THE THIRTEENTH ANNUAL Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum

TRANSFORMATIONAL LEARNING — EFFECTIVE KNOWLEDGE EXCHANGE

Mini Summit I:

Co-Pay Coupon Litigation Update

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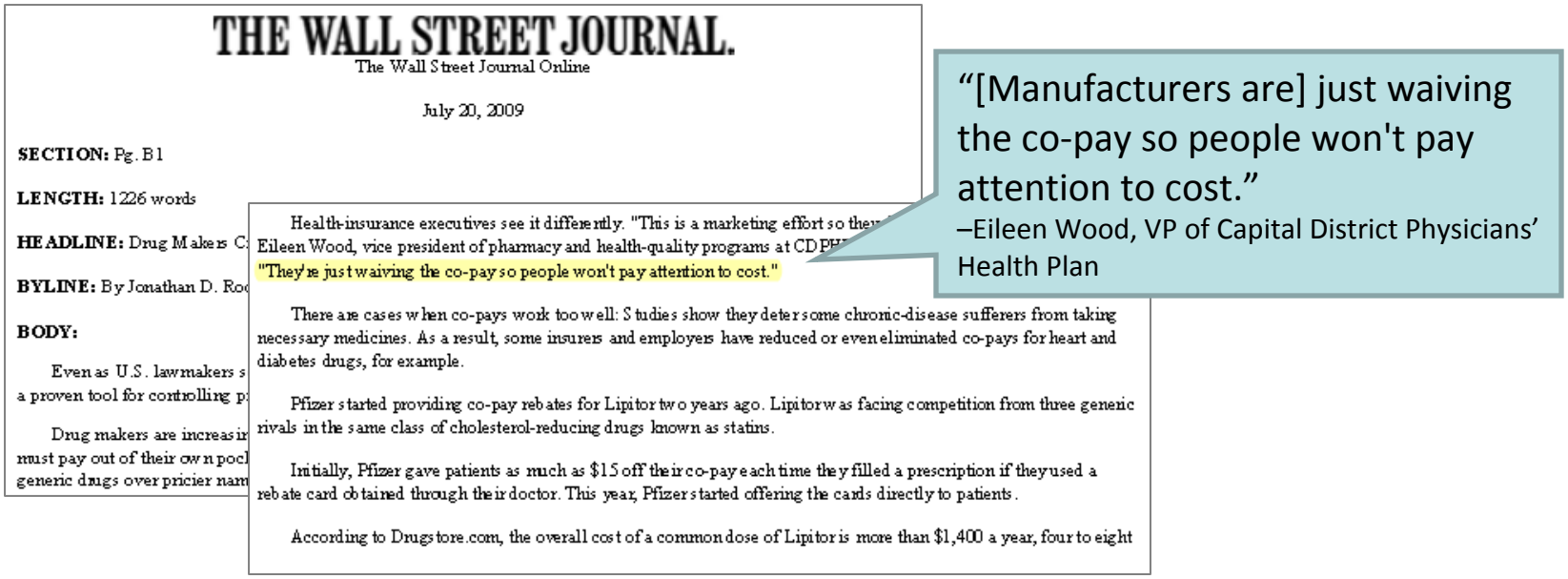
November 6, 2012

Agenda

- Overview of criticisms pertaining to co-pay coupon programs
- Description of plaintiffs' underlying theories
- Update on litigation
- Examination of key defenses and supporting data
- Review of manufacturers' compliance approaches pre- and post-litigation
- Discussion of Massachusetts' recent legislative changes and ambiguities in the amended statutory language

Co-Pay Coupon Programs: Widespread, But Subject to Criticism in the Press

- Despite the implicit endorsement of coupons found in CMS price reporting rules and in the failure of every state but Massachusetts to prohibit them, press reports criticize the more than 350 branded programs involving over 60 drug manufacturers.[1]
- The reports have been published for several years.



THE WALL STREET JOURNAL.
The Wall Street Journal Online

July 20, 2009

SECTION: Pg. B1

LENGTH: 1226 words

HEADLINE: Drug Makers C

BYLINE: By Jonathan D. Roc

BODY:

Even as U.S. lawmakers s
a proven tool for controlling p

Drug makers are increasir
must pay out of their own pocl
generic drugs over pricier nam

Health-insurance executives see it differently. "This is a marketing effort so their
Eileen Wood, vice president of pharmacy and health-quality programs at CDPH
"They're just waiving the co-pay so people won't pay attention to cost."

There are cases when co-pays work too well: Studies show they deter some chronic-disease sufferers from taking necessary medicines. As a result, some insurers and employers have reduced or even eliminated co-pays for heart and diabetes drugs, for example.

Pfizer started providing co-pay rebates for Lipitor two years ago. Lipitor was facing competition from three generic rivals in the same class of cholesterol-reducing drugs known as statins.

Initially, Pfizer gave patients as much as $15 off their co-pay each time they filled a prescription if they used a rebate card obtained through their doctor. This year, Pfizer started offering the cards directly to patients.

According to Drugstore.com, the overall cost of a common dose of Lipitor is more than $1,400 a year, four to eight

"[Manufacturers are] just waiving the co-pay so people won't pay attention to cost."
–Eileen Wood, VP of Capital District Physicians' Health Plan

[1] Cleveland Research Company, Medicis Pharmaceutical Corp. (MRS) Report (December 2, 2011).

Co-Pay Coupon Programs: Widespread, But Subject to Criticism in the Press (cont'd)

The New York Times

January 1, 2011

Coupons for Patients, but Higher Bills for Insurers

By ANDREW POLLACK

EXECUTIVES of a small insurance company in Albany were mystified when, almost overnight, its payments for a certain class of antibiotics nearly doubled, threatening to add about a half-million dollars annually in costs.

The reason, it turned out, was that patients were using a card distributed by the maker of an expensive antibiotic used to treat acne, sharply reducing their insurance co-payments. With their out-of-pocket costs much lower, consumers had switched from generic alternatives to the more expensive drug.

With drug prices rising and many people out of work, pharmaceutical companies are increasingly helping patients with their co-payments. The use of such co-payment cards and coupons and other types of discounts has more than tripled since mid-2006, according to IMS Health, an information company that tracks the pharmaceutical industry.

Last month, for instance, Pfizer introduced a new card that can reduce the co-pay on its blockbuster drug Lipitor to $4 a month, a savings of up to $50. That brings the out-of-pocket cost in line with what consumers might pay at Wal-Mart for a generic version of a competing cholesterol-lowering drug.

Drug companies say the plans help some patients afford medicines that they otherwise could not.

