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Endocrine-Disrupting Chemicals: Testing to Protect Future Generations

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ENDOCRINE-DISRUPTING CHEMICALS: TESTING TO PROTECT FUTURE GENERATIONS

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Abstract: Endocrine-disrupting chemicals (EDCs) are chemicals that interfere with human hormone processes. EDCs are omnipresent: pesticides, plastics, and drugs, among other common chemicals, all demonstrate endocrine-disrupting properties. Scientific studies have demonstrated the frightening effects EDCs have on human health, particularly for fetuses while they develop in utero. Given these health concerns, Congress passed the Food Quality Protection Act of 1996, which requires the EPA to test pesticides for their endocrine-disrupting properties. Frustratingly this testing, fifteen years later, has still not begun. Therefore this Note argues that citizens should bring suit under the Administrative Procedure Act to compel EPA to complete testing of pesticides for endocrine-disrupting properties, all with the goal of furthering effective regulation of EDCs.

Introduction

> *The ultimate success of this reform will rest with the professionalism and the common sense of the Environmental Protection Agency. Congress will be watching closely as we try to implement these reforms. We will, to ensure that science, not emotion, is the basis of pesticide regulation.*[1]

The synthetic estrogen drug, DES, is one of many known endocrine-disrupting chemicals, and an infamous example of why these chemicals need to be tested and regulated.[2] In the late 1960s, an unusual cluster of clear-cell adenocarcinoma—a rare form of vaginal cancer—appeared in Boston.[3] Doctors were particularly concerned not only because clear-cell adenocarcinoma is an incredibly unusual form of cancer, but also because the women diagnosed were all under twen-

* Editor in Chief, Boston College Environmental Affairs Law Review, 2010–11.

[1] 142 Cong. Rec. 18,588 (1996).

[2] *See* Theo Colborn et al., Our Stolen Future: Are We Threatening Our Fertility, Intelligence, and Survival?—A Scientific Detective Story 67 (Plume 1997) (1996).

[3] *Id.* at 55.

ty-two years old, when this cancer was previously reported predominantly in elderly women.[4] Researchers struggled to find a link between the cancers until they discovered that seven of the eight women's mothers took the drug DES while pregnant.[5]

Now that scientists were alerted to the potentially carcinogenic effects of DES on children in utero, they began to study the affects of DES in mice studies and compare those to humans exposed to DES in utero.[6] Evidence from animal studies, and from studies monitoring the health of DES offspring, shows that DES children are at greater risk for a startling array of health ills: gross abnormalities in the shape and size of cervix and uteri; stunted penises and testes in sons; ectopic pregnancies, miscarriages, and premature births in daughters; higher risk of prostate and breast cancers; and infertility in both sons and daughters.[7]

Endocrine-disrupting chemicals (EDCs) are chemicals, like DES, that interfere with human hormone processes.[8] Endocrine disruptors have been linked to a litany of health harms, ranging from reproductive abnormalities to metabolic disorders like insulin resistance, type 2 diabetes, and obesity.[9] Additionally, EDC exposure in the womb has a disproportionately large affect on fetuses' immediate and long-term health compared to EDC exposure in grown adults.[10] While there are on-going scientific studies on DES, there has been far too little scientific study of the potentially 87,000 chemicals that are also endocrine disruptors.[11] This leaves society without enough information to determine whether or not to restrict the use of EDCs.[12]

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[4] *Id.* at 54–55; Ctrs. for Disease Control & Prevention, DES: Yesterday, Today, Tomorrow 1 (n.d.), *available at* http://www.cdc.gov/DES/consumers/download/know2_des.pdf.

[5] *See* Colborn et al., *supra* note 2, at 55. Diesthylstilbestrol (DES), the first man-made estrogen, was developed in 1938. *Id.* 47–48. DES was immediately seen as a wonder drug for pregnant women, especially those at risk of miscarriage. *Id.* DES was widely prescribed between 1938 and 1971, initially to suppress miscarriage and later for other uses. *Id.*

[6] *See id.* at 58–59.

[7] *Id.* at 59; Ctrs. for Disease Control & Prevention, *supra* note 4, at 3.

[8] Colborn et al., *supra* note 2, at xv.

[9] Al Gore, *Foreward* to *id.* at vii; Noah Sachs, *Blocked Pathways: Potential Legal Responses to Endocrine Disrupting Chemicals*, 24 Colum. J. Envtl. L. 289, 290 (1999); *Living on Earth: Bisphenol A on the Burner* (Public Radio International broadcast Aug. 3, 2007) [hereinafter *Living on Earth*], *available at* http://www.loe.org/shows/segments.html?programID=07-P13-00031&segmentID=4 (interviewing two major endocrine disruption researchers, Dr. Ana Soto of Tufts University and Retha Newbold of the National Institute of Environmental Health Sciences, explaining their research into DES and BPA).

[10] *See* Colborn et al., *supra* note 2, at 73–74.

[11] *See* Sachs, *supra* note 9, at 302–03, 306.

[12] *See id.*

In 1996, Congress recognized this concern and amended the Food, Drug, and Cosmetic Act to require the Environmental Protection Agency (EPA) to test all pesticides to determine their effects on the endocrine, or hormone, system.[13] Although Congress gave EPA a strict three-year deadline to conduct these pesticide studies, EPA only began to mandate testing in 2009—ten years after its original deadline passed.[14] Additionally, and most disturbingly, EPA's testing policy allows pesticide companies to submit outdated testing data,[15] data that in many cases is specifically designed to show these chemicals are safe.[16] If EPA accepts outdated testing data instead of requiring new testing, pesticide companies will be allowed to side-step Congress's explicit mandate that pesticides are to be tested for endocrine effects.[17] If EPA does not force chemical companies to comply with new testing procedures it will fail to achieve the "ultimate purpose of the [testing program, which is] to provide information to the Agency that will allow the Agency to evaluate the risks associated with the use of a chemical and take appropriate steps to mitigate any risks."[18] If EPA fails to understand and properly mitigate risks from EDCs, society will continue to be exposed to potentially harmful chemicals on a daily basis.[19]

The purpose of this Note is to show that if EPA accepts outdated testing data, it will exceed its statutory authority, or alternatively, accepting outdated test data is an arbitrary and capricious action.[20] Congress in no uncertain terms dictated that EPA *shall* establish an endocrine testing program and *shall* test *all* pesticide chemicals under the testing program.[21] However, EPA promulgated a testing order that potentially allows pesticide producers to submit outdated, inaccurate data.[22] This Note argues, therefore, if EPA accepts outdated testing data, a review-

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[13] Food Quality Protection Act of 1996, Pub. L. No. 104-170, 110 Stat. 1489 (codified as amended at 21 U.S.C. § 346a(p) (2006)); COLBORN ET AL., *supra* note 2, at xvi.

[14] Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 346a(p)(7) (2006); *see* Endocrine Disruptor Screening Program; Tier 1 Screening Order Issuing Announcement, 74 Fed. Reg. 54,422, 54,425 (Oct. 21, 2009) [hereinafter Testing Order].

[15] *See* Testing Order, *supra* note 14, at 54,427.

[16] Alexander C. Hart, *Worries on Old Toxicity Data*, L.A. TIMES, Oct. 17, 2009, at A18 ("The order . . . would allow the pesticide makers to selectively submit outdated studies that show the pesticides are safe.").

[17] *See* 21 U.S.C. § 346a(p).

