

Concerns Revisited: Why are these things of concern?

- New, revolutionary technology
 - Many unknowns
- Some releases might not be easily retractable/reversible
 - Thus should be proactive, set correct institutions, regulatory agencies, systems in place ahead of time
- Past experience with new products (e.g. asbestos, lead paint, lead in candy in 19th century)
 - “I want to think that we’re above that”
- Could be cultural differences in approach
- Uses by the military?
- 24/7 soldier from materials – scary
 - How will that affect them?
 - “Playing God”
- Economics and prioritization
 - Current human needs vs. speculative applications
 - Frivolous vs. basic
- Post-human, afraid of losing our humanity
- Only certain people in certain countries will get enhancements
- Financial imbalances in society; already hard for the less well-off to compete
 - Situation would be much worse with superhumans
- Risk of overregulation, killing innovation
- “There will be evil”, but also positives
- Do we need to regulate?
 - Some things better off not being regulated
 - Let technology grow organically
- Unintentional harms
- Externalities
 - Affecting health, safety, and well-being of neighborhood
- Many externalities regarding nano
 - E.g. workers, landfills, water contamination
- Fantastical vs. here and now
 - What’s in my sunscreen right now?
 - Should we focus on the long term, or the more immediate?
 - What’s in what I’m drinking?
- Trust in manufacturers is not reliable, because of producer bias
- Need neutral review and disclosure
 - Generally provided by the government
 - Don’t always trust the Feds either
- Inventions tend to come about either by accident, or in response to necessity
- Dangerous things can also have benefits
- Have to do the research in order to advance

- There will be advancement
 - Need clinical trials
 - Drug testing is expensive
- “The more I know about corporations, the less I trust them”
- Innovation can also be primarily profit-driven, e.g. Ritalin.
 - Expanding populations/conditions for which drug is approved
 - Market-driven research, drug looking for an illness
 - Merck, Vioxx: clinical trials questionable -> heart problems
 - Knowing that clinical trials show harm, but lobbying for approval anyway
- FDA not that effective at looking out for consumer interests
- “I don’t like the way the FDA tests things”
- Need an independent agency, not tied to government or corporations
 - Venture capital?
- Who regulates chemicals and materials that go into products
 - Is there one agency, or several?
 - Imports?
- Do we need to re-evaluated the way that things are being studied?
 - Should be more than one government-sponsored program
 - Multiple levels of testing
 - Hear everyone’s perspective
- In global context, environmental concerns might be less immediate than feeding one’s family -> cutting of corners
 - Applies here too, e.g. family members that define health food as substituting turkey for beef in chili cheeseburger
- “I feel like regulation is so important”
- Even organics can be contaminated
 - Groundwater issues, GM
 - Not all organics as organic as advertised
- Certain things may need more regulatory attention, e.g. bottled water less stringently monitored than tap water, presented as healthier.
- Regulations should be specific, companies need to know what they have to do
- May be overregulation in some cases
- Thalidomide, double-edged sword
 - Approved in Europe but not U.S.
- Barless prison scenario, prisoners somewhat coerced
- Example of government stifling innovation: stem cells
 - Regulation where it shouldn’t be
- Perhaps problem is not lack of regulation, but inadequate oversight and enforcement?
 - Insufficient penalties, cheaper to just pay the fines?
- Handcuffed executives in Germany
- In a capitalist society, things may not happen if they’re not profitable
- Ideally, public and private sectors should push together

- Nano mostly in manufacturing/products at the moment
 - Working with non-human applications first
- Timeframe for human studies/applications?
- Should we prioritize applications other than human enhancement for the near future?
- Issues of academic licensing, patenting
- “I don’t want my universities in the business of business”
- Germany, university-government-industry cooperation better
- Overregulation could drive research to other countries
- Is there a reason why the privacy of (corporate) information is valuable?
 - KFC doesn’t reveal their secret recipe?
- Privacy of information perhaps not appropriate in case of public goods?
- Can we tax the hell out of corporations that don’t disclose?
- Who decides the “benefit of mankind”?
- Regulations from EU as models, e.g, REACH?
- Why not harmonize internationally?
- Berkeley Nano Ordinance
 - Reporting only
- Bayer is manufacturing nanomaterials in Berkeley
- What level of control will states (vs. Feds) have?
- Possibility of crazy patchwork of regulations
- Cost-sharing for toxicity research?
- Division of labor, industry consortium
- Proactive industry actions, prior to regulations
- Corporate concerns, acting to prevent litigation
- Look like good stewards
- How can regulatory agencies protect us before the fact?

