HealthTech:
What does it mean for compliance?

May 2018

Building a better working world

Agenda

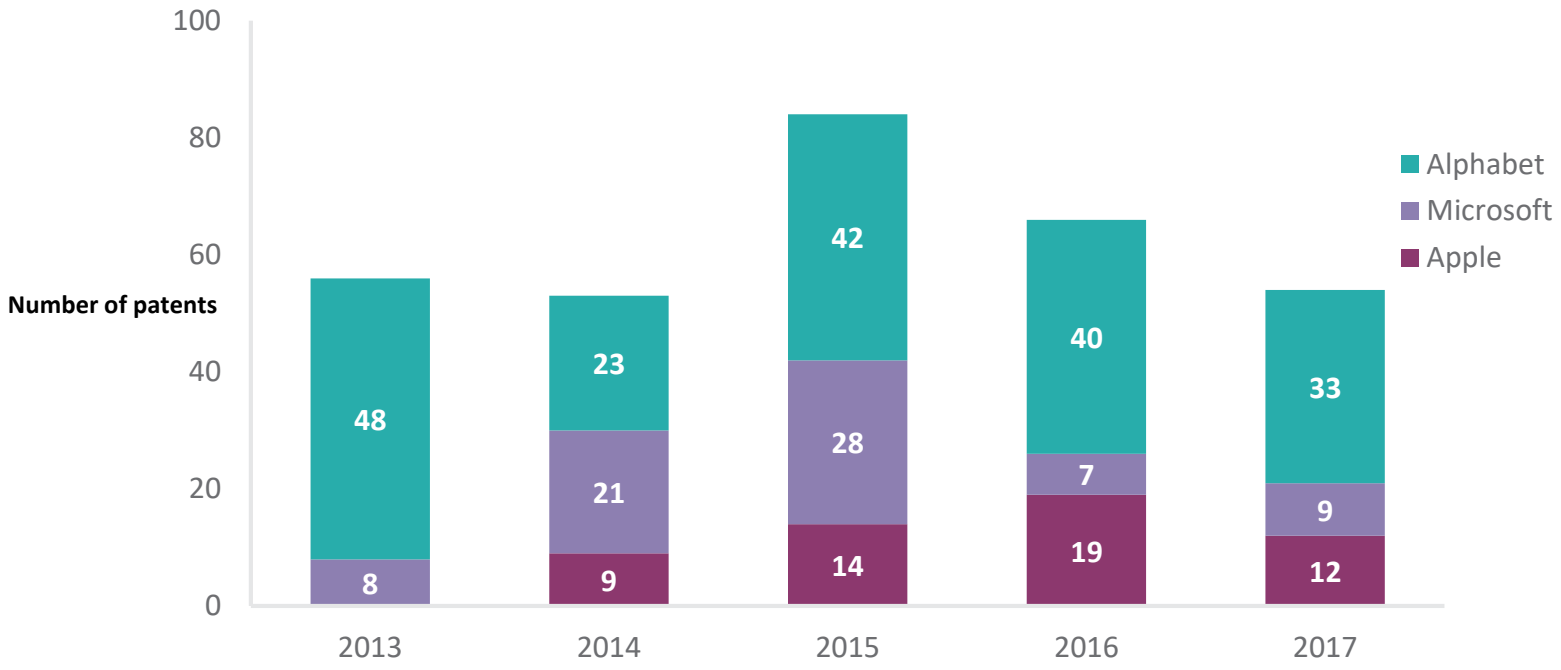
11:15 AM — 11:30 AM	**Introduction** Kathleen Meriwether, Americas Leader - Life Sciences Fraud Investigation & Dispute Services, EY
11:30 AM – 12:15 PM	**Panel** Oba Adewunmi, Legal Counsel, Verily Life Science Trish Gatley, Director of Corporate Compliance, Illumina Lori Russell, Global Ethics & Compliance Officer, bioMérieux Kathleen Meriwether, Americas Leader - Life Sciences Fraud Investigation & Dispute Services, EY Moderator: Ingmar de Gooijer, Director, Public Policy & Reimbursement, myTomorrows
12:15 PM — 12:30 PM	**Wrap-up and Q&A**

Health and Life Sciences 4.0

- **Data-driven Outcomes**
  - The ubiquity of data creates new opportunities for life sciences companies, including medical device and medical technology companies, to rethink innovation and work towards personalized health outcomes that the wider ecosystem of health stakeholders are demanding
- **Platforms to provide personalized precision medicine**
  - Platforms that connect, combine and share data will be a central enabler of this future value creation
- **Health companies will become data companies, and vice versa**
  - These platforms create a mechanism for companies to quickly and safely tap into diverse data streams and link them to scientific and clinical data
  - Companies will also need to consider developing new capabilities linked to customer engagement, personalization and data literacy that are central to emerging platforms of care
- **Transforming business models also transforms company risk profiles**
  - Life sciences companies may begin to access data capabilities by building them organically or through flexible partnerships or acquisitions
  - These customer-focused capabilities will help life sciences companies create shared value for themselves and health stakeholders across the ecosystem, but also come with inherent compliance risks