[18] Endocrine Disruptor Screening Program; Policies and Procedures for Initial Screening, 74 Fed. Reg. 17,560, 17,561 (Apr. 15, 2009) [hereinafter Testing Policies].

[19] *See* COLBORN ET AL., *supra* note 2, at 110, 219.

[20] *See* Administrative Procedure Act, 5 U.S.C. § 706(2)(A), (C) (2006).

[21] 21 U.S.C. § 346a(p).

[22] *See* Testing Order, *supra* note 14, at 54,427.

ing court must set aside the provision of the testing order allowing industry to submit old testing data in place of conducting new testing.[23] Furthermore, this Note argues that testing is an important first step, and should be extended to non-pesticide EDCs, but these chemicals must be properly regulated once EPA receives testing information.

Part I of this Note further explains what endocrine-disrupting chemicals are and enumerates their potential health harms.[24] Part II explains the current statutory and regulatory framework for testing chemical effects on the endocrine system.[25] Part III argues that the Administrative Procedure Act provides a tool for challenging EPA's final agency action as either in excess of statutory authority, or alternatively, as arbitrary and capricious.[26] Part IV identifies potential avenues for regulating EDCs that are found to negatively affect human health.[27]

I. Endocrine-Disrupting Chemicals

EDCs include a wide-ranging group of man-made as well as naturally occurring compounds that "trick the body and disrupt its own chemical messengers."[28] People absorb and store EDCs in small doses from many common sources every day.[29] Small amounts of these chemicals are in everything from drinking water to plastics used for water bottles and food storage. Atrazine, an herbicide used widely on crops, golf courses, and lawns, is now among the most common pollutants in drinking water.[30] Bisphenol-A (BPA) is one of the most commonly used chemicals in plastics in the United States.[31]

EDCs were previously considered benign because people are exposed to doses well below those that are fatal or known to cause cancer.[32] However, scientific studies are beginning to show these chemicals are, counter-intuitively, often more dangerous in lower doses than in

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[23] *See* 5 U.S.C. § 706(2)(A), (C).

[24] *See infra* Part I.

[25] *See infra* Part II.

[26] *See infra* Part III.

[27] *See infra* Part IV.

[28] Colborn et al., *supra* note 2, at 68.

[29] *See generally* Rachel Carson, *Elixirs of Death*, *in* Silent Spring 15–37 (Houghton Mifflin 1994) (1962) (explaining the omnipresence of chemicals in the environment, and the storage and latency of DDT and other chemicals in the human body).

[30] Charles Duhigg, *Debating How Much Weed Killer Is Safe in Your Water Glass*, N.Y. Times, Aug. 23, 2009, at A1.

[31] Sachs, *supra* note 9, at 305.

[32] *See* Colborn et al., *supra* note 2, at 205.

massive doses.[33] Scientists do not fully understand why small doses of EDCs can have greater ill effects than larger doses, especially because scientists generally expect that chemicals follow the adage "the dose makes the poison."[34] Nonetheless, it is clear that the body can be tricked into action by a hormone or hormone-mimicker at low doses, but as hormone levels rise the system eventually shuts off, thus stopping any ill effect.[35] Additionally, it is clear that when it comes to endocrine disruptors, the timing of exposure can have far more impact than the size of the dose.[36] This is why exposure to EDCs in the womb can have such a large impact on the health of a developing fetus, especially when EDC exposure occurs at certain points in fetal development.[37] A fetus exposed to an EDC after sexual differentiation or other major developmental milestone may suffer no ill effects, while a fetus exposed at crucial points in development may be permanently harmed.[38]

Endocrine disruptors are linked to a wide range of maladies. Among other ill effects, EDCs can potentially cause infertility, obesity, immune disorders such as type 2 diabetes, and cancers.[39] Although these disorders are wide-ranging, they all have a common link: these diseases affect components of the endocrine system.[40]

A. *The Endocrine System and Hormones*

The endocrine system, along with the immune and nervous systems, is one of the major regulating and integrating systems in the human body.[41] The endocrine system is composed of hormone-secreting glands including the pituitary, thyroid, and pancreas, among others.[42] Hormones regulate many of the body's most important functions, including metabolism, blood pressure, developmental mechanisms, and the nervous system.[43] Hormones travel through the blood stream to

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[33] *Id.*

[34] *Id.*

[35] *Id.* at 206.

[36] *Id.*

[37] *See id.* at 43, 62.

[38] *See* Colborn et al., *supra* note 2, at 43, 62.

[39] *See* Sachs, *supra* note 9, at 290; *Living on Earth*, *supra* note 9.

[40] *See* Sachs, *supra* note 9, at 290; *Living on Earth*, *supra* note 9.

[41] Risk Assessment Forum, EPA, Special Report on Environmental Endocrine Disruption: An Effects Assessment and Analysis 2 (1997) [hereinafter EPA Study], *available at* http://www.p2pays.org/ref/07/06070.pdf.

[42] *Id.*

[43] *Id.*

hormone receptors.[44] Once bonded to those receptors, hormones exert their influence and can cause systemic changes.[45] Endocrine disruptors can interfere with our endocrine system in many different ways.[46] EDCs can mimic our natural hormones and bond with receptors in organs and tissues, interfere with receptor bonding, or enhance or inhibit naturally occurring hormones.[47] EDCs' interruption of normal hormone functions can cause a cascade of effects.[48]

Additionally, and crucially, glands excrete hormones that act in infinitesimally small doses, registering as low as parts-per-trillion concentration in the bloodstream.[49] Therefore, it potentially only takes a tiny amount of a hormone or hormone-mimicker to affect huge changes in our bodies, particularly at crucial points in development.[50] EDCs therefore have a significantly more pronounced effect on fetuses than on adults, and correspondingly "[t]here are . . . concerns that exposure to low doses of certain chemicals at critical stages in organ development can result in abnormalities that lead to irreversible changes in the functioning of organ systems later in life."[51] Hormones in the womb are responsible for permanently programming cells, organs, the brain, and behavior, profoundly influencing physical and mental characteristics of the developing fetus.[52]

The consequences of malfunctioning hormones in the womb can appear immediately after birth, as physical deformities, but also in long-term diseases that arise well into adulthood.[53] For example, children whose mothers took the synthetic estrogen drug DES during pregnancy were not only born with physical abnormalities that were evident at birth,[54] they also were at greater risk for different kinds of

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[44] *Id.*

[45] *See id.*

[46] *See* COLBORN ET AL., *supra* note 2, at xvi.

[47] *See* Sachs, *supra* note 9, at 293 (describing the ways in which EDCs can interfere with normal hormone function).

[48] *See id.*

[49] COLBORN ET AL., *supra* note 2, at 40.

[50] *See id.* at 40–42.

[51] NAT'L RESEARCH COUNCIL, NAT'L ACADEMIES, HORMONALLY ACTIVE AGENTS IN THE ENVIRONMENT 119 (1999) [hereinafter NRC REPORT], *available at* http://www.nap.edu/openbook.php?record_id=6029&page=R1.

[52] COLBORN ET AL., *supra* note 2, at 39–40.

[53] *Id.* at 57–58.

[54] *Id.* at 59.

cancer, auto-immune diseases, and depression later in life.[55] On-going research is discovering other long-range harms.[56]

B. *Some Common Endocrine-Disrupting Chemicals*

Many common chemicals are known or suspected to interact with the endocrine system, and thus are in the family of endocrine disruptors.[57] Some of the most common classes of EDCs are described below.