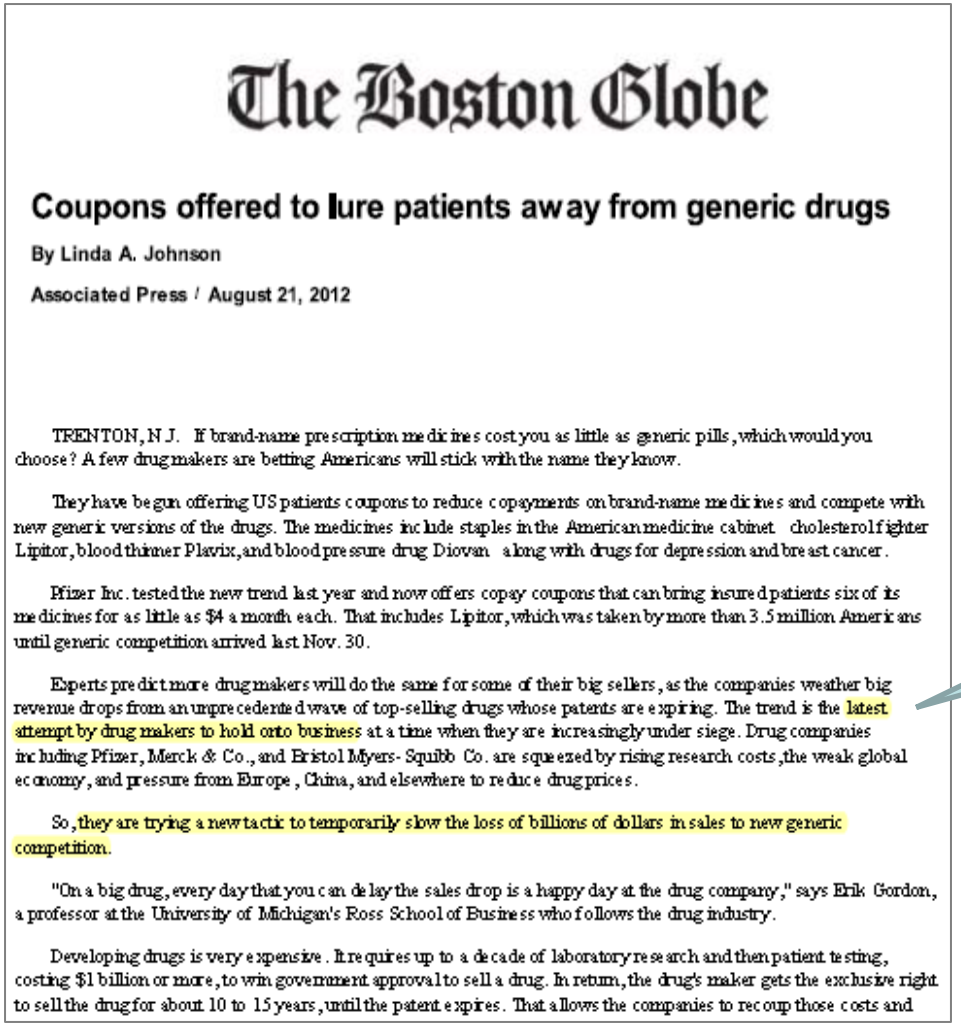
But health insurers and some consumer groups say that in many cases, the coupons are just marketing gimmicks that are leading to an overall increase in health care costs. That is because they circumvent the system of higher co-pays on costlier drugs that insurers use to encourage consumers to use less expensive products.

"The member is somewhat insulated from the cost of the prescription," said Kevin Slavik, senior director of pharmacy at the Health Care Service Corporation, which runs Blue Cross and Blue Shield plans in Illinois and three other states. "In essence, it drives up the total cost of providing the prescription benefit."

The Food and Drug Administration, meanwhile, is studying the effect of the discounts on consumer perceptions,

"[H]ealth insurers . . . say that in many cases, the coupons are just marketing gimmicks that are leading to an overall increase in health care costs."

Co-Pay Coupon Programs: Widespread, But Subject to Criticism in the Press (cont'd)



The Boston Globe

Coupons offered to lure patients away from generic drugs

By Linda A. Johnson

Associated Press / August 21, 2012

TRENTON, N.J. If brand-name prescription medicines cost you as little as generic pills, which would you choose? A few drug makers are betting Americans will stick with the name they know.

They have begun offering US patients coupons to reduce copayments on brand-name medicines and compete with new generic versions of the drugs. The medicines include staples in the American medicine cabinet: cholesterol fighter Lipitor, blood thinner Plavix, and blood pressure drug Diovan, along with drugs for depression and breast cancer.

Pfizer Inc. tested the new trend last year and now offers copay coupons that can bring insured patients six of its medicines for as little as $4 a month each. That includes Lipitor, which was taken by more than 3.5 million Americans until generic competition arrived last Nov. 30.

Experts predict more drug makers will do the same for some of their big sellers, as the companies weather big revenue drops from an unprecedented wave of top-selling drugs whose patents are expiring. The trend is the latest attempt by drug makers to hold onto business at a time when they are increasingly under siege. Drug companies including Pfizer, Merck & Co., and Bristol-Myers Squibb Co. are squeezed by rising research costs, the weak global economy, and pressure from Europe, China, and elsewhere to reduce drug prices.

So, they are trying a new tactic to temporarily slow the loss of billions of dollars in sales to new generic competition.

"On a big drug, every day that you can delay the sales drop is a happy day at the drug company," says Erik Gordon, a professor at the University of Michigan's Ross School of Business who follows the drug industry.

Developing drugs is very expensive. It requires up to a decade of laboratory research and then patient testing, costing $1 billion or more, to win government approval to sell a drug. In return, the drug's maker gets the exclusive right to sell the drug for about 10 to 15 years, until the patent expires. That allows the companies to recoup those costs and

"[Co-pay coupon programs are] the latest attempt by drug makers to hold onto business . . . [T]hey are trying a new tactic to temporarily slow the loss of billions of dollars in sales to new generic competition."

Publicized Harms Regarding Co-Pay Coupon Programs

- Recent press coverage has suggested that by sponsoring co-pay coupon programs, drug manufacturers are undermining the cost-sharing arrangements and formulary structures established by private payors to control costs.
  - Specifically, some insurers claim that co-pay coupon programs reduce out-of-pocket expenses on expensive branded drugs to such a degree that many patients are switching from cheaper therapies to more expensive ones.
  - These payors contend that, as a result, they are paying for an increased number of expensive prescriptions that their beneficiaries would not have otherwise used.

From the Press to the Courtroom: How Did We Get Here?

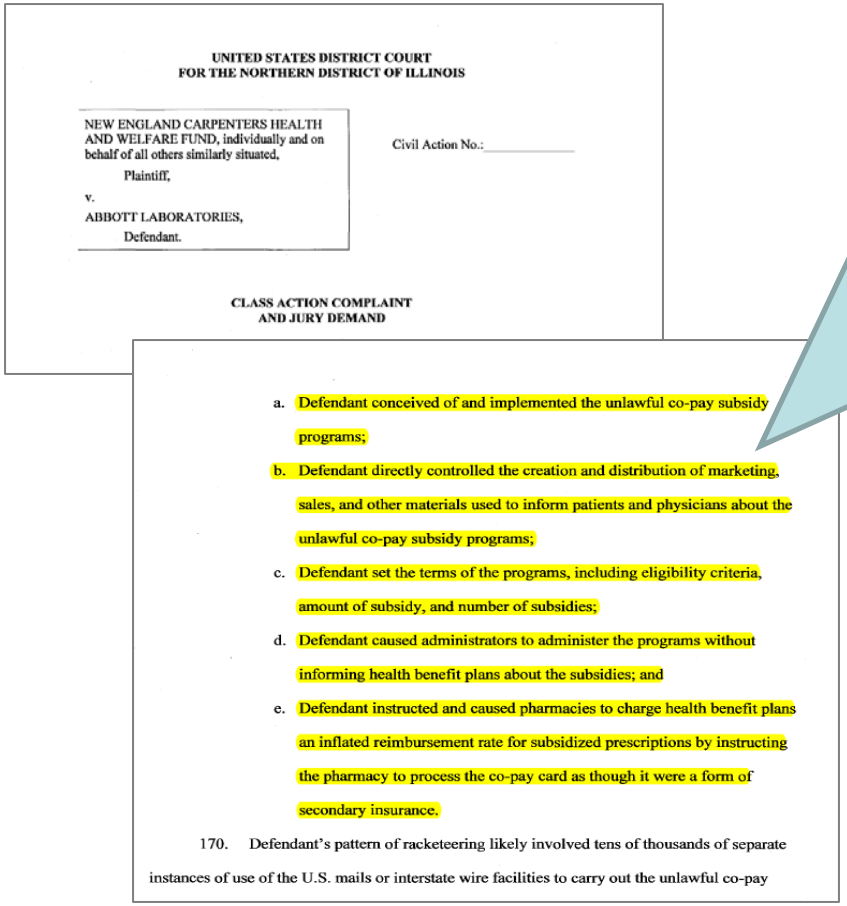
- In March 2012, certain private, union-sponsored health plans filed seven federal class action lawsuits against nine drug manufacturers in the Northern District of Illinois, District of New Jersey, Southern District of New York, and Eastern District of Pennsylvania.
- The plaintiffs are members of Prescription Access Litigation (PAL) – a national coalition of more than 130 organizations that works to make drug prices "more affordable" for consumers using class action litigation and public education.
  - PAL is a project of the consumer advocacy group, Community Catalyst.

