Public Policy Statement: Nanotechnology

Merck uses nanotechnology to a limited degree in a select number of its human and animal health products, and believes this new technology will continue to play an important role in future medical developments. We recognize that, as with any new technology, there are risks that must be balanced with the benefits. Merck has a long history of using a systematic and rigorous approach, based on sound science and best practices, to evaluate the safety and environmental impact of its products. We apply this same approach when evaluating the use of nanotechnology in the discovery, development and manufacture of our products. Our goal is to optimize the benefits of this new technology for patients and consumers, while delivering our products as safely and responsibly as possible. We will continue to monitor scientific and regulatory developments in this emerging field and adapt our existing risk management practices as necessary.

Nanotechnology is the study of manipulating matter on an atomic and molecular scale. Generally, nanotechnology deals with structures (nanoparticles) sized between 1 and 100 nanometer (sizes as small as 100,000th the width of a human hair) in at least one dimension, and involves developing materials or devices within that size range that contain unique properties attributed to these dimensions.

Nanomedicine is an area of biomedical research that seeks to use nanoscale materials and/or tools to improve health. Potential areas of application of nanomedicine include new therapeutic targets, identification of biomarkers, development of analytical tests, improving absorption, enhancing drug delivery to specific tissues and tissue compartments, molecular imaging to monitor the fate of therapeutic agents, and development of novel therapeutic approaches and molecules.
There is much debate on the future implications of nanotechnology due to the unique properties of nanoparticles (i.e., increased surface area, increased solubility, changes in charges, and increased ease of dispersion/distribution/transport) that may affect product safety and effectiveness. Nanotechnology may be able to create many new materials and devices with a vast range of applications, but it also raises many of the same issues as any new technology, including concerns about the potential impact of nanomaterials on human and animal health and the environment. These concerns have led to a debate among advocacy groups and governments on whether nanotechnology warrants special regulation. Some groups have advocated that nanotechnology should be specially regulated by governments due to its unknown risks. Others counter that overregulation would stifle scientific research and innovation, which could greatly benefit mankind.

Merck's Responsible Approach to Nanotechnology

Merck uses nanotechnology to a limited degree in a small number of its marketed human and animal health products. Merck is also pursuing the use of nanotechnology in investigational products through internal research and development efforts in collaboration with academia, biotechnology companies, and companies that support various platforms for drug discovery and development of novel therapeutics. Merck does not currently use engineered nanomaterials, including carbon nanotubes or "bucky-balls." Merck uses a precautionary approach during early development phases when information is limited.

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Merck is committed to ensuring the safety of our employees and customers and protection of the environment. Merck conducts rigorous testing and risk assessments on all of its investigational products to help ensure they are safe and effective for patient use. These assessments are also intended to minimize our employees' exposures to risks during product development and manufacturing and to ensure we meet the company's high standards of occupational safety and health and protection of the environment. We also conduct assessments of potential impacts on the environment for drug registrations. Based on our current knowledge of nanoparticles, we believe that our existing methods for assessing risks to humans, animals and the environment are well-suited for managing exposures to nanomaterials.

As new nano-based medicines are developed and scientific and regulatory developments evolve, we will reassess our product development and occupational and environmental control strategies to ensure they will continue to provide an appropriate level of protection. Merck will remain committed to adopting best practices as they are identified for nanomaterials as well as sharing our learnings in this area.

December 2014

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