1. Pharmaceuticals

Drugs like DES are designed specifically to mimic hormones.[58] There is popular concern that excess estrogen from birth-control pills, which are a synthetic version of estrogen and progestin, makes its way out of women's bodies, into wastewater treatment plants, and out into major water bodies.[59] However, estrogen from drugs used in humans accounts for approximately one percent of estrogen in the environment.[60] Meanwhile, approximately ninety percent of estrogen in the environment comes from livestock operations.[61] This is the result of injecting livestock with growth hormones and leaving hormone-rich manure untreated, which runs into surface and ground waters.[62] Regardless of the direct source, estrogenic pharmaceuticals are a significant source of endocrine disruptors in the environment.[63]

2. Estrogenic Additives

Compounds with estrogenic effects are widely used in detergents, paints, herbicides, pesticides, and cosmetics.[64] These chemicals are washed out of our homes and off our lawns in huge quantities.[65] Estro-

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[55] *Id.* at 62, 63, 65. *See generally* Ctrs. for Disease Control & Prevention, Recent DES Research (n.d.), *available at* http://www.cdc.gov/DES/consumers/download/learning2_research.pdf.

[56] *See id.*

[57] *See id.*

[58] Colborn et al., *supra* note 2, at 48.

[59] *See id.* at 133; Nicholas D. Kristoff, *It's Time to Learn from Frogs*, N.Y. Times, June 28, 2009, at WK9.

[60] *Endocrine Disrupting Compounds and Intersex Fish*, UCSF Program Reprod. Health & Env't, http://prhe.ucsf.edu/prhe/learn/kristof_edcs.html (last visited Apr. 15, 2011).

[61] *Id.*

[62] *Id.*; Ariele Lessing, *Killing Us Softly: How Sub-Theraputic Dosing of Livestock Causes Drug-Resistant Bacteria in Humans*, 37 B.C. Envtl Aff. L. Rev. 463, 467–68 (2010).

[63] *See id.*

[64] Colborn et al., *supra* note 2, at 129; Sachs, *supra* note 9, at 304.

[65] *See* Sachs, *supra* note 9, at 304.

genic additives that wash away either pass through water treatment systems or run directly into surface and ground waters, often polluting water bodies with high concentrations of estrogenic additives.[66] These water bodies then serve as drinking water sources.[67] These estrogenic additives have shown serious endocrine effects in fish. When government fisheries staff in England discovered that fish near the outfalls of wastewater treatment plants exhibit both male and female characteristics, referred to as "intersex," they investigated the source of the fishes' sexual confusion.[68] The major culprit turned out to be the detergents we use to clean our clothes and houses, which breaks down into the alkylphenol family of chemicals that act as estrogen mimickers.[69]

3. Pesticides

Endocrine-disrupting pesticides include infamous compounds such as DDT and kepone.[70] DDT was banned as a general use pesticide in the United States in 1972,[71] but is still manufactured for sale overseas.[72] However, DDT and other pesticides persist in the U.S. environment because they build up and remain stored in the fatty deposits of wildlife and humans.[73] This means that organisms further up the predatory food chain have larger concentrations of DDT in their systems.[74] Though DDT is banned as a pesticide, many pesticides still used on crops have similar impacts: heightening estrogen effects in the body while suppressing testosterone function.[75]

4. Industrial Chemicals

This class of suspected endocrine disruptors includes polychlorinated biphenyls (PCBs), which were used as heat transfer and hydraulic fluids, adhesives, and flame retardants among other purposes.[76] Congress banned production of most PCBs in 1976, but similar to DDT, PCBs

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[66] *See* COLBORN ET AL., *supra* note 2, at 129; Sachs, *supra* note 9, at 304.

[67] *See* COLBORN ET AL., *supra* note 2, at 129; Sachs, *supra* note 9, at 304.

[68] COLBORN ET AL., *supra* note 2, at 132.

[69] *See id.* at 134.

[70] *See* Sachs, *supra* note 9, at 303.

[71] Press Release, EPA, DDT Ban Takes Effect (Dec. 31, 1972), *available at* http://www.epa.gov/history/topics/ddt/01.htm.

[72] *See id.*

[73] CARSON, *supra* note 29, at 24, 48, 108.

[74] *Id.* at 48.

[75] *See* Sachs, *supra* note 9, at 303.

[76] *Id.* at 304.

persist in the environment and bio-accumulate in the food chain.[77] PCBs are particularly prevalent in fish that live in contaminated waters.[78]

5. Bisphenol-A (BPA)

BPA has gained national recognition in the past three years.[79] BPA, a "strong and resilient plastic," is one of the highest production volume EDCs because it is used in a wide variety of products.[80] BPA is used in plastic water bottles—including the popular Nalgene brand, which has recently switched to non-BPA plastics—contact lenses, baby bottles, and as a liner for many canned food products including infant formula.[81] BPA has been shown to interfere with hormone activity at very low levels, and there is concern that BPA causes an increase in prostate cancer, breast cancer, early onset of puberty in girls, and neurobehavioral problems.[82]

C. *Endocrine Disruption in Humans*

There is a paucity of scientific studies directly linking EDCs to human health effects, which is precisely why Congress directed EPA to implement a testing program.[83] To date, EPA has not conducted any endocrine chemical testing, and independent scientists have only studied the human health effects of select endocrine disruptors, among them BPA.[84] This is primarily because BPA is used in so many products that exposure to BPA is nearly universal.[85] A recent study by the Centers for Disease Control and Prevention found that ninety-five percent of people tested have traces of BPA in their urine.[86] Additionally, a recent study commissioned by the Environmental Working Group found that nine out of every ten samples of blood taken from umbilical cords

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[77] *Id.* at 304; Colborn et al., *supra* note 2, at 27.

[78] Sachs, *supra* note 9, at 304.

[79] Editorial, *Heightened Concern over BPA*, N.Y. Times, Jan. 21, 2010, at A38.

[80] *See Living on Earth*, *supra* note 9.

[81] Sachs, *supra* note 9, at 305; *Living on Earth*, *supra* note 9; Elaine Shannon, *BPA: Why Are We Still Easting This Stuff?*, Envtl. Working Group (Jan. 18, 2010), http://www.ewg.org/kid-safe-chemicals-act-blog/2010/01/bpa-why-are-we-still-eating-this-stuff/.

[82] *See Living on Earth*, *supra* note 9.

[83] Sachs, *supra* note 9, at 306; *see* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 346a(p) (2006).

[84] *See* Testing Order, *supra* note 14, at 54,427; *Living on Earth*, *supra* note 9.

[85] *See supra* Part I.B.5.

[86] *Living on Earth*, *supra* note 9.

of newborn babies shows BPA contamination.[87] The effect of endocrine disruption on fetal development is much greater than in adults, and can lead to both immediate and life-long health consequences for an exposed fetus.[88] Although it is challenging to establish a causal link between exposure to endocrine disruption and specific outcomes in humans, scientific studies have shown a strong association between BPA and many health effects: cognitive and behavioral impairments, reproductive system abnormalities, obesity, and some cancers.[89] Additionally, scientists have found a parallel between BPA and DES exposure, because both cause cystic ovaries and uterine fibroids.[90]

DES is fairly unique case study because it provides one of the few clear, direct causal links between EDCs and human health effects.[91] Of course, the unintended experiment with human health came with serious health consequences for DES-exposed offspring.[92] Animal studies are a useful addition to epidemiological studies on EDC effects in humans. Animal studies can aid in defining causal links, and potentially have much to teach us about endocrine disruption in humans.

