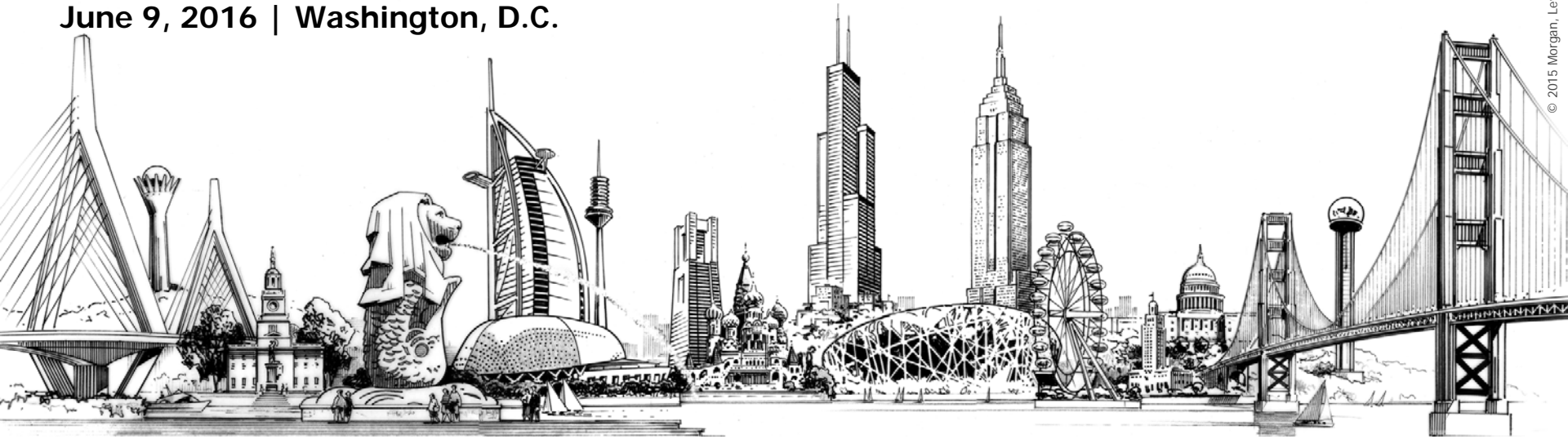


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RISK-SHARING ARRANGEMENTS FOR PHARMACEUTICALS AND MEDICAL DEVICES: ANTITRUST AND FDA REGULATORY ISSUES

