.	Pb
	2613		Reducing the environmental impact of cleaning state facilities.	DES
	2695		Creating a pilot program to screen children for lead poisoning.	Pb
	2800		Regarding the use and disposal of mercury-added products.	Hg
	2818		Concerning the duties of the Department of Ecology's office of waste reduction and sustainable production.	
	2882		Concerning the labeling of lead-containing products.	Pb
	3059		Requiring coverage for lead blood level assessments.	Pb
	3167		Evaluating environmental health conditions in state office buildings.	DES
		6502	Reducing the release of mercury into the environment.	Hg

3. Literature Review

As I am interested in evaluating the practical and political limitations to endocrine disruptor regulation, this literature review evaluates the state of understanding of the science of endocrine disruption, theories of science-policy interaction and case studies of chemicals policy broadly and the evolution of endocrine disruptor policy specifically.

3.1 State of the science of endocrine disruption

While the science of endocrine disruption has consistently sought to establish a language and understanding that supplements and contrasts with that of traditional toxicology, many of the earliest points of contention remain unresolved as new distinctions are explored and established. For example, while there is ample evidence that certain chemicals exert non-monotonic dose responses in animals, the exact mechanism producing these odd responses remains unclear. It appears likely that these responses are attributable to multiple different underlying mechanisms, varying with chemical and context. Further, while it is clear that some endocrine disruptors exert effects at concentrations below those considered in traditional toxicology or regulatory frameworks, there is still no consensus on precisely what constitutes a “low-dose effect.” Similarly, evidence pointing to the perinatal and pubertal periods as being critical windows of exposure has been produced at all observational levels, but truly robust demonstrations of the broad concept are inherently impractical. Perhaps most illustrative of the difficulty faced in resolving the diverse research of the field are the steady proliferation of acknowledged modes of action and the fundamental shift in testing methods required to accurately assess the impact of interaction effects.

3.1.1 Non-monotonic and low-dose effects

Uncertainty as to the mechanism and prevalence of non-monotonic dose-responses (NMDRs) and low-dose effects has been a consistent point of contention since the development of the field, and are perhaps the features of endocrine disruption research that most distinguish it from toxicology. Although many persuasive mechanistic explanations for the observed effects have been proposed, difficulties in holistic causal demonstration have allowed uncertainty as to the pervasiveness and significance of non-monotonic and low-dose effects to persist (Barlow et al., 2010; Melnick et al., 2002; Testai et al., 2013).

A review by Barlow et al. (2010) demonstrates the continuously contentious nature of these two effects, pointing back to the 1992 wingspread conference and subsequent meta-analyses, all of which continue to grapple with the same issue. Barlow et al. cite two commonly accepted explanations of NMDRs: that they can be explained by superimposition of grosser chemical effects onto typical hormone effects that themselves act at very low doses, and that they can be explained by competing observed agonistic and antagonistic effects of EDs on hormone receptors. Nevertheless, Barlow et al. note that a lack of scientific consensus persists due to frequent difficulties in replicating studies that claim to identify non-monotonic effects and a lack of holistic empirical demonstration of simultaneous contradictory effects of specific chemicals. Barlow et al. do note that one large critique of the non-monotonic hypothesis had recently been resolved: while skepticism had surrounded the theory due to the relatively low affinities of EDs to the two best-studied nuclear estrogen receptors, recent research demonstrated that ED’s effects can indeed be larger and more rapid, as illustrated by their action on

membrane estrogen receptors. In other words, these effects can be observed in animals without contradicting our granular understanding of effect pathways because they occur through alternate, understudied pathways. Thus, future study into membrane estrogen receptors promises to explain the effects of EDs currently inexplicable by nuclear receptors alone.

A review by Testai et al. (2013) enumerates elements of uncertainty within the NMDR hypothesis. Many theoretically plausible explanations for NMDRs can explain their appearance through mechanisms not specific to the endocrine system, such as cytotoxicity and loss of ED solubility at high doses. Were such generic causes the norm, it would undermine the separation of endocrine disruption from toxicology. Further, Testai et al. argue that, while methods of extrapolation from in vitro to in vivo tests is forthcoming, such translation remains insufficiently demonstrated. This speaks to the larger failures of translation: extrapolation from cells to organs to organisms remains beyond our current abilities, as does distinguishing between adverse and adaptive responses to exposure when observed only at the cellular level. Finally, they argue that a procedural requirement of the REACh regulations is increasingly at odds with the development of the field: while statistical power is best increased by increasing the number of in vivo replicates, this necessity is at odds with a tenet of REACh that requires measures to be taken to decrease the reliance on animal testing. This move away from animal testing in the EU impacts our understanding and ability to assess many of the uncertainties within the field.

Zoeller et al. (2014) take the evaluations of present practical limitations to their logical extremes, rightly concluding that observational studies can never provide satisfactory

evidence of low-dose effects due to limits to observable concentrations in vivo. Furthermore, for the purposes of human toxicity, Zoeller et al. argue that differences in sensitivities between individuals (due to age, gender, sympathetic exposures, etc.) renders general exposure thresholds indefinable. They explain that the determination of thresholds of effect relies on assumptions relating to mode of action and effect that cannot be borne out in whole organisms, thus rendering attempts to evaluate safe exposure thresholds, and by extension attempts to assess risk in a unified fashion, moot. Zoeller et al. conclude that "to move this debate forward, we must acknowledge first that dose thresholds are impossible to prove or disprove experimentally" (Zoeller et al., 2014, p. 5).

Zoeller et al. further note that "Low-dose" itself is a term used inconsistently, based upon whether it is couched in the toxicological presumption of effects, the observed biological active effect range, or the estimated exposure level. Thus, to move the debate forward, they contend that "low dose" must be employed consistently and "adverse" effects must be explicitly distinguished from adaptive effects.

Thus, it seems clear that NMDRs and low-dose effects, while understood with increasing sophistication at the granular level, defy translation to the population level. While there are certainly incremental improvements to be made in predictive abilities, and while the discipline would benefit from increased repetition of experimentation to thoroughly defend the prevailing theories, there is reason to believe that NMDRs and low-dose effects will stymie efforts at risk profiling at the population level for the foreseeable future.

3.1.2Critical periods of exposure

While evidence from animal studies continues to build the case that exposure to endocrine disruptors during the perinatal period increases the likelihood of developing many non-communicable diseases in adulthood, and while there is evidence in both humans and animals of immediate developmental impacts of endocrine disruptors during that period, translating early-life effects observed in animal studies to human effects remains a primary point of contention (Fudvoye et al., 2014; Testai et al., 2013; Vandenberg et al., 2009; Zoeller et al., 2014).

