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Regulation of nanotechnology: Are we doing enough?

On July 25, 2007, the Nanotechnology Task Force of the Food and Drug Administration (FDA) of the United States released a report which addressed the regulatory challenges presented by products that use nanotechnology (FDA 2007). Since most of these potential products involve nanomaterial interactions with biological tissues, this report directly speaks to the field of nanomedicine. A general finding of the report was that nanoscale materials present regulatory challenges similar to those posed by products using other emerging technologies, with one big difference. Regulatory challenges may be magnified because at this nanometer scale, properties of a material relevant to their safety and effectiveness might be amplified. As an example, the toxicity of a certain material in micron form may be enhanced by transforming it into the nanoscale since it increases that material's surface area and, thus, exposure to the body. But, do our regulatory agencies presently take into consideration if a product contains a nanomaterial?

As such, a number of excellent recommendations were made through this task force. They specifically dealt with requesting data and other information from those wishing to market nanotechnology-based products about the effects of nanoscale materials on product safety and effectiveness. Other recommendations suggested that the FDA provide guidance to manufacturers about when the use of nanoscale ingredients may require submission of additional data, change the product's regulatory status or pathway, or merit taking additional or special steps to address potential safety or product quality issues. Of particular concern, in the report was the fact that many nanotechnologies applied to medicine incorporate both drugs, biological products, and/or devices that contain nanoscale materials to serve multiple uses, such as both a diagnostic and a therapeutic intended use. The committee requested that the FDA seek public input on the process used to regulate such combined diagnostic/therapeutic technologies since traditionally, the regulatory pathways for materials intended to be devices (such as a hip implant) compared with those intended to deliver drugs have been different and when combined cumbersome. Although there are many, an example of such a combined nanomedicine device/drug delivery product is the carbon nanotube-based biosensor placed on a hip implant which detects if new bone growth occurs and depending on the response, delivers drugs to either eliminate infection, reduce inflammation, or increase bone growth. The task force also encouraged manufacturers to communicate with the agency early in the development process for products using nanoscale materials, particularly with regard to such highly integrated combination products.

While this report provided numerous helpful recommendations to the nanotechnology community, it clearly highlighted another example of science being well-ahead of public policy and commercial product regulation. Consider the following: (i) Many researchers in the nanotechnology field have been synthesizing and creating nanotechnology-based products for over 10–15 years. Yet, guidelines for nanotechnology regulation and safety remain few and far between. For example, it is recommended by numerous academic institutions to treat all nanomaterials as extremely toxic, since for the most part, we have insufficient data to determine otherwise. (ii) In 2002, the worldwide market for nanoscale devices was US$406 million dollars (CMS 2007). The key word in this sentence is "was". Perhaps surprisingly in light of the above, although

not regulated as such, several nanoscale devices have been approved by the FDA (for example, one for promoting bone growth). (iii) The National Nanotechnology Initiative in the United States was started by President Clinton in 2000. Again, key word in this sentence is "was". Keep in mind that one of the goals of the National Nanotechnology Initiative in the United States (and others around the world) is to develop and commercialize nanotechnology-based products.

While science may always be ahead of public policy, and it is of great value that this report was published by the FDA, couldn't we see the need for new regulatory measures for nanomaterials a long time ago? Will we ever be able to better anticipate and formulate regulation policies to protect consumers before such products have already been approved? I offer that perhaps, we have not and are not doing enough.

References

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