Rachel Lindor and Gary Marchant

Center for Law, Science & Innovation, ASU

Liability Drivers and Impediments to Individualized Medicine

Liability is an important, although often under-appreciated, legal tool for the governance of new technologies. Key actors in the development and application of technologies are often motivated by potential liability concerns. This is certainly the case in the medical field, where past experiences such as bendectin, DES, silicone breast implants, Vioxx, and medical malpractice have made both product developers and health care providers very sensitive to, and aware of, liability risks. Many of the most exciting innovations in health technology involve better targeting diagnostics and therapeutics to the health needs of the individual patients. Examples of such medical innovations include personalized medicine and pharmacogenomics, increased use of biomarkers, "smart" medicine, and many nanomedical applications. These types of individualized medical applications will present new or enhanced liability risks to both the product developers and providers for a number of reasons including: (i) failure to accurately convey risks of false positives and false negatives; (ii) inexperience and lack of training/expertise in applying new technologies; (iii) unrealistic or inflated patient expectations; (iv) disparities in the conduct of different manufacturers and providers in designing and applying new, rapidly evolving technologies; and (v) novel liability claims such as privacy risks from failure to properly handle individual data and violation of emerging duties such as a duty to disclose individual information to at risk relatives. This presentation will review these new liability risks, anchor them with existing case law and doctrinal developments, speculate on the positive and negative impacts such liability risks might have on the development of individualized medicine technologies, and suggest ways in which product manufacturers and health care providers might best manage these new liability risks.