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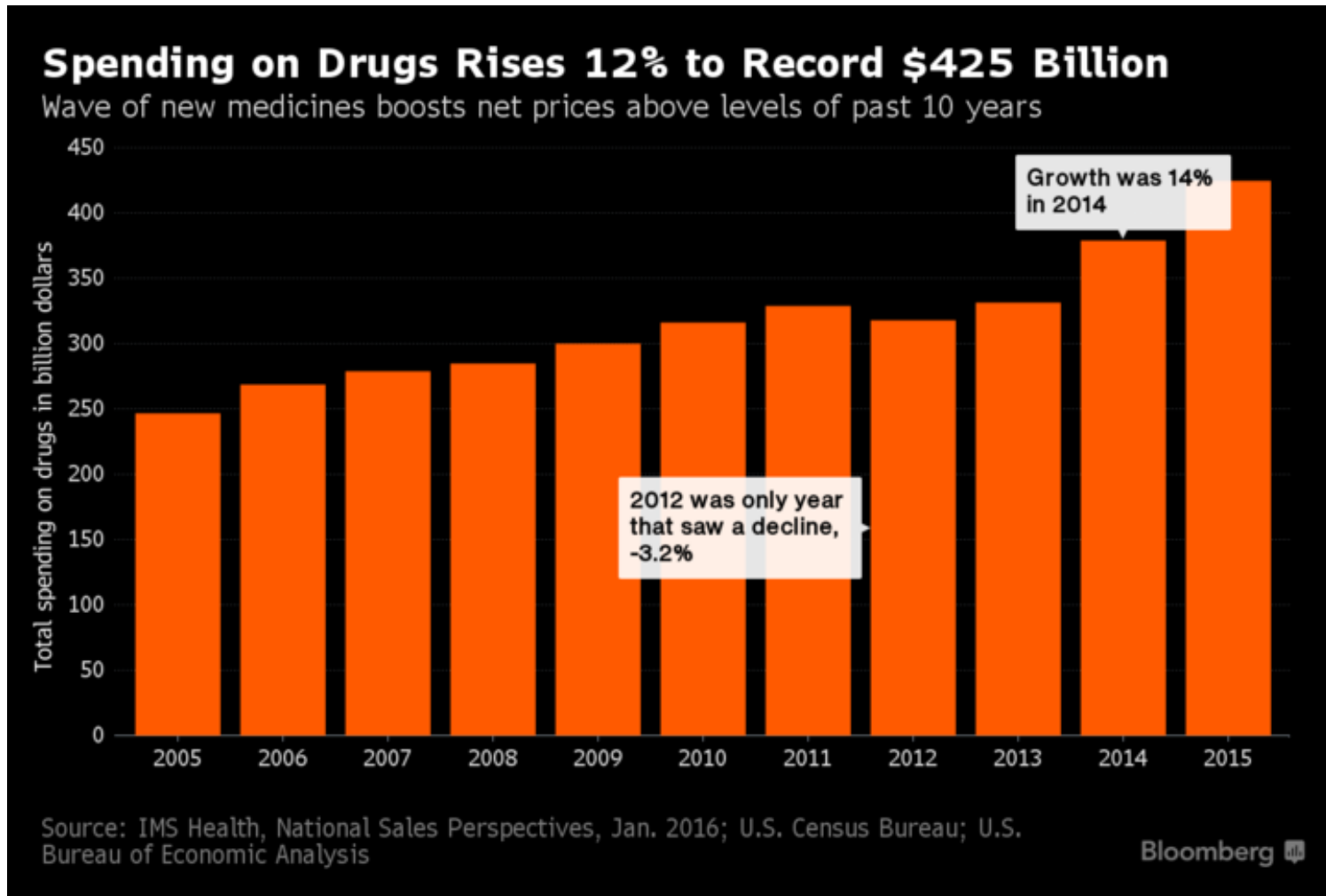
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