Moses & Singer LLP Attorney Linda Malek Leads Panel on “Personalized Medicine” for the American Bar Association.

As the pace of discovery in personalized genetics accelerates, what are the legal and ethical issues challenging the healthcare community?


“Personalized medicine” uses information about a person’s genes, proteins and environment to prevent, diagnose and treat their condition. While this is not a particularly new approach, rapid advancements are prompting greater attention among researchers, government agencies, private sector industries, payors and the media.

Panelists agreed that patients have concerns regarding privacy and confidentiality, use and ownership of tissue and data and equity in testing. The high personal cost of targeted and experimental therapies and potential lack of insurance coverage further clouds personalized medicine’s promise. While physicians, pharmaceutical companies and insurers see great opportunities for advancement, they share concerns over delivery costs as well as liability risks and training issues.

“From a legal perspective, the personalized medicine community needs to establish key guidelines to secure privacy and security in the handling of identifiable data, ensuring compliance as well as establishing a best practices approach and obtaining consent,” noted Linda. “Ethical questions need to be answered upfront, so that patients understand who has access to data and how this impacts their course of treatment.”

Another concern centers on ownership of outcomes from personalized medicine therapies. Panelists noted that diagnostic patents may be harder to obtain in the future, requiring a narrowing of claims to avoid “pre-emption of natural law.”

“The entire ethical and legal landscape is rapidly evolving as the technology in this area emerges,” noted Linda. “Before pursuing these therapies, health care institutions and the pharmaceutical industry need a set of professional standards against which to manage their businesses and the well being of their patients.”

Linda Malek, Chair of the Healthcare practice of Moses & Singer LLP has over 20 years experience serving the regulatory, technological and business matters concerning healthcare providers and related institutions. Moses & Singer, a New York City law firm founded in 1919, serves the legal needs of prominent industries and individuals in diversified commercial, professional and personal needs. This press release is provided for informational purposes only and does not constitute legal advice. It is not intended to create, and receipt does not constitute, an attorney-client relationship between the sender and the receiver.
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