From the Press to the Courtroom: How Did We Get Here? (cont'd)

- Rather than focusing on plan administrators, pharmacies, or the insureds, plaintiff private payors appear to be targeting manufacturers under the rationale that drug manufacturers exert control over the co-pay coupon programs in the following ways (as described in plaintiffs' RICO claims):
  - Conceive of program terms and implement the program,
  - Control the creation and distribution of marketing, sales and other materials relating to the program,
  - Cause administrators to withhold information about the co-pay coupons from benefit plans, and
  - Instruct pharmacies to process the co-pay coupon as though it were a form of secondary insurance.[2]
- Thus, plaintiffs did not name co-pay coupon program administrators (OPUS Health, TrialCard, Inc., Pharmacy Data Management, Inc., McKesson, PSKW LLC, and Emdeon) as co-defendants, but did allege that they were co-conspirators.

[2] *See e.g.*, Class Action Complaint and Jury Demand, *New England Carpenters Health & Welfare Fund v. Abbott Laboratories*, No. 1:12-CV-01662, ¶ 169 (N.D. Ill. filed Mar. 7, 2012).

From the Press to the Courtroom: How Did We Get Here? (cont'd)



UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

NEW ENGLAND CARPENTERS HEALTH AND WELFARE FUND, individually and on behalf of all others similarly situated,
Plaintiff,
v.
ABBOTT LABORATORIES,
Defendant.

Civil Action No.:_____

CLASS ACTION COMPLAINT
AND JURY DEMAND

a. Defendant conceived of and implemented the unlawful co-pay subsidy programs;

b. Defendant directly controlled the creation and distribution of marketing, sales, and other materials used to inform patients and physicians about the unlawful co-pay subsidy programs;

c. Defendant set the terms of the programs, including eligibility criteria, amount of subsidy, and number of subsidies;

d. Defendant caused administrators to administer the programs without informing health benefit plans about the subsidies; and

e. Defendant instructed and caused pharmacies to charge health benefit plans an inflated reimbursement rate for subsidized prescriptions by instructing the pharmacy to process the co-pay card as though it were a form of secondary insurance.

170. Defendant's pattern of racketeering likely involved tens of thousands of separate instances of use of the U.S. mails or interstate wire facilities to carry out the unlawful co-pay

"[D]efendant exerted control over the co-pay subsidy enterprises . . . in the following ways:
a. Defendant conceived of and implemented the unlawful co-pay subsidy programs;
b. . . . directly controlled the creation and distribution of marketing, sales, and other materials. . .;
c. . . . set the terms of the programs . . . ;
d. . . . caused administrators to administer the programs without informing health benefit plans about the subsidies;
and . . .
e. instructed and caused pharmacies to charge health benefit plans an inflated reimbursement rate for subsidized prescriptions by instructing the pharmacy to process the co-pay card as though it were a form of secondary insurance."[3]

[3] Class Action Complaint and Jury Demand, *New England Carpenters Health & Welfare Fund v. Abbott Laboratories*, No. 1:12-CV-01662, ¶ 169 (N.D. Ill. filed Mar. 7, 2012).

From the Press to the Courtroom: How Did We Get Here? (cont'd)

- Plaintiffs' "control" theory ignores that ultimately doctors control prescription decisions and ultimately health plans control whether and how they will pay for medications.
- Among other things, health plans could take the following steps to avoid any perceived influence by co-pay coupon programs:
  - Ban the use of coupons
    - As of January 1, 2013, UnitedHealthcare's network specialty pharmacies will be prohibited from redeeming co-pay coupons on six drugs.[4]
  - Require step therapy
  - Require prior authorization

[4] UnitedHealthcare to Limit Acceptance of Manufacturer Copay Coupons (Aug. 29, 2012), http://consultant.uhc.com/articleView-10051.

Plaintiffs' Litigation Theories

- The Complaints in the co-pay coupon litigation actions are based on the following theories:
  - Violations of the Racketeer Influenced and Corrupt Organizations Act (RICO)
  - Violations of the Robinson-Patman Act
  - Tortious interference with contractual relations

Plaintiffs' Theory: The Kitchen Sink
Racketeer Influenced and Corrupt Organizations Act

- 18 U.S.C. § 1962(c)
  - "It shall be unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity . . ."

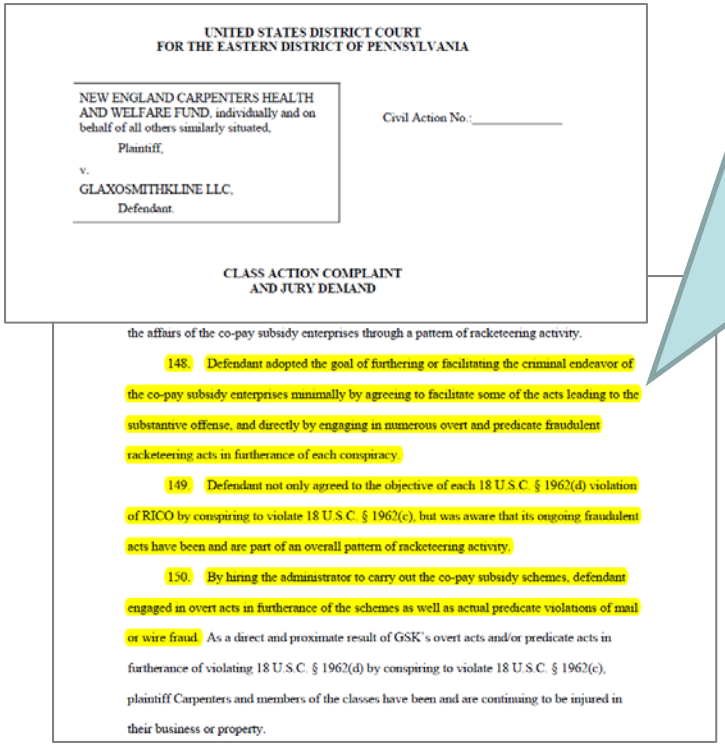
Plaintiffs' Theory: The Kitchen Sink
RICO (cont'd)

- Theory re: substantive violations: Payors allege that drug manufacturers with co-pay coupon programs "interfer[e] with . . . cost-sharing provisions, causing [plans] to pay for prescriptions [of more expensive drugs] . . . that they would not otherwise have paid for."
- Specifically, plaintiffs allege that drug manufacturers cause misrepresentations to be made using the mails or wires when:
  - "the member presents the co-pay card at the pharmacy . . . when, as instructed by the defendant, the pharmacist electronically charges . . . full benchmark prices without accounting for . . . co-pay subsidies[,]" and
  - "[manufacturers] report . . . benchmark prices to reporting agencies while failing to account for the routine waiver of co-pays."[5]

[5] Class Action Complaint and Jury Demand, *Plumbers and Pipefitters Local 572 Health and Welfare Fund v. Novartis Pharmaceuticals Corp.*, No. 2:12-01403, ¶¶ 138-40 (D.N.J. filed Mar. 7, 2012).

