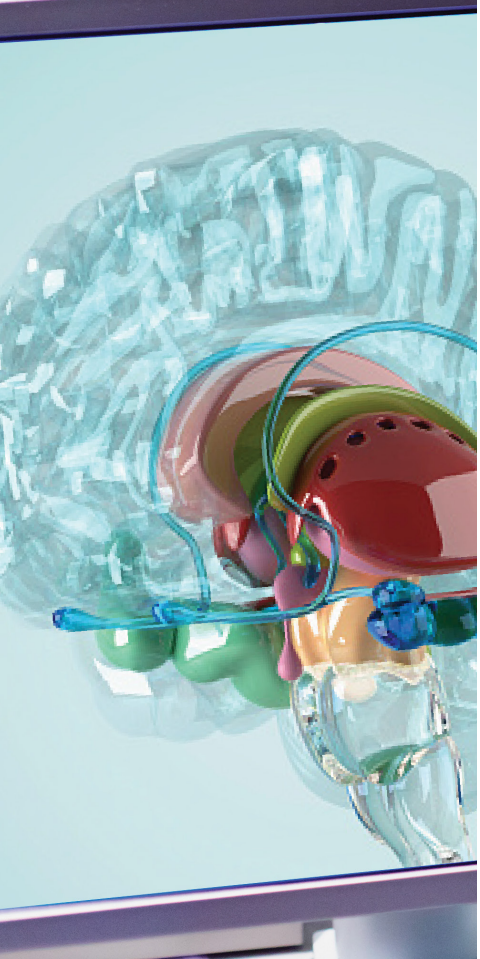
SIDLEY



LIFE SCIENCES ROUNDTABLE

MUST-HAVE STRATEGIES ON DIGITAL HEALTH

A DAY OF ROUNDTABLE TALKS WITH THOUGHT LEADERS ON PRIVACY, BIG DATA AND TAKING A MORE PROACTIVE APPROACH WITH REGULATORS

These are exciting times for the life sciences industry. Its players, drivers of global innovation, are embracing products and services that blur and stretch the boundaries between technology and healthcare. Yet industry participants are also contending with knotty challenges on this emerging terrain involving privacy and security, products that seemingly defy regulatory categories, and lagging business models that must morph if they are to keep pace with consumer demand.

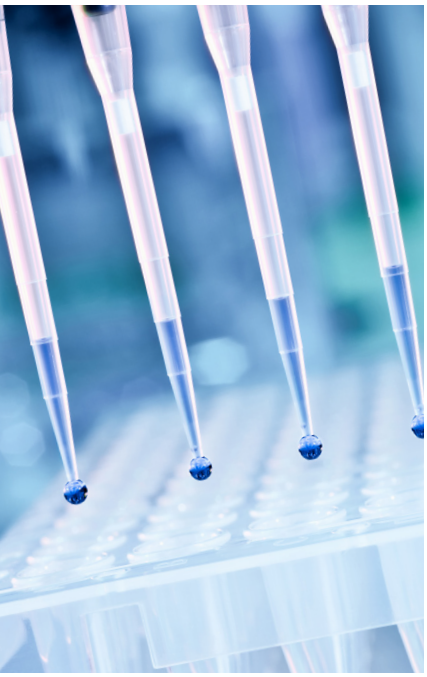
Keys to success on this evolving landscape include:

- Cross-industry collaboration
- Strategic business planning on the regulatory side
- Understanding how health data is best collected and harnessed

So said leading investors, general counsel and strategists in a provocative series of panel discussions featuring thought leaders from companies including Genentech, GE Ventures, Intel (Internet of Things Group), 23andMe and Roche Molecular. The panels were hosted by lawyers Jennifer Fitchen, Sharon Flanagan, Joshua Hofheimer, Coleen Klasmeier, Edward McNicholas, Anna Spencer, Nancy Stade and Sam Zucker of Sidley Austin LLP.

"As life sciences and technology converge, our clients are coming to us for advice on legal concerns that they've never before encountered," said Flanagan, managing partner of Sidley's San Francisco office. "This inspired us to put together an event that would bring together colleagues with leadership from across industries to share their experiences in the new frontier of digital health."

The day's roundtable talks—held fittingly at Mission Bay Conference Center at UCSF, a hub of bioentrepreneurship—spanned wearable devices and surveillance, cross-industry alliances, big data, relationship building with the FDA and even waxing eloquent on the philosophical underpinnings of the Internet.