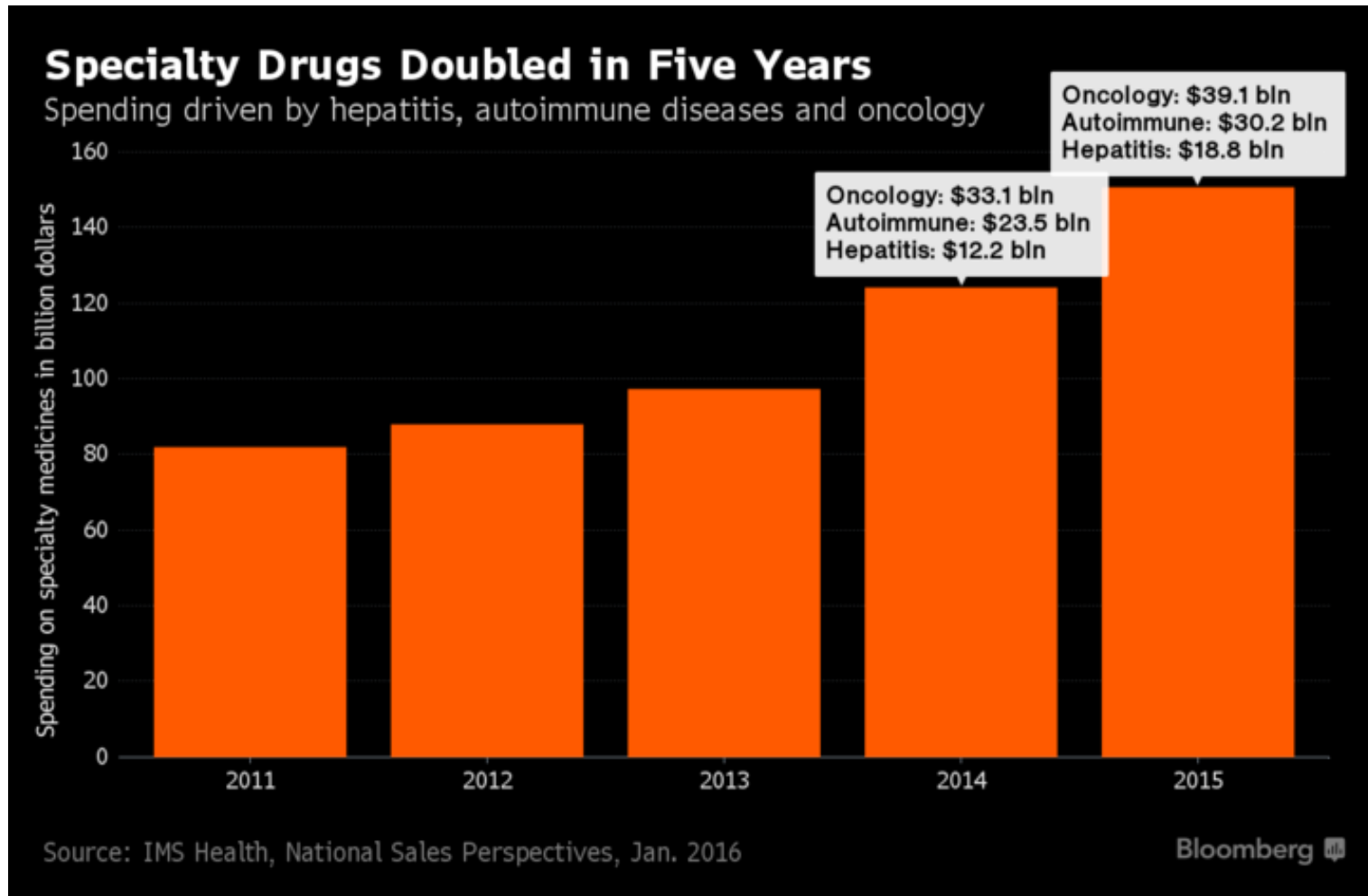
Risk-sharing Arrangements: Antitrust and FDA Regulatory Issues

