Morgan Lewis

HOSPITAL DEVELOPED TECHNOLOGIES

KEY FDA REGULATORY ISSUES

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Hospital Developed Technologies

- Hospitals are increasingly looking for technological solutions to better serve their patients, leverage patient data, and meet quality metrics:
  - In vitro diagnostics (IVDs)
  - Laboratory developed tests (LDTs)
  - Health information technology
  - Clinical decision support software
  - Telehealth systems and devices
  - Remote patient monitoring
  - Remote consultations
  - Big data/data analytics


IN VITRO DIAGNOSTICS
& LABORATORY
DEVELOPED TESTS

Factors Driving the Development of IVDs and LDTs

- Precision medicine initiative
- Cancer “moonshot”
- Pressure to reduce healthcare costs
- Ability to quickly translate impactful research findings to the clinic

Regulatory Challenges for Marketing IVDs or LDTs

- IVD exemptions not clearly understood by all stakeholders

- Uncertainty for future regulation of LDTs
- Uneven regulatory oversight

- High profile enforcement actions

FDA Regulation of IVDs

- *In vitro* diagnostic devices (IVDs) are regulated by FDA as medical devices
- Extent of regulation depends on the application device classification for the IVD
  - Class I - General Controls
  - Class II - General Controls, Special Controls, and 510(k) Clearance
  - Class III - General Controls and PMA Approval

Laboratory Developed Tests

- LDTs traditionally exempt from active FDA regulation
- Exemption applies only when the LDT is developed, manufactured, and used internally by a single clinical laboratory
- The clinical laboratory should meet the requirements for high-complexity testing under CLIA
- FDA's policy for LDTs does not apply to tests:
  - Developed by one lab and transferred to another
  - Sold by a laboratory to third parties (e.g., device manufacturers)
  - Designed or manufactured by a third-party contractor for a laboratory
  - Marketed for direct-to-consumer testing

FDA Proposal for Regulation of LDTs

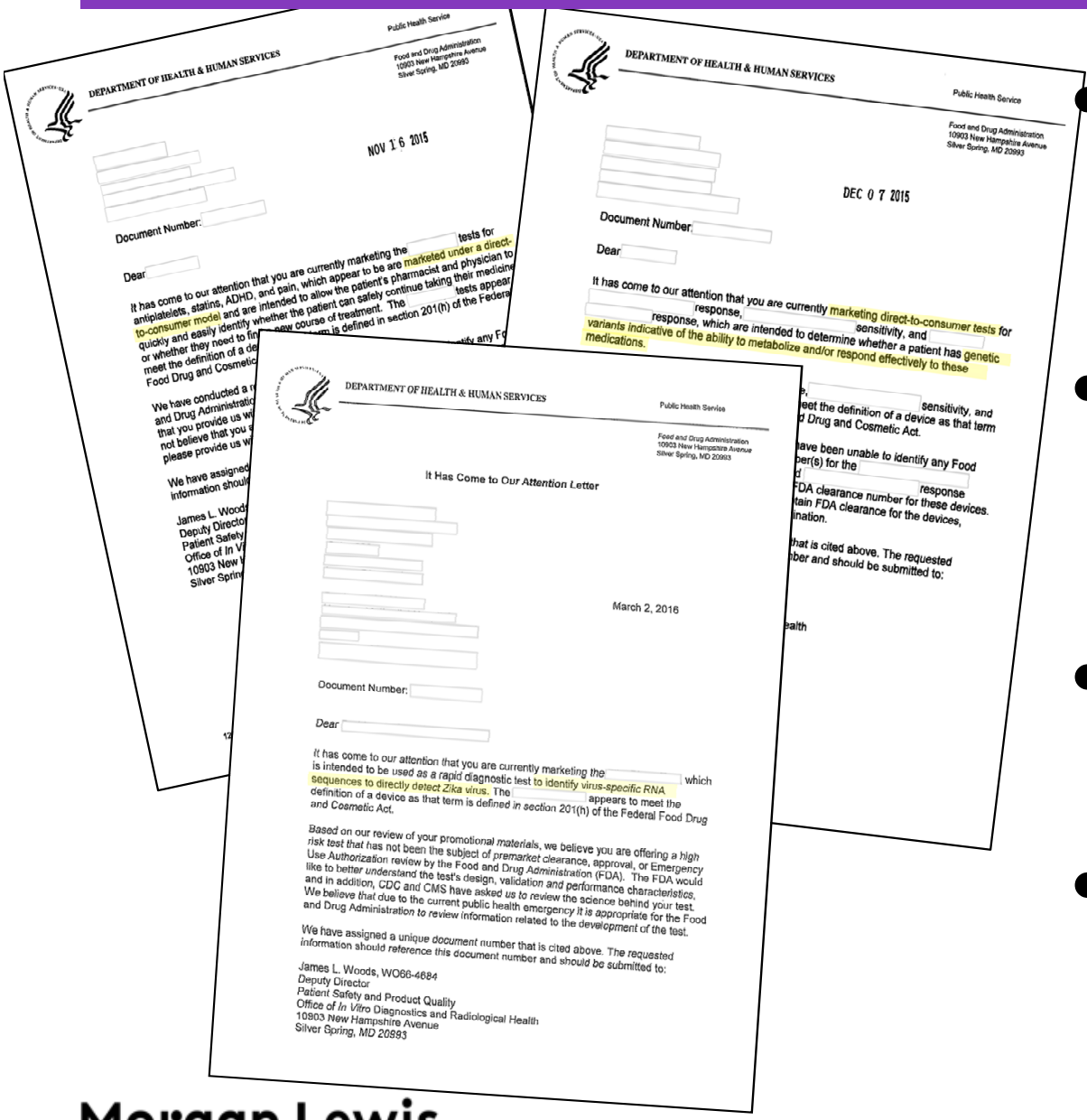
- 2014 Draft Guidance – Framework for Regulatory Oversight of Laboratory Developed Tests
  - Continued full enforcement discretion for:
    - LDTs used solely for forensic use
    - Certain LDTs for transplantation when used in CLIA certified labs
  - Continued enforcement discretion for premarket review and QSR requirements for:
    - Low-risk LDTs
    - LDTs for rare diseases and "traditional LDTs"
    - LDTs for unmet needs
  - Phased-in compliance timeline high- and moderate-risk LDTs

