

Morgan Lewis



#ML15MayRathon

HOT TOPICS IN DIGITAL HEALTH

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About Morgan Lewis Tech May-Rathon

- Morgan Lewis is proud to present Tech May-Rathon, a series of programs focused on current issues, trends and developments that are of key important to technology industry companies
- This year is our 5th annual May-Rathon and we are offering more than 16 in-person and virtual events
- Recordings of all of our Tech May-Rathon programs can be found at www.morganlewis.com
- Be sure to Tweet!  [#ML15MayRathon](https://twitter.com/ML15MayRathon)

Panelists



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Andrew Ray represents public and private companies, financial sponsors, and management teams in a broad range of corporate and finance matters. Additionally, he counsels extensively in the telecommunications, media, and technology (TMT); government contracts; energy; and financial services sectors. Various industry publications recognize Andy as a leader in both M&A and in communications. He recently led the team representing Oculus VR in its \$2 billion sale to Facebook, which was named the M&A Advisor M&A Deal of the Year.



**Andrew Ruskin,
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Andrew Ruskin counsels hospitals, pharmaceutical and medical device companies, and Medicare Advantage plans, among others, on a range of Medicare and Medicaid regulatory, litigation, and transactional matters. Andy advises on strategic issues surrounding coverage, reimbursement, and compliance, as well as drug pricing and price reporting. He defends clients in investigations by the US Attorney's Office and the Department of Health and Human Services Office of Inspector General, and he appears before several regulatory tribunals, such as the Provider Reimbursement Review Board and the HCPCS Committee.

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Carl Valenstein focuses his practice on domestic and international corporate and securities matters, mergers and acquisitions, project development, and transactional finance. He counsels extensively in the life science, telecom/electronics, and maritime industries, and he has worked broadly in Latin America, the Caribbean, Europe, Africa, Asia and the Middle East.



**Michele Buenafe,
Associate**

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Michele L. Buenafe advises clients on regulatory, compliance, and enforcement issues related to the development, manufacturing, marketing, labeling, and advertising of medical devices, human tissue products, pharmaceuticals, controlled substances, listed chemicals, and combination products. She also advises clients on emerging legal issues relating to mobile medical apps, clinical decision support software, telemedicine systems, wearable devices, and other health information technology.

Panelists



**Joe Statter,
President of
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Joe is President of Evergreen Advisors Capital and oversees our Northern Virginia Office of Evergreen Advisors in Tysons Corner. Over the course of his 25-year career in principal investing, financial management, public accounting, and investment banking, Joe has executed a broad spectrum of transactions including: convertible and high yield debt, IPOs and follow on equity offerings, private placements of debt and equity, mergers and acquisitions, and restructuring/bankruptcy advisory engagements. His expertise spans multiple industries, transaction types, and stages of company development. Over the past 15 years, Joe has been focused on advising high growth companies across the converging value chains of the communications and media industries.

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Agenda

- Introduction
- Organizing Digital Health
- Deal Landscape
- FDA Hot Topics
- Reimbursement Hot Topics
- Q&A

Organizing Digital Health

Patient Engagement

Care Coordination

Data Capture via Wearables and Sensors

Data Analytics/Predictive Analytics

Interoperability Tools and Technologies

Deal Landscape

- 2014 was a record year in funding with over \$4B. 2 x 2013. First quarter 2015 at slower pace.
- Top six digital health categories by venture funding are analytics/big data, healthcare consumer engagement, EHR/clinical workflow, digital diagnostics, population health management and digital medical device.
- There were 33 digital health M & A transactions in 2014. 2 x 2013. 2015 deals include Under Armour acquisition of MyFitnessPal, Athenahealth's acquisition of Razorinsights and webOMR and Fitbit's acquisition of FitStar.
- There were five digital health IPOs in 2014 (Carecom, Castlight, Everyday, IMS and Imprivata) but several are trading down post IPO. The 2015 IPO pipeline includes Fitbit and Teladoc with several others rumored to be about to file.

