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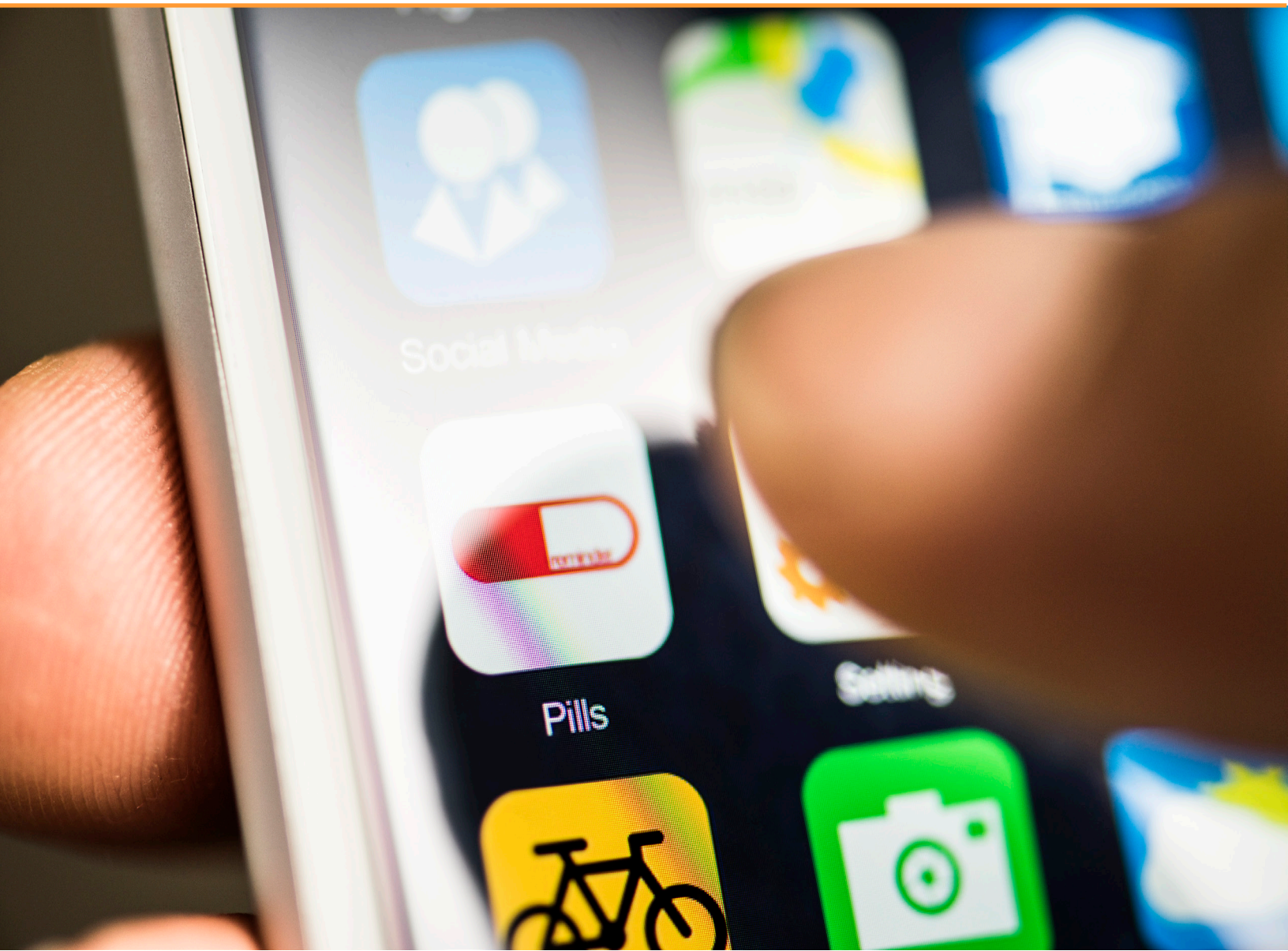
Strategies for Meeting Pharmaceutical Company Digital Health Business Objectives While Managing Regulatory Requirements



BUSINESS DRIVERS

Digital health strategies can deliver a better experience for patients, improve clinical outcomes, and reduce the total cost of care. First movers will capture opportunities to grow their top and bottom lines.

Regulatory Implications

The question is not whether pharmaceutical companies should pursue digital health strategies, but how. A major shift in strategy needs to be built around the recognition that the regulatory environment makes some strategies smarter than others. There are vast differences in the time to market and the cost associated with various uses of software platforms, as well as competitive implications. The wisdom of any given strategy is heavily impacted by regulatory requirements.

