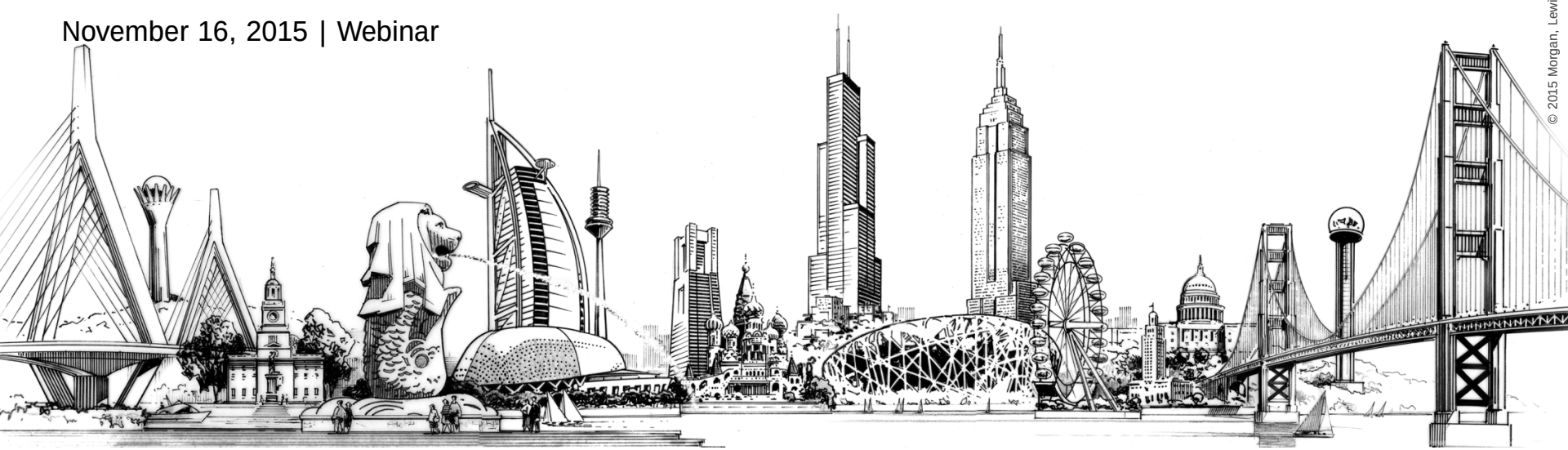
Morgan Lewis

MEDICINES PRICING AND REIMBURSEMENT:

DEMONSTRATING VALUE AND SHARING RISK IN THE EU AND UNITED STATES

Stephen Paul Mahinka, Partner
Donna Lee Yesner, Partner
Paul Ranson, Consultant
Christian Hill, Managing Director, MAP BioPharma

November 16, 2015 | Webinar



Introduction

- Medicines and devices pricing and reimbursement have become a major concern in both the EU and U.S.
- Globally, the perceived need to control healthcare product budgets has led to evidential demands to show value
- Focus of presentation
  - Cost-containment efforts and mechanisms
  - Developments in demonstrating value for new or modified products
  - Risk-sharing arrangements being used with governments and private payors to address cost and payment concerns

EU Pricing and Reimbursement Issues

- TFEU Article 168 - Price setting/reimbursement a national competence
- Transparency Laws – P&R Constraints on Member States
- Competition Laws – Pricing Constraints on Industry
- Off-label and unlicensed product cost-containment
- Joint procurement initiatives
- Early scientific advice from payers and HTA Harmonisation

Transparency Laws – P&R Constraints on Member States

- **Directive 89/105**
  - Price approvals, increase approvals, price freezes, profit controls, product coverage
  - Timelines, decision criteria and remedies
  - Abandoned revision
- **International reference pricing**
  - Incidence of IRP
  - Reasons for price differences
  - Perceived limitations of IRP
  - Publication or prices and deals

Competition Law – Pricing Constraints on Industry

- Article 34 TFEU - Free movement of goods
- Article 101 - Restrictive agreements
- Article 102 - Abuse of a dominant position
- 2008 Sector Inquiry

Cost-containment through Off-label and Unlicensed Use

- Unlicensed medicines
  - Article 5(1) MA exemption for special need exemption or named patient supply
  - *C-185/10 European Commission v Republic of Poland* - cost grounds
- Off-label use
  - Industry complaints of inconsistency with EU MA regime in France and Italy
    - 2/2015 - Italy
    - 9/2015 - RTUs in France

Joint procurement initiatives

- What is joint procurement?
- Joint Procurement Agreement for medicines for pandemics and cross-border threats to health
- Potential application to high-priced medicines
- Portuguese initiative re hepatitis C
- Belgium/Netherlands and Luxembourg grouping
- Netherlands Presidency priority