Plaintiffs' Theory: The Kitchen Sink
RICO (cont'd)

- Theory re: conspiracy allegations:



UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

NEW ENGLAND CARPENTERS HEALTH AND WELFARE FUND, individually and on behalf of all others similarly situated,
Plaintiff,
v.
GLAXOSMITHKLINE LLC,
Defendant.

Civil Action No.:_____

CLASS ACTION COMPLAINT
AND JURY DEMAND

the affairs of the co-pay subsidy enterprises through a pattern of racketeering activity.

148. Defendant adopted the goal of furthering or facilitating the criminal endeavor of the co-pay subsidy enterprises minimally by agreeing to facilitate some of the acts leading to the substantive offense, and directly by engaging in numerous overt and predicate fraudulent racketeering acts in furtherance of each conspiracy.

149. Defendant not only agreed to the objective of each 18 U.S.C. § 1962(d) violation of RICO by conspiring to violate 18 U.S.C. § 1962(c), but was aware that its ongoing fraudulent acts have been and are part of an overall pattern of racketeering activity.

150. By hiring the administrator to carry out the co-pay subsidy schemes, defendant engaged in overt acts in furtherance of the schemes as well as actual predicate violations of mail or wire fraud. As a direct and proximate result of GSK's overt acts and/or predicate acts in furtherance of violating 18 U.S.C. § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c), plaintiff Carpenters and members of the classes have been and are continuing to be injured in their business or property.

"Defendant adopted the goal of furthering or facilitating . . . the co-pay subsidy enterprises minimally by agreeing to facilitate. . .acts leading to the substantive offense, and directly by engaging in . . . overt and predicate fraudulent racketeering acts in furtherance of each conspiracy.

Defendant not only agreed to the objective of each . . . violation of RICO by conspiring to violate 18 U.S.C. § 1962(c), but was aware that its ongoing fraudulent acts . . . are part of an overall pattern of racketeering activity.

By hiring the administrator . . . defendant engaged in overt acts in furtherance of the schemes as well as actual predicate violations of mail or wire fraud."[6]

[6] Class Action Complaint and Jury Demand, *New England Carpenters Health & Welfare Fund v. GlaxoSmithKline LLC*, No. 2:12-CV-01191, ¶¶ 148-50 (E.D. Pa. filed Mar. 7, 2012).

Plaintiffs' Theory: The Robinson-Patman Act "Huh?"

- 15 U.S.C. § 13(c)
  - "It shall be unlawful for any person engaged in commerce . . . to pay or grant, or to receive or accept, anything of value as a commission, brokerage, *or other compensation, or any allowance or discount in lieu thereof* . . . either to the other party to such transaction or to *an agent, representative, or other intermediary . . .*" (emphasis added).
- Theory: Payors allege that the drug manufacturer is a "person" giving something of value (*i.e.*, the co-pay coupon) to an "agent, representative, or other intermediary" (*i.e.*, the insured individual) in violation of the Act.[7]
- Key asserted defenses:
  - Lack of a requisite "antitrust injury" that impairs competition between the plaintiff and its competitors
  - Failure to allege illegal payment to the plaintiff's fiduciary, as beneficiaries do not owe a fiduciary duty to their pension plans
  - Payments to the beneficiaries were not made in secret

[7] *See e.g.*, Class Action Complaint and Jury Demand, *New England Carpenters Health and Welfare Fund v. AstraZeneca, Inc.*, No. 2:12-CV-01192, ¶¶ 180-81 (E.D. Pa. filed Mar. 7, 2012).

Plaintiffs' Theory: Tortious Interference with Contractual Relations

- Theory: "Defendant tortiously interfere[d] with the contractual relations between the Fund and other Class members and their participants by causing the participants to breach their contractual obligations to pay co-pay amounts under the terms of their respective plans."
  - "Defendant is aware of the obligation of health plan beneficiaries to pay a higher co-pay for its branded . . . drugs than for equivalent generic . . . drugs . . .
  - Defendant's co-pay subsidy plan induces beneficiaries of the Fund and other class members' health plans to breach their obligation . . .
  - Defendants are aware of the existence of the contractual relationship between the Fund and other class members on the one hand and their respective participants on the other hand because, in order to obtain a coupon for Defendant's co-pay subsidy program, the beneficiary must advise Defendant that the beneficiary is covered by a private health insurance plan."[8]
- Though tortious interference was not alleged in the original Community Catalyst actions, it has been invoked in the more recent "follow-on" cases.

[8] *See e.g.*, Class Action Complaint and Jury Demand, *United Food and Commercial Workers International Union, Local 464A Health and Welfare Fund v. Merck & Co., Inc.*, No. 3:12-CV-03652, ¶¶ 5, 136, 138, 140 (D.N.J. filed Jun. 15, 2012).

Procedural Updates on the Co-Pay Coupon Litigation

- After bringing suit in different district courts, Plaintiffs sought to consolidate all of the cases in a Multi-District Litigation in the Northern District of Illinois. The defendants all opposed.
- On August 2, 2012, Plaintiffs' Multidistrict Litigation Petition for Consolidation of the seven class action lawsuits was denied, despite the filing of six additional cases in the Southern District of Illinois, the District of New Jersey, and the Eastern District of New York

> "Each action involves a different pharmaceutical manufacturer and different co-pay subsidy programs . . . [N]o plaintiff here alleges that any of the defendants conspired or collaborated to develop and implement these co-pay subsidy programs . . . [n]or do the defendants' co-pay subsidy programs overlap between actions."