D. *Endocrine Disruption in Animals*

Although there is concern in inferring human effects from endocrine disruption observed in animals, there is good reason to consider animal studies when trying to understand EDC's effect on humans.[93] The most important reason comes from DES and BPA studies in mice.[94] Once concerns about DES and BPA arose, scientists began controlled mouse studies to isolate cause and effect of administering these endocrine disruptors to mice in utero.[95] As researcher Retha Newbold stated, "[human health effects] are things that we actually predicted with [DES] animal studies."[96] Another researcher who conducted DES mouse studies, John McLachlan,

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[87] *See* Envtl. Working Group, Pollution in People: Cord Blood Contaminants in Minority Newborns 8 (2009), *available at* http://www.ewg.org/files/2009-Minority-Cord-Blood-Report.pdf.

[88] *See supra* Part I.A.

[89] Sachs, *supra* note 9, at 306; *Living on Earth*, *supra* note 9.

[90] *Living on Earth*, *supra* note 9.

[91] *See supra* Introduction.

[92] *See supra* notes 5–7 and accompanying text.

[93] *See* Sachs, *supra* note 9, at 293–94.

[94] *See* Colborn et al., *supra* note 2, at 58–59; *Living on Earth*, *supra* note 9.

[95] *See* Colborn et al., *supra* note 2, at 58–59; *Living on Earth*, *supra* note 9.

[96] *Living on Earth*, *supra* note 9.

> kept in close touch with Dr. Arthur "Hap" Haney, a physician . . . who was treating humans exposed to DES. Time and time again, McLachlan would find something in a mouse and discover, when he called Haney, that the physician had seen the same problem in humans as well. Once in a while, the mouse findings would signal problems long before they emerged in humans.[97]

Accordingly, endocrine effects in animals are often predictors of endocrine effects in humans.[98]

There are also many startling examples of endocrine disruption in wild animals that warn of potential endocrine effects in humans.[99] For example, the effect of DDT on bird species gained widespread recognition with Rachel Carson's seminal 1962 book, *Silent Spring*.[100] Carson described scientific studies that showed striking examples of EDC bioaccumulation in robin populations.[101] The high levels of DDT in bird testes and ovaries led to females who either could not lay eggs at all or laid eggs that were so defective that they did not hatch.[102]

The BPA and DES mouse studies showed that endocrine disruption in animals can often predict the course of endocrine disruption in humans.[103] Additionally, the DDT robin observations should serve as a warning about potential endocrine effects in humans.[104] Some of these particular studies are only of limited use, because they served their purpose—DES is no longer sold, and DDT is now banned as a general use pesticide.[105] Nonetheless, BPA remains in heavy use in the United States, regardless of the scary science that has emerged regarding BPA's endocrine effects.[106] Therefore, it is important to expand research and learn more about the affects of other EDCs that humans more commonly encounter on a daily basis.[107]

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[97] Colborn et al., *supra* note 2, at 59.

[98] *See id.*

[99] *See* Carson, *supra* note 29, at 103–27 (chronicling the effects of EDCs on robins and eagles).

[100] *See generally id.* (discussing the widespread use of DDT and its effect on bird species).

[101] *See id.* at 107–09.

[102] *See id.* at 108–09.

[103] *See* Colborn et al., *supra* note 2, at 59.

[104] *See id.*

[105] *Supra* Part I.B.3.

[106] *See supra* notes 80 and 96 and accompanying text.

[107] *See* Sachs, *supra* note 9, at 302–03.

E. *Implications for Regulations*

Existing science has begun to show that two key issues impact how EDCs affect animals and humans. First, *when* exposure occurs can make a big difference, especially if EDC exposure occurs during key stages of fetal development.[108] Therefore, it is crucial for future research

> to focus not only on direct mortality, but also on the far more common, but less easily measured, sublethal effects of endocrine disruption which may have detrimental consequences to populations in the long-term (and especially as these disruptions occur to embryos, adversely affecting the organization of the reproductive, immune, or nervous systems).[109]

Second, *how much* of an endocrine disruptor is needed to affect change can vary, and the effects of the same EDC can change when exposure occurs at different doses.[110] In fact, "testing with very high doses will miss some effects that would show up if the animals were given lower doses."[111] Therefore, it is important to test the same EDC at different doses, in order to understand what changes it causes at different doses.[112] It is crucial to learn more about the relationship between dose-response, and timing of exposure and response, in order to properly police human exposure to EDCs through legislation and regulation.[113]

II. The Statutory and Regulatory Framework for Testing Endocrine-Disrupting Chemicals

Existing science shows that EDCs are a threat to human health and the environment.[114] However, more specific scientific studies are needed in order to have a comprehensive picture of which chemicals are endocrine disruptors, and at what doses and in what manner these

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[108] *See* Colborn et al., *supra* note 2, at 62 ("Women whose mothers took DES after the twentieth week of pregnancy do not suffer from the reproductive tract deformities, while those exposed before the tenth week of pregnancy have a greater chance of developing vaginal or cervical cancer.").

[109] EPA Study, *supra* note 41, at 67.

[110] *See* Pete Meyers & Wendy Hessler, Does "the Dose Make the Poison?" 1 (2007), *available at* http://www.ourstolenfuture.org/newscience/lowdose/2007/2007-0525nmdrc.html (showing that mice exposed to DES at one part per billion grow to be grossly obese, while mice exposed to DES at 100 parts per billion are scrawny as adults.).

[111] Colborn et al., *supra* note 2, at 170.

[112] *See* Meyers & Hessler, *supra* note 110, at 2–3.

[113] *See id.* at 4.

[114] *See, e.g.*, Colborn et al., *supra* note 2, at 52–61 (explaining the wide-ranging effects of DES to fetuses exposed to DES in the womb).

chemicals act as endocrine disruptors in fetal, child, and adult humans.[115] Partially in recognition of this issue, Congress passed the Food Quality Protection Act of 1996, which requires EPA to test pesticide chemicals for endocrine-disrupting properties, and regulate those pesticides accordingly.[116]

A. *The Estrogenic Substances Screening Program*

The Food Quality Protection Act was designed to reform pesticide regulation and evaluate tolerances for pesticide residue in foods.[117] Motivated by the recent widespread attention to endocrine disruption following the publication of *Our Stolen Future,*[118] Congress included a provision in the Food Quality Protection Act to establish an endocrine screening program under the Federal Food, Drug, and Cosmetic Act.[119]

1. Structure of the Estrogenic Substances Screening Program

The Estrogenic Substances Screening Program under the Federal Food, Drug, and Cosmetic Act directs EPA to establish a testing program to determine if certain substances have endocrine effects.[120] Specifically, it requires that the Administrator of the EPA "provide for the testing of all pesticide chemicals" for endocrine effects,[121] and gives the Administrator discretion to test any other substance that "may have an effect that is cumulative to an effect of a pesticide" if a "substantial population" is exposed to the substance.[122] Therefore, although the Administrator is not required to test chemicals beyond pesticides, she is allowed discretion to test other substances with similar effects that reach a wide population, for example, BPA.[123] Additionally, although limited, Congress did give EPA enforcement mechanisms to obtain test results from anyone ordered to test a pesticide who fails to do so.[124]

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[115] *See id.* at 73–74; Sachs, *supra* note 9, at 300.