Over a hundred HTAs in EU

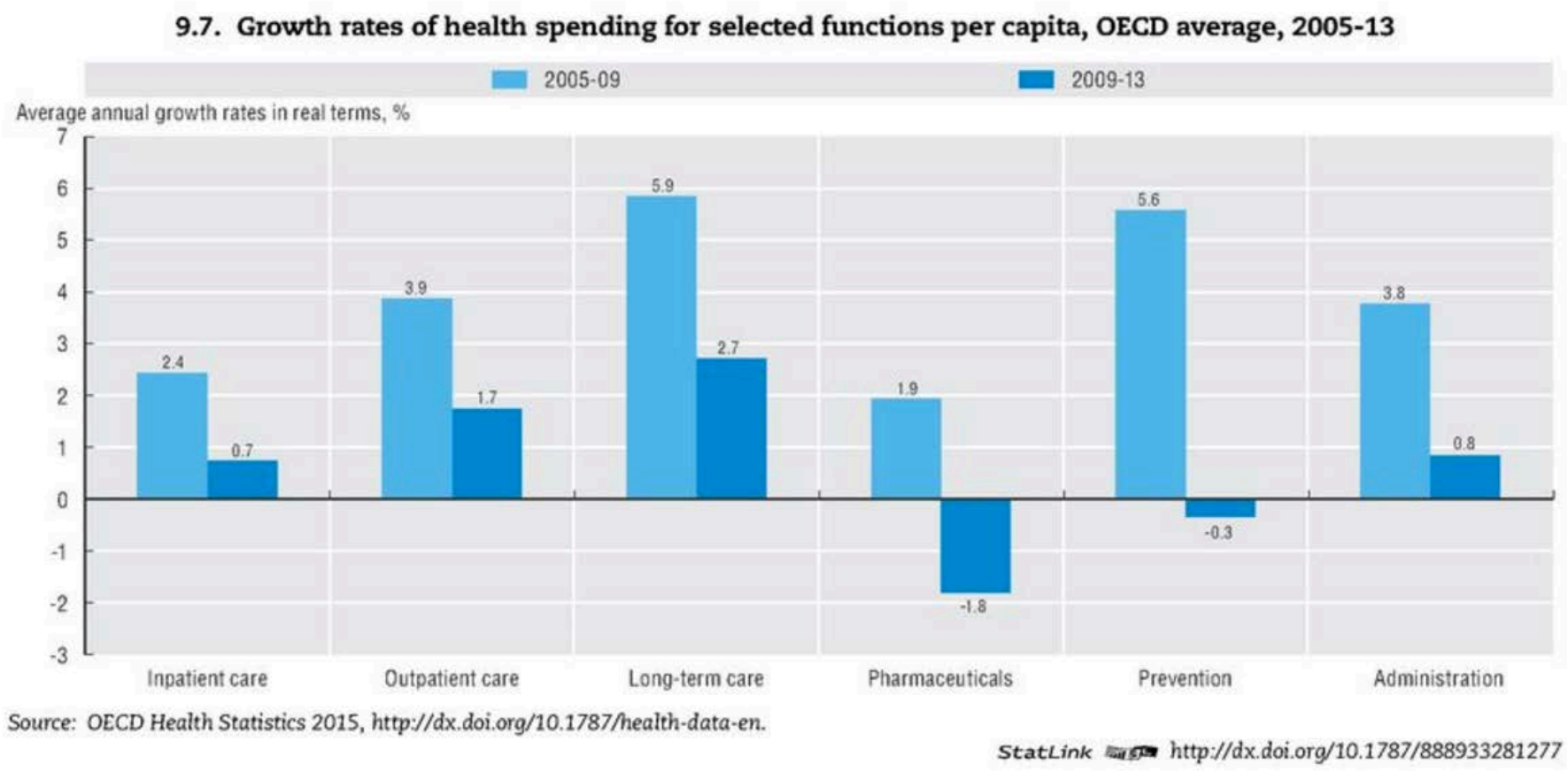
HTA Harmonisation and early scientific advice from payers

- Directive 2011/24/EU on patients' rights in cross-border healthcare
  - Art 15 – EU to support cooperation between HTA bodies
  - HTA Network
  - EUnetHTA
- Adaptive pathways and pricing
  - For medicines that address serious unmet medical needs from a limited to a wider population
  - Ongoing Pilot – 6 products moved forward in January 2015
  - Need for regulatory/payer coordination – precedents for post-launch price rises?
  - HTA bodies/payers across Europe may have different views

