1. Full citation.
   1. Vogel, D. *The Politics of Precaution: Regulating Health, Safety, and Environmental Risks in Europe and the United States*. Princeton Univers. Press, 2012.
2. What are the topics of the text?
   1. This chapter focuses on consumer safety, utilizing pharmaceuticals and chemicals present in children’s toys, and cosmetics as case studies for the argument. Specifically, Vogel explains the different development of regulation in regard to each of these in the EU and then the United States. In addition, he shows the influence of third party activist groups specific to these studies and how they played a vital role in the progress seen.
3. What is the main argument of the text?
   1. The main argument of the chapter is that, unlike the many policies discussed thus far in the book, this analysis reveals that the EU and American policies actually converged on both pharmaceuticals and the regulation of chemicals in children’s toys, while still diverging in regards to the regulation of chemicals in cosmetics. Further, specifically for pharmaceuticals, the United States was notably more stringent with its regulations, and then allowing them to become more lenient over time to converge with the European views. The main argument for this specific change was the drug lag seen between the United States, in which the EU was receiving successful drugs years before the United States due to the FDA’s strict pre-market testing process. In terms of cosmetics, activist groups were highly successful in pressuring the EU to ban phthalates, despite the controversial scientific evidence behind doing so. On the other hand in the United States, the American Congress was highly immune to such pressures, and the only progress seen for a reduction of hazardous chemical use in cosmetics was a result of direct pressure on the industry from activists along with state level regulations.
4. Describe at least three ways that the argument is supported.
   1. “The marked differences in the policy responses of the United States…to the thalidomide policy failure…demonstrates that there is not necessarily a causal relationship between an “unfortunate event”…and the adoption of more stringent risk regulations. Far more Europeans than Americans were injured from thalidomide, yet it was the United States which responded by adopting far more sweeping regulatory changes. By contrast, while more stringent approval policies were introduced in Europe…they were adopted more gradually and were much less demanding. In this case…”alarm bells” about insufficiently protective regulations and the risks of false negatives rang much more loudly in the United States than in the Europe before 1990…But transatlantic drug approval politics and policies after around 1990 reveal a very different pattern. Public demands for more stringent risk regulations did not increase in Europe and thus European risk management policies did not become progressively more stringent: on the contrary, they became more flexible.”
   2. “In both cases, public pressures prompted the EU to adopt a highly stringent risk regulation. For their part, deferral regulators did express concern about the safety of phthalates in children’s products, but acting on the basis of much of the same scientific evidence available to European policy makers, they did not consider a ban to be warranted. However, in this rather unusual case, thanks to Senator Feinstein’s ability to persuade Congress to include a provision in the CPSA imposing restrictions on phthalates in children’s products similar to that previously adopted by both the EU and California, the United States also adopted a precautionary approach to the risks posed by the chemical softeners in children’s products.”
   3. “Since 2002, the EU has steadily strengthened its cosmetics safety regulations. The most important statutory change was the Seventh Amendment…This amendment more than doubled the number of prohibited ingredients. As a result, the number of substances banned from use in cosmetics products grew to one thousand…By contrast, as of 2005, less than two dozen chemicals have been restricted or banned for use in cosmetic products in the United States.”
5. What three quotes capture the message of the text?
   1. “More fearful of the political consequences of permitting the marketing of a drug that turned out to be unsafe, than in delaying approval of a drug that turned out to be both safe and effective, American regulatory officials regularly demanded extensive pre-market testing.”
   2. “The politics and policies informing the European response to the health risks posed to children from contact with phthalates resemble those that occurred more than a decade earlier with respect to the health risks of beef hormones. For their part, federal regulators did express concern about the safety of phthalates in children’s products, but…they did not consider a ban to be warranted….the Republican congressional leaderships may have well chosen to defer the risk assessment of the CPSC, which has determined that most of the phthalates in children’s products did not pose any safety risks….Feinstein was able to take advantage of the policy window created by public outrage over unsafe toys from China to have a ban on phthalates included in the CPSC.”
   3. “The increased stringency of European cosmetics safety regulations has in part been driven by public pressures. NGO campaigns have had a substantial impact on European public opinion; they succeeded in increasing public concerns about the safety of the ingredients used in cosmetics….By contrast, the safety of the chemical ingredients used in cosmetics has not been as politically salient in the United States; the “alarm bells” rung by activists and reported in the media have not been widely amplified. In contrast to the EP, which was highly responsive to activists concerns about chemical safety, the American Congress has been indifferent to them.”
6. What three questions about environmental risk and precaution does this article leave you with?
   1. If political salience is not the stressor which influenced policy shifts regarding the pharmaceutical industry, then what was?