[116] Food Quality Protection Act of 1996, Pub. L. No. 104-170, 110 Stat. 1489 (codified as amended in 21 U.S.C. § 346a(p) (2006)).

[117] 142 Cong. Rec. 18,588 (1996).

[118] *See, e.g.*, Colborn et al., *supra* note 2, at xv–xvi.

[119] *See* 21 U.S.C. § 346a(p).

[120] *Id.* § 346a(p)(1).

[121] *Id.* § 346a(p)(3)(A).

[122] *Id.* § 346a(p)(3)(B).

[123] *See id.*; *supra* Part II.B.5.

[124] 21 U.S.C. § 346a(p)(5)(C)–(D).

2. Enforcement Mechanisms Under the Screening Program

The screening program does specifically provide sanctions against parties that refuse to comply with testing procedures for suspected EDCs.[125] The statute allows EPA to suspend the sale or distribution of a pesticide with a thirty day notice if the manufacturer of the substance refuses to comply with a testing order.[126] Additionally, parties other than pesticide registrants who fail to comply with testing orders—most likely non-pesticide producing parties who are required to provide data or conduct testing under the screening program—can be penalized under the Toxic Substances Control Act, which carries civil penalties up to $25,000.[127]

B. *Endocrine Disruptor Screening and Testing Advisory Committee*

While Congress granted the EPA Administrator wide latitude in determining which substances to test and in designing the screening program, it kept EPA to a very tight timetable.[128] Congress only gave EPA two years to develop the program, another year to conduct testing, and expected EPA to submit a report on the testing by 2000—four years after the Food Quality Protection Act was passed.[129] This timeline proved to be too ambitious. In fact, EPA only issued the first round of testing orders in October 2009,[130] which will not be completed until October 2011 at the earliest.[131] Thus, it will be years until EPA can deliver a report to Congress.

In 1996, EPA began the task of selecting which pesticide chemicals to test first, and designing and implementing a testing program, by convening an Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC).[132] EDSTAC was composed of stakeholders from various sectors: environmental groups, federal agencies, state agencies, public health organizations, industry, and scientists.[133] EDSTAC worked

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[125] *Id.*

[126] *See id.* § 346a(p)(5)(C).

[127] *Id.* § 346a(p)(5)(D); Toxic Substances Control Act, 15 U.S.C. § 2615 (2006).

[128] *See* 21 U.S.C. § 346a(p).

[129] *See id.* § 346a(p)(1)–(2), (7).

[130] *See* Testing Order, *supra* note 14, at 54,422.

[131] *See* Testing Policies, *supra* note 18, at 17,574.

[132] *See* Keith J. Jones, *Endocrine Disruptors and Risk Assessment: Potential for a Big Mistake*, 17 Vill. Envtl. L.J. 357, 361 (2006).

[133] *Id.*

for two years to set priorities among potential EDCs, and to design an appropriate screening and testing program.[134]

EDSTAC issued a final report in August 1998, with numerous recommendations.[135] EDSTAC recommended that the testing program should focus on endocrine effects on three primary hormone systems: the estrogen, androgen, and thyroid systems.[136] EDSTAC recognized that approximately 87,000 chemicals need to be tested for their endocrine-disrupting capabilities, but with limited resources, EPA must set priorities among the sea of chemicals to be treated.[137] Additionally, EDSTAC suggested that EPA incorporate a two-tier system to test pesticides.[138] Tier one is designed to separate out chemicals that do not interact with the endocrine system from those that do, so only established endocrine disruptors are subject to the next step of tier two testing.[139]

EPA essentially adopted EDSTAC's finding and published a notice in the Federal Register announcing the newly established Endocrine Disruptor Screening Program (the "Testing Program"), designed to reflect the recommendations of EDSTAC.[140]

C. *The Testing Program*

The Testing Program includes all the recommendations of EDSTAC, including a tier one and tier two testing structure.[141] Additionally, EPA identified the criteria by which it would select and prioritize pesticides to test under the Testing Program.[142]

The years from 1999 to 2008 were plagued by delays in moving the Testing Program forward.[143] Finally, the Natural Resources Defense Council (NRDC) filed suit against EPA to compel further action on the

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[134] *Endocrine Disruptor Screening and Testing Advisory Committee*, Envtl. Prot. Agency, http://epa.gov/endo/pubs/edspoverview/edstac.htm (last updated Apr. 22, 2010).

[135] *See generally* Endocrine Disruptor Screening & Testing Advisory Comm., Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC) Final Report—Executive Summary (1998) [hereinafter EDSTAC Report], *available at* http://epa.gov/endo/pubs/edstac/exesum14.pdf.

[136] *Id.* at ES–3.

[137] *See id.*

[138] *See id.*

[139] *See id.* at ES–4.

[140] Endocrine Disruptor Screening Program, 63 Fed. Reg. 42,852, 42,853 (Aug. 11, 1998); Jones, *supra* note 132, at 361.

[141] Endocrine Disruptor Screening Program, *supra* note 140, at 42,853–54.

[142] *Id.* at 42,854.

[143] *See* Press Release, Natural Res. Def. Council, NRDC Backrounder: *NRDC et al. vs. EPA* Presents Bellwether Choice for EPA Head Whitman (Feb. 22, 2001), *available at* www.nrdc.org/media/docs/fqpaback.doc.

Testing Program.[144] A final consent decree required EPA to abide by its settlement agreement with NRDC and begin screening chemicals under the Testing Program.[145] Although the settlement agreement specifically provided that EPA would test thirty-nine pesticides for their endocrine-disrupting properties by 2002,[146] there is no indication that EPA conducted such testing. In fact, EPA did not act until 2007, when it published a notice identifying the draft list of pesticides it would prioritize for testing.[147]

D. *Methods Required Under the Testing Program*

It was another two years before EPA next took significant action under the Testing Program. In 2009, EPA published a proposed notice of the policies and procedures for tier one testing[148] and the final list of initial pesticides prioritized for testing, which included sixty-seven pesticides.[149] The goal of tier one testing "is to identify substances that have the potential to interact with the estrogen, androgen, or thyroid hormone systems."[150] To achieve this goal, EPA designed the specific tests these pesticides must go through, factoring in all current scientific knowledge.[151] Thus, the final testing battery for pesticides reflects up-to-date science that takes into account, for example, the fact that *when* exposure occurs can significantly change an EDC's health effect.[152] EPA has not yet promulgated rules for tier two testing, but EPA has stated that the purpose of tier two testing is to "establish a dose-response relationship for any adverse effects that might result from the interactions identified through [Tier 1]."[153] Therefore, tier two testing aims to establish the relationship between the amount of EDC—i.e., dose—and

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[144] *See* Jones, *supra* note 132, at 361–62; Press Release, Natural Res. Def. Council, *supra* note 143.

[145] *See* Natural Res. Def. Council v. Whitman, 2001 WL 1456783 at *1 (N.D. Cal. 2001).

[146] Press Release, Natural Res. Def. Council, *supra* note 143.

[147] Draft List of Initial Pesticide Active Ingredients and Pesticide Inerts to be Considered for Screening, 72 Fed. Reg. 33,486, 33,486 (June 18, 2007).

[148] Testing Policies, *supra* note 18, at 17,560–79.