A review by Vandenberg et al. (2009) provides a substantive distinction between critical and non-critical periods of exposure. They argue that exposure during non-critical periods is primarily of an “activational” nature, altering the expression of established systems solely during the period of exposure. In contrast, exposure during critical periods causes “organizational” impacts, effecting long-term development and overall health. In support of this, they point to the hypothesis, provisionally demonstrated, that “different receptors are likely represented in different cell types at different developmental times and response stages,” (Vandenberg et al., 2009, p. 81) meaning that EDs interact with different systems during those critical periods than they would at other times. Vandenberg et al. note that critical periods of exposure have been observed in human subjects, as in the case of DES, in which subsequent studies of “DES daughters” and sons have correlated exposure at different times during pregnancy to different outcomes. Vandenberg et al. also point out the utility of unintentional chemical exposures for demonstrating this principle, citing an accidental dioxin release in Seveso, Italy,

following a chemical plant explosion, where breast cancer risk was observed to increase most in in perinatal, pubertal, and pregnant individuals.

Attributing the difference critical and non-critical periods to a different mechanism, Testai et al. (2013) argue that adult organisms contain mechanisms for “adaptive endocrine modulation” that developing organisms lack, leaving the latter more susceptible to adverse reactions following ED exposure. Testai et al. also make the point, in illustrating the limits of our current testing methods to accurately distinguish the impact of critical periods, that current procedures for evaluating perinatal exposures fail to observe all possible endpoints, and have not been satisfactorily proven to be translatable to human exposures. Thus, we most likely do not have a complete understanding of the difference in effect between critical and non-critical periods of exposure.

A meta-analysis of early-life effects of endocrine disruptors concluded that direct causal relationships between EDs and fetal development are scarce, but the heightened significance of hormones in fetal development is well-understood (Fudvoye et al., 2014). Further, paralleling the claims by Vandenberg et al. and Testai et al., Fudvoye et al. note that fetuses may lack biotransformation enzymes that are known to reduce ED concentrations in adult organisms. While Fudvoye et al. similarly noted the limitation of human data availability, they further noted that even in extant studies, estimates of exposure level remain too stochastic to provide predictive power for effect estimates in moderately-scaled studies. Further, they note that PBDE exposure in utero has been associated with immediate adverse effects in humans, but has produced non-analogous results in animal studies, suggesting further the difficulty of translation from animal to

human of even short-term effects. Specifically looking towards the critical period of puberty, Fudvoye et al. note that impacts of EDs on pubertal development are difficult to evaluate due to the inconsistent timing of puberty and the uncertain relationship between perinatal exposure and subsequent effects on and during puberty.

Ultimately, limitations to our understanding of developmental biology impose themselves on our understanding of ED exposure during periods of development. While animal testing allows for rapid evaluation of multiple generations-worth of effects within a short period of time, there are demonstrable difference between effects of certain EDs in animals and humans. Further, while studies of these effects in humans remain unethical and impractical, accidental chemical exposures have decisively demonstrated the proof of concept.

3.1.3 Multiple modes of action

One significant aspect of endocrine disruption, mentioned earlier as a partial explanation of both non-monotonic dose-responses and critical periods of exposure, is the fact that a single chemical may exert myriad effects through discrete modes of action (Barlow et al., 2010; Testai et al., 2013; Vandenberg et al., 2009). From the original concern with estrogenic nuclear steroid at the 1991 Wingspread conference (Colborn and Clement, 1992), concern has expanded to include many additional hormones and hormone systems, for example androgens and thyroid hormones, and many additional endpoints, for example membrane receptors and steroid inhibitors (Barlow et al., 2010). Further, additional endpoints caused by disruption of these various mechanisms has been associated with an increasing number of effects; the proliferation of “diseases, mechanisms and modes of action” requires an increasing number of sophisticated tests to

evaluate, leaving the evaluation of many modes of action in the realm of modeling and hypothesis for the time being (Barlow et al., 2010). Furthermore, even in isolation, a single chemical can exert differing effects depending on which tissues it is exposed to; these effects become increasingly unpredictable when considering exposure to multiple endocrine disruptors (Barlow et al., 2010).

3.1.4 Mixture and interaction effects

Mixture effects of endocrine disruptors have long been studied within the discipline (Barlow et al., 2010; Testai et al., 2013). Most studies in vivo have focused on multiple chemicals known to exert similar effects, such as multiple anti-androgens, or chemically related, such as multiple PCBs or pthalates, and have found additive effects, demonstrating the potential for straightforward modeling of combined effects from the same mode of action (Barlow et al., 2010; Testai et al., 2013). A recent meta-analysis of studies of pesticide cocktails, in which 90% of reviewed studies focused on endocrine disruption as a mode of action, found that about half of studied mixtures reported additive effects, and about one third reported synergistic effects (Rizzati et al., 2016). While the fact of these effects may be well established, one of the largest barriers to comprehensive analysis, especially for synergistic effects, is the question of ensuring consideration of all relevant chemicals in modeling (Kortenkamp, 2014). This issue is exacerbated by the broad lack of data on the endocrine-disrupting potential of many known and suspected endocrine disruptors.

3.2 Transitioning from toxicology to endocrinology

Roberts (2009) characterizes the issue of low-dose toxicity as posing a challenge to the production of both science and policy, highlights difficulties in transitioning from toxicology to endocrinology, and reflects on issues in transitioning to a more proactive approach to federal chemical policy in the United States. Roberts characterizes endocrinology as treating the body as "a system in constant communication with its environment," (Roberts, 2009, p. 8) with multi-modal and iterative responses that undermine linear dose-response relationship that characterizes toxicology in contradistinction. Roberts attributes the new paradigm of endocrinology to improvements in "analytical and instrumental technologies and experimental methods," (Roberts, 2009, p. 8) citing increasing numbers of biomonitoring studies as indicators of this trend. Roberts then describes a proposed REACh-like system for the US, summarized as a permission-based model of chemical regulation, and a trespass model, wherein chemical exposure is interpreted as a trespass on our own human bodies when such exposure occurs without permission. However, Roberts characterized both of these approaches as being impracticable due to a lack of robust pre-market methods for toxicity testing. Roberts concludes that, regardless of the precise policy instrument adopted, any new regulations should allow for the dynamic adoption of new testing methods, to ensure that our regulatory "institutions [are] as flexible as the current science" (Roberts, 2009, p. 21).

A more recent consensus statement by Vandenberg et al. (2013) addressed this issue, and made the case for the employment of endocrine disruption principles to regulate EDs, largely due to the distinctions addressed in section 3.1, above. Responding to the lack of certainty highlighted by Roberts, Vandenberg et al. promote a weight of evidence

approach to chemical evaluation that aligns with principles of endocrinology. Vandenberg et al. claim that a weight of evidence approach, wherein evidence supporting one side of an argument is compared to evidence supporting the other side in order to determine which is more valid, is the default response to uncertain and contradictory studies. This granted, Vandenberg et al. further claim that evaluating the weight of evidence requires expressing one's own values and using one's own professional judgment. Vandenberg et al. cite several common, illogical normative decisions made in evaluating the worth of contrasting claims, namely that failure to refute a null hypothesis is commonly conflated with accepting that null hypothesis, and that "Good Laboratory Practice" guidelines are taken as a proxy for appropriate study design, despite only being an indicator of procedural quality. Vandenberg et al. then contrast these capricious weighting methods with methods couched in the current understanding of endocrinology: that reliable studies must find no evidence of contamination by agonists or antagonists related to the effect being studied, must be capable of identifying low-dose effects if they occur, must test species or strains sensitive to the effect in question, and should contain both positive and negative controls. These four requirements concisely illustrate the core distinctions between toxicology and endocrinology as applied to risk management or any other political endpoint, and it is clear that adherence to these principles would lead to more uniform and defensible decisions in the face of uncertainty.

