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THE HEALTH CARE AND LIFE SCIENCES PRACTICE OF

EPSTEIN BECKER & GREEN, P.C.

Announces...

ClinTrials Law Initiative

EPSTEIN BECKER & GREEN, P.C. IS PLEASED TO ANNOUNCE THE LAUNCH OF OUR NEW EBG CLINTRIALS LAW TEAM.

THOUGHT LEADERS IN HEALTH LAW®

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Our Goal

The goal of the EBG ClinTrials Team is to provide to clinical trial sponsors, CROs, clinical sites, investigators, ethics committees, and other entities involved in planning, structuring, and executing pharmaceutical or medical device clinical trials, in the United States and worldwide, a fully integrated legal, regulatory and reimbursement service.

Process

To be systematic and look at the issues through the eyes of the client, EBG spent several months talking with leaders in pharmaceutical and device companies regarding the drivers of the clinical trials process today and in the years to come.

Below is an outline of the trends and drivers we identified:

- ✓ **Greater competition for investigators due to:**
  - More trials being conducted
  - Growing complexity of trials, resulting in fewer investigators being qualified to conduct them
- ✓ **This greater competition leads to:**
  - Pressure to be more creative in recruitment of investigators and subjects
  - Competition in the global market for investigators and subjects
- ✓ **The globalization of clinical trials is also fed by:**
  - The globalization of business and markets
  - A growing receptivity at the FDA, the EMEA, and other regulatory bodies to data developed outside their jurisdiction
- ✓ **Globalization leads to greater legal risks such as compliance with the U.S. Foreign Corrupt Practices Act, and compliance with laws in multiple jurisdictions**
- ✓ **Growth of post approval clinical trials driven by both regulators and payers:**
  - These trials produce unique challenges in data management and the complexity of study designs
- ✓ **The need for GCP compliance programs similar to GMP systems**
- ✓ **The staggering cost of trials as they become more complex and larger:**
  - Getting reimbursement for investigational device trials that are very expensive—perhaps because combination products are involved
  - The lack of clarity around what costs payers will reimburse
- ✓ **Compliance with clinical trial registries**
- ✓ **Privacy protection, at both the federal and state levels**

EBG used this information to assemble our Team in all countries focused on the needs of those engaged in clinical trials. Our Team is now comprised of more than 40 experienced lawyers and consultants in regulatory, clinical, and reimbursement affairs.

How can we help?

Considering those trends and the challenges they create, EBG sees two areas–broadly speaking–where we can help.

Planning, structuring, and executing

When you are planning and structuring pharmaceutical and medical device clinical trials in the United States, Europe, Asia or other regions, you need expert legal, regulatory, and reimbursement help.

The EBG ClinTrials Team has years of experience helping clients develop, negotiate, and put into place master services agreements, investigator and site agreements, material transfer agreements, informed consents, supply service agreements and other such documents.

Further, minimizing risk does not happen by chance. It happens because companies put systems in place to ensure that potential risks are methodically identified and addressed, and compliance is achieved. We help with that, tailoring systems to the individual business needs and cultures that each client presents.

Corrective action and advocacy

Despite best efforts, sometimes companies find noncompliance. EBG can help there too by developing a corrective action plan. Sometimes regulators get involved, and we serve as advocates, ensuring that our client is treated fairly. With the country's largest health care law practice, EBG has helped clients in every segment of the health industry negotiate hundreds of agreements with regulators to resolve compliance issues.

So what did we do to launch our Team?

Recruited more international expertise

Based on the interviews EBG conducted, we systematically assessed our knowledge and skill base, looking for gaps in our abilities. While EBG already had most of the skills and abilities required, we did find that we needed to bolster our international capabilities and to organize ourselves in a way that enhanced quality and service. Here are three steps we have taken to add international capabilities:

① **Internal Experience**

To add to our existing internal legal capability, we recruited **Kevin F. Cunningham** to help handle the transactional side of international clinical trials. Mr. Cunningham was Senior Counsel and Vice President of Bristol-Myers Squibb Company, where he handled legal\business matters of prescription pharmaceuticals, OTC pharmaceuticals, Mead Johnson Nutritional products, ConVatec (a device company), and Worldwide Beauty Care. He assisted these clients, which had a combined budget of over U.S. $2 billion dollars, in the U.S., Europe, North and South America, the Caribbean, Iberia, the Middle East, and the Pacific Rim. He has substantial experience in negotiating clinical trials agreements around the world, and handling other legal issues that arise out of clinical trials.

② **Organized overseas legal resources**

EBG put together a list of top attorneys outside the United States (Europe, Eastern Europe, Asia, Japan, China, India, Latin America) who can help us with clinical trial issues. We obtained names from our own experience, from the International Lawyers Network (ILN) that we helped to found, and from pharmaceutical and device company referrals.

③ Formed strategic alliances with regulatory consultants overseas

EBG has entered into strategic alliances with two consulting firms that have deep experience in the regulatory requirements and business issues associated with clinical trials outside the United States.

Asia–Pacific Bridge Medical

Based in Washington, DC, Pacific Bridge Medical focuses on helping drug and device companies navigate regulatory requirements in all Asian countries. The firm's founder, Ames Gross, is recognized nationally and internationally as a leader in the Asian medical markets. Mr. Gross founded PBM in 1988 and has helped over 200 medical companies with business development and regulatory issues in Asia. Mr. Gross is joined by about a half dozen staffers in Washington, DC and in Asia, as well as by a network of contractors throughout the region. You can read more about them at www.pacificbridgemedical.com.

Europe–Donawa Consulting

Donawa Consulting–based in Europe and the United States–provides the clinical, regulatory, and quality system services that medical technology companies need to meet their strategic objectives and deadlines. Since 1986, Maria Donawa, M.D., founder of the company and former official of FDA's Center for Devices and Radiological Health, has used her background and knowledge of issues facing the medical device industry to assemble a talented team of senior professionals. Donawa Consulting staff has firsthand senior level experience in the medical profession, device industry and regulatory agencies, combining to offer a unique perspective on resolving your clinical, regulatory, and quality system problems in Europe. Donawa Consulting also helps clients in addressing other critical issues, which are often overlooked, such as risk management of clinical studies to avoid undue delays and excess costs, and study auditing for compliance with good clinical practices. To find out how Donawa Consulting can help you, visit www.donawa.com.

Organized ourselves for quality and speed

Beyond those international resources, the EBG ClinTrials Law Team includes:

- Over 40 lawyers who assist with all types of pharmaceutical and medical device agreements, privacy, FDA regulatory, reimbursement, fraud and abuse, and litigation
- A U.S. regulatory consulting firm named Anson Group (www.ansongroup.com)
- EBG's own reimbursement consulting group called EBG Advisors, Inc. (www.ebgadvisors.com)

To be service oriented, EBG has organized our institutional knowledge with the goal of assisting clinical trial clients efficiently, quickly, and to the highest quality standards.

May we help you?

When you need expert legal, regulatory or reimbursement help for pharmaceutical and medial device clinical trials worldwide, call us. We can help.

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EBGLAW.COM