Europe:
Trends, Responses and Implications

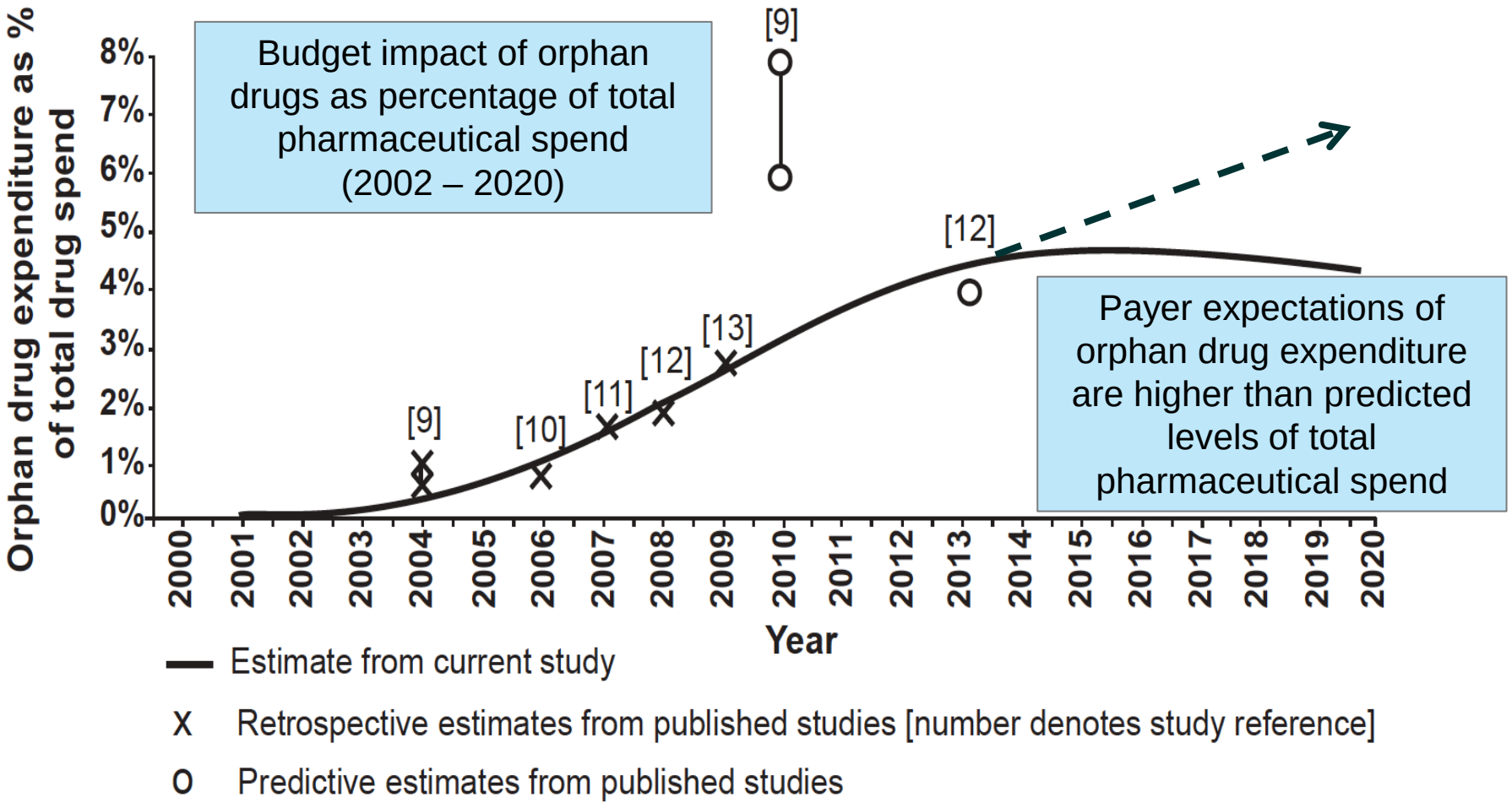
- EU BioPharma trends compared with total health expenditure
- EU Payer responses: Value judgments, processes and methodology for evaluation of innovations in health care
- Implications of drug spend and payer responses for the pharma industry
- What this may mean for other countries

Trends in drug spend are not in line with overall health expenditure



Health at a glance 2015 OECD Indicators (10.1787/health_glance-2015-en)

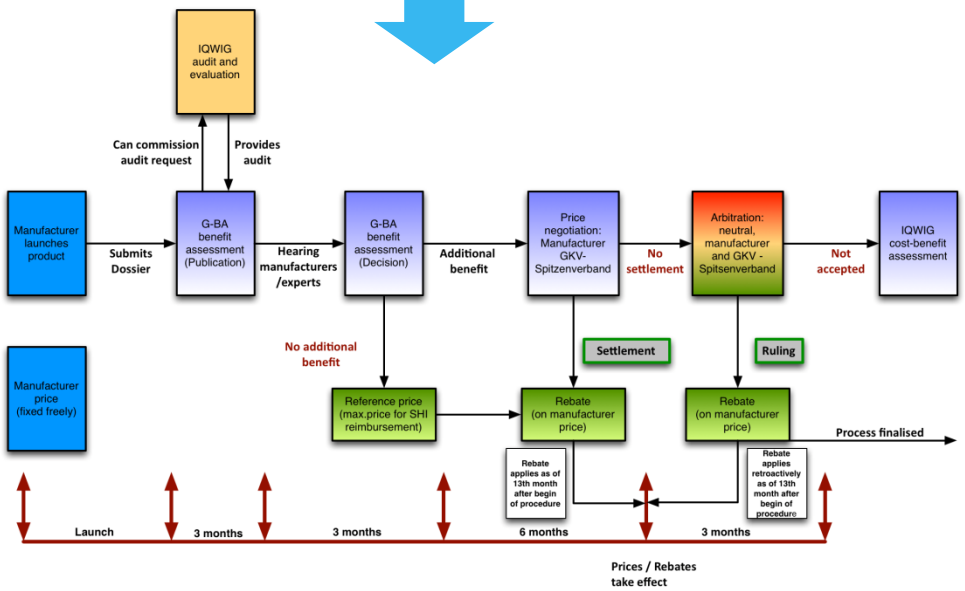
European research suggests spending will plateau in terms of the orphan drug share of the total European pharmaceutical market



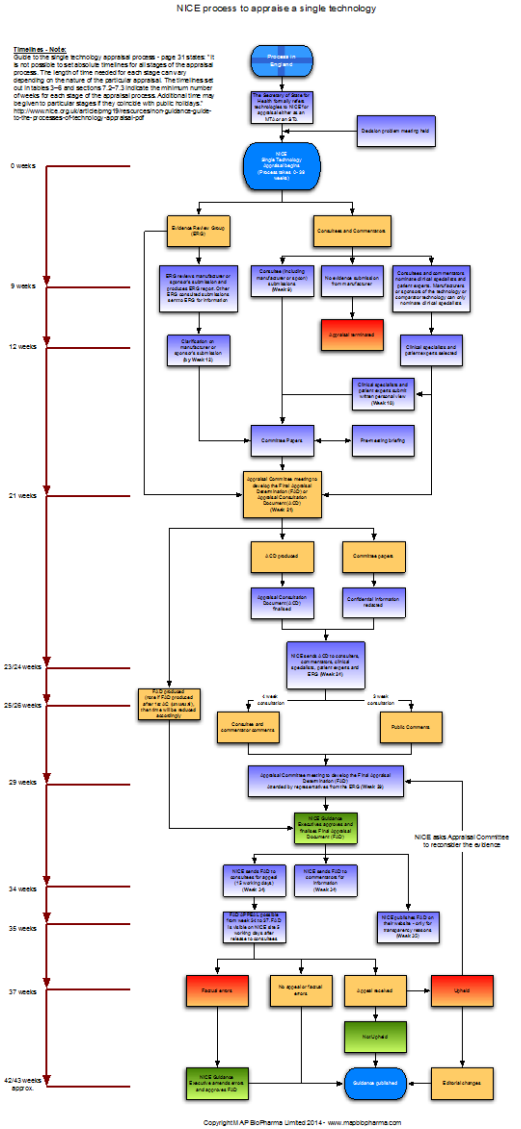
Schey et al. Orphanet Journal of Rare Diseases 2011, 6:62

