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on behalf of ETC Group
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"100 Years after The Pure Food & Drug Act: FDA's current regulatory framework inadequate to address new nano-scale technologies"

Thank you for the opportunity to present the views of ETC Group. We are an international civil society organization based in Canada. Our work focuses on the social and economic impacts of emerging technologies and their implications, especially for marginalized communities. I'm based in ETC Group's North Carolina office.

ETC Group has been monitoring the development of nano-scale technologies since 2000. Though we focus on the socio-economic impacts of technologies, in the case of nanotech, we couldn't ignore the potential health and safety impacts. Five years ago, we were stunned to realize that there were no internationally-accepted scientific standards governing lab research or the introduction of nanomaterials in commercial products. There were virtually no toxicology studies devoted to synthetic nanomaterials. There were no standards for describing or even measuring nano-scale materials. There were no labeling requirements. In short, there was a regulatory vacuum. And that regulatory vacuum persists today, despite the fact that hundreds of products containing engineered nanomaterials have been commercialized. The reality is that the discussion of nanotech regulation is at least a decade overdue. We can't congratulate ourselves on being pro-active or for "getting it right this time." Instead, let's focus on the urgent need to address the situation: The first generation of nanotech products – those that incorporate engineered nanoparticles – have slipped through the cracks of the existing regulatory framework.

In the summer of 2002, ETC Group urged governments to establish a moratorium on the commercialization of new products containing novel, engineered nanoparticles until lab protocols could be established to protect workers, and until regulations were in place to

protect consumers and the environment. Our proposal received a less-than-enthusiastic response from nanotech proponents, but our call for a moratorium was *not* motivated by a desire to rain on the parade of exciting new consumer products. We saw that public debate was non-existent and the current regulatory framework inadequate to address these novel materials and their unknown effects on human health and the environment. And until their safety could be assured for consumers and for workers, the technology could not develop in a healthy and transparent way.

As everyone in this room is now aware, substances produced at the nano-scale can behave as if they were altogether different substances from their familiar, larger-scale counterparts. Their novel properties are precisely why there is so much scientific and commercial interest in nano-scale materials. And why the US Patent and Trademark Office has been swamped by nanotech patent applications – so much so that one market research firm estimates there are more than 2,700 outstanding nanotech patent applications. As a 1998 Nobel Laureate in physics explained: With nanotechnology, "The possibilities to create new things appear limitless."

That limitlessness has created – and will continue to create – daunting challenges for FDA, as the regulatory agency responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, the nation's food supply, cosmetics and products that emit radiation. Every one of these categories includes or will soon include products that incorporate engineered, nano-scale substances. And the onslaught of nanotech products won't stop. A second wave of products – those that result from the convergence of nanotech and biotechnology or nanotech and synthetic biology – will soon be on FDA's doorstep.

I'll give just one small example of the challenges facing FDA – the example of titanium dioxide in foods. FDA approved TiO_2 as a food color additive in 1966 with the stipulation that the additive was "not to exceed 1% by weight"

(http://www.cfsan.fda.gov/~dms/opa-col2.html). (Micron-sized particles of TiO_2 are white in color and can be added to icings on cookies and cakes). The FDA approved TiO_2 as a "food contact substance" as well, meaning that it's safe to incorporate it into food packaging. TiO_2 is now being formulated at the nano-scale and the transparent particles are being used in clear plastic food wraps for UV protection. Because TiO_2 has already been approved as a food contact substance, this nano-scale use in packaging will not trigger further regulatory scrutiny. This is also true for nano-TiO_2's use as a food additive, which is relevant because companies *are* exploring the use of nano-scale TiO_2 in foods. For example, foods are being coated with nano-scale titanium dioxide to keep out moisture and oxygen. The percent-by-weight limits set back in the 1960s aren't relevant to today's nano-scale formulations since tiny amounts can produce large effects. But nano-scale TiO_2 in food is just one example. Market analysts predict that the nanotech market for food and food packaging could be $20 billion by 2010. We've been told that every major food corporation has a nanotech R&D program or is looking to develop one.

Today, there is a virtual consensus among scientists that the toxicology of engineered nanomaterials is largely unknown, and that toxicity data cannot be extrapolated from existing toxicology studies conducted on larger-scale materials. In short, we don't know what accumulated amounts of any human-made nanomaterial will do in our lungs or our livers or our guts, even if we do know how bigger particles of the same material behave in our bodies. The closest thing we have to go on is our experience with similarly-sized ultrafine particulate matter in air pollution, and no toxicologist in the world is arguing for the benign nature of air pollution.

Unfortunately, the US government has so far acted as a cheerleader – not a regulator – in addressing the nanotech revolution. In the all-out race to secure economic advantage, health and environmental considerations have taken a backseat, and socioeconomic impacts are a distant concern. There is no doubt that FDA is under-staffed, under-funded and currently ill-equipped to deal with the nanotech revolution. But that has to change.

FDA must be given the resources it needs to address the challenges posed by nano-scale technologies. In an article devoted to FDA's centennial, *Chemical & Engineering News* noted that FDA employs 0.5% of the nation's 2 million government workers, yet it must regulate products worth 29 cents of every dollar spent in the US.

We urge the FDA to embrace the scientific consensus that size matters. Because engineered nanomaterials behave differently from their larger-scale counterparts, they should be regulated as new substances. FDA must take a precautionary stance, and not fall back on the weak notion that a lack of evidence of harm is an adequate assurance of safety. *"Probably adequate"* – as FDA now considers its current framework with regard to nano-scale materials – is not good enough. Regulations must be mandatory, not voluntary. Products containing engineered nanomaterials should be labeled as such. The FDA must fulfill its responsibility to protect public health, rather than the health of the companies that pay it user fees.