A review by Molander (2015) focused on providing "insights and methods related to the risk assessment and risk management of chemicals in consumer products" (Molander, 2015, p. vii) identifies two key tenets for improving the risk assessment process: developing an evaluation process, akin to that proposed by Vandenberg et al. (2013) that

identifies relevant and valid studies more accurately than currently accepted guidelines, and the use of web-based tools to facilitate in the identification and evaluation of relevant studies. Reflecting Vandenberg et al.'s complaint, the development of alternative study selection guidelines was spurred by overemphasis of procedural quality and other non-crucial considerations in commonly accepted guidelines. The SciRAP model developed by Molander, and first described in Beronius et al. (2014), divides criteria of reliability into two tiers, fulfillment of the first of which which requires only qualitative analysis and indicates presence of all information essential for the "evaluation of reliability," (Molander, 2015, p. 25) and fulfillment of the second of which, in combination with external criteria to determine relevance, provides the user with a final evaluation of the "study's adequacy for health risk assessment" (Molander, 2015, p. 25). Molander combined the insight derived from SciRAP with another web-based tool that provides visualization features for study results. Molander's initial exploration of these tools seems to indicate that they are effective in distinguishing the more significant studies from the less. One major impediment to extensive testing of these tools is a lack of transparency in study design.

It seems clear that commonly accepted evaluation criteria for endocrine disruptor studies do not reflect the criteria that endocrine disruptor researchers consider to be most important. Further it seems that these procedural requirements may be occurring at the expense of more significant but less understood tenets of endocrine disruption, such as ensuring the absence of unintended agonists or antagonists within studies and thoroughly documenting study design. While the dedicated work of a small number of individuals could easily revolutionize the ability to stratify studies based upon their regulatory utility,

as is evidenced by the recent creation of web-based tools, future insistence on onerous and relatively insignificant procedural laboratory requirements may do more to limit the availability of useful studies than to promote them.

3.3 Models of science-policy interaction

How does a science with as many remaining uncertainties as endocrine disruption interact with the policy sphere, and how do stakeholders interpret that interaction? This interface has been elaborated on in many different forms, all of which have both positive and normative implications as to how best to promote scientific research and structure policy based upon incomplete knowledge. Being able to associate stakeholders' understanding of science-policy interaction would recommend certain approaches to policy and science improvements above others, and could help to ensure that research being produced aligns with the requirements of the policy sphere. Millstone et al. (2004) illustrate a clear hierarchy of increasingly complex models, all of which begin from the precept of a clear division between science and policy. Funtowicz (2006) describes similar models in order to contrast them with others which normatively defy the distinction between science and policy.

Millstone et al. (2004) review three regulatory conflicts with the aim of evaluating stakeholders' understanding of the science-policy nexus. They compare regulator's perspectives on the issues, highlighting differences between the US and EU and within the EU. Millstone et al. further evaluate the prescriptive and descriptive value of several models of science-policy interaction: the technocratic, decisionist, and a novel "transparent" model, all of which they argue reflect different concomitant elements of policy production.

Prescriptively, a technocratic model implies that every regulatory decision is made with deference only to robust scientific evidence, in a manner nominally more objective than regulations based upon political considerations. However, Millstone et al. observe that the assumption of adherence to a purely technocratic model leads representatives to assume *a priori* that regulations within their jurisdiction are based objectively on sound science, and that any jurisdictions producing contradictory regulations must be influenced by political considerations. Millstone et al. illustrate this point with an exploration of how precaution is treated in differing jurisdictions. Noting that, in general usage, precaution is treated as a response to scientific uncertainty, Millstone et al. note that the technocratic perspective either assumes precaution as an inherent result of sound science, or dismisses precaution as an unscientific consideration. Millstone et al. go on to note that absolute deference to scientific certainty can lead to paralysis in its absence, due to a lack of evidence sufficient to support debate and decision. Given the increasing acknowledgement of scientific uncertainty, Millstone et al. conclude that most decisions cannot be explained on the basis of scientific truth alone, and that the technocratic model fails to account for social elements of the decision-making process.

Millstone et al. contend that the decisionist model is dominant in all their studied jurisdictions. The decisionist model contends that science occurs independently of and prior to political decisions, and that political decisions are founded on scientific conclusions, but inexorably account for “social, political, cultural and economic” concerns. In this formulation, the scientific process of risk assessment is explicitly and entirely distinct from the political process of risk management, the former being objective and the latter subjective. While this framework more readily explains the differences in

regulations between jurisdictions with access to the same scientific knowledge, it fails to explain differences in presumed-objective risk assessments. In this framework, precaution is applicable only to the political, second step, and is entirely distinct from the scientific process.

Addressing the shortcomings in the decisionist model, Millstone et al. propose a modified version, the “transparent” model, that presents the process of risk assessment not as being entirely objective, but as being influenced “by legal requirements and by social, economic and political judgments” (Millstone et al., 2004, p. 26). This model is labeled “transparent” in the belief that, were those “up-stream” assumptions that influence risk assessment made transparent, the reasons for differing results of risk assessments would be self-evident. Belief in this model would prompt risk assessors to be more transparent about the assumptions underpinning their own work, and would policy makers to carefully consider the impacts of risk assessment policy on risk management. In this model, precaution can be considered as one of the up-stream assumptions that risk assessors must implicitly or explicitly consider in framing the risk assessment process.

Funtowicz (2006) presented a series of models of science-policy interaction developed within the Joint Research Centre of the European Commission. These models are distinguished by the importance that positive factual “contributions of experts” and normative value-laden “contributions of other sectors” have in the policy making process, with a goal of “assuring the quality of knowledge-inputs to the decision making process.” (Funtowicz, 2006, p. 139) The practical application of these models to environmental problems has subsequently been tested in several case studies (Dessai & Van Der Sluijs, 2007; Lemus, 2015; Udovyk, 2014; Van Der Sluijs et al., 2008). Funtowicz describes four

models of science-policy interaction: The Initial Modern Model, The Precautionary Model, The Model of Framing, and The Model of Extended Participation.

The “modern” model of science policy interaction, also called the linear or knowledge transfer model (Pregernig & Böcher, 2012) and closely paralleling the “technocratic” model described by Millstone et al. (2004), sees the relationship of science and policy as “speaking truth to power.” Frequently associated with the concept of technocracy, this model assumes that all scientific knowledge is purely positive, but provides sufficient (commonly formulated as complete) information to enable normative policy decisions to be made. In this formulation, science and policy spheres are completely separate, with the latter simply drawing from the knowledge of the former; hence a “linear” model of science-policy interaction.