Due to national competency: HTA processes differ significantly

Germany: AMNOG process takes a strict 12 month followed by negotiations with sick-funds



England & Wales: NICE STA process variable with large number of steps and high level of stakeholder engagement time taken minimum 39 weeks, typically a lot longer



Morgan Lewis

Due to national competency: national methodologies differ significantly

Country	Price Changes (since 2008)					Drug Lists		Contracting Arrangements				HTA requirements (formal like NICE or as part of contract)			
	One off price cuts / extraordinary price reviews	Changes in VAT rates (+/-)	Reduction in marks ups for distributors	Intro of external reference pricing / changed method	Effective generic pressure e.g. incentives to prescribe	Positive	Negative / delisting	Price-volume	Managed entry schemes	Outcomes based schemes	Cost / Risk Sharing	Clinical Effectiveness, Safety, Budget Impact	ICER (cost / QALY)	Cost Minimisation Analysis	Health Economic Simulation
Germany			*			✘	✔	✔		✔	✔	✔	✘	Rarely	Rarely
France	✔				✔	✔	✘	✔		✔	✔	✔	✘	✔	✔
UK	✔				✔	✘	✔	✔	✔	✔	✔	✔	✔	Rarely	✔
Italy	✔				✔	✔	✘	✔	✔	✔	✔	✔	✘	✔	Rarely
Spain	✔		✔	✔	✔	✘	✔	✔				✔	✔	✔	✔
Austria	✔	✔			✔	✔	✔				✔	✔	✘	✔	✔
Belgium	✔					✔	✘					✔	✘	Rarely	✘
Czech Republic	✔	✔	✔			✔	✘	✘			✔	✔	✔	✔	✔
Denmark						✔	✘	✔				✔			
Finland						✘	✔					✔			
Greece	✔	✔	✔	✔	✔	✘	✔	✔				✔			
Hungary			✔		✔	✔	✔	✔		✔	✔	✔	✔	✔	Possible
Ireland	✔		✔			✔	✘	✔		✔	✔	✔	✔	✔	✔
Netherlands						✔	✔	✔		✔	✔	✔	✔	✔	✔
Norway						✔		✔				✔			
Poland						✔	✘	✔			✔	✔	✔	✔	✔
Portugal	✔	✔	✔	✔	✔	✔	✔	✔		✔	✔	✔	✔	✔	✔
Sweden						✔	✔	✔				✔	✔	✔	✔
Switzerland	✔					✔	✘	✔		✔	✔	✔	✘	✘	✘

*Germany also increased rebates to distributors

Ref: OECD/DELSA HEA (2015) and MAP BioPharma Limited (http://www.mapbiopharma.com/europe)

EU level efforts towards a more harmonised approach – some examples

International Reference Pricing

– Does not account for country GDP or ability or willingness to pay

HTA and Regulatory Harmonisation

– EUnetHTA supports the collaboration between European HTA organisations

– EMA – Adaptive Pathways Approach

– Mechanism of Coordinated Access to orphan medicinal products (MoCA)

Joint Procurement

– Bilateral engagement of member states in discussions about the joint procurement/purchasing of innovative medicines

– Belgium and the Netherlands initiative; also Bulgaria and Romania

– Pilots in 2016 might lead to broader cooperation

– Dutch Minister of Health claims that Austria and France have expressed interest in a possible joint procurement of “medicines that are used less frequently”; no agreement from Germany and the UK

Medical devices

– Directives changing due to review of regulations

– Lessons to be learned from BioPharma experience

Europe – Status and Developments

- Growth in drug spend is lower than commentators and governments expected e.g. UK PPRS
- More cooperation in pricing and reimbursement matters between Member States, supported by the Commission and patient organisations
- The system of 28 different P&R schemes will remain largely unchanged for legal reasons and due to their different approach to health care
- MedTech regulations are due to change in December – pros and cons in terms of implications for processes and methods of evaluation
- What has happened to BioPharma is likely to happen for MedTech
- US impact: re-importation proposals in the presidential election could lead companies to sacrifice EU markets to protect price in the US