Other IVD Exemptions

- Research Use Only (RUO)
  - Diagnostic products that are in the laboratory research phase of development and do not yet have FDA clearance or approval
  - May be marketed for non-clinical research
  - May not be marketed for clinical research or clinical diagnostic use

- Investigational Use Only (IUO)
  - Diagnostic products that are in the clinical trial research phase of development and do not yet have FDA clearance or approval
  - May be marketed for investigational diagnostic use, in compliance with FDA's Investigational Device Exemption (IDE) regulations
  - May not be marketed for non-investigational diagnostic use

FDA Enforcement for IVDs and LDTs



- Unapproved Zika tests
- Tests marketed direct-to-consumer
- Genomic tests
- Tests developed by one entity and transferred to another

Recent Developments and Ongoing Issues

- Uptick in FDA guidance documents
- Continued industry opposition to LDT regulation
- CLIA enforcement
- Senate HELP Hearing

IVDs and LDTs


HEALTH INFORMATION
TECHNOLOGY & DIGITAL
HEALTH

Increased Demand for Digital Health Technologies

- Big data/data analytics
- Increased demand for telehealth services
- Desire to leverage EHR data
- Leveraging technology to improve quality metrics
- Remote monitoring to reduce patient readmissions

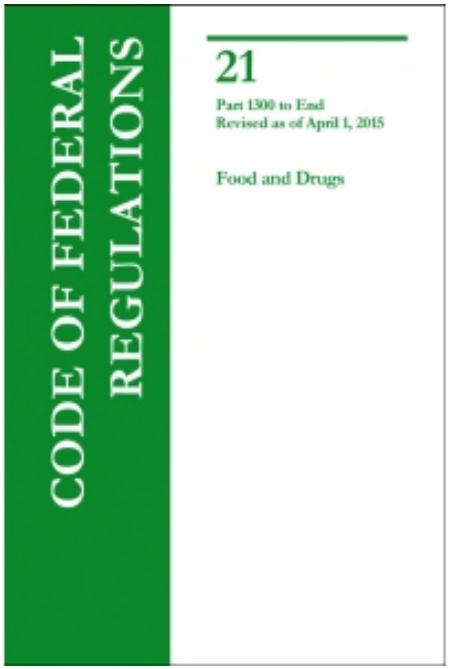
Current FDA Regulatory Climate

- Factors creating uncertainty regarding the current regulatory status of health IT and other digital health technologies:

  - Recent actions by FDA to deregulate low-risk digital health technologies
  - FDA's use of enforcement discretion
  - Outstanding gaps in FDA guidance
  - FTC enforcement and regulation
  - Congressional legislation

Assessing the Impact of FDA Regulation

- Is my product regulated by FDA?
  - Is it a "medical device" or "accessory"?
  - If it's a medical device, is it subject to enforcement discretion?
    - Is it a health IT product?
    - Is it an MDDS or medical image communications or storage system?
    - Is it a mobile medical app?
    - Is it a "general wellness" device?