The precautionary model discussed by Funtowicz reflects a strong formulation of the precautionary principle. Essentially, any possible threat must be responded to and avoided, regardless of cost. This model does not take comprehensive scientific knowledge as a given, and in fact assumes persistent scientific uncertainties. Nonetheless, in this model policy remains wholly dependent upon scientific understanding, with the added caveat that policy-makers may frequently call upon scientists to improve the state of understanding to relieve the state of uncertainty. Thus, policy makers may have large impacts on the precise avenues of scientific inquiry, but said inquiry is still assumed to remain wholly positive.

Another formation of this principle, not explored by Funtowicz is the “weak” formulation of the precautionary principle, commonly associated with the 1992 UN Rio Declaration on Environment and Development, which requires precaution only in the

face of the possibility of “serious or irreversible damage.” This reformulation primarily changes the requests that policy-makers would make of scientists, and subsequently the issues that scientists would study, effectively implementing a narrower form of triage than the “strong” formulation.

The consensus model explored by Udovyk (2014) is in many respects similar to Millstone et al.’s (2004) “decisionist” model. Rather than there being a single truth illuminated by science, the consensus model admits of multiple, conflicting truths. The realm of science is thus tasked with consensus-seeking, prior to presenting finding to the policy realm. In this formulation, however, the two realms remain distinct and science is still seen as having a solely positive role. Certainty of evidence, in contrast to the modern model, is not considered *a priori* to be absolute, and thus it is only through conscious efforts to confirm the robustness of data that it can then be found of use in policy-making: the onus remains on the science realm to demonstrate significance before an issue is considered in the policy realm.

Funtowicz (2006) approaches this model somewhat differently, in his “Model of Framing.” This model ascribes differences in truths to differences in the scientific framework from which the question was approached, adjoining a normative aspect to the scientific process based upon the underlying assumptions of the varying disciplines. By introducing normative values to the scientific sphere, this model blurs the lines between the two, and presents disciplines as stakeholders defending their beliefs. Choosing one over the other then is inherently a matter of choice, and thus disagreements in this model are normatively resolved with little respect to the degree of certainty underlying any given result.

The extended participation model denies science an authoritative position as the sole purveyor of truth, giving equal weight to the informal knowledge of citizens or other groups (Funtowicz, 2006). By giving equal footing to all knowledge, this model sustains no distinction between the science and policy spheres. Because scientific findings are only indirectly equated with knowledge, the question of certainty becomes only indirectly relevant. The "co-production of knowledge" (Funtowicz, 2006, p. 139) ensures that the question of uncertainty is dealt with before entering the realm of science-policy interaction.

The different models of science-policy interaction all differ in many respects. Of special interest to this thesis is the degree of certainty required to stimulate policy production. Both the adaptive management and the extended participation model ignore the question of uncertainty during policy production, and as such cannot be grouped. The remaining models, however, can be ordered along a spectrum of required certainty (Table 6).

Table 6: Policy models in order from most to least reliance upon certainty

Model	**Degree of uncertainty acceptable for policy production, from least to greatest**
"Modern"/Technocratic Model	Burden of proof rests on the shoulders of the science sphere in order to influence the policy sphere
Consensus/Decisionist Model	Inter-disciplinary certainty required to inform policy
Model of Framing/Transparent Model	Significance of certainty dwarfed by prior assumptions of disciplines most relevant to policy
"Weak" Precautionary Model	Uncertainty maintaining the possibility of "serious or irreversible damage" is taken seriously.
"Strong" Precautionary Model	All uncertainty is acknowledged and actively embraced

3.4 Relevant case studies

Wurtz and Sorenson (2011) report on a series of workshops organized by the Nordic Council of Ministers. Motivated by the idea that robust regulation of endocrine disruptors would not be enacted for decades, participants in the workshops reviewed soft regulatory approaches and risk communication strategies intended to reduce chemical exposure in the interim. Workshop participants described the regulatory landscapes, successes, and failures in the Nordic countries. The Danish EPA executed a campaign to raise awareness about ED hazards posed to toddlers, publishes list of medications known to not contain pthalates, regularly produces lists of “undesirable chemical substances,” and regularly conducts consumer surveys focusing on chemical exposure. This work is supplemented by Danish NGOs who regularly pursue chemical bans. The Norwegian Climate and Pollution agency stressed stressed cooperation and an understanding of the target audience as being crucial to soft regulatory success. The agency promotes “eco-labeled products” and “green public procurement,” coordinates with industries to promote chemical reform, and administers a web page describing and highlighting common sources of “the 13 most dangerous substances in consumer products.” Similar to the Danish EPA, Norway’s agency targets its information campaigns towards groups capable of moderating the exposure of the most vulnerable groups. The Swedish government developed a national action plan due to increasing consumer concern, largely due to a documentary illustrating pervasive contamination. The goal of the plan was to improve the dialogue with industries and to promote voluntary regulation. This work has been supplemented by consumer outreach materials, primarily targeting the parents of young children and and daycare centers. In contrast to the other Nordic countries, Finland

observed a decrease in NGO interest in chemicals following the passage of REACh. The government is able to cooperate effectively with business groups, and chemical regulations are generally understood to be adequate. While consumer awareness campaigns had also been pursued, the largest shift in chemicals management in Finland was the unification of regulatory authority within a single agency.

Shamasunder and Morello-Frosch (2015) interviewed chemical regulation stakeholders throughout the USA to identify points of agreement or contention in regards to biomonitoring as a scientific and policy tool. Shamasunder and Morello-Frosch confidentially interviewed advocacy, government, industry, and academic scientists who had been vocal in the literature and/or in government or industry meetings. Interviews were in-depth and semi-structured, and were coded using a two-tiered system, wherein primary codes related to the interviewee's relationship to the issue, and sub-codes reflected specific issues, including the intersection of biomonitoring and policy. Shamasunder and Morello-Frosch observed that while advocacy scientists believe that biomonitoring influences policy, and that biomonitoring is relevant in promoting policy change, industry scientists believed neither statement to be true. Regulatory scientists found the first statement to be true in certain cases, and considered the second statement a matter of open debate. Academic scientists indicated that the former statement was partially true, but generally agreed with the latter. The simple delineation of issues surrounding biomonitoring, valuation of responses as being either positive, negative, or mixed, and clear prior delineation of scientific spheres lend themselves to concise, comprehensible results.

A study of this kind, combining document study and semi-structured interviews, was performed by Udovyk (2014). Udovyk attempted to characterize the model of science-policy interaction underlying bisphenol-a management at the international, national, and municipal level in Gothenburg, Sweden. This thesis adopts many of the models of science-policy interaction put forth in Udovyk's study. Udovyk found that most policy was informed by the modern model of science-policy interaction, and thus had the most to say about the particular pros and cons of that model. Subsequently, the other models were only evaluated relative to the de facto standard of the modern model.