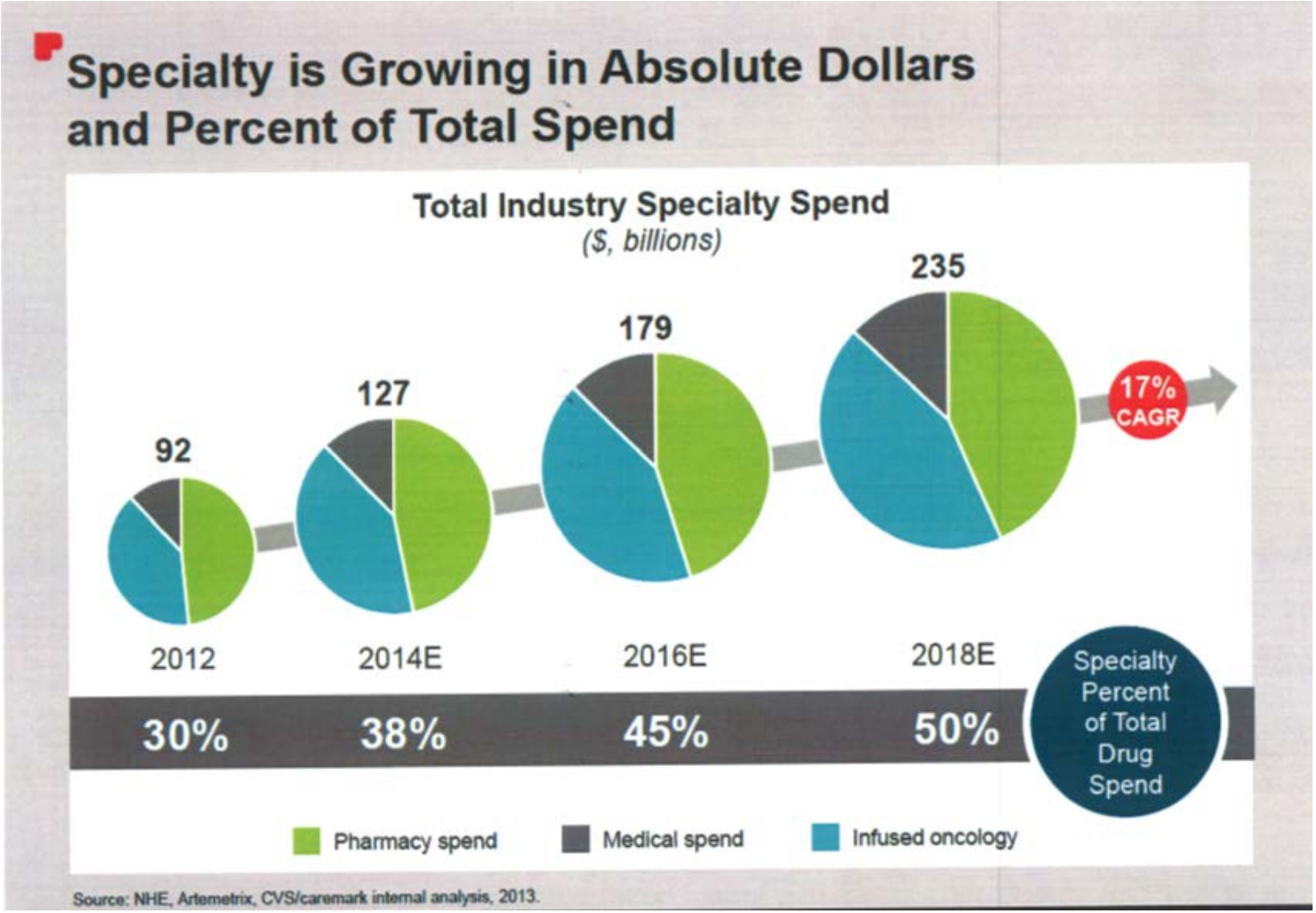
Payor Concerns Regarding High Prices

- In the U.S., 90% of the population is insured by government programs and commercial managed care organizations, which exert substantial control over their beneficiaries' access to prescription drugs and biologics
- Payors have expressed concerns regarding two different situations
  - Launch prices of Hepatitis C virus drugs (that cure the disease and avoid far costlier treatments for liver failure or cancer)
  - Increases to the prices of old, under-valued drugs, by new owners of the drugs (e.g., Daraprim)
- Drug pricing is a significant political issue notwithstanding government policies that emphasize value-based health care
- Medical devices pricing also of increasing concern
  - e.g., increasing use of value analysis committees by hospital systems in making evidence-based determinations on purchasing of medical devices

