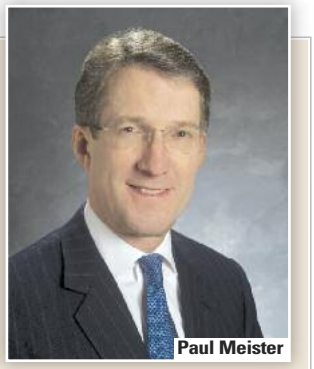
What's New

NEW HEALTHCARE-RELATED PRODUCTS, SERVICES, AND COMPANIES

inVentiv Health and Mehlman Vogel Castagnetti

Launch Breakaway Policy Strategies

TRENDING NOW: Strategic initiative helps clients with changes to U.S. healthcare policy.


Paul Meister

inVentiv Health has launched **BREAKAWAY POLICY STRATEGIES**, a joint venture between inVentiv and the partners of Mehlman Vogel Castagnetti, a bipartisan lobbying firm.

Breakaway helps companies address the diverse challenges posed by a nationwide healthcare system being reshaped by increasing government regulation and dramatic shifts in the private healthcare market. The firm provides strategic analysis and policy guidance to help healthcare stakeholders navigate transformative changes arising from decisions made daily by federal and state policymakers.

Changes already under way include the emergence of Accountable Care Organizations, Health Insurance Exchanges, and bundled payment arrangements. Additional changes will take effect next year, leading to dramatic expansions of health coverage for American consumers and increasing government influence over hospitals, health plans, employers, doctors, patients, employers, biopharmaceutical firms, and device companies.

"Now more than ever, clients must have a sophisticated understanding of the sweeping changes taking place in America's healthcare system," says Paul Meister, CEO of inVentiv Health. "Navigating this new landscape requires seasoned experts with historical knowledge, a deep understanding of political context, and the ability to anticipate what's next."

The collaboration expands inVentiv's presence in Washington, D.C., and enhances its broad portfolio of services.

For Breakaway, the investment enables an expansion of research capabilities and the addition of top-notch talent.

Breakaway's team combines extensive experience in the public sector with equally deep private sector expertise. The team has extensive know-how in private health insurance markets, private programs in Medicare and Medicaid, and emerging delivery models. Drawing on all this experience, Breakaway delivers analysis, strategic solutions, and practical advice to guide clients through changes in how healthcare will be delivered, consumed and paid for.

Dean Rosen, one of the nation's top policy experts and former health policy director for Senate Majority Leader William H. Frist, serves as Breakaway's president and CEO.

"Federal and state policymakers are reshaping the future of healthcare daily," Mr. Rosen says. "No matter what policies are written or how healthcare may change, Breakaway understands policy details, knows the decision makers, and is closely connected to the system in which these decisions are taking place."

Breakaway tracks policy developments at the state and federal level, providing timely, comprehensive reports, including the Weekly Breakdown Newsletter, the Monthly Affordable Care Act (ACA) Implementation Guide, and in-depth analysis of topics such as Medicare Physician Payment Reform. Beyond research, Breakaway's approach to policy analysis provides strategies for the real world.


Janet Woodcock

FDA Forms Program Alignment Group

For the **FDA** to best adapt to the ongoing rapid changes in the regulatory environment, driven by scientific innovation, globalization, the increasing complexity of regulated products, new legal authorities, and additional user fee programs, FDA Commissioner Margaret A. Hamburg, M.D., has formed a Program Alignment Group (PAG). Comprised of senior agency leaders, the PAG is charged with identifying and developing plans to modify FDA's functions, processes, and possibly its structure to address these matters and best achieve mission-critical agency objectives.

This initiative provides an opportunity for CDER to continue modernization of operations in order to address the challenges and to implement the new legislative responsibilities, including those imposed by the FDA Safety and Innovation Act and the Generic Drug User Fee Amendments of 2012 (GDUFA).