Cáceres, Silvetti & Díaz (2016) use a case study of an Argentinian law that protects native forests in order to evaluate the descriptive power of two alternate formations of science-policy interaction in the case of legislative failure. They found that the "information deficit model," which corresponds most closely to the "modern" model, failed to adequately describe the origin of enacted legislation. Instead, they found that a "power-dynamics model," in which legislation is iteratively influenced by many "actors and types of knowledge," (Cáceres et al., 2016, p. 57) best explained why certain legislation with less stringently scientific underpinnings was enacted in lieu of a more thoroughly researched policy. They concluded that a "modern" model of science-policy interaction fails to reflect the roles played by "institutions, subjectivities, values, interests, power relationships, [and] knowledge" (Cáceres et al., 2016, p. 62) in the creation of policy.

Lemus (2015) compared the differing approaches of Denmark to BPA regulation, with a focus on the role of uncertainty. Lemus found that Denmark's more active approach to regulating BPA at a national level stemmed from approaching the problem

from an “endocrine-perspective,” which encouraged common understanding among multiple stakeholders, including scientists and regulators. This in turn led to the exploration of technical questions in a regulatory setting, and subsequent funding support to adequately answer these questions. The case of Denmark, according to Lemus, highlights the failure of the “modern” model of science-policy interaction to account for multiple and divergent truths with which science speaks to policy (Funtowicz and Strand, 2007). In the context of Norway, Lemus observes that BPA has consistently been regulated as an environmental, rather than as an endocrine-disrupting, chemical of concern. Lemus explains that this occurs as the result of the greater power afforded to the technocratic food regulators, who treat BPA from a risk management perspective. Meanwhile, the environmental authorities of Norway, who promote a precautionary approach, lack the influence to enact such an approach. Thus, stemming from differing normative goals, there exists an uncomfortable disagreement amongst Norwegian experts as to the best approach for regulating BPA.

4. Methods and Results

While the science underpinning endocrine disruptors continues to develop, it is clear that the available data remains insufficient to engender their regulation under the preexisting regulatory framework: the mode of action of endocrine disruption undermines many of the primary assumptions of toxicology, necessitating—at a minimum—translational tools that do not yet exist and cannot be produced without a significant amount of primary research. Meanwhile, many alternative policy instruments and holistic methods of measuring hazard have been developed and employed to varying degrees of success in jurisdictions beyond Washington. From the review of proposed and recently enacted legislation related to endocrine disruptors in Washington, it is clear that certain proposed policy alternatives and testing methods have been afforded regulatory consideration, while others have not. To determine how the choices that have defined and delimited our current policy landscape were made, and with what degree of autonomy, I pursued a qualitative policy analysis focused on a document review of primary and secondary sources relating to proposed regulations and on stakeholder interviews encompassing the full spectrum of active participants, focusing my efforts on current policy limitations and contemporary scientific and geopolitical advances.

4.1 Qualitative policy analysis

I chose to approach the issue of endocrine disruptor policy from a qualitative perspective due to a vast range of perspectives relevant to the study. Because policies in Washington have rarely addressed the concept of “endocrine disruptor,” it was unclear initially whether the concept was broadly used, or whether it was translated into other terms for the purposes of policy. Further, without a broad understanding of historical

attempts to regulate endocrine disruptors, any quantitative approach might have overlooked or overemphasized certain approaches. Further, evaluating models of science-policy interaction involves an understanding of historical intent, and within the body of literature consistently relies on qualitative analysis. Most generally, addressing the issue through a qualitative lens allowed for the discovery of salient considerations that would potentially be overlooked in a purely quantitative study. Approaching the issue from a qualitative perspective enriches any subsequent research by providing a baseline context and preliminary interpretations.

I was mindful of my own biases throughout the research process, and strove to overcome them by making them explicit. Having more experience with toxicology than endocrinology, I was more comfortable with the uncertainties of the field than most stakeholders would, and was by extension predisposed to accept a hazard based approach as being a sound basis for regulation. Bearing these biases in mind as I evaluated my data, I focused more on the positive logic of my interviewees statements than the normative content of their statements, attempting to weigh equally all internally sound arguments.

4.2 Research design

The overall format of this project was primarily influenced by three earlier papers focused on chemicals management. Lemus' (2015) case study and comparative analysis of Bisphenol A regulation in Denmark and Norway was conducted primarily through document review and stakeholder interviews. The questions asked in that case study, and the epistemological considerations discussed, were useful in the framing of my own research. Shamasunder's (2011) study on biomonitoring data's influence on US chemical

policy was useful in its content and its methodological approach, specifically in terms of its approach to defining and delineating policy stakeholders. Matus, Clark, Anastas, and Zimmerman's (2012) analysis of barriers to green chemistry implementation provided a further delineation of stakeholders, as well as a framework for evaluating and distinguishing issues. Trujillo's (2016) case study of microplastics, demonstrated the feasibility of looking at a class of materials or chemicals at a broader scale.

I chose to perform a case study because of the lack of existing case studies looking at chemical policy on the same scale. While the above-mentioned papers reviewed individual chemicals, scientific methods and policy tools, Trujillo's focus on microplastics as a broad class, encompassing many aspects of policy, demonstrated the feasibility and utility of such an approach. While chemical policy in Washington State addresses persistent bioaccumulative toxins, this grouping is slightly different from that of Europe and other jurisdictions introducing REACh-like chemicals policy. Thus, a case study focusing on endocrine disruptors in the context of Washington State stood to re-frame existing policy, allowing for subsequent comparisons to other jurisdiction's policies, and for ease of future policies on those grounds within the state.

4.3 Data collection

4.3.1 Policy documents

My primary concern in collecting policy documents for analysis was casting a wide-enough net to ensure the capture of the full range relevant documents. Within the legislature, I reviewed all enacted laws, and house and senate bills dating back as far as were available. Having identified laws relating to endocrine disruptors, I identified the

range of State Departments granted regulatory authority. I then reviewed the regulations related to those laws as enacted by the various departments, and further searched for other relevant programs and initiatives sponsored by those agencies. In pursuit of relevant policies, and given the un-institutionalized nature of the concept “endocrine disruptor,” I initially took a broad view of what could be considered relevant policy. Additional documents submitted by non-governmental stakeholders in response to various policies were considered when available. Finally, I systematically included a question regarding past and current relevant policies in the interview process, to identify anything of significance that I may have missed.

4.3.2 Stakeholder interviews

The first step in approaching stakeholders was classifying them in terms of their relation to endocrine disruptor policy. I began by defining groups of stakeholders based in part upon the groups described by Shamasunder (2011) and Matus et al. (2012), and identifying local organizations, agencies, and institutions that fit those categories. This identification process stemmed from reviewing authorship of the aforementioned policy documents and observing and reviewing public comment sessions relating to proposed legislations and regulations. From the broad list of stakeholders, I classified individuals and organizations as being either policy-makers, policy-analysts, policy-enforcers, scientists, public interest representatives, or private interest representatives. Additionally, during the interview process, additional interview participants were identified using the snowball technique.