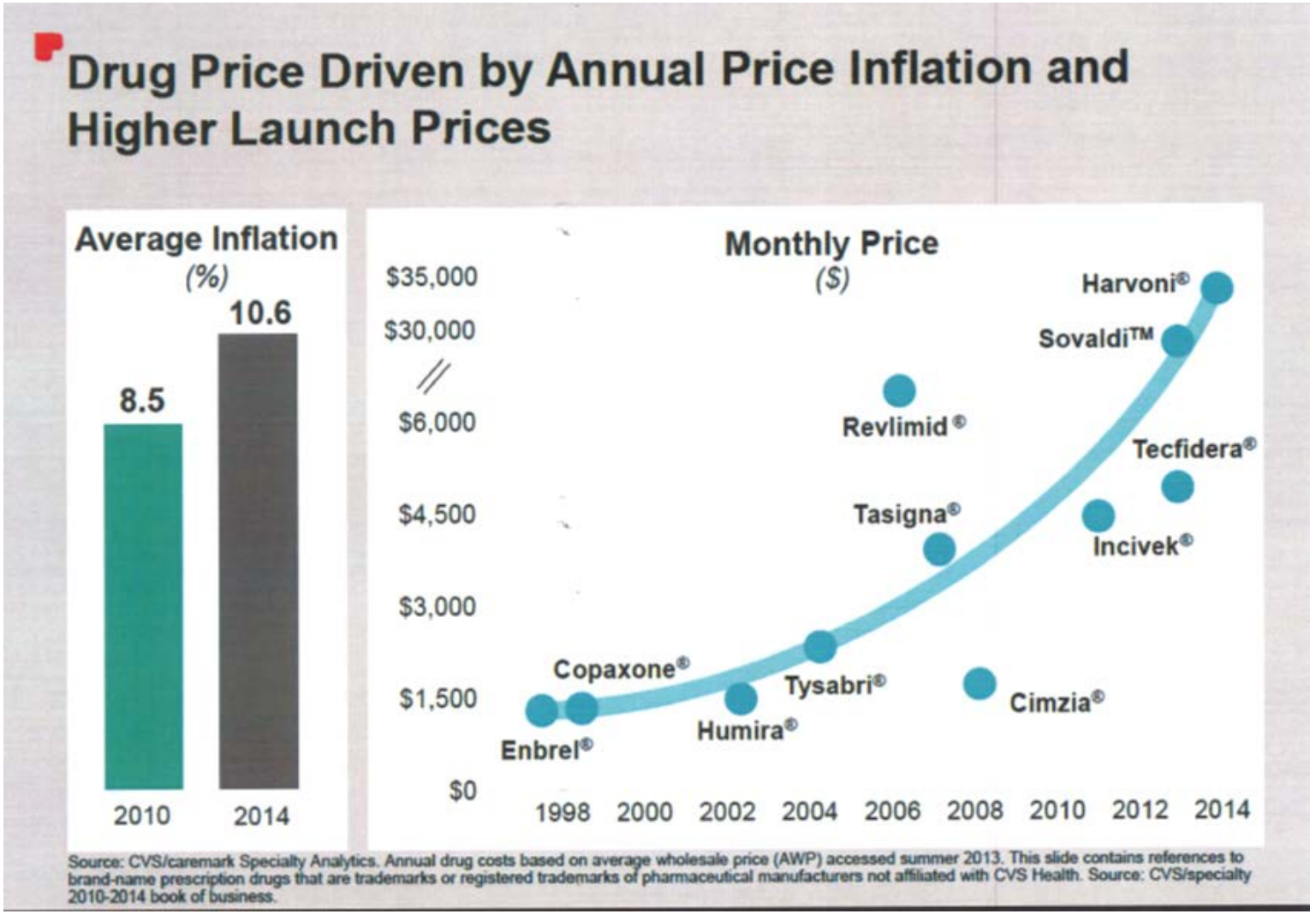
Specialty Drugs

- In 2014, after years of price stability, spending on prescription drugs in the U.S. increased 13% to $374 billion
- Specialty drugs accounted for over 33% of spend for pharmaceuticals in the US in 2014, up 27% over the prior year; projected to reach half by 2018
- Insurers that cover specialty drugs pay the overwhelming share of costs

Payors' View of Expenditures



Payors' View of Pricing Trends



Commercial Insurers' Efforts to Control Prices by Limiting Access

- Payors in the U.S. focus on current outlays; less focus on patient's long term cost savings in part because a patient's current healthcare plan may not be the same plan in the future
- Efforts to manage specialty drug costs through restricted access to drugs
  - Require prior authorization before dispensing
  - Impose step therapy (must try another drug first)
  - Increase co-pays
  - Deny or restrict coverage based on patient conditions (e.g., with HCV drugs, coverage has required certain viral load and liver disease progression evaluated from biopsies) or requirement for consultation with specialists
  - Broaden therapeutic classes to increase formulary competition
- Other efforts to manage costs
  - Contracting for discounts, rebates, and price protection clauses
  - Dispensing protocols
  - Disease management and case management

Commercial Insurers' Efforts to Control Prices by Limiting Access

- Consequences
  - More direct to patient discounts such as co-pay assistance to prevent rejected prescriptions due to high co-pay
    - Not available to assist with patient share of costs under government programs
  - Increase in Patient Assistance Programs
  - Beneficiary complaints to payors and government
  - Legal challenges by patients to coverage denials by insurers

Efforts by U.S. Government Actions to Control Prices

- Federal programs such as Medicaid and Medicare also focus on current outlays and impact of drug spend on current budgets
- Restrictions on access and ability to control prices vary by program depending on the authorizing statute
- Medicaid
  - Must cover drugs of manufacturers with agreement to pay mandatory rebate
  - State plans use prior authorization and Preferred Drug Lists to obtain supplemental rebates, but preference for generics discourages participation
  - CMS recently instructed states to cease imposing conditions on HCV drugs that effectively denied coverage, and to take advantage of competition and negotiate supplemental rebates
  - Significant penalties for increasing commercial prices of drugs and biologics - restrains prices on those with high Medicaid and 340B program utilization
  - Congressional, federal, and state government investigations regarding drug pricing, costs, and patient access