- Antitrust laws focus on the competitive effects of pricing and discounting in risk-sharing arrangements
- Many common risk-sharing arrangements by drug and device manufacturers with insurers, GPOs, hospitals, accountable care organizations (ACOs) and integrated delivery networks (IDNs) potentially raise antitrust concerns
- Focus and enforcement of the antitrust laws on competition are often in conflict with the focus of the healthcare system on attaining efficiencies from coordination among healthcare delivery systems
- FDA regulatory constraints relating to communication of healthcare outcomes effectiveness research (HOER) also may adversely affect negotiation of risk-sharing arrangements

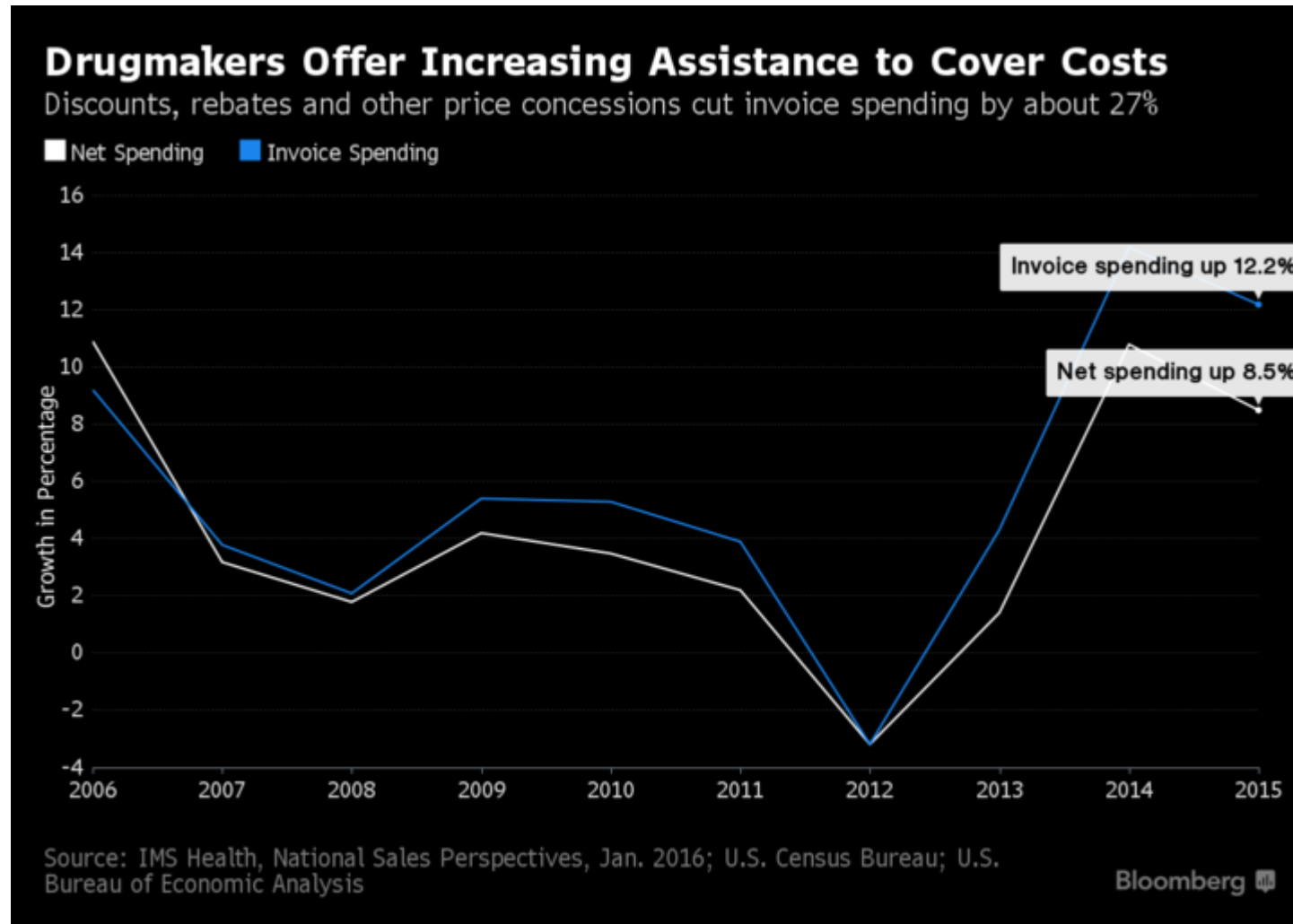
Continuing Rise in Drug Expenditures



Continuing Rise in Drug Expenditures



Rise in Drug Discounting / Rebate Activity



Payor Focus on Value-based Pricing and Risk-sharing

- 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, reduced disease complications)
- Metrics to establish value-based pricing that are acceptable and useful are unclear and controversial
- Emerging use of healthcare outcomes effectiveness research (HOER), in lieu of or in addition to clinical data

Payor Focus on Value-based Pricing and Risk-sharing

- Strategies include performance contracting and risk-sharing arrangements, in which prices/discounts/rebates are dependent on achievement of measurable goals
- Examples include:
 - Harvard Pilgrim Health Care contract with Amgen (for Repatha) on outcomes-based pricing, based on performance parameters (degree of LDL cholesterol reduction and patient utilization rates)
 - Cigna and Express Scripts arrangements with Amgen (for Repatha) and Sanofi/Regeneron (on Praluent), with price caps and controlled-use
 - CVS Health value-based contract with Amgen (for Repatha)
 - Cigna outcomes-based contract with Merck (for Januvia)
 - Aetna and Cigna outcomes-based contracts with Novartis (for Entresto)
- Lilly and Anthem also have suggested to CMS that it explore how to overcome “best price” reimbursement issues and other obstacles to outcomes-based contracting
 - Lilly/Anthem joint position paper to CMS (Jan. 29, 2016)