– U.S. Judicial Panel on Multidistrict Litigation

Procedural Updates on the Co-Pay Coupon Litigation (cont'd)

Action	Motion to Dismiss Filed by Defendant(s)*	Responsive Pleading Not Yet Filed by Defendant(s)*	Voluntary Dismissal Filed by Plaintiff(s)*
New England Carpenters Health and Welfare Fund v. Abbott Laboratories (N.D. Ill.)	X		
Plumbers and Pipefitters Local 572 Health and Welfare Fund v. Merck & Co., Inc. (D.N.J.)	X		
American Federation of State County and Municipal Employees District Council 37 Health & Security Plan, et al. v. Bristol-Myers Squibb Co. et al. (S.D.N.Y.)	X		
New England Carpenters Health and Welfare Fund v. GlaxoSmithKline LLC (E.D. Pa.)	X		
Plumbers and Pipefitters Local 572 Health and Welfare Fund v. Novartis Pharmaceuticals Corp. (D.N.J.)		X	
American Federation of State County and Municipal Employees District Council 37 Health & Security Plan, et al. v. Amgen, Inc., et al. (S.D.N.Y.)	X		X**
New England Carpenters Health and Welfare Fund v. AstraZeneca, Inc. (E.D. Pa.)			X

** As of October 8, 2012.*

***Notice of voluntary dismissal filed for Amgen, but Pfizer remains a Defendant in the case.*

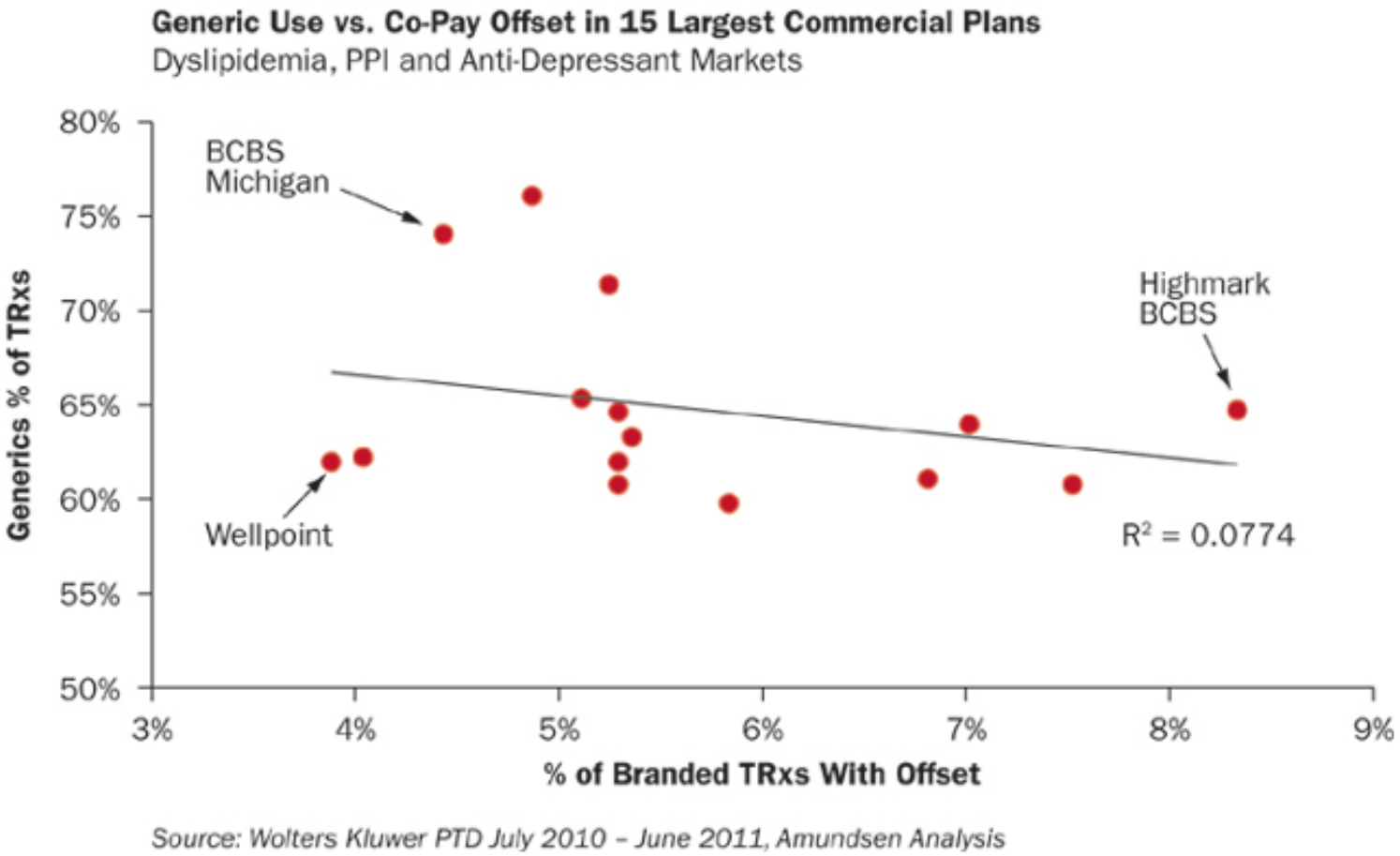
Manufacturers' Key Defenses

Lack of Standing	Failure to State A Claim	Other Defenses
Robinson-Patman Act –Lack of a requisite "antitrust injury" that impairs competition between the plaintiff and its competitors RICO –Failure to plead a cognizable RICO injury (paying for a more expensive drug is insufficiently concrete) –Insufficient causal relationship between the coupon programs and the alleged harm, especially given the physician's role as prescriber	Robinson-Patman Act –Failure to allege illegal payment to plaintiff's fiduciary, as beneficiaries do not owe a fiduciary duty to their pension plans –Payments to the beneficiaries were not made in secret RICO –Insufficient particularity in the pleadings to satisfy Rule 9(b) –Alleged non-disclosure is not fraudulent absent duty to disclose –Failure to allege specific intent to deceive –Failure to establish the existence of a RICO enterprise Tortious Interference –Failure to identify a specific contractual term barring coupon use –Failure to plead that manufacturers acted with malice –Failure to show proximate cause where learned intermediaries break the chain	Misguided Litigation –Complaints should be filed against plan administrators (not manufacturers) given their fiduciary duty owed to the pension plans Policy Arguments –Co-pay coupon programs provide clinical benefits –Increases in reimbursement associated with coupon use stem from patients who would have gone untreated and improved adherence to treatment plans

Support for Key Defenses

- Alleged harm: Increased branded drug costs where generics are available.
- Defense: The alleged harm does not constitute a "concrete financial loss" caused by the alleged RICO violation, and the relationship between the co-pay coupon programs and the alleged harm is too attenuated.
  - According to a study conducted by The Amundsen Group, in the highest-dollar-value therapeutic classes among the 15 largest commercial payors, no correlation exists between the use of generics and the prevalence of prescriptions for branded drugs with co-pay coupon programs in place.

Support for Key Defenses (cont'd)



Source: Wolters Kluwer PTD July 2010 – June 2011, Amundsen Analysis

Support for Key Defenses (cont'd)

- Alleged harm: Increased branded drug costs where other less expensive therapies are available.
- Defense: Many of the co-pay coupon programs offered by manufacturers are for specialty drugs that lack more affordable substitutes.
  - The Amundsen Group estimates that specialty branded drugs that lack less expensive alternatives represent just over 51 percent of manufacturers' total annual spending on co-pay coupon programs.[9]
    - Raises the issue of what "equivalent" therapies are – a sensitive and politicized issue.