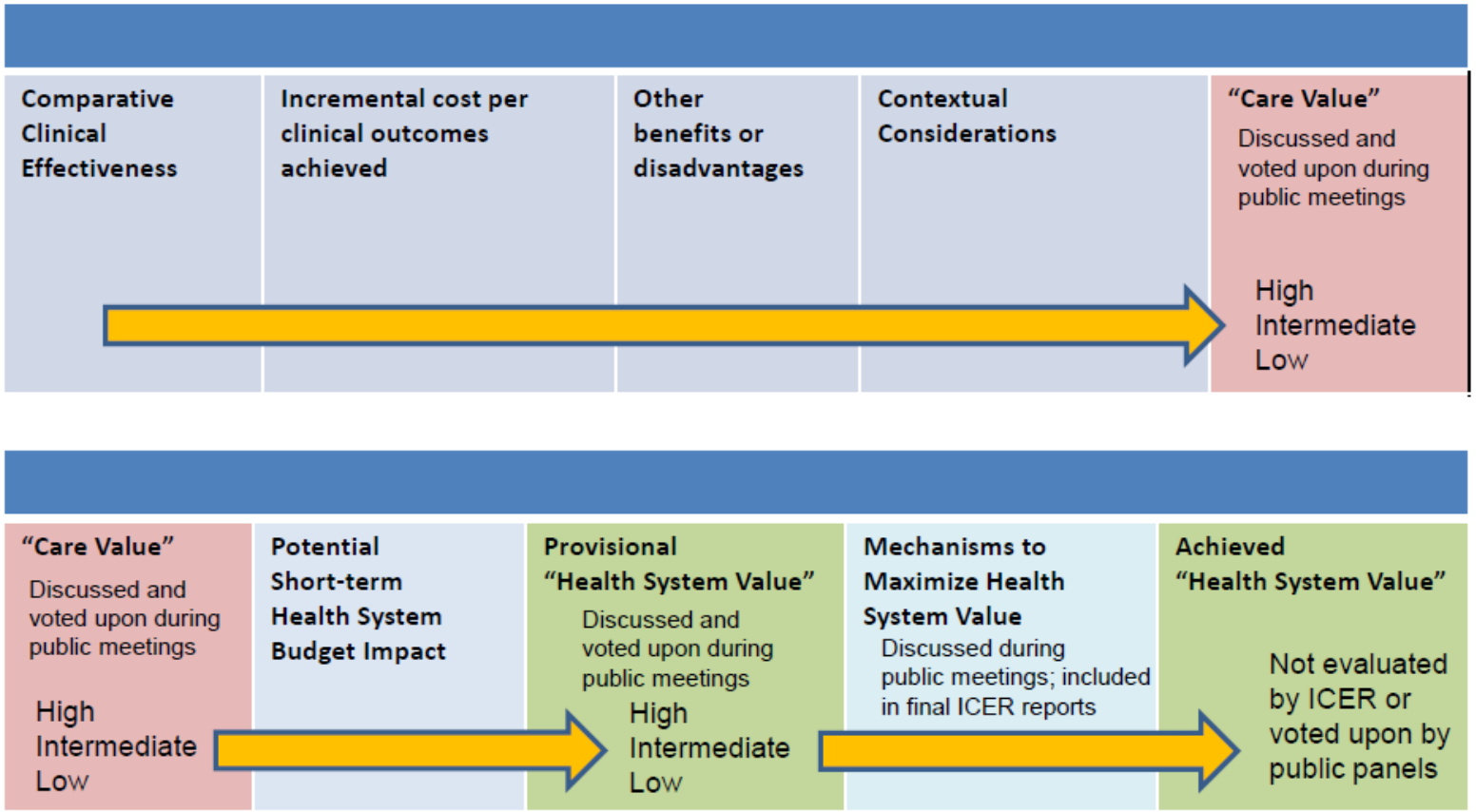
Efforts by U.S. Government Programs to Control Prices

- Medicare Part D (outpatient pharmacy benefit)
  - Implemented through commercial plans that manage formularies
  - Regulatory limits on ability to restrict access – protected classes and at least two drugs per therapeutic class
  - No mandatory discounts (except to patient in coverage gap)
- Medicare Part B (outpatient physician-administered)
  - Physicians buy and bill; managed care has less control
  - No mandatory manufacturer discounts
  - Payment based on mark-up over Average Sales Price of all products in same billing code
  - Little disincentive to use expensive innovator products that don't share a billing code
- Veterans Affairs (VA) Health Care System
  - VA is budget driven; has very restrictive formulary
  - Long delays in reviewing new drugs; requires significant experiential data

Price vs. Value

- Payors are focused on demonstration of value of drugs /devices
  - Better patient outcomes
  - Near and long term cost savings (e.g., reduced side effects, avoided hospitalizations and surgery, disease complications)
- Metrics that are acceptable are unclear
- Potential use of economic data and modeling, in lieu of clinical data
- FDA restrictions regarding communications with buyers and use of non-clinical trial data to demonstrate outcomes
  - Potential effect of decision in Amarin Pharma, Inc. v. FDA (S.D.N.Y. 2015), restricting FDA efforts to prohibit truthful and non-misleading communications on drug products

The ICER Value Framework



ICER
INSTITUTE FOR CLINICAL AND ECONOMIC REVIEW

Value-Based Contracting Strategies

- Payors and providers are seeking to participate in value-based purchasing arrangements, including DoD and CMS
- Strategies include
  - Performance contracting and risk-sharing agreements, in which prices/discounts are dependent on achievement of measurable goals
    - e.g., Harvard Pilgrim's agreement with Amgen on an outcomes-based pricing contract for its cholesterol-reducer drug Repatha (announced Nov. 9, 2015)
    - issues include definition of the performance parameters (for this contract, degree of LDL cholesterol reduction and patient utilization rates)
  - Bundling arrangements, in which sales price is based on purchase of a combination of products
  - Exclusivity agreements, in which discounts are provided for exclusive purchases for/coverage in the therapeutic class
  - Differentiated pricing, tailored to specific indications based on outcomes/effectiveness data, volumes purchased, or other parameters

Legal Risks Regarding Value-Based Contracting

- FDA – off-label promotion and claims substantiation regulation
- Antitrust – price discrimination, tying, exclusive dealing, use of most-favored-nations (MFN) clauses
- Price reporting – complex pricing arrangements and time-lagged rebates/discounts present potential price reporting issues
- Anti-kickback Act – provision for remuneration in exchange for purchase or referral issues if arrangement does not come within safe harbor
- Tort liability – contract terms could implicate manufacturer in medical decision-making
- State insurance laws – if manufacturer guarantees results and bears financial risk, it might be considered an insurer in some states

THANK YOU

Biography

Stephen Paul Mahinka

Washington D.C.
T +1.202.739.5205
E smahinka@morganlewis.com

Stephen Paul Mahinka is a partner in Morgan Lewis' FDA Practice Group, in the Washington, D.C. office. He has practiced in both the FDA regulatory and antitrust areas throughout his career, and is the founder of the Firm's FDA practice, a former leader of its Antitrust practice, and co-founder and former chair of its Life Sciences industry practice.

