A Hard Pill to Swallow: *Barriers to Effective Regulation of Nanotechnology-Based Dietary Supplements*

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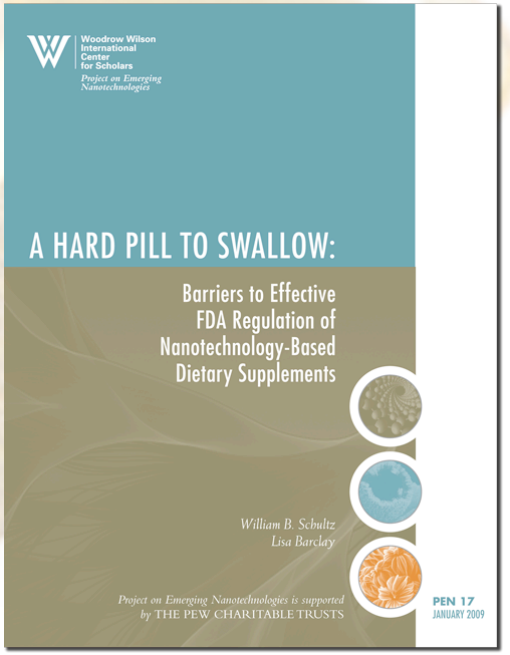

Historical Perspective

- The regulation of dietary supplements has been a significant challenge for FDA for many years.
- Congress has given FDA minimal regulatory authority to insure the safety of dietary supplements.
- Introducing the use of engineered nanoparticles into products creates an additional layer of complexity for FDA and additional risk to patients.

Market Share

- Dietary supplements are used by millions of people every day.
- Market has increased dramatically since FDA's authority to regulate them was restricted in 1994 by DSHEA.
- Technology has evolved as the market increased.
  - 44 products listed on PENs CPI
    - 26 of which were added since the FDA held its initial public meeting on nanotechnology in October of 2006

FDA Lacks Information

- FDA has little information on the safety of many dietary supplements.
- Similarly, it has little information on the safety of the use of nanomaterials in dietary supplements.
- There is no basis for concluding that the supplements industry is conducting the rigorous testing needed to understand the effects of nanomaterials in supplements.
- Consumers are potentially exposed to unknown risks.

FDA Has Limited Regulatory Authority Over Dietary Supplements

- No pre-market approval authority
- Manufacturers are required to disclose very little information to FDA
- When safety issues are raised, FDA must meet a very high standard for removal of a product
- No authority to require post-market testing
- No mandatory recall authority

FDA Lacks Resources

- The dietary supplements program has always been understaffed.
  - Insufficient staff to examine adverse reactions, safety or support testing on products
- In recent years, the resources available for dietary supplements have been reduced even further.

Recommendation 1: Actions FDA Can Take

- Before receiving additional appropriations or regulatory authority, FDA should take the following actions:
  - Increase resources dedicated to dietary supplements made with nanotechnology
  - Identify dietary supplements made using nanotechnology
  - Study the safety of dietary supplements made using nanotechnology

- Potential regulatory actions
  - Consider issuing guidance/regulations declaring dietary supplements made with nanotechnology to be new dietary ingredients
  - Consider issuing guidance/regulations declaring dietary supplements made with nanotechnology to be unsafe
  - Initiate regulatory action against products that are unsafe

Recommendation 2: Legislative Authority

- Congress should provide FDA with regulatory authority in the following areas
  1. Product Registration
  2. Establishment of Safety Standards
  3. Pre-Market Testing
  4. Pre-market Review
  5. Expanded Adverse Event Reporting

Recommendation 3: Legislative Appropriations

- Congress should provide FDA with resources sufficient to regulate dietary supplements under the new regulatory authority described previously.
  - Scientific Staff
  - Regulatory Staff
  - Research

Concluding Remarks

- FDA has no effective regulatory presence with regard to dietary supplements made with nanotechnology, due to its limited authority and extremely limited resources.
- This creates a public health threat that must be addressed.
- In the short run, FDA should devote resources to studying, identifying and regulating dietary supplements made with nanotechnology.
- In the long run, Congressional legislation and additional appropriations will be necessary to protect the public health.