Having classified the various groups, I strove to interview a representative portion of each group, to collect as many perspectives and present as broad a view of each group as

possible. Interviews were arranged either by phone call, e-mail, or in person and occurred between March and May of 2017. Interviews were recorded and subsequently transcribed, and were conducted under the auspices of confidentiality. In total, 11 interviews were conducted, ranging from 15 to 90 minutes. Unfortunately, I was unable to interview what I believe to be a representative portion of policy-makers or private interest representatives.

While the interviews were conducted in an open-ended fashion, I also relied on a set of questions designed to correspond to the questions of interest identified by the literature review. This list of questions was stylistically inspired by the questions in Lemus (2016)**.** See appendix two for the list of questions. However, this list served as more of a baseline than as a rigid structure for the interview; different sections were more salient to different stakeholders' experiences, and certain questions were skipped if earlier questions indicated a lack of relevance.

4.3.3 Iterative approach

It is important to note that these processes did not occur independently of each other. While I began with an initial document review, additional documents were subsequently brought to my attention through the interview process, as were additional points of interest meriting additional lines of inquiry in subsequent interviews.

4.4 Data analysis

Once the interviews had been transcribed, they were coded using the RQDA library of the R statistical computing platform. The coding structure was based in part on the format used by Shamasunder (2011), in conjunction with the discrete areas of consideration

identified in the literature review. After initial coding, additional categories presented themselves, and interviews were re-coded. From the identified policy documents, those which were considered most relevant were also coded in the same manner.

Following the coding, the basic perspectives of the different stakeholder groups were compared, both semi-quantitatively, by comparing the presence and frequency of certain perspectives and arguments, and qualitatively. Responses were used to evaluate compatibility with various policy approaches and consideration. Additionally, the various theories of science-policy interaction were compared to the facts and opinions expressed in the interviews.

4.5 Results

Interviewees largely agreed as to the limitations of Washington State's current endocrine disruptor policies. The information in the following section is presented in a manner intended to aggregate the most common concerns and highlight disagreements amongst stakeholders where they exist. Results related to scientific advances and potential policy improvements are presented without reference to the role of their originator, except to highlight the occasional differences between stakeholder groups in these matters: while many suggestions were made for future policy approaches, few of them were directly contradictory.

4.5.1 Current limitations of Washington State endocrine disruptor policy

Undoubtedly the largest impediment to the further adoption of endocrine disruptor legislation described by interviewees was that of scientific uncertainty. Most interviewees referenced a lack of information sufficient to expand legislation under the current system.

Certain scientists and citizens group representatives, however, referenced bodies of evidence that they saw as being sufficient cause for increased legislation. However, while they described this evidence as being sufficient to necessitate policy, it was simultaneously insufficient to dictate the precise formulation of that policy. The table below delineates the most frequently cited impediments, and their perceived significance within stakeholder groups.

Table 7: Stakeholder assessment of current impediments

Impediments	**Of concern to…?**				
Limitation	**Regulatory**	**Legislative**	**Industry**	**Advocacy**	**Academic**
Scientific Uncertainty	Yes	Yes	Yes	Yes	Yes
Shared Data Inavailability	Yes	---	Yes	Yes	Yes
Multiple Definitions of EDC	Yes	---	Yes	No	Yes
Inability to Target Vulnerable Demographics	Yes	Yes	No	Yes	---
Reliance on Individual Chemical Regulation	Yes	No	No	Yes	---
Regrettable Substitution	Yes	---	Yes	Yes	Yes
Funding	Yes	Yes	---	Yes	Yes
Political Will	Yes	Yes	Yes	Yes	Yes

While representatives of the business community felt that there was extensive testing being done on commercial chemicals, they felt that there was still extreme uncertainty surrounding the sources of exposure. This relationship between source and outcome was repeatedly mentioned as being under-researched, albeit not as strongly emphasized by other interviewees. An interview from the Department of Ecology highlighted these issues stating that the department doesn't "have methods [to biomonitor] most …

chemicals [and] ... only [has] methods for about 500 chemicals… and we've got probably 30,000 [chemicals] in commerce, and we've probably got a couple thousand that are high production volume." In general, the failure to firmly establish cause and effect in an environmental context was seen as clouding the case for legislation.

One of the most immediate problems, as discussed by scientists, is that at the finest level of observation, adverse and adaptive changes to the endocrine system are indistinguishable, necessitating more taxing observations of indirect effect to determine the ultimate endpoint. Ultimately, the difficulty of establishing a cause and effect relationship appears to be the greatest remaining point of contention, and the most immediate impediment to the implementation of any broad or precautionary endocrine disruptor legislation.

One concern that added to the uncertainty was that of trading data with the EU and Canada. Many interviewees expressed remorse and dissatisfaction stemming from the difficulties of sharing data with Canada, despite our countries' parallel efforts in this field. This lack of collaboration between Canada and Washington state was attributed to Washington's inability to ensure the confidentiality of provided data, due to the state's right-to-know laws. This has led to repetition and duplication of existing work, and contributed to the unnecessary persistence of uncertainty.

Contentions of the definition and scope of the phrase "endocrine disruptor" among interviewees mimicked those of the overall debate. Interviewees from state agencies acknowledged the issue and clarified their own stance as essentially coming down to triage; excluding from consideration, for example, those that don't have an effect at an environmentally relevant level. While most were uncomfortable with the fuzziness of the

definition, participants generally considered this to be a smaller issue than that of uncertainty.

Because of practical limitations, policies attempting to target a certain demographic must employ proxies for that demographic that are frequently imprecise. As described by an Ecology employee, “the sports containers [clause] was the attempt to get at women of childbearing age, since half of all pregnancies in the US are unintended.” In the case of legislation addressing specific materials or products, there was consensus that the choice of material or product to regulate influenced which demographics were impacted by the legislation.

Paralleling the consideration of the level of specificity at which to regulate products is the question of scale at which to regulate chemicals, if a broader policy were to be implemented. While interviewees who mentioned the topic agreed on the insufficiency of regulating a singular chemical, several mentioned difficulties of addressing chemical classes as a whole. In the example of the proposed PFAS in grease-resistant food liners legislation, it was mentioned that while palpable risk has been demonstrated for *long-chain* PFASs, *short-chain* PFASs have not been demonstrated to present the same risk. While manufacturers have largely switched to short chain PFASs in that application, the combined uncertainty contributed to the bill’s failure. Additionally, an Ecology interviewee mentioned the issue of generalizing whole classes for the purposes of endpoints, as chemicals in a given class may be generally dangerous, but may be so by differing mechanisms. Thus, the question of the specificity of endpoint becomes entangled with the question of specificity of chemical or class.

A corollary to this frustration with the frequent limitations to scope of endocrine disruptor regulation is the demonstrable fear that regulation of individual chemicals in the absence of replacement guidelines leads to regrettable substitutions. This was illustrated by an advocate as having taken place following the PBDE ban: because only a single flame retardant was regulated, despite contemporary evidence that similar chemicals within the same family had similarly deleterious effects, PBDEs in plastics were slowly replaced by a similar chemical with similar beneficial and harmful properties. This concern was shared by industry groups, who expressed interest in avoiding subsequent replacement costs that would result from the continued expansion of regulation.

