

RESEARCH PLAN

Name: Susie Student

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Subject: FDA Regulation of Nanotechnology Products

Cases or Administrative Decisions

I need to find cases where two administrative agencies (best if they are EPA or FDA against the USPTO) have conflicting law in place and the court has to resolve which one's interpretation is going to have force of law.

I also need to research whether there are specific administrative courts for conflicts arising out of these agencies (like a tax court for the IRS) and research whether there has been any relevant law or case that has been handled by that court.

I will locate nanotechnology inventions that have been subjected to the more lenient standard of review, and try to determine whether any of them have led to safety problems.

Legislative

I need to find legislative material (perhaps when Congress passed the NNI, the National Nanotechnology Initiative) that expresses concern over the risk of nanotechnology, and whether there was any funding put aside (like ELSI for the Human Genome Project) to examine safety issues in nanotechnology.

- debate language
- committee reports
- congressional record
- public law
- federal register (for previously introduced but failed administrative law)
- CIS

I will use Lexis Congressional as one method of tracking down this legislative material

I will search the CFR for regulations relating specifically to nanotechnology, as there may be some for the USPTO in place already. (37 CFR holds most relevant language)

Other Publications

I will find everything currently published by the EPA, FDA, and USPTO on their specific policy towards nanotechnology, including how those inventions or applications are currently treated, whether they request(ed) recommendations from the public before

changing their policies, whether they have a mechanism in place for receiving continuing feedback, what action they would take if a nanotechnology invention was found to be unsafe, etc.

I will look for articles in medical, scientific and technology journals that address the legal or safety concerns about nanotechnology research. The relevant databases include PubMed, JSTOR, and Medline via the National Library of Medicine. I will broaden the scope of my search by looking to Business Source Premier, other economics journals, and engineering journals.

I will also search nanotechnology-specific journals, like Nature Nanotechnology or Nanotechnology Business & Law, to see if they have articles addressing the safety issue.

I will find public comments that have already been posted for recommendations to the FDA and EPA regarding how to address nanotechnology.