In the FDA area, his practice focuses on regulatory, transactional, and compliance matters throughout the product lifecycle, including approval, acquisition, licensing, marketing, distribution, pricing, and enforcement concerning pharmaceuticals, biologics, biosimilars, food and food additives and packaging, and medical devices; FTC, DOJ, FDA, and state investigations; and consumer protection matters.

In the antitrust area, his practice includes mergers, joint ventures, and collaboration and distribution agreements, pricing and price discrimination, marketing and advertising, and government investigations.

Mr. Mahinka has published over 75 articles on FDA and antitrust issues, and is a co-author of several books, including *Food and Drug Law and Regulation* (3rd ed. 2015); *Life Sciences Mergers and Acquisitions* (2008); and the ABA Antitrust Section's *Pharmaceutical Industry Antitrust Handbook* (2009). He is a member of the Editorial Advisory Board of *Life Sciences Law360*, and a former editor of the *Food and Drug Law Journal.* Mr. Mahinka is a graduate of Johns Hopkins University, *Phi Beta Kappa*, and of the Harvard Law School.

Biography

Paul Ranson

London
T +44.20.3201.5565
E pranson@morganlewis.com

Paul Ranson is a consultant who focuses on the regulatory and commercial needs of the pharmaceutical, biotechnology, and medical devices sectors. Paul's regulatory expertise covers both marketing authorisation-related matters and market access, pricing, and reimbursement issues. His commercial work is concentrated on transactions with a high degree of industry specificity including collaborations and outsourcing transactions.

Paul spent the early part of his career in in-house roles with Smith Kline, Merck Sharp, and Dohme, and has subsequently maintained this industry focus.

Paul is the legal adviser to the UK trade association for smaller and medium-sized companies (Ethical Medicines Industry Group) and the principal author of the legal module of an MSc on pharmaceutical licensing. He has also been a non-executive director of a specialty pharmaceutical company for some 10 years and was a member of an independent ethics committee for some 5 years.

As a result of his expertise Paul is a frequent speaker at conferences on a variety of topics including licensing, health technology assessment and various regulatory topics including during 2015 the Informa EU Pharmaceutical Law Forum in Europe and BIO and ISPOR in the United States. He has written some 10 reports on pharmaceutical and medical device regulatory issues and has authored/co-authored numerous journal articles.

Biography

Donna Lee Yesner

Washington D.C.
T +1.202.739.5887
E. dyesner@morganlewis.com

Donna Lee Yesner represents clients in transactions, disputes, regulatory compliance, and strategic business planning relating to public healthcare programs and government contracts. Primarily representing clients in the pharmaceutical, biological, and medical device industries, Donna advises on US Federal Supply Schedule contracting, pharmaceutical research and development agreements, and other federal grants and contracts. She counsels companies on federal healthcare program reimbursement, drug price reporting, and compliance requirements, and their potential business impact on the companies.

Donna advises clients on issues involving the acquisition and reimbursement of healthcare supplies and services, particularly contracts involving the Department of Veterans Affairs, the Department of Defense, and the Department of Health and Human Services. She also counsels on compliance issues relating to Medicaid, Medicare, Tricare, and the 340B drug discount programs; debarment and public policy affecting these programs; and healthcare fraud.

Additionally, Donna has represented clients in protests, claims, litigation and alternative dispute resolution matters before US District Courts and Courts of Appeals, the US Court of Federal Claims, the General Accountability Office and boards of contract appeals.

Donna serves as vice-chair of the ABA Public Contracts Section Health Care Contracting Committee, and co-chair of the Coalition for Government Procurement Health Care Committee. She also publishes and lectures frequently on procurement, pricing, and reimbursement of medical supplies.

Biography

Christian Hill

T +44.1480.832360
E. christian@mapbiopharma.com

Christian Hill is Managing Director at MAP BioPharma and a Director of MAP MedTech and MAP Market Access. MAP provides market access guidance for biotech, pharmaceutical, medical device, diagnostics and vaccines businesses in Europe and beyond.

Christian has over 18 years of experience in the life sciences industry, holding senior market-access-related positions at companies including Genzyme, Pfizer, Gilead Sciences and InterMune. He also serves on the board of EUCOPE, an EU trade organisation.

MAP LTD BioPharma
BIOPHARMA AND MEDTECH MARKET ACCESS MADE SIMPLE

Our Global Reach

Africa
Asia Pacific
Europe
Latin America
Middle East
North America

Our Locations

Almaty
Astana
Beijing
Boston
Brussels
Chicago
Dallas
Dubai
Frankfurt
Hartford
Houston
London
Los Angeles
Miami
Moscow
New York
Orange County
Paris
Philadelphia
Pittsburgh
Princeton
San Francisco
Santa Monica
Silicon Valley
Singapore
Tokyo
Washington, DC
Wilmington

Morgan Lewis