Along these lines, a department of ecology employee highlighted the difficulty of public education in the context of products that may be doing both good and harm:

> There's chemicals in sunscreen that are probably endocrine disruptors, but you have to be very careful about that in public health, because we also want people to protect their skin from the sun, because we know UV light is a mutagen. We know it causes skin cancer… So, same thing with chemicals in breast milk … we have to be very careful when we're putting those messages out, because we want women to breastfeed.

This sentiment reflects a prime concern shared by the majority of stakeholders, illustrating a fundamental issue posed by uncertainty. There may not, at least in the short term, be substitutes for critical chemicals that do not share some of their negative effects. Thus, the majority of stakeholders acknowledged that evaluating both risks and hazards requires an understanding of the benefits and harms of the chemical in question as well as the benefits and harms of potential substitutes.

Alongside purely practical matters of implementation, many stakeholders described the economic restraints hindering the implementation of wider-reaching policies. In

regards to current policy, however, representatives from Ecology noted that the Department is in a relatively comfortable position, specifically in comparison to other states. However, Ecology and business representatives mentioned that Ecology's capacities for product testing were dwarfed by many companies in the state. Health's work in relation to endocrine disruptors is less well funded. While outreach is funded through the state, the biomonitoring program was the result of a federal grant that went un-renewed due to competition from other states. This lack of population survey data impacts the ability of Health to best inform citizens, and for Ecology to determine which chemicals are of greatest concern.

Interviewees presented a unified view in describing the political considerations relevant to passing policy. Certain legislators have, in the past, championed specific causes, and repeatedly brought bills before the house or senate. Now, on the other hand, legislative committees on environmental issues are relatively cool to any toxics proposals. Furthermore, by some unspoken tradition, it is unlikely for bills to gain traction during their first or second legislative session. This is indicated by the multiple "failed" bills that end up being iterated on for several years before being passed, and appears to be an accepted aspect of the process. Broadly speaking, changing membership of relevant house and senate committees, and partisan politics in the house and senate mean that the actual passage of certain regulations in any given year is due more to political caprices than to the actual substance of the bill.

4.5.2 Scientific advancements and endocrine disruptor policy

As indicated by the literature review, progress surrounding endocrine disruptors has expanded the scope of the field while simultaneously coming up against obstacles in

analysis that are understood to be insurmountable. Nevertheless, while advances in understanding may not have materialized, many incidental aspects of the science have improved and potentially lend themselves to incorporation into future regulation. The following table delineates scientific advances by the role that they would play in future regulation, and indicates the specific examples of each role discussed in the interviews.

Table 8: Elements and specific applications of scientific advances

Scientific Advances	
Blacklists	EU and California Lists of Chemicals of Concern
Whitelists	EPA Safer Chemical Ingredients List
Knowledge-sharing	Interstate Chemicals Clearinghouse (IC2)
Hazard Assessment Tools	GreenScreen and TiPED
Mixture Effects	NRC's *Pthalates and Cumulative Risk Assessment (2009)*
Data Collection Efficiency	EPA procedure for high-throughput chemical screening

While various blacklists, or lists of suspected or known endocrine disruptors exist, the lists administrated by the European Union and by California denote chemicals thoroughly demonstrated to be endocrine disruptors. These lists were identified as being of use by a regulatory representative, who explained that they are sufficiently robust to recommend the addition of chemicals to the CSPA list without much further analysis.

While a robust analysis of the potential harm of a chemical or chemicals may remain beyond the means of an individual state, the Interstate Chemicals Clearinghouse collects chemical studies produced by Washington and other member states for the benefit of all.

This reduces redundant testing and allows for access to thorough documentation of a wide range of chemicals that can be interpreted to reflect any regulatory standards.

In contrast to the lists of known bad actors indicated in the above-mentioned blacklists, the EPA Safer Chemical Ingredients List, provides a whitelist that guarantees the safety of a wide range of chemicals. This is of use both in the Department of Enterprise Service's current procurement role, and in Ecology's work promoting green chemistry and alternatives assessment to industry.

Central to Ecology's advocacy work in the field of green chemistry are GreenScreen and TiPED, screening protocols for chemical production that are designed to maximize the efficiency of the testing process by identifying endocrine disruptors through the simplest possible process. Essentially, both protocols delineate a series of tests ascending in complexity from computer model-based to *in vivo* mammalian experiments, balancing the cost of iterative assays that increase in certainty against the high base cost of *in vivo* assays alone.

While the above scientific advances all take the form of redundancy avoidance, advances in the understanding of mixture effects, the high-throughput chemical screening assay developed by the EPA in service of the Endocrine Disruptor Screening Program and the principles described by the National Research Council in Pthalates and Cumulative Risk Assessment promise to reduce the work needed to estimate dose-response curves and to evaluate the interaction effects of multiple chemicals from the same class, respectively. These both reduce the cost and time required to fully evaluate the endocrine-disrupting properties of a given chemical, and allow for extrapolation of that information into the context of interaction effects.

4.5.3 Policy recommendations

The recommendations presented in the table below and further described at length represent aggregations of recommendations made by multiple interviewees. Recommendations primarily fell into one of the four categories below. Of recommendations that directly addressed the existing regulatory framework, some fundamentally altered some aspect of the framework while others merely adapted it in attempts to better the nature of the endocrine disruptor issue. Beyond these recommendations that were intended to alter stakeholders' relationships to existing regulation, either by addressing industry or by addressing consumers. The most frequent and most open-ended recommendations are laid out in the following table and described below, as are several more specific recommendations.

Table 9: Recommended policy changes, grouped by degree of alteration and target audience

Fundamental Alterations:	**Minor Adaptations:**	**Industry-Focused Recommendations:**	**Consumer-Focused Recommendation:**
Cede deliberative authority to agencies	Expand CSPA to regulate additional products/ materials	Share standardized risk/hazard metrics w/ industry	Encourage consumer exercise of preferential purchasing
Adopt a hazard assessment paradigm	Group chemicals by class by default	Promote or require alternatives assessments	Increase consumer education
Mandate Biomonitoring	---	Promote or require green chemistry	---

While controversial among legislators and industry representatives, the recommendation to cede agencies, specifically the Departments of Ecology and Health, the authority to regulate chemicals following their own thorough analysis, was supported by the remaining stakeholders. This step was seen by many as a natural extension of the current process, wherein Ecology develops the case for regulating a chemical, goes before the legislature to receive authority to regulate said chemical, and proceeds to regulate the chemical.

Similarly, the recommendation that chemical regulation be founded on the basis of hazard is echoed by regulatory, advocacy, and academic stakeholders. Notably, however, this view was not expressed by representatives of the Department of Health, wherein risk analysis is more frequently required and produced. Both industry and legislative interviewees considered the determination of risk as significant to future regulation of endocrine disruptors, for the purposes of cost-benefits analysis and of evaluative legislative parity, respectively.

