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Antitrust Issues Regarding Risk-Sharing Arrangements and Communications with ACOs and Other Healthcare Integrated Delivery Systems

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Antitrust Issues Regarding Risk-Sharing Arrangements

- Antitrust laws are focused on competitive effects of pricing and discounting and competing sellers and buyers
- Many common risk-sharing arrangements by healthcare product manufacturers with accountable care organizations (ACOs) and other integrated delivery systems (IDSs) potentially raise antitrust concerns
- Focus and enforcement of antitrust laws are often in conflict with the focus on attaining efficiencies from consolidation of healthcare delivery systems, group purchasing, and new risk-sharing arrangements

Overview of U.S. Antitrust Laws

- Sherman Act
  - Section 1 prohibits agreements that reduce competition
  - Section 2 prohibits monopolization and attempts to monopolize
- Clayton Act
  - Section 3 prohibits certain types of conduct when anticompetitive, such as exclusive dealing and tying
  - Section 7 prohibits mergers and joint ventures that may substantially lessen competition
- Robinson-Patman Act (Section 2(a) of the Clayton Act)
  - Prohibits price discrimination: the contemporaneous sale of products of like grade and quality at different prices to competing buyers where the effect is to injure competition in resale of the product
- Federal Trade Commission Act
  - Generally prohibits the same practices as the Sherman and Clayton Acts, as well as practices that are unfair and deceptive

Overview of U.S. Antitrust Laws: U.S. Antitrust Enforcement & Health Care

- The antitrust laws are intended to
  - ensure independent decision-making in pricing and distribution
  - protect competition, not competitors
  - **most important focus for understanding antitrust is: follow the effect on prices**

"Antitrust enforcement can improve health care in two ways. First, by preventing or stopping anticompetitive agreements to raise prices, antitrust enforcement saves money that consumers, employers, and governments otherwise would spend on health care. Second, competition spurs innovation that improves care and expands access."

» Richard Feinstein, Director of the FTC Bureau of Competition, Statement before the House Representatives Subcommittee on Courts and Competition Policy (Dec. 1, 2010)

Overview of U.S. Antitrust Laws:
Consequences of Antitrust Violations

- Corporate:
  - Government Fines
  - Private Treble Damages
  - Legal fees
  - Business disruption

- Individual:
  - Fines
  - Job Loss
  - Jail Time

Overview of U.S. Antitrust Laws:
Per Se Illegal vs. Rule of Reason Analysis

- Certain agreements among competitors to limit competition are ***per se*** illegal and considered felonies under the U.S. antitrust laws

- ***Per se*** illegal agreements include: price-fixing, bid-rigging, market/customer allocation, and output reduction or restriction

- **Rule of Reason** analysis involves a case-by-case evaluation of the overall competitive effect of the activity, weighing the procompetitive benefits against the anticompetitive harms

- **Rule of Reason** applies to all other agreements (i.e., agreements that are not *per se* illegal)
- Examples include exclusive dealing arrangements, requirements contracts, most favored nation (MFN) agreements, consortium bidding arrangements, and joint ventures

Overview of U.S. Antitrust Principles:
Market Definition & "Market Power"

- Traditional Rule of Reason analysis requires proof of "market power," i.e., the ability to raise prices above those that would be charged in a competitive market in a properly defined *antitrust* product and geographic market
  - Market power is not simply equivalent to market share

- Antitrust markets are typically defined from the perspective of the customer for the relevant goods and services
  - Are the products substitutable: function; prices
  - What would the customer response be to a 5-10% price increase?

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 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** still applies outside the safety zone

Application of U.S. Antitrust Laws:
Most Favored Nation Clauses (MFN)

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 IDSs)

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

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
  - Mandatory and permissive MFNs
- 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:
Joint Ventures (JVs)

Definition

- JVs in antitrust analysis include all collaborations other than mergers, including some types of healthcare risk-sharing arrangements between product suppliers and buyers
- JVs are common and ordinarily procompetitive, e.g., by allowing expansion into new products or markets, funding innovation activities, and lowering production or distribution costs

Risk Analysis

- JVs may raise antitrust concerns if a JV is likely to harm competition by increasing the ability or incentive profitably to raise price above, or reduce output, quality, service, or innovation below, what likely would occur in the absence of the JV. *FTC and DOJ, Antitrust Guidelines for Collaboration Among Competitors (2000)*

Current Antitrust Enforcement Issues – ACOs / GPOs / IDSs

- DOJ/FTC have expressed continued concerns regarding risk-sharing arrangements with ACOs and similar 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 Mahinka, et al., FTC/DOJ Final Statement on Accountable Care Organizations: Important Antitrust Issues Remain Unanswered, BNA Health Care Reporter (Dec. 1, 2011)
    - See Remarks by Deborah Feinstein, Director, FTC Bureau of Competition, "Antitrust Enforcement in Health Care: Proscription, not Prescription" (June 19, 2014)
- Principal antitrust concerns include: preventing payers from steering patients to certain providers; tying sales of an ACO's services to other services from providers outside the ACO; and requiring exclusivity

Antitrust Enforcement Issues – MFN Clauses

- MFNs with ACOs and similar purchasing entities raise potential antitrust concerns regarding exclusion of competing sellers and regarding unlawful price discrimination
  - See, e.g., United States v. Blue Cross Blue Shield of Michigan, (E.D. Mich) (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) (follow-on class action by individual buyers and small businesses alleging damages from use of the MFN clauses)
  - See also United States v. Apple, Inc., 952 F. Supp. 2d 638 (S.D.N.Y. 2013) (MFN clause held unlawful even in absence of any current market share)
- MFN clauses may raise potential price discrimination concerns, by creating possible price differentials among customers
  - Questions to consider include: volume discount and/or functional discount defenses; whether the affected buyers are in the same class of trade; the likely resale impact of the price differentials in the marketplace

Antitrust / Challenges and Issues – Exclusivity Arrangements

- Exclusive dealing arrangements / loyalty discounts
  - United States v. Dentsply, Inc., 399 F.3d 181 (3d Cir. 2005) (exclusive supply agreements held unlawful; foreclosure of rival suppliers)
  - 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)
  - 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)

Antitrust / Challenges and Issues – Exclusivity Arrangements

- 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)
- 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)

Antitrust Developments – Exclusivity Arrangements

- Eisai, Inc. v. Sanofi-Aventis U.S., Civ. No. 14-2017 (D.N.J., March 28, 2014) (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)
- 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)
- Note recent initiative by pharmaceutical buyers to use restricted formularies to make 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)

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

- FDA policy with respect to communications with purchasers and payers, 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, in accordance with its letter of acceptance of drug industry citizen petitions (June 6, 2014)

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 Casenote, 127 Harvard L. Rev. 1815 (2014)
  - 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 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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