Value-based Contracting Strategies

- Other risk-based contracting strategies include:
 - Exclusivity agreements, in which discounts are provided from a manufacturer for exclusive purchases for/coverage in the therapeutic class
 - Bundling arrangements, in which sales price is based on purchase of a combination of products from the same manufacturer
 - Differentiated pricing, tailored by the manufacturer to specific indications, based on outcomes/effectiveness data, volumes purchased, share of buyer's purchases, or other parameters
- Such risk-based contracting strategies raise various antitrust concerns

Application of U.S. Antitrust Laws: Exclusive Dealing / Loyalty Discounts

Definition

- Customer agrees to purchase its product needs only from one supplier for a period of time, or the supplier provides “loyalty discounts” that effectively result in main or sole supplier situations
- Types: exclusive dealing contracts, sole source arrangements, requirements contracts, high compliance commitments
- Normally considered procompetitive due to reduced negotiation costs for buyers and assured supply volumes by seller
- Generally, commitments for >30% of a product market’s sales would not present any exclusive dealing antitrust issues

Risk Analysis

- Using market power to illegally foreclose competition
- >35% foreclosure of a defined market is generally considered in the safety zone for healthcare industry agreements. FTC and DOJ, Improving Health Care: A Dose of Competition (July 2004)
- Rule of Reason antitrust analysis, assessing competitive effects of the agreement, still applies outside the safety zone

Antitrust / Challenges and Issues – Exclusivity Arrangements

- Exclusive dealing arrangements / loyalty discounts
 - Eisai, Inc. v. Sanofi-Aventis U.S., No. 14-2017 (3d Cir. 2016) (affirmed rejection of challenge to loyalty discounts, requiring that hospitals purchase 90% of their anticoagulant drugs in order to obtain a discount of up to 30% of their total purchases, since the defendant's discounted prices were not below cost and that market share-based discounts were common in this market)
 - McWane, Inc. v. FTC, 783 F.3d 814 (11th Cir. 2015), cert. denied (March 21, 2016) (manufacturer of pipe fittings violated antitrust laws through requiring exclusive contracts on risk of being denied rebates)
 - ZF Meritor, LLC v. Eaton Corp., 696 F.3d 254 (3d Cir. 2012) (affirming jury finding of antitrust violation based on effects of long-term supply agreements combined with loyalty discounts in exchange for commitments to purchase 90% of buyer's requirements)
 - \$500 million settlement subsequently paid by Eaton (Law360, June 30, 2014)

Antitrust / Challenges and Issues – Exclusivity Arrangements

- Southeast Missouri Hospital v. C.R. Bard, Inc., 642 F.3d 608 (8th Cir. 2011) (rejection of antitrust challenge to contracting practices for medical devices sold to hospitals through GPOs, including use of market share-based discounts, sole-service contracts with GPOs, and bundled discounts, based on the absence of lock-in of buyers through the agreements)
- Allied Orthopedic Appliances, Inc. v. Tyco Health Care Group, 592 F.3d 991 (9th Cir. 2010) (summary judgment affirmed for defendant in challenge to use of market share-based discounts and sole-source agreements with GPOs, based on terminability of the contracts and absence of any contractual obligation to purchase)
- United States v. Dentsply, Inc., 399 F.3d 181 (3d Cir. 2005) (exclusive supply agreements held unlawful; foreclosure of rival dental product suppliers)

Antitrust / Challenges and Issues – Exclusivity Arrangements

- In re: Victrex, Plc (FTC Consent Order, April 28, 2016) (consent settlement with Invibio, Inc., a supplier of a polymer for medical devices, regarding use of exclusive supply contracts and threats to withhold critical supply or support services.)
- Department of Justice settlement with United Regional Health Care System (N.D. Texas, Feb. 25, 2011), of unlawful monopolization challenge, by ending the practice of requiring most commercial health insurers to enter into contracts that effectively prohibited them from contracting with competitors for certain surgical services by requiring the insurers to pay significantly higher prices