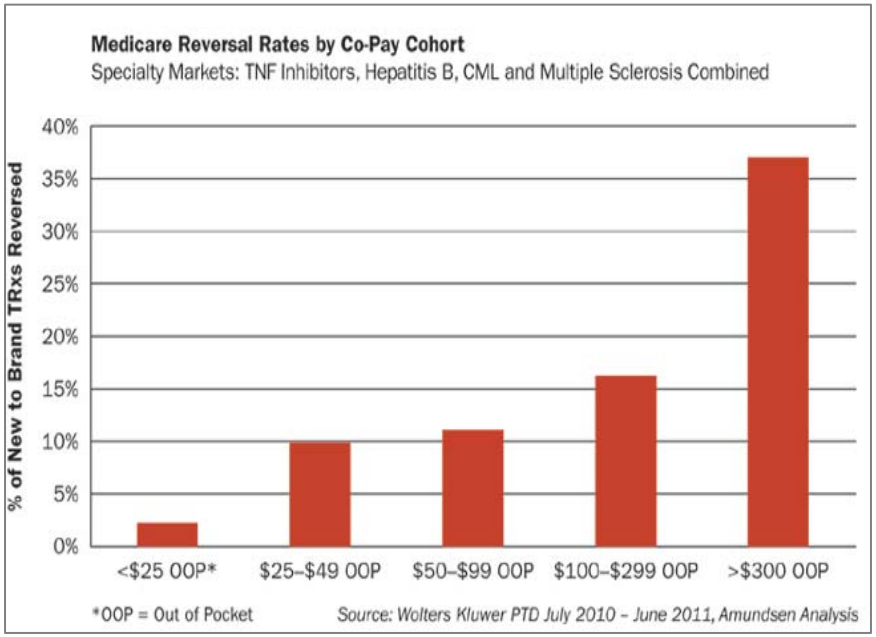
[9] Mason Tenaglia, *Copay Cards and Coupons: Letting the Facts Get in the Way*, PHARMEXEC.COM (Jan. 1, 2012), http://www.pharmexec.com/pharmexec/Commentary/Letting-the-Facts-Get-in-the-Way/ArticleStandard/Article/detail/755091.

Support for Key Defenses (cont'd)

- Defense: Data suggests that it is more likely that the increase in costs seen by insurers has not been driven by patients choosing more expensive drugs, but rather by patients who would have otherwise gone untreated due to high out-of-pocket expenses and by improved adherence to treatment plans.
  - However, critics may still point to ROI rates on these co-pay coupon programs in attempting to establish damages.
  - That said, we are aware that some Congressional members have encouraged, in certain circumstances, manufacturer-sponsored co-pay coupon programs to alleviate the financial burden on low-income, uninsured, or underinsured individuals.

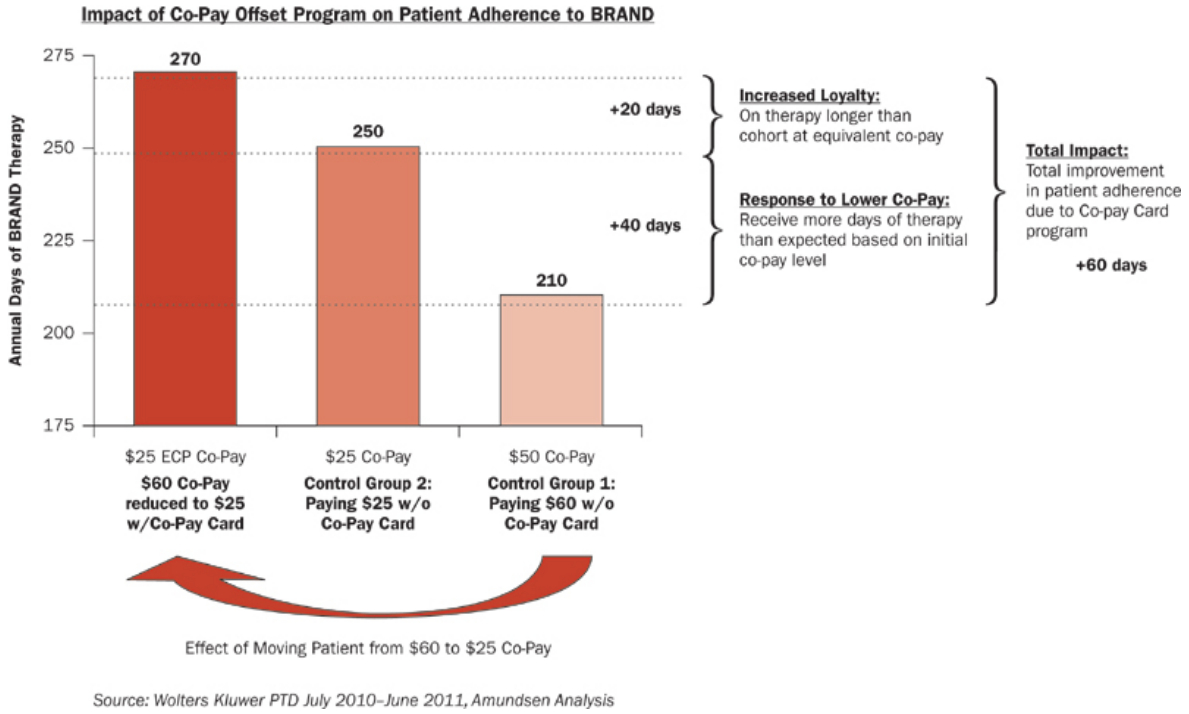
Support for Key Defenses (cont'd)

- While the graph is based on a sample of Medicare patients, it reflects broader patient tendencies to abandon prescriptions when faced with large co-pays. Thus, the study concludes that a substantial portion of drug manufacturers' ROI likely comes from patients who would have gone untreated had the co-pay coupon program not been in place.
  - Defense: Large co-pays appear to interfere with appropriate utilization.



Support for Key Defenses (cont'd)

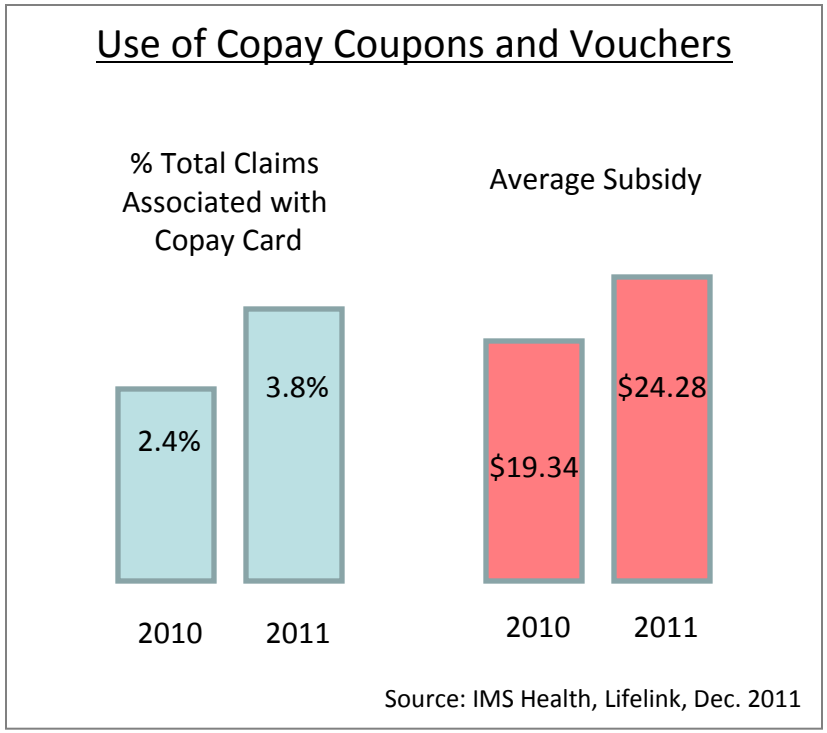
- The study also found improved treatment adherence rates associated with co-pay coupon use – another substantial source of drug manufacturers' ROI according to the report.
  - Defense: Overall health care costs should be reduced by such improved adherence.