WHEN TO FIGHT AND WHEN TO FOLD

Regulatory strategy and the FDA

Transformative health products and services challenge traditional regulatory models. Inevitably differences of opinion occur on the path toward market authorization and beyond. In a roundtable talk on integrating regulatory strategy into business planning, Klasmeier, who leads Sidley's Food, Drug and Medical Device Regulatory practice, asked of her panelists, "Can you disagree with the FDA and survive?".

"Absolutely," said Michael Listgarten of Genentech, who said his company had done so successfully in the past by being highly strategic. "We strengthened the relationship because we handled the process in a way that was really respectful," he said.

Stade, a partner at Sidley and former Deputy Director for Policy, Center for Devices and Radiological Health at the FDA, agreed with Listgarten's approach. She advised that companies should pursue formal appeal procedures when disagreements arise rather than butting heads with the review team or other staff. "That might be damaging to you, particularly if additional products come up later before the same team."

Stade said companies should not forgo dispute processes because of fear of reprisal when they have a legitimate scientific or regulatory basis for challenging the FDA's actions because the officials who hear appeals view the process as part of doing business. "You might not at the end of the day get exactly the resolution you are looking for, but you will decrease the odds of reprisal, and increase the odds for a successful appeal or at least a mediated solution."

Kathy Hibbs, Chief Legal and Regulatory Officer at 23andMe, who was also a panelist, shared insight into what has been one of the most high-profile regulatory issues involving direct-to-consumer (DTC) genetic tests. Hibbs worked for two years with the FDA to gain approval for the 23andMe test—after the agency told it to stop presenting health data and ordered it off the market in 2013. The company was successful in relaunching a more limited series of DTC tests last year.

Hibbs recalled the painstaking process of moving from the aftermath of the FDA's warning letter to market authorization, which she said included reading the three thick binders of correspondence between 23andMe and the FDA about nine times. "I was able to tell them, 'I've read it; I understand the level of work that the agency has put in over the years in giving feedback. We're going to get back to you but we're going to do so in a way that will understand some of the regulations and takes into account the feedback. So I am going to have questions for you but they're going to be informed,'" Hibbs said.

Her approach was well received and helped pave the way for a fruitful collaboration. "The door was open from day one. Ultimately, if you have a solid relationship and they trust you, they will be more inclined to trust your judgment," she said.

Nonetheless, Klasmeier cautioned counsel in interpreting signals from government. "When the director of CDRH says you have a great product that doesn't mean you get a pass."

> "Can you disagree with the FDA and survive?"
>
> —COLEEN KLASMEIER

"People are becoming more comfortable giving their health information because it can deliver what they need."

—REESE JONES

"IT'S A BIT LIKE SURVEILLANCE"

Navigating the digital health opportunity

In addition to the regulatory concerns, inventors of groundbreaking products must also contend with complex privacy and security issues. The Health Insurance Portability and Accountability Act (HIPAA) privacy regulations, first proposed in 1999, pre-date the iPhone, the completion of the human genome project and the widespread adoption of electronic medical records. The rules were clearly not designed with digital health in mind. As a result, we're seeing new technologies seriously test the boundaries of the law.

"Our health is in our phone, tracked by global companies that don't consider themselves subject to regulatory rules," said Reese Jones of Singularity University. He was a panelist in a roundtable discussion on digital health, moderated by Spencer, a partner at Sidley who focuses her practice on the privacy and security of health information.

Jones got to the heart rather quickly of the great promise, and potential legal concerns, inherent in mobile health applications and other components under the ever-widening rubric of digital health. He cited the important privacy concern that intimate health data can be collected from mobile phones even when they aren't on. "It's a bit like surveillance," he said. Yet Jones also pointed out the pioneering benefits—that tracking our whereabouts and habits can yield data that can be predictive of a health problem such as heart attack or diabetes. "There are downsides in privacy but upsides, too," Jones said, adding, "People are becoming more comfortable giving their health information because it can deliver what they need."

Businesses can avoid issues surrounding patient privacy and data security by identifying product and process vulnerabilities early on, said Josh Stein of AdhereTech, a company that produces bottles with sensors that track medication adherence. Stein says he engaged legal counsel at the outset of his product's development to assess how to best comply with regulations, how patient information should be stored on the company's servers, and even on the design of his product. Doing so, Stein said, "was a valuable investment for us."

He says AdhereTech dealt with consent issues surrounding HIPAA by having patients opt-in to use his company's bottles, which are marketed to top hospital systems and pharmacies. Securing patient consent is important to being able to process sensitive health-related information, but it can be tricky to implement with the Internet of Things, especially where there is no direct interface with a consumer.

