OUR PRACTICE

Medical Research/Clinical Trials

The process of inventing, testing and bringing to market a new drug or medical device is complex and expensive, involving multiple layers of law and regulation. At every stage, organizations and individuals who work on clinical trials must comply with HIPAA, the federal Anti-Kickback Statute and myriad FDA rules. Some states have added their own regulations. For publicly traded companies, SEC regulations come into play. With increasing frequency, clinical trials also involve companies, organizations and research subjects in Europe, Asia and Latin America.

As of August 1, 2013, there's a new legal hurdle to clear. Pharmaceutical companies and medical device makers must comply with – and physicians must constantly be aware of – the Physician Payments Sunshine Act, part of the Affordable Care Act (ACA), which requires companies to publicly report most payments and gifts to physicians and hospitals, including direct payments of as little as $10.

Clinical trials are, in short, no place for inexperienced or unsophisticated lawyers.

The attorneys in Baker Donelson's Health Law Department have experience representing institutions and investigators in every major stage of the clinical research process, from Phase I evaluations of safety to Phase IV post-marketing studies. Our clients have included a wide array of participants: medical device and pharmaceutical companies, life science companies, Principal Investigators (PIs), Contract Research Organizations (CROs), Site Management Organizations (SMOs), Institutional Review Boards (IRBs), independent research sites and clinical laboratories and other service providers.

Beyond health care regulation, clinical research arrangements involve complicated legal questions relating to intellectual property law, licensing, allocation of contractual risk and indemnification and malpractice insurance, among other areas. Have participants been adequately informed? Who will be responsible for errors? Who owns the data?

By design, the leaders of our Health Law Department have built a multidisciplinary team with wide-ranging experience in law and business. We take pride in working together for the benefit of our clients. We track legal developments such as the Sunshine Act, as well as business trends that are compelling physicians to look at clinical trials as an additional source of revenue. With each new drug taking years and millions of dollars to develop – and with six or seven failures for every success – our clients have too much at stake to do anything less.