Source: Wolters Kluwer PTD July 2010–June 2011, Amundsen Analysis

Support for Key Defenses (cont'd)

- Defense: Even where co-pay coupon programs exist for branded drugs, the use of coupons does not appear to be as prevalent as some might believe.
  - Though patient use of co-pay coupons increased from 2010 to 2011, such use was reportedly limited to less than 5% of dispensed brand prescriptions.



Litigation Factual Analytics: Other Plaintiff Arguments

Potential Arguments	Potential Analytics - Identify Evidence Supporting:
Co-pay coupons have been implicitly endorsed by government agencies	• FDA: Prescription Drug Marketing Act (PDMA) restrictions on counterfeiting and/or trafficking of co-pay coupons, FDA direct-to-consumer guidance on money saving methods. • CMS: Medicaid Drug Rebate Program specifically exempts co-pay coupons from pricing calculations. • Sunshine: Vermont disclosure laws include co-pay coupons in definition of product sample, and does not include coupons among banned activities (e.g. gifts). • Massachusetts: Now allows coupons
Co-pay coupons do not waive co-pay and instead simply divide the payment	Utilize coupon and plaintiff payment data to test, with the goal of definitively proving, that no co-pays were waived.
Co-pay coupons are not a form of secondary insurance	• No assumption of risk in any aspect of agreement • Cards revocable at will • No payment of premium (or anything) to manufacturer by patient • Any parallel provisions from insurance or consumer arenas?

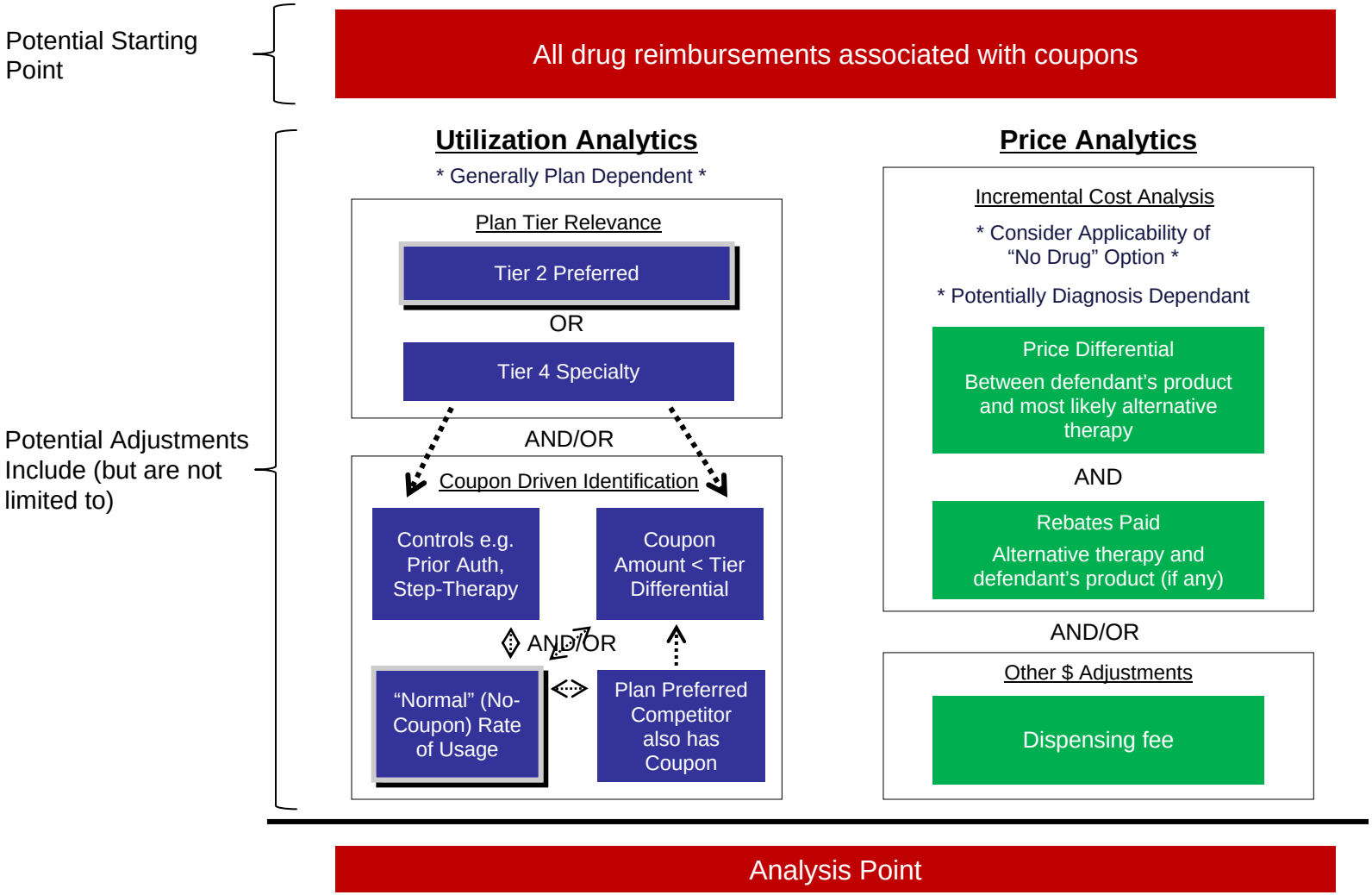
Litigation Factual Analytics: Other Plaintiff Arguments (cont'd)

Potential Arguments	Potential Analytics - Identify Evidence Supporting:
Co-pay coupons processing is not designed to hide activity in a "shadow system"	• Efficiency & consistency with industry practice • Refute payer lack of knowledge as vendor business requirement, value proposition, requirement or assessment criteria. • APLD data as credible back-end alternative.
The TPA vendor relationship was normal operating relationship and not a RICO enterprise	• Normal customer/vendor relationship with focus on positive goals and efficient performance • No overlapping leadership, common training or other indicators of an enterprise. • Potential facts related to proximate cause?
AWP was not relevant and/or not misstated	• Manufacturer reporting periods • Prior settlements and indemnifications • Government pricing and/or litigation definitions of key terms (e.g. WAC)