Antitrust Developments – Exclusivity Arrangements

- For recent discussions of the appropriate modes of antitrust analysis regarding exclusivity arrangements, see:
 - Remarks by Fiona Scott-Morton, Deputy Assistant Attorney General, DOJ Antitrust Division, “Contracts that Reference Rivals” (April 5, 2012)
 - Remarks by Joshua D. Wright, FTC Commissioner, “Simple but Wrong or Complex but More Accurate?: The Case for an Exclusive Dealing-Based Approach to Evaluating Loyalty Discounts” (June 3, 2013)
 - B. Klein & A. Lerner, “Price-Cost Tests in Antitrust Analysis of Single Product Loyalty Contracts,” 80 Antitrust L. J. 631 (2016)
- Compare initiatives by pharmaceutical buyers to use restricted formularies to agree to exclusive supply contracts with manufacturers in return for enhanced discounts on hepatitis C drugs:
 - Express Scripts agreement with AbbVie (on Viekira Pak); CVS Health and Anthem agreements with Gilead Sciences (on Harvoni). (Bloomberg BNA Life Sciences Law and Industry Report, Jan. 9, 2015; Inside CMS, Jan. 15, 2015)

Application of U.S. Antitrust Laws: Tying and Bundling

Definition

- Tying and bundling arrangements generally provide that a seller may or will supply a desired product only if the buyer also agrees to purchase other separate products, or a group of products
- Offering bundled purchase options, even at a discount, to buyers, ordinarily would not likely be found unlawful if the products remain open for purchase separately

Risk Analysis

- Extending market power in one market into another market resulting in higher prices and “forcing” buyers to buy products they don’t want or would have purchased for less elsewhere
 - Market share of less than 30% generally would not present tying concerns
- Tying can create barriers to customers switching to other competing suppliers, adversely affecting competition

Application of U.S. Antitrust Laws: Tying and Bundling

- Suture Express, Inc. v. Owens & Minor Distribution, Inc., and Cardinal Health 200, LLC, Case No. 12-2760-DDC-KGS (April 7, 2016) (medical supply bundling contracts that financially penalized customers for also ordering from other manufacturers held not violative of the antitrust laws)
- Schuylkill Health System v. Cardinal Health 200, LLC, Civ. No. 12-7065 (E.D. Pa., July 30, 2014) (denial of motion to dismiss action challenging seller discount program as unlawful tying and bundling and exclusive dealing that allegedly made it prohibitively costly to use a competing supplier for one line of products by charging penalty prices on all other product lines provided by the defendants)

Application of U.S. Antitrust Laws: Most Favored Nation Clauses (MFN) and Price Discrimination and Discounting

Definition

- MFN provisions may require a supplier to reduce customer A's prices if the supplier charges a lower price to customer B
- Often demanded by large buyers (e.g., GPOs and IDNs)

Risk Analysis

- MFNs can be subject to scrutiny if they disincentivize normal competitive price reductions, or raise barriers to entry for other competitors
- Assess competitive effects and market share of supplier
- Raises Robinson-Patman Act price discrimination issues

Antitrust Enforcement Issues – MFN Clauses

- MFNs with buyers, including group purchasing entities, raise potential antitrust concerns regarding exclusion of competing sellers and regarding unlawful price discrimination
 - See United States v. Blue Cross Blue Shield of Michigan, (E.D. Mich. 2012) (complaint dismissed in 2013 after a Michigan statute was enacted prohibiting health insurers from using MFN clauses in provider contracts)
 - See Shane Group v. Blue Cross Blue Shield of Michigan, (E.D. Mich. 2015) (\$30 million settlement of follow-on class action by individual buyers and small businesses alleging damages from use of MFN clauses)
 - See also United States v. Apple, Inc., 791 F. 3d 290 (2d Cir. 2015) (MFN clause held unlawful even in absence of any current market share)
 - See also United States v. American Express Co., 88 F. Supp. 3d 143 (E.D.N.Y. 2015) (use of card non-discrimination provision found violative of the antitrust laws)

Antitrust Enforcement Issues – MFN Clauses

- MFN clauses may raise potential price discrimination concerns, by creating possible price differentials among customers
- See Cash & Henderson Drugs v. Johnson & Johnson, Case No. 12-4689-cv (2d Cir. 2015) (affirming summary judgment against plaintiff retail pharmacies asserting that rebates and discounts on drugs to favored purchasers including mail order pharmacies constituted unlawful price discrimination)
- Questions to consider include: availability of volume discount and/or functional discount defenses; whether the affected buyers are in the same class of trade; likely degree of resale impact of the price differentials in the marketplace