Possible policies and regulation: what would the ideal look like?

- Possible categories of regulation that came up: funding (and incentives), enforcement, disclosure, testing, public education, values/goals.
- For ex., with regards to food would have information on GMOs, ingredients and presence of nanomaterials. Clear and strict guidelines.
- Military: concern about the 24/7 soldier, would want consent to be critical to avoid any risk of coercion.
- Now know to be afraid; would want tests to take place in a remote place.
- Public disclosure of information and test results.
- Public education with regards to drugs: pharmaceutical doing NBIC technologies has the responsibility to educate and make people aware.
- How to set funding priorities: is it possible to fast track urgent needs? For ex., could develop a score system, provide tax credits, or use profits from cosmetics and donut sales to help finance health care (the point was that apparently frivolous but profitable uses can help reduce the cost of necessary but unprofitable/expensive health care).
- Could try a panel or commission with experts and public participants to review nano products. Would need to approve products by consensus. Like a gateway regulatory commission. Difficult thing would be how to keep participants independent- would need

- to switch them every 2 years. All stakeholders present. Non-partisan and independent of top government (US pres.)
- Also need workers safety, rights to be looked after.
 - Private corporations can fund R+D so tax payers can “save” this money. The issue is how to make sure they are independent and transparent.
 - Ideally would all abide by the “do no harm” principle. But how do we define harm? Both harm and benefits could be defined by expert-public panels. The problem is we don’t know today what are the harms and benefits- there is too much uncertainty. So it needs to be flexible, on-going. Need continuous testing and follow-up.
 - There are also some really dangerous industries, like nuclear. We need safeguards so these don’t fall into the hands of terrorists.
 - Companies need to be responsible for the products they produce over their entire life-span. Lifecycle responsibility for companies!
 - The drivers and underlying factors motivating their demands for more regulation: fear, concern, public safety, transparency, coercion, equality, costs/who pays for what is not profitable.
 - Concern about the tension between corporate and public interest.
 - Who decides what risks are acceptable?
 - However: we all agree that we should be developing these things, the question is how to do it responsibly. We are all aware of the potential benefits, we all want to cure diabetes. But need to think of the short term applications as well as the long term impact.
 - Will an agency really want to work on all this?
 - Yes if they get the funding and personnel to do so. Its prestige and power for them.
 - No if they are overwhelmed
 - What is the role of Congress with regards to the agencies on all this?
 - Proposed using the 3 branches of government as a model. So within FDA the Director (executive) would be checked by a group of advisors (Congress) and a judicial oversight person.
 - One of the tricks is who does this work: employment practices are important. Should have less political appointments, more independent of interests.
 - The Head of FDA should think of...
 - Reversibility and take back: if an error occurs in genetic manipulation, in a program, can it be undone?
 - Priorities for funding: focus on real needs
 - How to make this available to all and not an elitist thing
 - Proposed having 2 separate agencies doing same work, so the check and balance each other. Don’t trust just one to do the job right. The thing is how to avoid having them fight over their territory.
 - Homeland Security is also important/needs to be involved.
 - Companies should be required to develop financial plans to ensure communities with few resources have access and protect the environment.
 - For ex., contingency fund, takes, someone in each company responsible for ensuring access and affordability.

