1. Full citation:

Vogel, David. "Chapter Six: Consumer Safety." *The Politics of Precaution*. Princeton: Princeton UP, 2012. 189-218. Print.

2. Where did/does the author work, what else has s/he written about, and what are her/his credentials:

David Vogel is a professor in the Political Science Department at the University of California at Berkeley. He has also written about food safety, corporate social responsibility, as well as various environmental ethical issues. In addition to being a professor at Berkeley, their credentials also include being the Solomon P. Lee Chair in Business Ethics, as well as a Ph.D. in Politics from Princeton University.

3. What are the topics of the text:

The sixth chapter in Vogel's book, *The Politics of Precaution*, discusses regulation in regards to consumer safety.

4. What is the main argument of the text:

The main argument of the sixth chapter deviates slightly from those in previous chapters because Vogel utilizes examples to show how European and American risk regulations have actually converged in the area of consumer safety. Vogel does make sure to note that the dynamics through which this occurred differ substantially.

5. Describe at least three ways that the argument is supported:

a) Vogel discusses the contrast between political saliency in the European Union and United States.
b) Vogel gives some examples of policy changes in the US.
c) Vogel gives some examples of policy changes in the EU.

6. What three quotes capture the message of the text:

a) "Pharmaceutical regulation constitutes the most important exception to the broader pattern of increased transatlantic regulatory policy divergence. What makes this area of regulatory policy distinctive is that its political salience—or public pressures on policy makers to change how risk regulations were being made—increased in the United States but not in Europe. The demands of activist groups in the United States led to changes in American regulations in ways that brought them into closer alignment with those of the European Union, whose regulatory policies remained relatively stable even after they were harmonized."
b) "Although the 1962 Kefauver-Harris amendments did not address Kefauver's original concern, namely the high price of drugs, they did significantly change government

regulation of the pharmaceutical industry. The legislation's most important provision required manufacturers to provide "substantial evidence" that a new drug was "effective" before it could be approved. This standard was also applied retroactively to previously approved drugs. The 1962 amendments also involved the FDA in the clinical research process for the first time. Before testing any drug on humans, a firm was required to submit a drug investigational plan that included the results of animal testing as well as its plans for human tests."

c) "For its part, the EU enacted its first pharmaceutical directive in 1965. It established common criteria for quality, safety, and efficacy for national regulatory authorities to adopt before approving a new drug, though the latter requirement was much weaker than the one in force in the United States. But even this minimal standard was only adopted by seven of the (then) twelve member states. In 1975, the EU established a European regulatory authority for drugs, known as the Committee for Proprietary Medicinal Products (CPMP), as well as an EU-wide system of mutual recognition of drugs licensed by each member state. Under this system, if a country disagreed with another country's drug approval, it could seek arbitration from the CPMP."

7. What three questions about environmental risk and precaution does this article leave you with:

a) How many pharmaceutical rejections are there in the United States?
b) How many drug recalls are there in the United States?
c) How large is the pharmaceutical industry?

8. What three points, details or references from the text did you follow up on to advance your perspective on environmental risk and precaution:

a) The Food and Drug Administration is approving more drugs lately. (Source: http://www.forbes.com/sites/matthewherper/2012/12/05/new-drug-approval-rate-at-near-record-high-fda-says/)
b) While I could not find specific numbers, after visiting the FDA's website, it seemed that there were lots of drug recalls, almost daily. (Source: http://www.fda.gov/Safety/Recalls/default.htm)
c) The pharmecutical industry is a little under $500 billion. (Source: http://www.pharmalive.com/pl-index-ad.html?gotourl=http://pharmalive.com/magazines/medad/?date=09%2F2007)