Liability Prevention and Intergenerational Genomic or Epigenetic Harm

Biotech animals and crops will soon be reaping the benefit of new breeding methods that do not use the traditional recombinant DNA viral vectors, like RNA silencing or interference (RNAi) and all the other plant breeding methods – directed oligonucleotides, zinc fingers, methylation along an epigenetic chromosome and others. At the present time, the regulatory attitudes of various nations are evaluating how these methods will be regulated.

Regulators will need to be convinced that plant and animal breeding is evolving toward more precision and that this is the only tool for eliminating defects in DNA and epigenetics. Chemical or radiation mutagenesis causes more off target DNA changes than rDNA, and new genetic editing tools are not only more precise – they would also be able to clean up the stray DNA in other crops, if it were deemed hazardous.

Unfortunately, new plant breeding methods will not get a "hall pass" and avoid all regulations, even if scientists show it is a more precise way to do this, even with genes from within the same plant's genome (i.e., "cisgenic"). Regardless of scientific reasons to see less risk, some new plant breeding methods will prove objectionable to anti-GMO activists. In fact, activists already are targeting "excessive RNA" in some breeding processes.

It is important for this emerging industry to understand how DNA and subtle immunologic or endocrine effects have been involved in proving billions of dollars in harm in past litigation. This session will review the law and facts involved in the first GE personal injury cases (Di Rosa v. Showa Denko KK, r the "l-tryptophan" cases), and claims involving cross-linked DNA theories (Aguayo v PGE, or the "Erin Brockovich" cases). Intergenerational liability as established in the DES cases will also be discussed, along with the "market-share" approach to awarding damages against an entire industry without requiring product tracing to particular companies.

While it is probably very unlikely that any such stray DNA is causing serious health effects, a sound liability prevention program will seek to prove that via research establishing that off target effects are not potentially harmful to health. A child born to two parents has plenty of variability in DNA, and various retroviruses and transposons are changing DNA, sometimes for the worse, all the time. A convincing case needs to be made through reasonable liability prevention steps, taken before regulatory approval requirements are imposed, which traces and assesses all the reasonably foreseeable risks of off-target DNA or epigenetic effects of new genetic editing or silencing methods. What genetic editing or silencing will allow us to do, as it evolves toward greater speed and precision, is optimize crop and animal responses to various stimuli in the environment, turning genes on and off.