   2. What process insures that third party assessments are done properly and accurately if a second clinical trial is no longer mandated? (Pharmaceutical industry)
   3. What about store brand medication? How does FDA approval take into account these drugs?
   4. Why did the FDA take a precautionary approach to drugs, but a reactive approach to cosmetics and GMOs?
7. What three points, details or references from the text did you follow up on to advance your perspective on environmental risk and precaution? (Provide citations, with a brief explanation of what you learned.  One of these should be fully annotated, as your second required reading for each week.)
   1. FDA Modernization Act
      1. The FDA Modernization Act of 1997 was mainly implemented in order to acknowledge the advancement of technological, trade, and public health complexities. This meant, among other things, reducing the time required for a drug review, increasing patient access to experimental drugs and medical devices and to accelerate review of important new medications, allowing third party experts to conduct risk assessments on certain medical devices, and reducing the number of required clinical investigations of a drug from two to one. Some of the criticisms of this act have been that it was essentially a gift to the pharmaceutical industry. The drop in standards associated with approving new drugs has led to an enormous amount of safety issues as a result of off-label marketing. For example, the Vioxx controversy in the early 2000s may have led to 140,000 heart attacks in Americans, with as many as 55,000 deaths. Many physicians have complained about the lack of dissemination of knowledge from the FDA about the potential side effects from taking these drugs.
         1. <http://www.publicintegrity.org/2005/07/07/5785/fda-shell-its-former-self>
         2. http://en.wikipedia.org/wiki/Food\_and\_Drug\_Administration\_Modernization\_Act\_of\_1997
   2. Drug Lag
      1. “Drug lag” is a term used to describe the time difference it takes for a country to receive pharmaceutical drugs in their market which are available elsewhere in the world. Today, while it may not be found in the United States when compared with Europe, it is present in other parts of the world. One developed nation which is currently working diligently to shrink their “drug lag” is Japan. Between 2005 and 2006, Japan was able to reduce this lag from 3 years to somewhere between 1.5 and 2. A primary reason associated with this lag in Japan is the requirement of the Japanese Pharmaceuticals and Medical Devices Agency’s (PMDA) that drug companies conduct separate and additional safety studies in Japanese patients as a safety concern. Is reducing the lag worth it though? In Chapter 6, Vogel quotes that without this lag, the United States no longer has the advantage of watching how things play out in foreign nations. While certain life-saving drugs may be worth the risk, should such a massive change have been made to the entire industry?
         1. http://jnci.oxfordjournals.org/content/102/3/148.extract
   3. The Estrogen Replacement Controversy in the USA and UK: Different Answers to the Same Question?
      1. Full citation.
         1. McCrea, Frances B., and Gerald E. Markle. “The Estrogen Replacement Controversy in the USA and UK: Different Answers to the Same Question?” *Social Studies of Science* 14.1 (1984): 1–26. Web. 19 Mar. 2013.
      2. Where did/does the author work, what else has s/he written about, and what are her/his credentials?  (This question only has to be answered once for Vogel.)
         1. Frances B.McCrea is an associate professor of sociology at Grand Valley State University in Michigan. She has published research in social movements and women’s health, and is the author of *Minutes* *to Midnight: Nuclear Weapons Protest in America*, recipient of the 1991 Distinguished Scholarship Award from the North Central Sociological Association. She received a diploma on “Worker Self-Management” from the University of Sarajevo. Gerald E. Markle is a professor of sociology at Western Michigan University and conducts research in the sociology of knowledge. He is author or editor of several books, such as the *Handbook of Science, Technology and Society and The Gray Zone: Holocaust, Culture and Society.*
      3. What are the topics of the text?
         1. The topics of the text are examinations of cross cultural differences in medical research communities, physician practices, feminist and consumer groups, regulatory policy, and pharmaceutical industry. The three questions which these examinations were centered around answering were: Is ERT a risk to health? What are the benefits of ERT? Are the purported benefits of ERT worth the purported risks?
      4. What is the main argument of the text?
         1. The main argument of this article is about understanding how it is that the United States and the United Kingdom, which represent two English speaking countries with access to the same data, can interpret this information in such different ways in regards to their policies on ERT. Through an examination of cross cultural differences in the two countries, it is found that the five key areas, as mentioned under topics, all play a role in the answer to this conundrum. In the conclusion of the article, the authors found two main cultural influences which they believe to be the core reasons behind these differences. The first is that British medicine is nationalized while the United States is privatized. The alternative answer was that the US system is highly linked with “selling technology” while the British system is “almost antitechnological”. Further, American medicine is focused on diagnosing and treating illness while British medicine focuses on maintaining health and dealing with everyday working conditions.