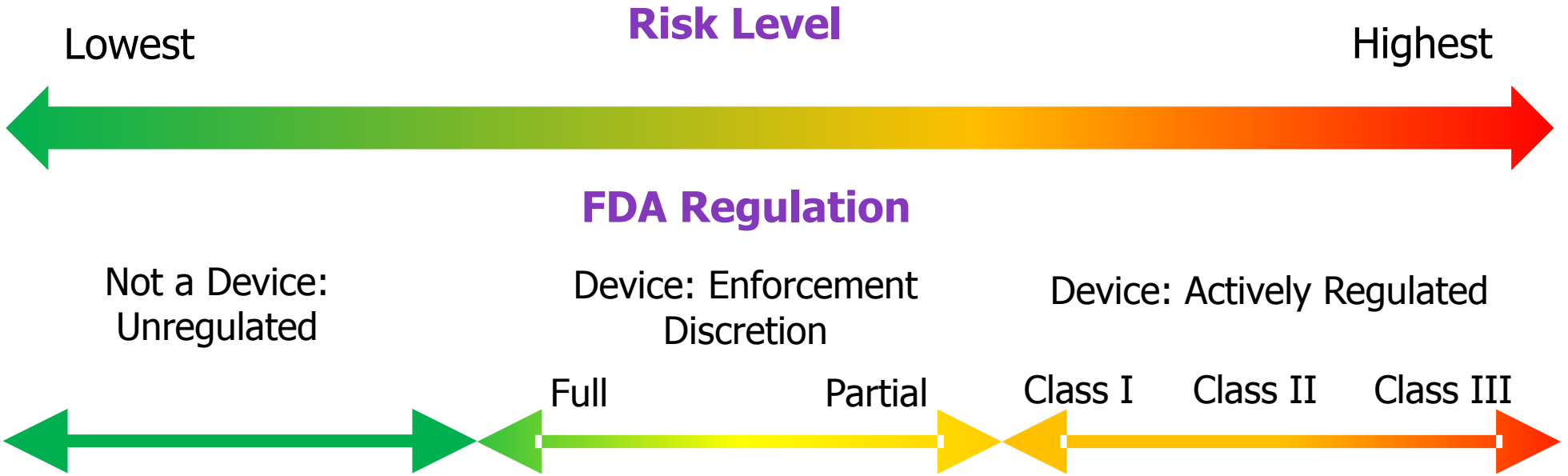
- If it's an FDA-regulated device, what pre- and post-market requirements apply?

Is My Product A Medical Device?

- Under the FFDCA, a device includes:
  - Any thing (any instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or other similar related article, including any component, part, or accessory)
  - Intended to be used for a health/medical purpose (intended for use in the diagnosis of disease or other conditions, or in the cure, treatment, or prevention of disease, or to affect the structure or function of the body)
  - Which is not a drug (i.e., does not achieve its principal purposes by chemical action in or on the body of man or by being metabolized)

Enforcement Discretion

- FDA may choose not to actively regulate low risk devices under a policy of *enforcement discretion*
- FDA may apply enforcement discretion to exempt certain devices from *all* or *some* of the FDA regulatory requirements (*e.g.*, enforcement discretion for 510(k) requirement only)



FDASIA Health IT Report

- Mandated by Congress under the Food and Drug Administration Safety and Innovation Act ("FDASIA")
- Proposes a limited approach that "relies on ONC-coordinated activities and private sector capabilities"
- Focused primarily on health IT in health care settings or used by or under the supervision of a health care provider
- Does not address health IT marketed for use by consumers/patients