To the idea of monetizing patient data, Stein said, "Absolutely not. It would put our customers at risk."

Michael Taborn of Intel Internet of Things Group, echoed concerns regarding privacy and data security. He pointed out that medical equipment can last a long time and is expensive to replace. Such pieces, he said, in effect put data vulnerabilities literally at the bedside of patients. "Healthcare companies place patient safety and health at the top of everything they do, but they need to be more vigilant regarding security," Taborn said.

PLAYING IN SOMEONE ELSE'S SANDBOX

Cross-industry alliances

But how do healthcare companies harness the talent and management needed to move their businesses to the forefront of technological innovation? They seek out novel strategic partnerships and third-party collaborations as they expand their operations to offer products and services that test the boundaries of traditional healthcare.

A panel moderated by Hofheimer, a partner at Sidley who represents clients in the biotech, medical device, agribusiness and food, and information technology sectors, offered up some practical considerations on how to bring together different cultural mindsets from university think tanks and the business community.

"Nail down the business model for what is expected in terms of value for both parties," said Sarah Jane Militello of Samsung Digital Health Innovation Lab. "Think through 'What is success?' then put the infrastructure in."

The panelists, who also included Matthew Gunnison of General Electric Ventures and Kevin Marks of Roche Molecular Diagnostics, agreed that strong communication and transparency of process are vital to cross-industry projects. These ideals, they said, will aid in defining clearly the key goals and the criteria for success in measurable terms.

There will invariably be bumps in the road in such endeavors. "Maintain flexibility, and be prepared to pivot, while staying true to the overall goals," advised Marks. Gunnison offered simple, if sage advice: "Define the rules of engagement, pick the right talent and have good management there as a guide."

GETTING META ABOUT DATA
Monetizing big data

Big data can be analyzed for insights that lead to strategic business opportunities. Yet, traditional, coded clinical data sets still dominate the life sciences big data landscape. Companies as yet do not have the abilities to analyze real-time information feeds to predict, and potentially even prevent, negative outcomes. A panel moderated by McNicholas, a co-leader of Sidley's Privacy, Data Security, and Information Law practice, highlighted some of the complexities.

Part of the problem, said Andro Hsu of Syapse, is that "Data systems don't talk to each other and are not designed to capture what is going on biologically and in diagnostics." He said health systems, for example, have difficulty tracking things that aren't billable.

Vicki Seyfert-Margolis of My Own Med said that a lot of clinic metrics are being missed, including valuable data about a patient's location, culture and economic status. "Knowing more accurately who is being managed will help healthcare systems develop better models for individual populations. That would yield valuable information," she said, adding that research is rapidly moving from "blockbuster to niche indication."

Seyfert-Margolis also underlined the tension between the data derived from traditional healthcare settings and what is captured from technologies such as mobile health apps. "The quality of data coming from these devices needs work," she said. "Defining clinical practice versus what is a regulatable device—an algorithm versus clinical practice. We are still working through those definitions."

"TECHNOLOGY IS SO FUN AND SEDUCTIVE"

Despite all the recent technological advances and ones on the horizon, it's important to keep perspective, to always be skeptical. So said Jaron Lanier, a philosopher and computer scientist, in an irreverent keynote address. He was introduced by Sam Zucker, a partner at Sidley who concentrates on corporate transactions for high-growth, life sciences, healthcare and technology companies.

Lanier implored of the day's attendees and Silicon Valley at large, "Don't drink your own whiskey." He was seeking to drive home the point that technology, although "fun and seductive," is not perfect. Discussing its faults, while unpopular, is worthwhile—even a moral imperative—so we can use it well.

Contacts

Jennifer F. Fitchen
Partner
Palo Alto
jfitchen@sidley.com
+1 650 565 7122

Sharon R. Flanagan
Partner
San Francisco
sflanagan@sidley.com
+1 415 772 1271

Joshua Hofheimer
Partner
Los Angeles
jhofheimer@sidley.com
+1 213 896 6061

Coleen Klasmeier
Partner
Washington, D.C.
cklasmeier@sidley.com
+1 202 736 8132

Edward McNicholas
Partner
Washington, D.C.
emcnicholas@sidley.com
+1 202 736 8010

Anna Spencer
Partner
Washington, D.C.
aspencer@sidley.com
+1 202 736 8445

Nancy Stade
Partner
Washington, D.C.
nstade@sidley.com
+1 202 736 8364

Sam Zucker
Partner
Palo Alto
szucker@sidley.com
+1 650 565 7111

MN-4088 7/16