Sources: RockHealth and Mobilhealthnews

FDA Hot Topics

- FDA Guidance – Mobile Medical Applications (finalized Sept. 25, 2013, updated Feb. 9, 2015)
 - Describes “FDA’s intentions to focus its oversight on a subset of mobile apps,” that “pose[] the same or similar risks to the public health as currently regulated devices if they fail to function as intended.”
 - Identifies three categories of apps: regulated, subject to enforcement discretion, and not regulated
- FDASIA Health IT Report (issued on Apr. 3, 2014 by FDA, ONC, and FCC)
 - Provides a proposed strategy and recommendations for the regulation of health IT
 - Proposes a limited approach that “relies on ONC-coordinated activities and private sector capabilities”
- FDA Draft Guidance – General Wellness: Policy for Low Risk Devices (Jan. 20, 2015)
 - Would exempt from FDA oversight products that:
 - Are intended only for general wellness uses, and
 - Present a very low risk to users’ safety

FDA Hot Topics

- FDA Draft Guidance – Medical Device Accessories: Defining Accessories and Classification Pathway for New Accessory Types (Jan. 20, 2015)
- FDA Guidance - Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices (finalized Feb. 9, 2015)
- Anticipated FDA Draft Guidance on Clinical Decision Support Software
 - Expected before the end of FY2015 (Sept. 30, 2015)
- Potential legislation
 - 21st Century Cures Act
 - SOFTWARE Act and MEDTECH Act
- Recent FTC Enforcement
 - January 2015 complaint against Focus Education, LLC
 - February 2015 actions against MelApp and Mole Detective
 - FTC enforcement thus far is generally consistent with FDA's policies for mobile medical apps and other digital health products
- Ex-US regulation

Medicare Hot Topics

- Payment Fundamentals
 - Payment building blocks:
 - Coverage
 - Coding
 - Reimbursement
 - Coverage is a concept regarding whether payment is sometimes available or is categorically excluded
 - Related concept of “benefit category”, such as vision care or dental, versus medical

Medicare Hot Topics (*cont.*)

- Payment Fundamentals (*cont.*)
 - Coding means that, if it cannot be identified, then it cannot be paid for
 - CPT codes
 - HCPCS codes
 - Payer-specific codes

Medicare Hot Topics (*cont.*)

- Payment Fundamentals (*cont.*)
 - Payment encompasses the conditions of payment as well as the payment rate. There are separate payment methodologies for (among others):
 - Hospital inpatient payment
 - Pay for performance trend
 - Hospital outpatient payment
 - Physician payment
 - Home health payment
 - Durable medical equipment payment
 - These payments are all prospective, meaning no separate payment to cover costs

Medicare Hot Topics (*cont.*)

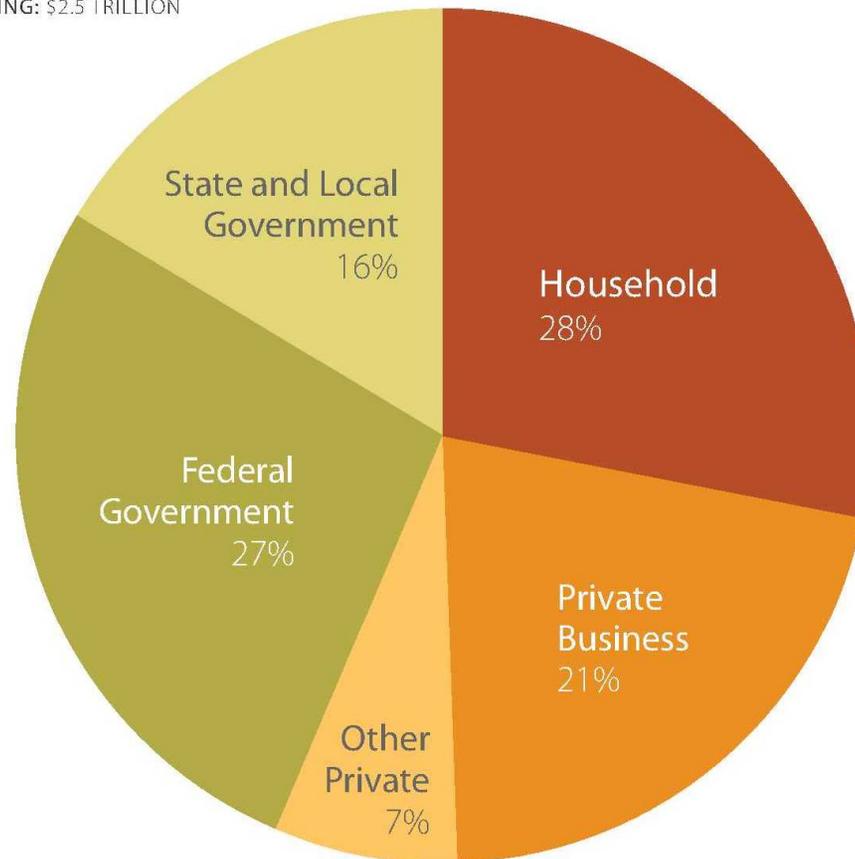
- Is payment available for HIT?
 - It depends. First question is one of benefit category.
 - There is no benefit category for such items as wearable technology that do not require a physician prescription and physician interpretation
 - HIT used in a hospital by clinicians may fall within the covered costs of care, but there is no separate payment
 - Technology that reduces hospital costs will be very appealing