      5. Describe at least three ways that the argument is supported.
         1. “In 1979, at a Consensus Development Conference on Estrogen Use and Postmenopausal Women - sponsored by the US National Institute on Aging - researchers unanimously concluded that ERT substantially increases the risk of endometrial cancer. The final report of the conference concluded that ERT is only effective in the treatment of hot flushes and vaginal atrophy, and, if used at all, should be administered on a cyclical basis (three weeks of estrogen, one week off), at the lowest dose for the shortest possible time…By contrast, British research is skeptical of the cancer link, and instead has focused on the benefits of ERT. For example, our analysis of the 1979 Consensus Development Conference bibliography showed that nine British research studies were cited; all nine emphasized the benefits of ERT. And at the Twentieth British Congress of Obstetrics and Gynecology the consensus was to endorse the efficacy of ERT. As Cooper stated, 'providing estrogens are administered on a cyclical basis, most gynecologists today dismiss the cancer link completely.’”
         2. “US physicians have viewed the use of ERT as a political issue, and their endorsement of the therapy as an exercise of professional control. Editorials in the Journal of the American Medical Association, the official journal of US physicians, have been critical of outside interference into the doctor-patient relationship. Thus, in 1979, an Editorial criticized the FDA Commissioner for mandating a 'biased' warning: 'In doing so he has officially expressed his distrust of the medical profession.'" And, in 1980, an Editorial again castigated the FDA for creating unnecessary 'public anxiety'. Contradicting almost all current US research, the Editorial concluded that 'Estrogens already rank among the safest of all pharmaceuticals.'…A small proportion of the ten million menopausal and post- menopausal British women have received ERT. The pharmaceutical industry estimated that, in 1973, some 50,000 women were receiving ERT, whereas by 1978 that figure was nearer to 200,000. In 1979, an article in the London Times claimed that about 500,000 women were receiving ERT; and a survey of 40,000 people in a general practice population found that three percent of women aged 40 to 79 had received at least one ERT prescription during the year. Whether the actual number of women on ERT is 200,000 or 500,000 - from two percent to five percent of the population at risk - it is considerably less than the estimated twenty percent (six to seven million) of US women in that age bracket who were still receiving estrogens in 1979 - and certainly an indication of the British GP's reluctance to prescribe the therapy.”
         3. “First, the data are ambiguous: there is no conclusive evidence that ERT causes cancer, as most American researchers contend, or that it prevents osteo- porosis, as most of their British counterparts contend… British researchers first conducted research on the role of estrogens in osteoporosis, whereas American researchers conducted the cancer studies. Both sides have clung to their initial findings and are sceptical of the other country's findings. Second, American and British researchers have evolved different criteria which are necessary to impute carcinogenicity….in the US a demonstrated risk, as determined by scientific consensus, is sufficient. A persistent British criticism has been that retrospective epidemiological studies…cannot prove a cause and effect relationship between estrogens and cancer. Only double-blind, randomly assigned prospective studies, conducted over a span of several decades, can establish the carcinogenicity of estrogens.”
      6. What three quotes capture the message of the text?
         1. “These cancer studies have been attacked on every conceivable basis, but they have withstood the criticism and the test of time. The association of endometrial cancer with estrogen exposure is nearly as strong as the association of lung cancer with cigarette smoking. In fact the association is so well established that no further research grants are offered to study it.”
            1. Harry K. Ziel, a researcher at the Kaiser Permanente Medical Center in LA
         2. “In both settings, feminist and consumer groups are in opposition to prevailing research conclusions in each country. Thus, the US and Great Britain appear in mirror image with regard to ERT: group alignment is identical, but direction is opposite.”
         3. “The US and British women's movements have developed along different ideological and political lines…. The US movement is best described as 'free floating', not aligned with any particular political party or class movement. The locus of women's oppression is seen as rooted, not in social class, but in biological inferiority arguments. US feminists have tried to settle the nature-nurture debate by showing that differential socialization, and not biological differences, accounts for women's inferior status…. The feminist movement in Britain, as in most European countries, is closely aligned with the socialist movement." Marxist feminists contend that sexism and women's oppression are an inherent function of capitalism, and thus advocate a radical restructuring of society along socialist lines.'07 Since the locus of women's oppression is seen as structurally located, it appears that the biological debate as a feminist issue has a lower priority for the British feminist movement.”
      7. What three questions about environmental risk and precaution does this article leave you with?
         1. Why do physicians recommend ERT in the United States if the studies have proven its negative effects? Is it simply about the money? Does it have to do with slow dissemination of the recent studies?
         2. What was the NHS’s view on ERT? Did they provide the clinic services because of the demand? Why not request physicians to increase recommendations?
         3. Did the FDA revisit this decision after the modernization act?