FUTURE CHALLENGES NOT SO FAR AWAY: Emerging Law of Nanotechnology in the REPORT Before THE COUNCIL OF EUROPE

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I. Nanotechnology's revolution for commerce can revolutionize pubéic health, but it requires forethought in European law.

In 2012, the Council of Europe (CoE) Parliamentary Assembly began the first steps towards nanotechnology regulation with a view to respecting the scientific precautionary principles. 1. The CoE is the health and human rights vanguard for law governing the right to health, public health and consumer protection throughout Europe, and its human rights court has remained a leading model for jurisprudence throughout the world. The CoE has 47 (forty seven) Member nations. Its jurisdiction therefore embraces 800 million people. Switzerland is a member of the CoE, as are many nations that are excluded from the European Union.

The CoE commissioned an expert report, "Nanotechnology: balancing benefits and risks to public health and the environment" prepared by author of this forthcoming dissertation. My expert report on nanotechnology was enthusiastically accepted at the CoE meeting of the Committee on Social Affairs, Health and Sustainable Development in Moscow, Russian Federation on November 19, 2012. 2. The same report is slated for public debate before the entire Council of Europe Parliamentary Assembly in the main headquarters at Strasbourg France, on or before April 26, 2012.

The report outlines essential European legal concepts for public discourse concerning nanotechnology safety and the regulation of nanotechnology in commerce:

1. First, the report was praised because of its excellent synthesis of leading issues in nanotechnology regulation confronting all civil society, including but not limited to bioethics issues, impact on human and non-human health, environmental impact ant the promising impact of nanomedicine for improving everyone's quality of life.

2. Second, the CoE is using the report as one of several resources for determining which path it will follow regarding possible treaties or international agreements governing the use and monitoring of nanotechnology.

3. Third, CoE legal instruments frequently are the basis of juridical determinations in the Court of Human rights and serve as influential models for the entire world.

II. Statement of the Public Health Law and Risk Management Problem:

How can the benefits of nanotechnology be realized, while minimizing the risk of harm?

Scientists and governments agree there are unknown risks and have begun drafting laws. Examples include Swiss federation (Precautionary Matrix 2008) Royal Society on Environmental Pollution, German Governmental science commission, Public testimony sought by USA National Institute for Occupational Safety and Health (NIOSH, Feb 2011), OECD working group (since 2007) WHO working group (in process of formation), ISO, WTO, several industrial groups, and various non-governmental organizations, as discussed in the Case Report about regulation.3.

Therefore there is consensus that nanotechnology poses risks of significant harm to presently exposed populations, the greater ecological environment and to the public health. 4.But qualitative data to protect exposed people and the greater ecological system that surrounds the human environment lags behind industrial use, research and application of nanotechnology to consumer products. Thus, the precautionary principles of science, embedded into many laws may apply until a coherent regulation

system fills this void. There are many systems in development phase but few efforts towards harmonization. 5.

Recognizing that nanotechnology is already here in hundreds of consumer products: tennis balls, cars, refrigerators, cameras, cosmetics, the Committee noted that consumer products applying nanotechnology are predicted to be 3 trillion US dollars by 2015. The question how to regulate in advance of cumulative doses that may present undue risks to the general public and the global disease burden absorbed by public health systems, while nonetheless supporting important economic development that will incubate nanotechnology industries requires careful forethought when approaching the effort for legislative drafting,6

I. Legislative Approaches:

Key questions to be decided by European lawmakers include but are not limited to the definition of key terms, such as: “nanomaterials”, “nanoparticles”, “nanoinformatics” and perhaps even, “nanotechnology” itself:

1. How to define nanotechnology, nanoparticles and “other nano things” that should be regulated, if at all, under law and
2. Whether to follow a so-called “list” approach or instead to craft a flexible umbrella of criteria regarding nanotechnology developments and risks.

One narrow approach would be to define these terms, using a list based on existing state of the art technology. This approach is quick for the users, especially bureaucrats involved in enforcement of precautions, but is seductively easy without allowing for changes in the list if it omits a problem that is important, includes by happenstance an application that was not intended for regulation but fits the list description, and worst of all, is rigid so that it cannot embrace new technological changes that improve existing items on the list or new problems that could not have been anticipated at the time of its writing. Lists therefore are deceptively simple: lists look easy but are a foe to progress! “Things change, but the list stays the same, unless a committee of experts is convened with the power to change it.”

The alternative approach that has been successful throughout the late twentieth century is to create flexible criteria under law. These criteria are designed to take into account several variables, and can be applied to situations that were not expected when the laws were written. The WHO Constitution is a shining example of an international legal text whose definition is flexible and has withstood the test of time. No one could have anticipated HIV or AIDS at the time of its writing in 1948, but everyone in the world expected WHO to pro actively attack the problem from the outset of the HIV epidemic in the 1980s, and then praised WHO programs without questioning the agency's underlying jurisdiction to do the work. So too laws can change society with a stroke of the legislative pen, without defining their main subject.7. For example, the UN Convention on the Prevention of Discrimination Against People With Disabilities (PWA) does not define disability. These documents list criteria for coverage by the statute, without specifically defining key terms. This keeps the statute flexible on a case by case basis without clogging the regulatory system with new problems that do not fit the regulatory framework.

This presentation tackles these thorny jurisprudential questions.

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