EPSTEIN BECKER GREEN

# Post-*Roe* Considerations for Research Institutions, Medical Product Developers, and Research Services Providers

- ☐ Businesses that conduct, fund, or are otherwise materially involved in pre-clinical and clinical development of biologics, drugs, and medical devices, including the performance of clinical research studies, should evaluate their research portfolios to determine whether any ongoing or anticipated research activities relate to any one of the following:
  - ○ Embryonic stem cells or tissue
  - ○ Reproductive health products or technology
  - ○ Contraceptive products
  - ○ Fetal research (in utero or specimen research)
  - ○ Abortion-inducing drugs or devices
  - ○ Any other product or process that is connected to abortion
- ☐ Companies engaged in pre-clinical research should consider the impact of changing state laws on their ability to continue research involving these products/tissues in any state where the research is performed.
  - ○ Consider potential impacts on the availability of human reproductive tissues required for ongoing and planned pre-clinical research activities.
- ☐ Clinical research sponsors with participating sites in different states should consider conducting an impact analysis of changing state laws on the ability of each site (and/or the principal investigator and the study subjects) to continue participation in the study.
- ☐ Clinical research sites and research institutions should consider whether the changes in state law impact:
  - ○ Their ability to continue any existing research studies;
  - ○ Their policies governing the types of research in which the organization may engage going forward;
  - ○ Their guidance and policies applicable to the local IRB's oversight of the research; or
  - ○ Terms of existing template agreements related to research, including, for example, clinical trial agreements or material transfer agreements.
- ☐ Entities that make biological material or human tissues available to other businesses for research purposes (for example, donor centers, IVF centers, biobanks, tissue banks) should consider whether the changes in state law impact:
  - ○ The types of material or tissue they are permitted to store and/or distribute under applicable state law, or
  - ○ Terms of existing template agreements related to research, including, for example, material transfer agreements.
- ☐ Commercial IRBs and local/institutional IRBs, particularly those that serve as a single IRB over multi-jurisdictional research, should consider whether the changes in state law impact:
  - ○ Their screening process in connection with the review of study protocols, including the determination of whether the study is considered illegal in any states, or
  - ○ Their review processes for protocols and informed consents more broadly, depending on the state(s) in which any particular study is being conducted.
- ☐ Potential civil and criminal liabilities arising from the performance of research involving abortion-related products or services may impact:
  - ○ Manufacturers, researchers, and service providers that distribute medication abortion drugs into a ban state in connection with clinical research, and
  - ○ Manufacturers, researchers, and service providers that conduct clinical research involving abortion-related products and services in a ban state.



If you are a health care provider or life sciences organization with questions about how the decision affects your business, please contact Amy Dow at adow@ebglaw.com. If you are an employer with questions about your workplace policies or benefits offerings, please contact Susan Gross Sholinsky at sgross@ebglaw.com.

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