Medicare Hot Topics (*cont.*)

- Is payment available for telehealth?
 - It depends on your definition of telehealth
 - For Medicare, telehealth means that there is a practitioner in one location and a patient at another location who are using audio and visual technology to communicate in real time
 - There are very few procedures that are covered using telehealth
 - The patient must be at a site that is rural or is in a health professional shortage area
 - Medicare laws do not pre-empt State laws, which put some physicians at danger of being found to have practiced medicine without a license

Medicare Hot Topics (*cont.*)

TOTAL SPENDING: \$2.5 TRILLION



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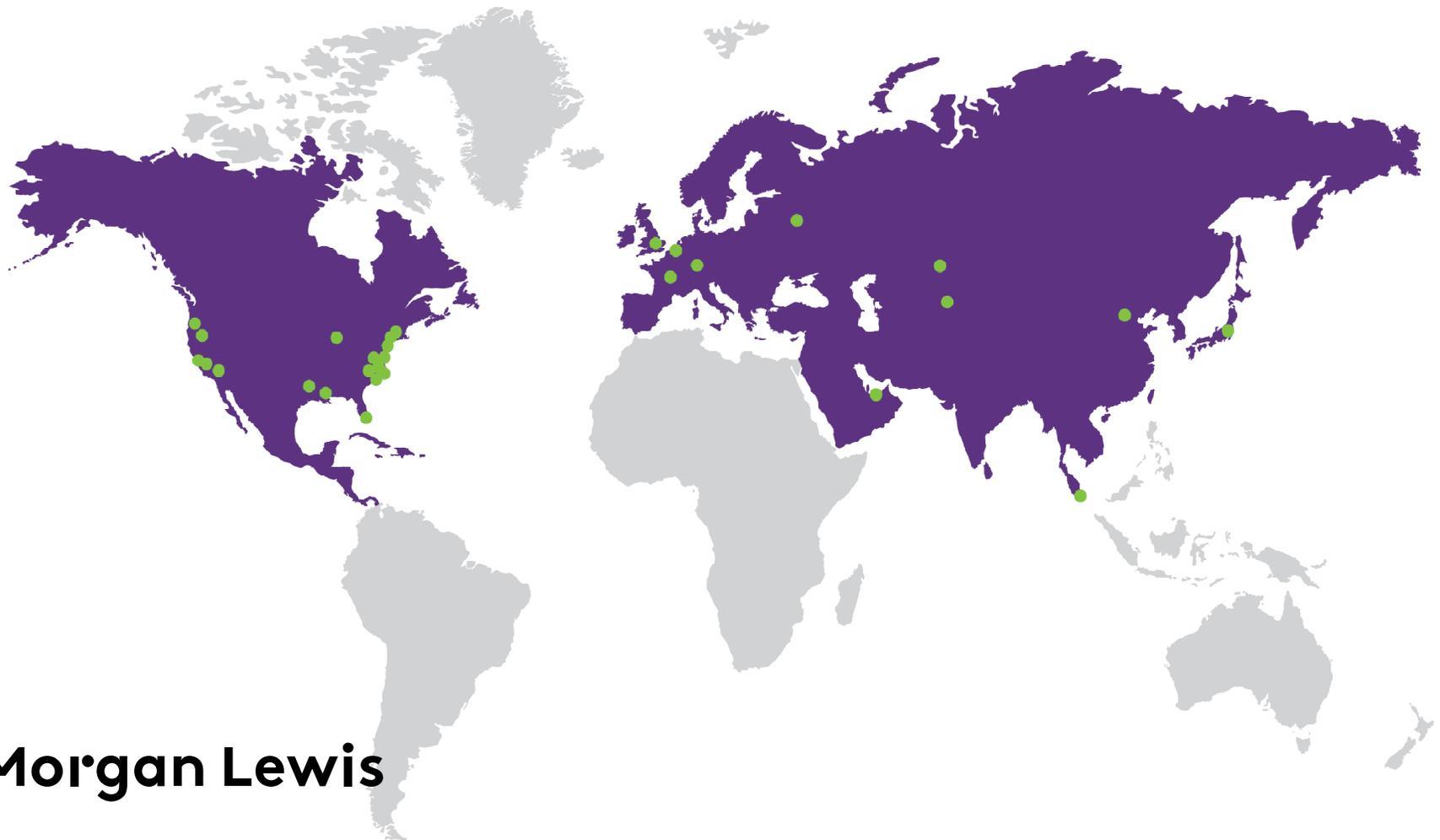
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