As if not complex enough, the regulatory environment also is constantly changing. President Trump promises deregulation, but, at the same time, the U.S. Food and Drug Administration (FDA) is participating in the International Medical Device Regulators Forum, as it drives toward a more globally uniform approach to regulating software as a medical device. On December 13, 2016, then-President Obama signed into law the 21st Century Cures Act, which, in section 3060, **fundamentally changes the way FDA approaches software**. For the first time in over 40 years, Congress significantly revised the definition of a medical device to carve out several important categories of software, effectively deregulating them. More than that, Congress imposed new principles for discerning when software accessorizes a medical device, and how to handle software that includes both regulated and unregulated components.

How We Can Help

Through a multidisciplinary practice that involves attorneys at the law firm of Epstein Becker Green as well as consultants at our affiliated consultancy EBG Advisors, Inc.—we assist clients in navigating both strategy and execution. In particular, our team offers:

- Business strategies that help meet the overall goals of a company, recognizing that there is profit to be made for those that can adeptly navigate regulatory requirements
- Regulatory strategies that minimize the cost and delays associated with compliance
- Regulatory opinions to give comfort to the company that its chosen pathway is lawful
- Assistance with the organization and conduct of FDA meetings addressing digital health topics
- Assistance with drafting regulatory submissions

We Stand Apart

Many organizations offer to help pharmaceutical companies with the regulatory implications of their digital health strategies. But how do you pick the one with the right skill set as well as a commitment to client service? In addition to the typical considerations of reputation and price, clients should consider three factors:

1

An eye on the future. We understand what the future is likely to be with regard to the regulation of software used with pharmaceuticals, because we play an active role in shaping that future. A significant portion of our practice is focused on representing coalitions in discussions with policymakers at FDA and in Congress on what the future of software regulation—including pharmaceutical apps—ought to look like.

THESE COALITIONS INCLUDE:

mHealth Regulatory Coalition. Over the lifetime of this coalition, from 2009 until 2015, we represented the coalition in its efforts to seek a sensible approach to discerning which mobile apps require FDA regulation based on risk. The coalition successfully advocated for the publication of three guidance documents that now serve as the regulatory roadmap for all mobile medical apps, including those that serve as accessories to medical devices and those that manage wellness.

Clinical Decision Support (CDS) Coalition. Members of this coalition include not only drug and medical device companies but also technology companies and hospital systems developing innovative software for CDS. Since 2011, Epstein Becker Green has been representing this coalition as it seeks clarity from both Congress and FDA with regard to determining which CDS raised to a level that requires FDA regulation. The 21st Century Cures Act clarified that FDA does not regulate CDS that is transparent.

Going forward, the coalition will:

- Work with FDA to clarify the rules concerning software used in conjunction with pharmaceutical products, as requested in the coalition's Citizens Petition filed in August 2016.
- Work with the agency toward the publication of a guidance document that explains in detail how the agency applies its risk-based framework to CDS generally.
- Actively participate in the policy making of the International Medical Device Regulators Forum with regard to software as a medical device.

Combination Product Coalition. Since 2003, the firm's lawyers have represented this coalition as it works with FDA to improve the regulatory oversight of combination products. Members of the coalition include eight of the 10 largest pharmaceutical companies in the world, as well as numerous other companies. The coalition is interested in clarifying FDA's approach to combination products comprised of pharmaceutical products and software.

Public Service. **EBG's Brad Thompson served on a workgroup created by the U.S. Department of Health and Human Services and the Federal Communications Commission and charged with identifying key considerations to improve patient safety and promote innovation in health information technology, including mobile medical applications. He co-chaired the workgroup's Regulations Subcommittee, which focused on identifying regulatory best practices for such technologies.**

2

Experience. There is no substitute for it. But mere repetition is not enough. It's important to have a diverse set of experiences to develop a broad understanding of the issues as well as how others in industry address them.

RECENT PROJECTS:

Fortune 500 Pharmaceutical Companies:

- Guidance on the regulatory classification of an innovative, new software program designed to identify hospital patients in need of care.
- Assistance with drafting a 510(k) submission for a novel software app for calculating drug dosage.
- Help preparing for a pre-submission meeting with FDA to validate the company's plans for conducting a human factors evaluation of a novel mobile app.
- An assessment of whether an app intended for use in cognitive behavioral therapy to treat a mental illness would constitute a medical device.

Venture Backed Startups:

- Identifying the various regulatory pathways for a versatile drug dosage calculator, together with assistance with drafting a business plan for funding.
- Guidance in understanding the regulatory implications of its strategic marketing partnership with a major pharmaceutical company.
- Developing human factors testing of its drug dosage calculator, and then assisting with assembling a 510(k) and responding to FDA's questions.
- Assessing a regulatory strategy for a novel drug dose calculator based on a machine learning algorithm, which included evaluating de novo and traditional 510(k) pathways. The startup needed guidance through the pre-submission process, including drafting the pre-submission package, participating in the pre-submission meeting, and advising on follow-up activities based upon on FDA's feedback.
- Analysis of the regulatory pathways available to it for a combination product involving a drug and software that provides complementary cognitive behavioral therapy, and the competitive implications of those pathways.
- Developing a regulatory strategy for a drug-delivery device regulated as a combination product that would keep the associated mobile app unregulated.