Current Antitrust Enforcement Issues – ACOs / GPOs / IDNs

- DOJ/FTC have expressed continued concerns regarding risk-sharing arrangements with ACOs and similar group purchasing entities, notwithstanding the Affordable Care Act's goals of containing costs and improving quality through such entities
 - FTC & DOJ, Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program (Oct. 20, 2011)
 - See Remarks by Deborah Feinstein, Director, FTC Bureau of Competition, "Antitrust Enforcement in Health Care: Proscription, not Prescription" (June 19, 2014)
 - See Mahinka, et al., FTC/DOJ Final Statement on Accountable Care Organizations: Important Antitrust Issues Remain Unanswered, BNA Health Care Reporter (Dec. 1, 2011)
- Principal antitrust concerns include: preventing payers from steering patients to certain providers; tying sales of an group purchaser's services to other services from providers outside the group; and requiring exclusivity

Competition Issues Regarding Communication of Healthcare Outcomes Effectiveness Research (HOER)

- FDA policy with respect to communications with purchasers and payors, including formulary committees, under challenge to modify its traditional restrictive approach by reason of First Amendment concerns
- Food and Drug Modernization Act of 2010, Section 114, allowing provision of health care economic information provided to a formulary committee or similar entity if it relates to an approved indication for a drug or biologic (not off-label uses)
 - FDA expected to replace its current draft guidance on permissible dissemination and discussion of truthful and non-misleading scientific information regarding off-label uses

FDA Regulatory Issues Regarding Communication of Healthcare Outcomes Effectiveness Research (HOER)

- Recent successful challenges to FDA off-label promotion restrictions
 - Amarin Pharma, Inc. v. FDA, 119 F. Supp. 3d 196 (S.D.N.Y. 2015) (preliminary injunction) (FDA may not bring a drug misbranding action based on truthful promotional activity)
 - Amarin Pharma, Inc. v. FDA, No. 1:15-CV-03588 (S.D.N.Y. 2016) (approving settlement whereby FDA agreed to be bound by court's earlier decision that the company could engage in truthful and non-misleading speech promoting off-label use, and may not be prosecuted for alleged misbranding based on that speech)
 - Pacira Pharmaceuticals, Inc. v. FDA, No. 15 Civ. 7055 (S.D.N.Y. 2015) (settlement and general release regarding FDA challenge to off-label drug promotion)
 - United States v. Vascular Solutions, Inc., No. 5:14-CR-00926 (W.D. Texas 2016) (defendants found not guilty in jury trial regarding dissemination of information concerning unapproved uses of medical device)

Competition Issues Regarding Communication of (HOER)

- Potential for competition challenges based on dissemination of HOER
 - ONY, Inc. v. Cornerstone Therapeutics, Inc., et al., 720 F.3d 490 (2d Cir. 2013) (affirming dismissal of unfair competition challenge by competitor to dissemination of a peer-reviewed comparative effectiveness study in a leading scientific journal, on the basis that statements made as part of an ongoing scientific discourse are more closely akin to matters of opinion for purposes of the First Amendment)
 - See Endo Pharmaceuticals, Inc. v. Actavis, Inc., Civ. No. 13-3981 (3d Cir., Dec. 15, 2014) (vacating dismissal and remanding a false advertising / unfair competition challenge for alleged false marketing by a generic competitor of its product as therapeutically equivalent to the pioneer product)

Competition Issues Regarding Communication of (HOER)

- Challenges illustrate the need, in communications of HOER to formularies and other purchasing entities, to:
 - Disclose details regarding the data and methodology used
 - Disclose any potential conflicts of interest and researchers' affiliations
 - Consider distributing the entire article or study with any press release or promotional materials
 - Consider limiting circulation of HOER to medical / healthcare professional recipients
 - Closely review and script any oral presentations on HOER to formularies and other payer or prescribing audiences

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