[149] Final List of Initial Pesticide Active Ingredients and Pesticide Inert Ingredients to be Screened, 74 Fed. Reg. 17,579, 17,579 (Apr. 15, 2009).

[150] Testing Policies, *supra* note 18, at 17,561.

[151] *See* Endocrine Disruptor Screening Program (EDSP); Announcing the Availability of the Tier 1 Screening Battery and Related Test Guidelines, 74 Fed. Reg. 54,416, 54,417 (Oct. 21, 2009).

[152] *See id.*; *supra* Part I.E.

[153] Testing Policies, *supra* note 18, at 17,561.

effect on the organism—i.e., response—for those pesticides that initially demonstrate endocrine-disrupting properties.[154]

EPA included a concession in its policies and procedures that "recipients of . . . test orders [have] the option of submitting or citing existing data, along with a rationale that explains how the cited or submitted study satisfies the Tier 1 Order."[155] EPA was trying to be fair with this concession: EPA would allow individuals who receive test orders to submit previously conducted tests, so long as the prior data is designed to show whether or not the pesticide has an effect on the endocrine system.[156] Therefore, EPA clearly states that any previously conducted data must satisfy the specific, up-to-date testing methods under the tier one protocol.[157]

E. *Final Hurdle to Testing: Approval under the Paperwork Reduction Act*

EPA had one last hurdle to clear before issuing the first testing orders: it had to obtain approval to issue testing orders from the Office of Management and Budget (OMB).[158] This is due to the Paperwork Reduction Act, which mandates that any federal agencies wishing to collect information from the public must meet certain criteria.[159] Specifically, an agency must submit its proposal to collect information to OMB and get approval before collecting any information from the public.[160] When EPA issues a test order, it requests information from the public, which, in this case, consists of pesticide producers.[161] Therefore EPA was required to draft an information collection request and submit it to OMB for approval.[162]

Unfortunately, the information request that OMB approved included a major modification to the proposal drafted by EPA.[163] EPA's

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[154] *See id.*

[155] *Id.* at 17,566.

[156] *See id.*

[157] *See id.*

[158] *See* Paperwork Reduction Act, 44 U.S.C. § 3507(a) (2006).

[159] *Id.*

[160] *Id.*

[161] *See id.*

[162] Agency Information Collection Activities; Submission to OMB for Review and Approval, 74 Fed. Reg. 17,477, 17,477–79 (Apr. 15, 2009).

[163] *See* Memorandum—Notice of Action from Kevin F. Neyland, Deputy Adm'r, Office of Mgmt. & Budget, to EPA (Oct. 2, 2009) [Hereinafter OMB Memo], *available at* http://www.reginfo.gov/public/do/DownloadNOA?requestID=220264; Matt Schudtz, *Sunstein Watch: OMB Meddling on Endocrine Disruptor Screening Program Means Shifting a Key Burden from Industry to EPA*, Ctr. Progressive Reform Blog (Oct. 20, 2009), http://www.progressivereform.org/CPRBlog.cfm (follow "Matt Shudtz" hyperlink; then follow "Next").

Testing Program required new, up-to-date tests properly constructed to show endocrine effects, but allowed an exception for "functionally equivalent" data from old tests.[164] The approved information request form from OMB, however, states that,

> under the principles of the [Paperwork Reduction Act], EPA should promote and encourage test order recipients to submit Other Scientifically Relevant Information (OSRI) in lieu of performing all or some of the Tier I [tests], and EPA should accept OSRI as sufficient to satisfy the test orders to the greatest extent possible.[165]

The OMB approval also demanded that EPA report to OMB every instance where it found that other scientifically relevant data was insufficient to satisfy the testing order.[166] Ironically, OMB created these burdens for EPA under a statute with the purpose of minimizing paperwork and reducing the cost of collecting information to the federal government.[167]

Beyond the burden imposed on EPA, this language is concerning because previous data generally comes from industry-developed research that is designed to show that their chemicals do *not* cause unreasonable endocrine effects.[168] Older testing models are based on outdated science that may allow some endocrine effects to go unnoticed.[169] If EPA is encouraged to accept outdated testing data that indicates chemicals are *not* endocrine disruptors—even when modern test may show endocrine effects—then the entire purpose of the Testing Program will be undermined.[170] Thus, although the OMB is not preventing EPA from achieving its purpose, OMB is making EPA's job more difficult and encouraging it to rely on outdated, ineffective testing methods and data.[171]

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[164] *See supra* Part II.D.
[165] OMB Memo, *supra* note 163.
[166] *See id.*
[167] *See* Paperwork Reduction Act, 44 U.S.C. § 3501 (2006).
[168] Schudtz, *supra* note 163.
[169] *See id.*
[170] *See id.*; *supra* Part II.D.
[171] *See supra* Part II.D.

III. The Administrative Procedure Act Should Be Used to Compel New Testing

As noted by Congress at the passing of the Food Quality Protection Act, "[t]he ultimate success of this reform will rest with the professionalism and the common sense of the Environmental Protection Agency. Congress will be watching closely as we try to implement these reforms. We will, to ensure that science, not emotion, is the basis of pesticide regulation."[172] However, if EPA accepts old test data that does not conform to tier one testing standards, then EPA has not lived up to its "common sense" mandate.[173] Congress has thus far failed to "closely watch" EPA and OMB to ensure pesticides are tested with current technology to assess their endocrine-disrupting potential.[174] Therefore, it is up to citizens to monitor EPA's progress in obtaining and reviewing test data to ensure the Agency is carrying out its congressional mandate.[175]

A. *Administrative Procedure Act*

If citizens are discouraged with EPA's progress in testing pesticides under the Endocrine Disruptor Screening Program, the Administrative Procedure Act (APA) offers a potential solution.[176] Specifically, the APA provides that a "person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof."[177] Furthermore, the APA states that a reviewing court must either compel or set aside agency action found to be: (1) "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law"; or (2) "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right."[178] If EPA does accept outdated, unreliable testing data then nearly any member of the public is a person aggrieved within the meaning of the Food Quality Protection Act of 1996, as we are all regularly exposed to endocrine-disrupting pesticides and other EDCs that the Act is designed to test and regulate.[179] If an aggrieved citizen did bring a claim under the APA to challenge EPA's testing rules and program, a

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[172] 142 Cong. Rec. 18,588 (1996).
[173] *See id.*; *supra* Part II.E.
[174] *See supra* Part II.E.
[175] *See* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 346a(p) (2006).
[176] *See* Administrative Procedure Act, 5 U.S.C. §§ 702, 706 (2006).
[177] *Id.* § 702.
[178] *Id.* § 706.
[179] *See* 21 U.S.C. § 346a(p).

reviewing court would review the agency action using the *Chevron* standard.