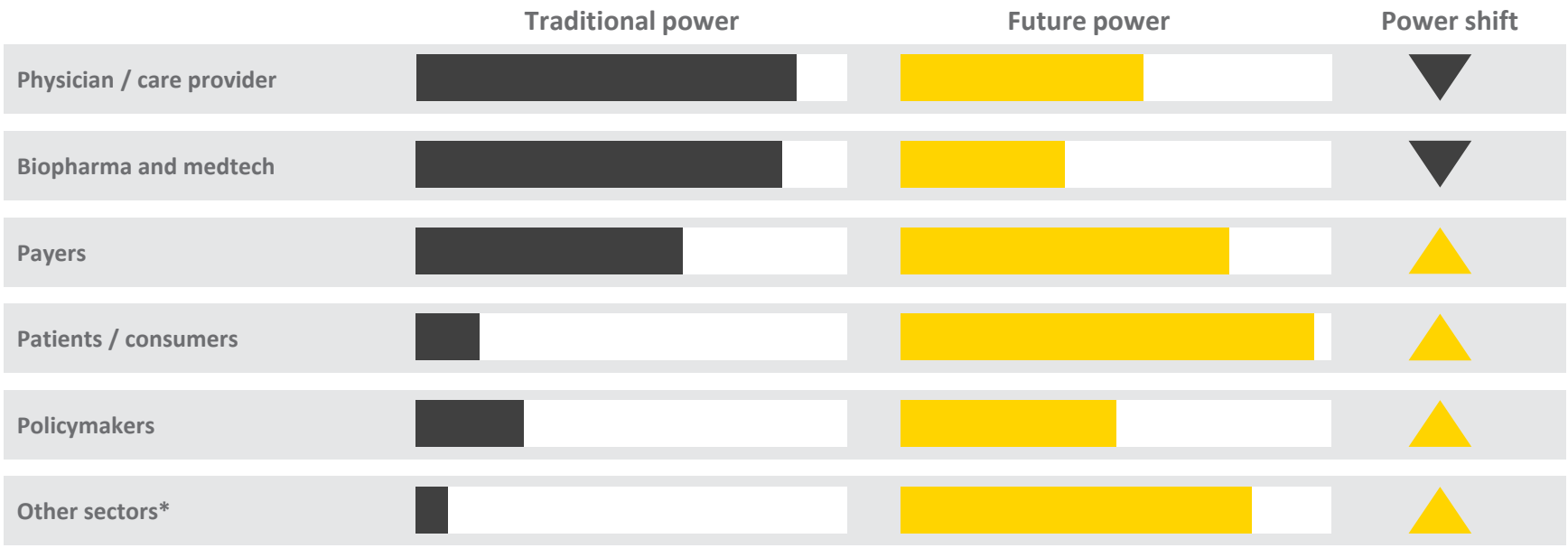
Technology giants are already significantly investing in health, blurring the lines between health and technology

US health care patent applications by technology giants



Source: EY, United States Patent and Trademark Office. Analysis as of 31 January 2018. Analysis is based on year of patent filing filtered by company for select search terms in the patent abstract or claim: health, medical, patient, disease, wellness and physical activity.

Technology advancement and disruption are creating opportunities for power to shift amongst stakeholder groups



** "Other sectors" includes retail, technology, manufacturing and industrial products, and consumer products.*

Evolving regulatory environment

- **Innovation will precede regulation**
  - Health and life sciences companies will be operating in an area of ambiguity
  - Compliance professionals must provide a framework to provide guidance and tone for employees to make proper decisions that are consistent with their organization's culture.
- **Partnering with Regulators**
  - Industry companies must work with regulators to shape policies that make expanded volumes of clinical and real-world data more accessible
  - Close cooperation between companies and regulators will also be needed to validate the use of digital technologies that will generate future clinical data and treatment paradigms
  - US Example: U.S. Food & Drug Administration's Software Precertification Pilot Program, which brings together technology and life sciences constituents, is just the latest initiative to create regulations that may be more in line with the digital health revolution.

Evolving compliance considerations

- **Compliance effectiveness:** How does compliance effectively keep abreast of business and technology developments, assess the associated risks and provide guidance to business partners?
- **Regulatory partnership**: How do you effectively partner with regulators and industry peers to help shape the future regulatory landscape?
- **Third-party risk**: How do you effectively assess the risks of third-party technology companies who are new to the industry and may not be sensitive to requirements?
- **Standards/Education**: How do you create meaningful principles-based standards for the business, and provide sufficient training so your organization is well-educated on new, evolving risks so people can make the right decisions?
- **Data privacy:** How to you remain compliant with data privacy requirements, while also remaining competitive in utilizing technology advancement?
- **Global considerations:** How do organizations manage patient privacy rights and data protections risks differently across Europe and the Americas?
- **Patient consent:** What do patients need to consent to? At what level of detail? When you obtain consent, to what extent/for how long can you use the data?

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