Many of CDER's current modernization efforts center around the regulation of pharmaceutical quality. Most are aware of the proposed elevation of the Office of Generic Drugs to a super office, and the concomitant efforts to establish a new Office of Pharmaceutical Quality (OPQ). The work to establish OPQ will need to be closely coordinated with the Office of Regulatory Affairs (ORA).

"We recognize that to accomplish GDUFA and other commitments, CDER and ORA need to have an integrated program for regulating pharmaceutical quality, with well-defined leads, coherent policy and strategy development, well-designed and coordinated policy implementation, and a de-layered management structure," says Janet Woodcock, M.D., the director of the Center for Drug Evaluation and Research (CDER). "Moving toward this new model will take time and a level of organizational change across CDER and ORA, including streamlining management and decision making and clarifying roles and responsibilities, metrics, and accountability, and decision rights. Similar considerations apply to other inspectional programs."

INC Research Offers Clinical Research Monitor Credential

INC Research has launched a new **CLINICAL RESEARCH MONITOR ACCREDITATION** program aimed at standardizing the training of its CRAs.


Alistair Macdonald

"The Clinical Credential program validates INC Research monitors' capabilities against globally recognized best practices, including recognition and reporting of adverse events, understanding regulatory processes, preparing for successful site initiations and site visits and more," says Alistair Macdonald, chief operating officer. "Customers can, therefore, be confident the CRAs assigned to their studies are not only well-trained and field tested, but also that their skills have been certified against an independent quality standard."

Launched in response to the industry's growing demand for accreditation of clinical research professionals, the credentialing process focuses on independent verification according to International Academy of Clinical Research standards of an individual's ability to monitor clinical trials effectively in real-life situations.

GSW Launches iQ.3Dbooth to Enhance the Virtual Trade-Show Experience

GSW, an **inVentiv Health company,** has released **IQ.3DBOOTH,** an immersive virtual reality (VR) application that brings a vivid trade show experience to computers, iPads, and other tablet devices. Optimized for the pharmaceutical industry, the app enables drug companies to give physicians and other customers an interactive tour of their products, expanding the potential audience and extending the life of the exhibit.


Joe Daley

"The experience is completely engaging and is the next best thing to actually being there in person, but without the hassles and expenses of travel," says Dean Thornberry, VP of product marketing at GSW. "For viewers, they get to stay home. For marketers, they get to extend the trade show well beyond the show date and reach a larger audience on a broad, global scale."

With iQ.3Dbooth, GSW can provide all the functional requirements and options pharma companies require on a pre-packaged technology platform, in a fraction of the time, and at a lower cost. The marketer can now promote the product in an exciting fashion on almost any device or browser before, during or after the event.

"3Dbooth is another example of the commitment GSW has shown toward new product development," says GSW President Joe Daley, who explained that the app is just one of many such products in the pipeline. "We will continue to innovate based on learnings from the front-lines of healthcare and we'll develop new products like this to fit the ever-changing needs of physicians."

Creating a virtual booth with iQ.3Dbooth takes just a few steps. First, the vendor creates a physical model of the booth. Next, the creator of the booth assigns locations where each of these "assets" will reside in the computer-generated model. GSW receives then loads the data onto a server and sends the vendor a passcode or token, which is typed into the login screen on the iPad app. PV

WHAT'S NEW ON THE SHELVES

The Regulatory Affairs Professionals Society (RAPS) has published a new book that covers the regulation of pharmaceutical marketing and promotions by the FDA. The book, FDA Requirements for Prescription Drug Promotion, by John Driscoll, addresses topics such as fair balance, material facts, off-label promotion and Internet and social media communications.

The book's first chapter, Prescription Drug Labeling, is publicly available online. Mr. Driscoll devotes other chapters to FDA's Office of Prescription Drug Promotion, product claim requirements, preapproval and promotion to healthcare professionals, and direct-to-consumer promotion.

For more information, visit raps.org.