B. Chevron *and Agency Statutory Interpretation*

In *Chevron U.S.A., Inc. v. Natural Resources Defense Council*, the Supreme Court outlines the process for judicial review of an administrative agency's interpretation of its statutory authority.[180] Specifically, the *Chevron* Court directed:

> When a court reviews an agency's construction of the statute which it administers, it is confronted with two questions. First, always, is the question whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.
>
> If, however, the court determines Congress has not directly addressed the precise question at issue. . . . [I]f the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute.[181]

Under this analysis, a court must look to the statutory language to determine if it is unambiguous and thus communicates clear congressional intent.[182] If the statutory language is clear, and the agency has acted within the bounds of the statutory language, then the analysis is done.[183] However, as the Court further notes, "[t]he judiciary . . . must reject administrative constructions which are contrary to clear congressional intent."[184]

B. *EPA Will Fail to Fulfill Its Congressional Mandate If It Accepts Outdated Testing Data*

If EPA accepts outdated testing results, a court reviewing a challenge to EPA's Testing Program would most likely find that the Agency acted in excess of statutory jurisdiction and therefore the provision al-

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[180] *See* 467 U.S. 837, 842–43 (1984).
[181] *Id.*
[182] *Id.*
[183] *Id.*
[184] *Id.* at 843 n.9.

lowing old test data would be set aside.[185] The statutory language mandating the Testing Program is unambiguous.[186] The Screening Program specifically directs that EPA "*shall* develop a screening program, using appropriate validated test system" and "*shall* provide for the testing of *all* pesticide chemicals" in order to implement the new testing system.[187] Although Congress affords EPA discretion in selecting which chemicals to test *beyond* pesticides, Congress was unambiguous in directing the Agency to develop a new testing program to establish endocrine effects of all pesticides.[188] EPA's decision to accept old testing data at best sidesteps, and potentially contradicts, Congress's clear mandate to EPA.[189]

If EPA does actually accept old test data not designed to show if a chemical acts as an endocrine disruptor, then EPA is not, as the APA requires, acting within its statutory authority.[190] This is because Congress only granted EPA discretion in how to structure the testing program, but did not delegate the ability to choose whether or not to test pesticides for their endocrine effects.[191] EPA must test all pesticides for endocrine effects, and has failed to do so if it allows for submission of old data from tests incapable of detecting endocrine effects.[192] Thus, a reviewing court will likely determine that EPA is not entitled to *Chevron* deference in this situation, and must instead abide by its clear statutory directive to execute the endocrine testing program.[193] A court can thus stop at the initial inquiry, and as a result, an arbitrary and capricious analysis is not necessary.[194]

C. *Arbitrary and Capricious Standard*

If, however, a reviewing court found that EPA did not act in opposition to its clear statutory mandate to test pesticides, there is an additional avenue for relief.[195] Even when a court has determined that an agency has acted within the scope of its statutory authority, agency ac-

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[185] *See Chevron*, 467 U.S. at 843.

[186] *See* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 346a(p)(1), (3)(A) (2006).

[187] *Id.* (emphasis added).

[188] *See id.*

[189] *See id.*

[190] *See* Administrative Procedure Act, 5 U.S.C. § 706(2)(C)(2006).

[191] *See* 21 U.S.C. §§ 346a(p)(1), (3)(A).

[192] *See id.*

[193] *See id.* §§ 346a(p)(1), (3)(A); Chevron U.S.A. v. Natural Res. Def. Council, 467 U.S. 837, 843 (1984); *supra* Part III.F.1.

[194] *See* Motor Vehicle Mfg. Ass'n of the U.S. v. State Farm Mut. Auto. Ins., 463 U.S. 29, 42–43 (1983).

[195] Citizens to Protect Overton Park v. Volpe, 401 U.S. 402, 416 (1971).

tion can nonetheless be set aside if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."[196] In *Motor Vehicle Manufacturers Ass'n of the United States v. State Farm Mutual Automobile Insurance,* the Court identified a series of factors to analyze when considering whether or not an agency action is arbitrary and capricious:

> Normally, an agency rule would be arbitrary and capricious if the agency has [1] relied on factors which Congress has not intended it to consider, [2] entirely failed to consider an important aspect of the problem, [3] offered an explanation for its decision that runs counter to the evidence before the agency, or [4] is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.[197]

There is a compelling argument under these factors that EPA's action in establishing the Testing Program was arbitrary and capricious.[198] In particular, the record regarding the Testing Program shows that if it chooses to accept old data, EPA "entirely failed to consider an important aspect of the problem," and its decision would be "so implausible that it could not be ascribed to a difference in view."[199]

D. *If EPA Accepts Outdated Test Data, Its Actions Are Arbitrary and Capricious*

A court engaging in an arbitrary and capricious analysis would look to EPA's record in formulating the Testing Program, and determine whether or not EPA articulated a satisfactory explanation for its action, including a rational connection between facts and final action.[200] EPA's record includes: the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC) recommendations to the Agency; EPA's promulgation of rules adopting EDSTAC's testing suggestions; and EPA's policies and procedures for the testing program.[201] EDSTAC's report and even EPA's policies and procedures clearly state that previously conducted test data is only acceptable if it conforms to tier one testing standards.[202] There is no rational connection between the record, which clearly calls for new, higher-technology testing of pesticides,

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[196] *Id.*; *see* Administrative Procedure Act, 5 U.S.C. § 706 (2006).
[197] 463 U.S. 29, 43 (1983).
[198] *See id.*
[199] *See id.*
[200] *See id.* at 43.
[201] *See id.*
[202] *Supra* Part II.B–.D.

and an agency action that would accept outdated test data.[203] Additionally, if EPA does not submit pesticides to higher-technology standards like those under the tier one testing protocol, they will have "failed to consider an important aspect of the problem."[204] Therefore, if EPA decides to accept outdated test data that is *not* designed to show endocrine effects, that decision will most likely be found to be arbitrary and capricious.[205] A reviewing court would thus set aside the portion of the final rule allowing for outdated test data in lieu of conducting new testing under the tier one testing protocol.[206]

Although the APA provides potent tools for a citizen suit to enforce Congress' intended Testing Program, test data is only valuable once its findings are applied to the regulation of endocrine disruptors.

IV. Regulating Established Endocrine Disruptors

It is currently unclear what will happen after EPA completes the Testing Program and reports back to Congress. The Testing Program includes a sweeping statement that "any substance that is found, as a result of testing and evaluation under this section to have an endocrine effect on humans, the [EPA] Administrator shall, as appropriate, take action under such statutory authority as is available . . . necessary to ensure the protection of public health."[207] This language is incredibly broad and discretionary, which makes it unclear how EPA will ultimately regulate pesticides and other chemicals that are found to have endocrine effects through the Testing Program.[208]

Congress likely did not provide EPA a new regulatory structure for controlling EDCs because existing statutes already provide EPA the ability to regulate pesticides and toxic substances.[209] However, it will likely be up to citizen enforcers to take the lead in ensuring that EPA acts on the data it collects, and takes steps to regulate proven EDCs to protect human health and the environment. Two major statutes provide avenues for regulating EDCs: the Federal Insecticide, Fungicide, and Rodenticide Act, and the Toxic Substances Control Act.[210]

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[203] *See State Farm*, 463 U.S. at 29, 43.

[204] *See id.*

[205] *See id.* at 42–43.

[206] *See id.*

[207] Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 346a(p)(6) (2006).

[208] *See id.*

[209] *See* Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136–136y (2006); Toxic Substances Control Act, 15 U.S.C. §§ 2601–2695(d) (2006).

[210] *See* 7 U.S.C. §§ 136–136y; 15 U.S.C. §§ 2601–2695(d).