- Environmental justice issues, siting of factories, testing sites.
- Patenting and access rights: need to be in compliance.
 - NAFTA: IP provisions protected US companies but not Mexican ones. US companies got the benefits from cheap labor without having to transfer any technology to Mexican companies.
 - How to disperse corporate power?
 - Need to comply with international labor standards
- Proposed to have citizens and scientists as ambassadors for the US with regards to other countries to work out international laws and policies.
- Privacy issues: if police, for example, have bionic eyes, do we need to think of new ways to protect people? Or, for example, how to protect medical devices from hackers who can alter your medication levels?
- International agencies: they are important but can be so cumbersome. How to give them some teeth? Alternatives are boycotts, criminal liability for executives that have polluting companies (as happens in Germany), fines.
 - The UN needs to evolve. Would be easier to just handle our own country.
 - If we work alone we would lose access to information. So there is a trade-off between cooperating and working alone.
 - With nano, we need to work with other countries to pool resources and develop things faster. Research is going on all over the world, it would be inefficient to do it alone.
- Its not a good idea to be thinking about creating new agencies. Would be better to parse this out into existing agencies, because the issue cuts across many sectors. The question is what reforms are needed if we insert this into the existing framework.
- For ex., maybe there should be a Department of Emerging Technologies at the EPA.

Sized down list of questions for experts

1. Funding sources for regulators?
 - a. Where specifically does funding come from (taxes, profits from other products)
2. Are there international bodies engaged in regulating nanotechnologies?
3. Who decides who regulates?
4. What is going on with nanotechnology already (that we don't know)?
 - a. Is it being applied to people?
 - b. Do replacement parts/tissues/organs already exist?
 - c. Is it used for immunization purposes?
5. How will the standards for drug testing change? Will we take extra precautions in testing nanomaterials?
6. If it doesn't exist already, when will it exist?
 - a. What can we expect in 5 years? In 10 years?
 - b. In particular, what can we expect with regards to human enhancement?

7. Have we yet discovered any potential negative aspects of nanotechnology?
8. What wastes are generated from nanomaterials?
 - a. Can they be recycled?
 - b. Can they be removed from the environment/body once introduced?
 - c. Can they be restored to their bulk size? If so, do they retain nano properties or go back to 'normal'?
 - d. What is the life cycle of a nanomaterial?
 - e. As consumers, how can we know a product contains nanomaterials, and that material's life cycle?
 - i. How can we, as consumers, know a company's responsibility in the whole process?
 - ii. Are hand-held scans that can be used in supermarkets and shops possible? (scan a product to detect nanomaterials)
 - iii. Are labels a possibility?

Types of experts they would like to talk to

- Regulators. Specifically, Congress people who know which agencies are responsible for different parts of the process. For example, maybe there are members of a relevant subcommittee?
- Regulators from FDA, Consumer Product Safety Commission, or other relevant agency.
- Environmentalist
- Independent military analyst
- Researchers from industry and academia (more independent). Specifically, from pharmaceutical industry and medical researchers.
- Company representatives
- Bioethicist, sociologist. To answer for ex., are clones human?
- Health insurance industry expert/representative
- Some of the authors of the Background Materials/experts cited there
- A transhumanist
- Technoluddite
- Someone from Homeland Security/security expert
- Someone who has researched transparency in the production chain process/who knows about life cycle assessments
- Representative from an international organization working on regulating nanomaterials
- Career counselor, someone who knows about the jobs arising from this
- Economist to talk about global economic impacts on US/other countries' economies, about economic shifts and positive/negative effects
- Technology transfer office worker
- Labor union representatives or someone who knows about workers' rights, occupational health and safety

Closing comments

- Thanked us for food. Asked for more green salad and hot water for tea; no bioengineered foods, chicken salad yummy.
- Thanked participant for bringing home-made jam.
- Suggestion to take notes while doing online sessions beyond what will be available in the transcripts.
- Surprised at quality of discussion, interests of participants. “I have gained an education this weekend”.
- 3M post it method liked, and our filtering down/transcription of Saturday’s notes.
- Felt that every voice was honored and validated; good group cohesion.