3

A multidisciplinary practice. These issues are simply too complex for any one person or even a small group to appropriately analyze. No one is that smart or that broadly trained. Instead, we collaborate as a team that includes a half-dozen lawyers (in a firm of over 250) as well as a core group of a half-dozen of our more than 250 consultants. Our consultants include experts well-versed in pharmaceutical regulation, medical device regulation, combination product regulation, the regulatory requirements of the European Union (EU) and Asia, software engineering, quality systems, clinical practice, privacy and security, and Medicare, Medicaid, and private party reimbursement.

FEATURED ATTORNEY AND CONSULTANTS:

Bradley Merrill Thompson, MBA, JD, RAC. Brad, a member of Epstein Becker Green and Chairman of the Board of EBG Advisors, has more than 30 years of experience counseling pharmaceutical and medical device companies on a wide range of FDA regulatory, reimbursement, and digital health strategies. He leads Epstein Becker Green's Medical Device Regulatory Practice and Digital Health Initiative. For trade groups, Brad has served as counsel to AdvaMed for payment issues, and as General Counsel to the Combination Products Coalition, the mHealth Regulatory Coalition, and the CDS Coalition. He also serves as FDA counsel to the Personal Connected Health Alliance, a HIMSS organization. Brad is a frequent writer of blog posts, articles, chapters, and books, such as *FDA Regulation of mHealth (Second Edition*). He received his BA, *cum laude*, and an MBA from the University of Illinois and his JD, *cum laude*, from the University of Michigan Law School..

Carol Clark-Evans, MS. Carol has more than 25 years of regulatory affairs experience that includes pre- and post-approval phases for drugs, biologics, and medical devices in small, mid-size, and large companies. Most recently, she served as Vice President of Regulatory Affairs for the Specialty Pharmaceuticals business unit of BTG International. While there, Carol established regulatory strategy and processes for BTG's digital health initiatives to develop mobile medical applications and pharmaceutical apps for BTG's marketed products. She successfully merged innovative, flexible thinking needed in digital health care with compliance to relevant medical device and pharmaceutical regulatory requirements. Carol has a master's degree in analytical chemistry from Western Kentucky University.

Robin F. Martin, MBA, RAC. Robin has more than 10 years of medical device industry experience, having served in her last position as Director of Regulatory Affairs for GE Healthcare. She has a comprehensive understanding of global regulatory landscape and a demonstrated record of over 15 successful FDA submissions, including 510(k)s, premarket approval (PMA) supplements, and investigational device exemptions (IDEs), as well as premarket registrations globally (e.g., Brazil, Canada, China, the EU, and Japan). Her experience includes combination drug/device products and medical device software applications. Robin earned a bachelor's degree in biomedical engineering and an MBA, both from Marquette University.

Scott A. Bednar, MBA, CQA. An expert in software development, Scott has more than 25 years of experience in quality system implementation and compliance, new product development, and the manufacturing of medical devices. Having held technical positions, such as Senior Principal Quality Engineer, Combination Products, for Bayer Healthcare, Scott understands the details and complexities of melding medical device software requirements with a pharmaceutical quality system. He has a bachelor's degree in quantitative analysis from Penn State and an MBA from Waynesburg University.

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FOR MORE INFORMATION

Contact Brad Thompson, Member of the Firm at Epstein Becker and Green and Chairman of the Board of EBG Advisors, at 317.514.5008 or BThompson@EBGLaw.com.

ABOUT EPSTEIN BECKER GREEN

Epstein Becker & Green, P.C., is a national law firm with a primary focus on health care and life sciences; employment, labor, and workforce management; and litigation and business disputes. Founded in 1973 as an industry-focused firm, Epstein Becker Green has decades of experience serving clients in health care, financial services, retail, hospitality, and technology, among other industries, representing entities from startups to Fortune 100 companies. Operating in offices throughout the U.S. and supporting clients in the U.S. and abroad, the firm's attorneys are committed to uncompromising client service and legal excellence. For more information, visit www.ebglaw.com.

ABOUT EBG ADVISORS

EBG Advisors is a national strategy and management consultancy that serves leading organizations on health care and employment matters. With a far-reaching network of skilled professionals, EBG Advisors is capable of supporting client innovations from ideation to full implementation. We further aid transactions, operational improvement, compliance, and data security to promote the growth and sustainability of businesses. EBG Advisors consultants often collaborate with Epstein Becker Green attorneys on engagements that require a multidisciplinary approach spanning strategic, policy, regulatory, governance, clinical, and economic topics. Visit www.ebgadvisors.com.