A. *Federal Insecticide, Fungicide, and Rodenticide Act*

Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA regulates pesticides' entry into the market through labeling, sale, and distribution regulations.[211] It is important to note that FIFRA only applies to pesticide chemicals.[212] FIFRA first provides that all new pesticides must be registered with EPA.[213] EPA must approve registrations for pesticides that perform their intended function "without unreasonable adverse effects on the environment."[214] "Unreasonable adverse effects on the environment" are further defined as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide."[215] Therefore FIFRA has an inherent cost-balancing test within its regulatory structure.[216] However, EPA can cancel a registration and take a pesticide off the market if it finds that the pesticide causes an unreasonable adverse effect, subject to this cost-benefit balancing test.[217]

However, this method of regulating pesticides under FIFRA poses significant problems. First, under FIFRA economic costs are frequently given far more emphasis in the balancing test than issues like endocrine disruption.[218] Therefore it is challenging to get a pesticide registration cancelled.[219] Additionally, even if EPA does cancel a registration, a blanket prohibition on selling a particular pesticide is a blunt, extreme solution. That is because FIFRA is a front-end statute; it is designed to control the entry point of pesticides, but has little ability to fine tune the use of pesticides after registration.[220] Although a crude solution, the ability to cancel a registration under FIFRA at least provides one avenue for regulating pesticides under existing environmental law, and could provide an avenue for relief if the Testing Program shows that a particular pesticide is highly toxic with widespread

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[211] Zygmunt J.B. Plater et al., Environmental Law and Policy: Nature, Law, and Society 820 (3d ed. 2004); *see* Federal Insecticide, Fungicide, and Rodenticide Act 7 U.S.C. § 136a (2006).

[212] *See* Plater et al., *supra* note 211, at 820.

[213] *See* 7 U.S.C. § 136a.

[214] *Id.* § 136a(c)(5).

[215] *Id.* § 136(z), (bb).

[216] *See id.* § 136(z)(bb); Sachs, *supra* note 9, at 313–15.

[217] *See* 7 U.S.C. § 136d(b).

[218] *See* Plater et al., *supra* note 211, at 839.

[219] *See Pesticide Cancellation Under EPA's Own Initiative*, Envtl. Prot. Agency, http://www.epa.gov/opp00001/regulating/cancellations.htm (last updated Feb. 16, 2011).

[220] *See id.* at 820.

endocrine disruption. Again, pesticides are the only class of endocrine disruptors EPA is currently required to test under the Testing Program, so having a regulatory structure to manage pesticides, even an imperfect one, is crucial.[221]

B. *Toxic Substances Control Act*

The Toxic Substances Control Act (TSCA) is a broader and potentially more helpful statute than FIFRA. TSCA allows EPA to test and regulate certain chemical substances.[222] The threshold test for whether or not EPA can act under TSCA is whether or not a chemical "present[s] an unreasonable risk of injury to health or the environment."[223] If EPA reasonably concludes that a chemical does present an unreasonable risk of injury to health or the environment, it can require further testing or restrict a chemical's use.[224] However, EPA is significantly limited in testing and regulating chemicals because TSCA further interprets "unreasonable risk of injury to health or the environment" to include a cost-balancing requirement.[225] This means that EPA must take into account the benefits of the chemical, availability of substitutes, and economic consequences of when it considers restricting a chemical.[226] Additionally, TSCA only allows EPA to impose "the least burdensome" restrictions necessary to protect against unreasonable risk.[227] In practice, this means EPA has rarely limited toxic chemicals once they are on the market.[228]

Additionally, the definition section of TSCA specifically exempts pesticides from the definition of "chemical substance" and therefore from regulation under TSCA.[229] Thus, EPA cannot regulate pesticides under TSCA, and pesticides are the only class of chemicals that EPA has

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[221] *See* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 346a(p)(3)(A) (2006).

[222] *See* 15 U.S.C. §§ 2603, 2605; PLATER ET AL., *supra* note 211, at 818–20.

[223] 15 U.S.C. §§ 2603, 2605.

[224] *See id.* Restrictions can include, among other options, prohibiting manufacture or distribution of a substance or requiring warning labels. *Id.* § 2605. Additionally, TSCA is a disfavored statute for regulating chemicals: EPA can only restrict a chemical under TSCA if no other statute provides a way to eliminate or reduce a risk of injury to health or the environment. *See id.*

[225] *See id.* § 2605(c); PLATER ET AL., *supra* note 222, at 839.

[226] 15 U.S.C. § 2605(c).

[227] *Id.* § 2605(a).

[228] Sachs, *supra* note 9, at 314–15.

[229] *See* 15 U.S.C. §§ 2602, 2605.

been mandated, rather than simply granted permission, to test under section 408(p) of the Federal Food Quality Protection Act.[230]

Therefore, at this stage of testing, TSCA is a largely inadequate tool to regulate endocrine disruptors because it is limited to regulating non-pesticide chemicals, while EPA is only mandated to test pesticides.[231] However, if EPA expands testing to non-pesticide EDCs, they could potentially be regulated under TSCA, with greater options for remedies than FIFRA's single, extreme cancellation procedure.[232]

C. *Future Regulation of Endocrine Disruptors*

Neither TSCA nor FIFRA offer perfect solutions to regulating endocrine disruptors.[233] However, these statutes are the best available tools for regulating EDCs, and at least provide a possible avenue for post-testing regulation.[234] Presuming that testing on EDCs shows the potential for human and environmental health harms, it is crucial for EPA to regulate EDCs to protect against these harms. Given the largely inadequate existing structures under TSCA and FIFRA, new testing data might provide the needed impetus for proposing new legislation to comprehensively monitor and minimize dangerous chemicals in this country.

Conclusion

It is crucial that society has adequate information regarding the many chemicals that are present in our drinking water, food, containers, plastics, detergents, and more.[235] Chemicals that individuals encounter and ingest in small doses every day could have potentially serious health consequences, both for current and future generations. EDCs can potentially cause infertility, immune disorders, metabolic disorders, and cancer.[236] Without sufficient scientific data, EPA is unable to properly assess whether or not the chemicals that surround us on a daily basis pose an "unreasonable risk of harm to human health"

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[230] Pub. L. No. 104–170, 110 Stat. 1489 (codified as amended at 21 U.S.C. § 346a(p) (2006)).

[231] *See* 15 U.S.C. § 2605; 21 U.S.C. § 346a(p).

[232] *See* 15 U.S.C. §§ 2602, 2605.

[233] *See infra* Parts IV A.–.B.

[234] *See* Sachs, *supra* note 9, at 313–15.

[235] *Supra* Part I.B.

[236] *Supra* Part I.C.–.E.

and should therefore be regulated under laws such as FIFRA and TSCA.[237]

Congress took the first important step towards this regulation: Congress mandated that EPA must test all pesticide chemicals for their endocrine effects.[238] It is everyone's duty as active citizens to force EPA to fulfill these statutory obligations, and require that industry submit their pesticides to stringent new testing technologies.[239] If EPA fails its mandate, the citizen suit provisions of the Administrative Procedure Act can serve as a tool to force the Agency to require up-to-date testing of pesticides.[240] Additionally, once EPA fulfills its mandates, citizens should further advocate for the testing of all endocrine disruptors beyond just pesticides.[241] Finally, citizens should not stop at testing, but should pressure EPA to appropriately regulate EDCs after testing is complete.[242]

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[237] *See* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 346a(p)(6)(2006); *supra* Part IV.

[238] *See* 21 U.S.C. §§ 346a(p)(1), (3)(A).

[239] *See id.*; *supra* Part II.E.

[240] *See* Administrative Procedure Act, 5 U.S.C. § 706 (2006).

[241] *See supra* Part II.

[242] *See supra* Part IV.