FDASIA Health IT Report

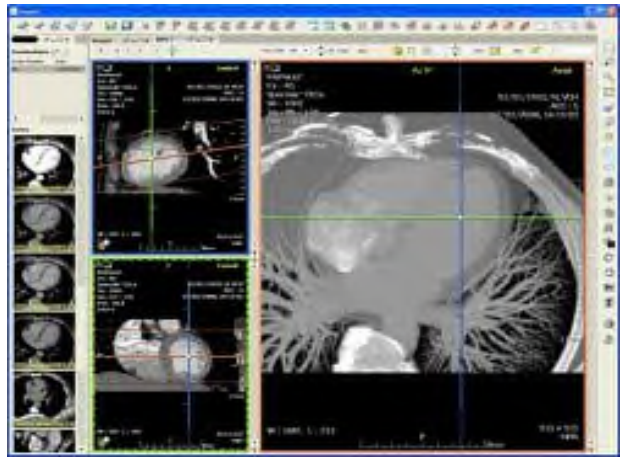
- Identifies three categories of health IT based on function:
  - Administrative health IT functions
    - *E.g.*, billing, claims processing, practice and inventory management, general purpose communications, and scheduling
    - Not subject to FDA oversight
  - Health management health IT functions
    - *E.g.*, health information and data management, data capture and encounter documentation, electronic access to clinical results, medication management, electronic communication and coordination, provider order entry, knowledge management, patient identification and management, and "most clinical decision support" technologies
    - Not subject to FDA oversight
  - Medical device health IT functions
    - *E.g.*, computer-aided detection and diagnosis, remote display of alarms from bedside monitors, radiation treatment planning, robotic surgical planning and controls, and electrocardiography analytical software
    - Subject to FDA oversight

MDDS and Medical Image Management

- February 2015 Guidance exempted the following types of devices from active FDA regulation:
  - Medical Device Data Systems (MDDS), which provide one or more of the following uses
    - The electronic transfer of medical device data
    - The electronic storage of medical device data
    - The electronic conversion of medical device data from one format to another format in accordance with a preset specification;
    - The electronic display of medical device data
  - Medical Image Communications Devices
  - Medical Image Storage Devices

MDDS and Medical Image Management (cont'd)

- Limitations on exemption – does not include:
  - Systems with active patient monitoring or alarm functions
  - Systems that control or alter the function or parameters of connected medical devices
  - Systems that analyze the medical device data
  - Systems that alter the image data
  - Systems with complex quantitative functions
  - Picture Archiving and Communications Systems (PACS)



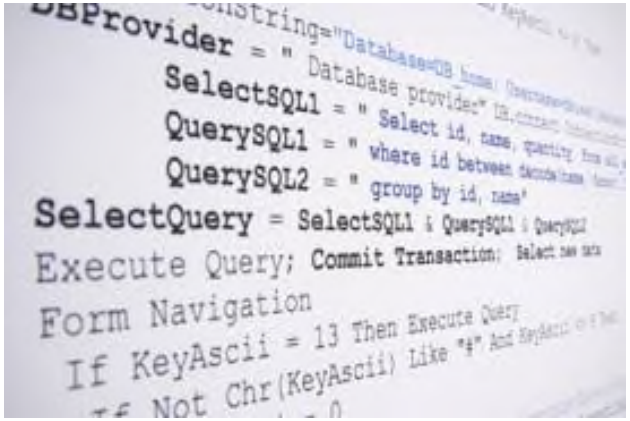
Mobile Medical Applications

- Final guidance 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:
  - Apps that FDA intends to regulate as medical devices
  - Apps that may meet the statutory definition of a "device" but for which FDA intends to exercise enforcement discretion
  - Apps that do not meet the statutory definition of a "device" and which FDA will not regulate

Mobile Medical Applications (cont'd)

- Regulated Apps:
  - Apps that are an extension of a medical device or control a medical device
  - Apps used for active patient monitoring
  - Apps that transform a mobile platform into a regulated medical device
  - Apps that perform sophisticated analyses or interpret data
- Enforcement discretion:
  - Apps to facilitate communications between patients and health care providers
  - Apps that perform simple calculations routinely used in clinical practice
  - Apps that provide or facilitate supplemental clinical care by coaching or prompting
  - Apps that enable interaction with EHR or PHR systems
- Unregulated:
  - Apps that automate general office functions
  - Apps used for educational tools for medical training
  - Apps for general patient education

Who is Responsible for FDA Compliance?



- Generally, FDA puts the responsibility for FDA compliance on the device "manufacturer"
- A "manufacturer" includes more than physical manufacturer of a device
- Activities that result in manufacturer responsibilities:
  - Manufacture, preparation, propagation, compounding, assembly, or processing of a medical device
  - Repackaging to change the container, wrapper, or labeling
  - Initial importation of a device
  - Initiation of device specifications
- FDA regulates the manufacturer of the final, *finished device* – not component manufacturers

FDA Regulatory Obligations for Devices

- Premarket Obligations
  - Design controls
  - Clinical testing compliance (if applicable)
  - Premarket submission (if applicable)
- Postmarket Obligations
  - Establishment registration and device listing
  - Good manufacturing practices (GMPs)/Quality System Regulation (QSR)
  - Labeling
  - Medical device reporting
  - Reporting of corrections and removals

Recent and Anticipated Developments

- Outstanding FDA Guidance
  - Clinical decision support
  - Device accessories
  - Machine learning
- FTC Regulation and Enforcement
  - FTC enforcement thus far is generally consistent with FDA's policies
  - New web-based tool for developers of health-related apps
- Pending Legislation

Digital Health


QUESTIONS?