While not explicitly mentioned by all stakeholders, the suggestion to mandate biomonitoring was proposed by regulatory, advocacy, and academic stakeholders. Biomonitoring was described as a crucial tool in the ultimate development of risk and exposure estimates, and thus would seem to reflect the interests of industry and legislative representatives who rely on risk analysis.

Two simple adaptations of the current law, illustrated by the failed electronics amendment and PFAS bill from the 2017 legislative session, are the expansion of

CSPA to mandate reporting on a broader range of products and materials, and the holistic regulating of chemical classes, rather than individual chemicals. While both bills were criticized during session for their expanded scope, wide-scale support for their implementation remains.

While the exact nature of the relationship differed in the telling between industry and regulatory interviewees, both parties seemed interested in fostering a closer relationship. The sharing of standard metrics, much like the IC2 data sharing, would obviate the possibility of potentially disruptive differences in interpretation of scientific data and of regulatory requirements. For instance, industry and agency scientists agreed to use the same tests and decision framework in testing for evidence of endocrine disruption. Further, in line with existing programs at Ecology, both parties would be happy to see the Department expand their advocacy for alternatives assessment and green chemistry. Certain regulators and advocates would like to see these principles enshrined in regulation.

Finally, given that interviewees worked directly or indirectly for the public, there was near-unanimous interest in improving consumer awareness, and enthusiasm for consumers' power to direct market forces away from endocrine disruptors, if so inclined. While note in opposition to the notion, legislators noted the wide range of issues that the public is expected to be aware of, and questioned the emphasis of this issue over others. Additionally, advocates and academics

recommended caution and context in the explanation, so as to produce a lasting understanding of the issue rather than ephemeral panic.

5. Discussion, Conclusion and Recommendations

5.1 Discussion

It is very possible that certain seeming differences between stakeholder groups are in fact merely artifacts of the improvement of my interview style over time. I spoke to industry representatives near the beginning of the interview process, and while I subsequently reviewed my questions, I did not have the opportunity to meet with industry representatives later in the process. Conversely, I met with advocacy representatives near the close of my research, and perhaps for that reason spoke with them on a wider variety of subjects. It would no doubt have been helpful to increase the number of interviewees, or to perform small follow-up interviews to address topics previously overlooked.

By far the most diverse stakeholder group was that of the legislators, representing as they did different parts of the state with wildly varying interests. It is this stakeholder group that is simultaneously most significant for the evaluating of policy practicality, and this group that is more stochastic. No doubt further interviews with legislators would have yielded the greatest improvements to my results.

Perhaps unsurprisingly, given the relatively steady state of the science as characterized in the literature review, there was very little contention or discussion about the validity of the science. Certain interviewees preferred a risk-based approach to a hazard-based approach, or vice versa, but none seemed concerned with the uncertainties surrounding endocrinology. Whether this is because they understood the science to be effectively settled, as reflected in the numerous consensus statements made by endocrinologists, or didn’t realize that there were fundamental questions unanswered and unanswerable, was not immediately clear. More to the point, it seems as if the public conversation is simply

focused on issues more fundamental than uncertainty or interaction effects for the time being.

5.2 Conclusion and recommendations

From what I've gathered of the legislative process, the simple adaptations of existing regulation have already been set in motion, and are awaiting a politically favorable climate, and substantial public scrutiny, on their roundabout journey to legalization. Even some of the grander regulatory goals are being fomented; Ecology continues to demonstrate their ability to evaluate the safety of chemicals in a manner satisfactory to the legislature,

It is clear, however, that the slow pace of scientific advancement combined with the deliberative legislative system has ensured that this is an issue that will evolve not over years but over decades. Barring a sea-change in one process or the other, the dominoes will continue to fall slowly.

While the robustness of these results are limited due to the small number of interviews, the underlying topics of interest identified and the specific policies suggested provide a substantial underpinning for follow-up, semi-quantitative research, such as stakeholder surveys. Such a survey would provide broader evaluation of the potential popularity of many of the concepts merely identified within this work, allowing for a much clearer delineation of values.

It is for that reason that the application of this thesis to the legislation of endocrine disruptors in other states, or other potentially harmful classes of materials in any jurisdiction is so important: any pitfall identified in the process as being easily skirted

could point to the format of future legislation and allow that legislation to approach its final form that much earlier in the process. A review of this thesis, contrasting the observed process with that which occurred during the regulation of heavy metals, or that occurring with the regulation of microplastics, pharmaceuticals, and nanometals, could highlight even more fundamental stages of policy progression, and allow for future motions to be moved through with less resistance.

Other states, such as Oregon, have begun to explicitly follow in Washington's footsteps in regards to endocrine disruptor policy, producing their own response to the Children's Safe Products Act. There is already healthy communication between Washington and Oregon, but a careful analysis of similarities and differences would no doubt provide valuable information both about the jurisdictions and the process.

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Appendices

Appendix 1: List of interview questions

Opening Questions:

Could you please explain your work as it relates to endocrine disrupting chemicals?

What regulations, policies or practices are relevant for your work with EDCs?

Questions relating to the science of EDCs

Are there debates in your field related to EDCs, or is there largely consensus?

How do the fields of toxicology and endocrinology factor into the decision-making process?

In your own opinion, what is the best way of dealing with scientific uncertainty? Who decides?

Where do you get your scientific information from? Is there enough research/competence on the topic?

Questions relating to state policy

Could you explain how local, state, federal and international policies impact your work with EDCs?

How much leeway is there for individual states to regulate EDCs under the federal umbrella?

How economically prepared are we to deal with EDCs in Washington State?

How are the responsibilities relating to EDCs organized in Washington?

Are EDCs high on the political agenda?

Questions regarding best policy approach

In your opinion, how successful is current Washington State EDC policy?

Which factors should drive policy-making: scientific, environmental, social, ethical, economic?

What are some simple changes that could substantially improve WA EDC policy?

What would an ideal EDC policy look like?

Questions regarding local stakeholders

What stakeholder groups are impacted by the regulation of EDCs?

Are there some stakeholders that are more influential than others in dictating policy?

Appendix 2: List of codes

Policy Considerations

Economic – *References to $/labor/time costs of ED legislation*

Environmental

Political

Practical – *physical/temporal limitations to/requirements of implementation*

Redundancy – *related to question of nexus of power – is this already done by companies or mandated at the federal level?*

Social – *Which groups do/should care and why?*

Uncertainty

Policy Debates

Collaboration – *Between regulatory bodies e.g. Health, Ecology, other states, feds, etc.*

DefinitionEDC – *Which definition is being/should be used?*

Funding

Goal-Vision – *does the regulation adopt a goal-based or a vision-based approach?*

GreenChem – *are principles of green chemistry/predictive modeling etc. being employed?*

Institutionalization – *who has the authority; how much authority; applied how broadly?*

Risk-Hazard – *should we maintain a risk-based or a hazard-based approach to regulation*

StakeholderInvolvement

StateVsFed – *At what level should/can regulations occur? Policy Considerations*