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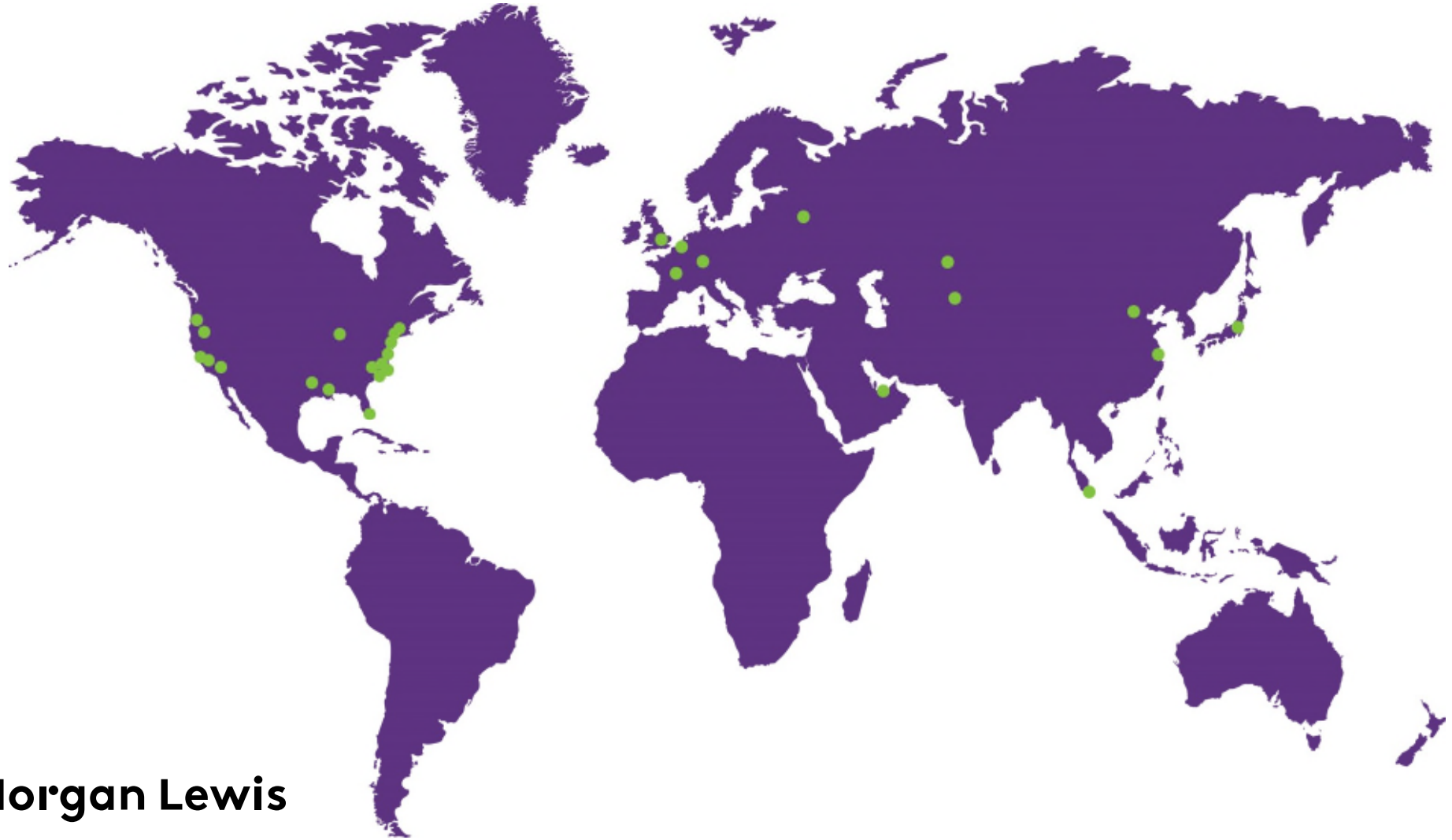

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