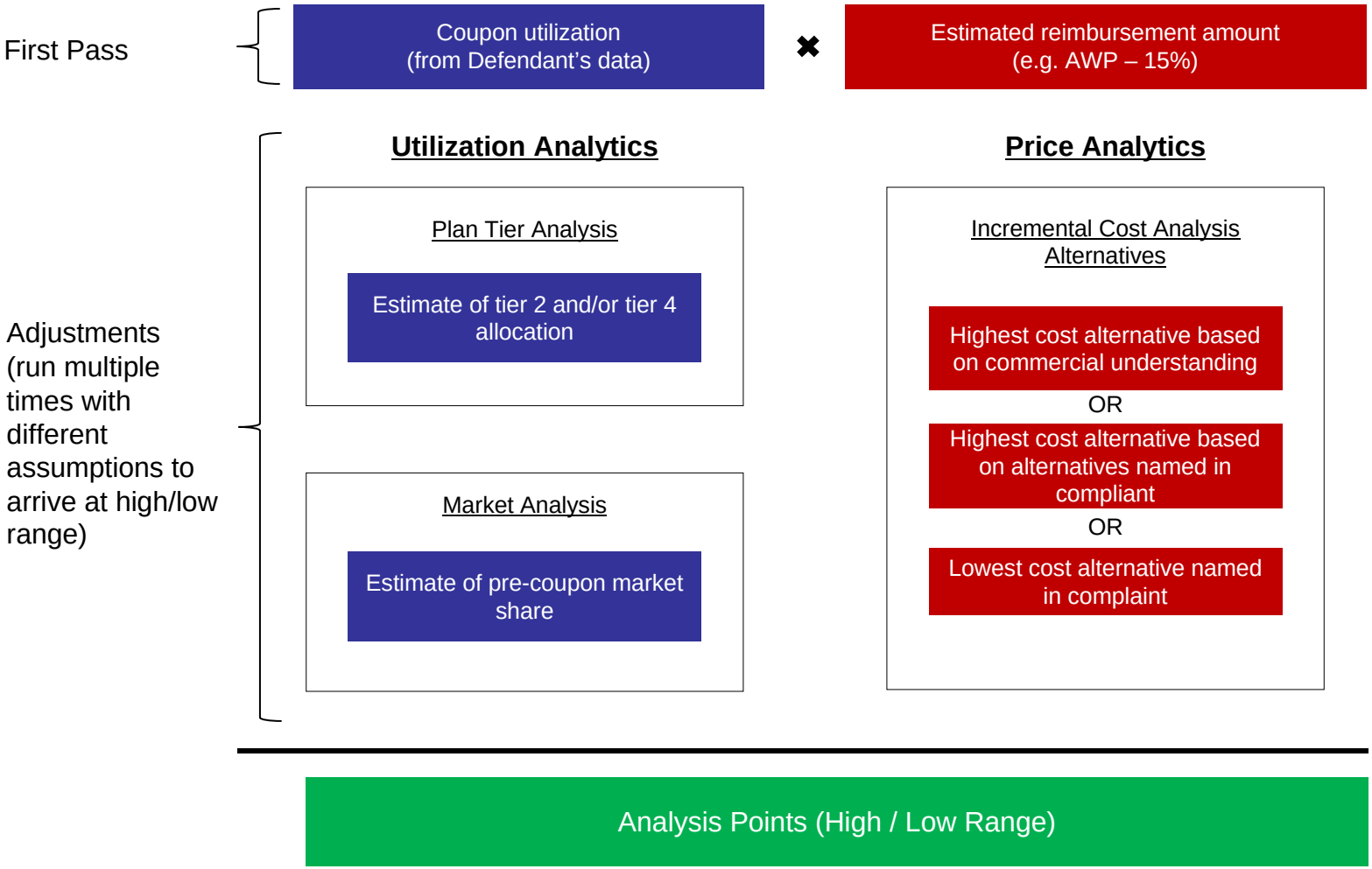
Litigation Factual Analytics: General Context

Potential Arguments	Potential Analytics - Identify Evidence Supporting:
Plaintiff's are not the unwitting and/or helpless victims that may be implied.	• Analyze history of plan payment mechanisms and tiers • Analyze commercial alternatives such as co-pay differentials, formulary rebates, mail order, and various utilization management techniques.
Information provided about the environment unsupported, unlikely and/or inaccurate.	Examples include growth/dollar projections, correlation of coupons to spend changes, drug price differentials, etc.

Litigation Risk Analysis: Numerical Analysis with All Data



Litigation Factual Analytics: Numerical Analysis with Limited Data



Manufacturers' Compliance Approaches Pre-Litigation

- To minimize risk, manufacturers have taken a wide variety of compliance approaches in their respective co-pay coupon programs.
  - General initiatives
    - Limiting the number of coupons distributed to patients
  - FHCP initiatives
    - Instituting front-end and back-end checks to prevent coupon use by FHCP beneficiaries
  - Private payor initiatives
    - Providing notification of coupon use to pharmacies and/or payors
    - Reducing the total discount provided to patients by instituting minimum patient responsibility amounts or caps (or both)
    - Some transparency letters to payors (interesting, no history of opt-out requests)
    - Some government disclosures in the form of price reporting, assumption letters
  - State-specific initiatives
    - Voiding coupon programs in Massachusetts, though some manufacturers have adopted a broader approach by voiding the program in other states

Manufacturers' Compliance Approaches Post-Litigation

- It appears that most manufacturers have not made material alterations to their co-pay coupon programs since the litigation ensued earlier this year.

Question	Results
Front-end checks: Do you have "patient activation" requirements to screen out federal health care program (FHCP) enrollees, including Part D enrollees?	Slightly more than 50% of responding manufacturers have implemented front-end checks.
Back-end checks: Have any of your vendors implemented safeguards to ensure compliance with "patient activation" requirements?	0% of responding manufacturers were aware of vendors implementing back-end checks.
Have you materially altered your co-pay coupon programs since the Community Catalyst litigation ensued earlier this year?	0% of responding manufacturers have made material alterations.

Recent Legislative Changes in Massachusetts

- Mass. Gen. Laws ch. 175H, § 3: The state anti-kickback statute shall not apply…
  - "to any discount or free product vouchers **that a retail pharmacy provides to a consumer** in connection with a pharmacy service, item or prescription transfer offer or to any discount, rebate, product voucher or other reduction in an individual's out-of-pocket expenses, including **co-payments and deductibles**, on: (i) **any biological product** . . . or (ii) any prescription drug provided by a pharmaceutical manufacturing company, . . . that is made available to an individual if **the discount, rebate, product voucher or other reduction** is provided directly . . . **to the individual or through a point of sale or mail-in rebate, or through similar means**; provided, however, that a pharmaceutical manufacturing company shall not **exclude or favor any pharmacy** in the redemption of such discount . . ."
- Potential interpretive issues:
  - **What are the permitted distribution channels for the co-pay coupons?**
  - **How should we interpret the omission of "co-payments and deductibles" after section (ii)?**
  - **Are biological products not subject to the same restrictions as prescription drugs?**
  - **What does it mean to "exclude or favor" any pharmacy?**
  - How might the Attorney General or Courts interpret the statute?

How to Respond to the Recent Activity Surrounding Co-Pay Coupon Programs?

- The co-pay coupon litigation highlights the importance of preventing federal health care program (FHCP) beneficiaries from using co-pay coupon programs.
  - In most suits alleging health care fraud against drug manufacturers, claims are typically filed under the Federal False Claims Act (FCA) and/or the Federal Anti-Kickback Statute (AKS) and their state equivalents, if applicable.
    - Under the FCA whistleblower provisions, complaints usually originate as *qui tam* actions with eventual intervention by the federal government.
  - However, neither the FCA nor the AKS is clearly applicable to drug manufacturers' co-pay coupon programs so long as the coupons are not extended to FHCP beneficiaries.
    - That said, *qui tam* actions may still arise if the Relator alleges that though the coupon program, as advertised, did not extend to FHCP programs, the coupons, in practice, were distributed to FHCP participants nonetheless.

How to Respond to the Recent Activity Surrounding Co-Pay Coupon Programs? (cont'd)

- For FHCP beneficiaries:
  - With regard to retailers, the U.S. Department of Justice has already intervened where retailers were alleged to have issued gift cards to FHCP beneficiaries for prescription transfers.
    - *E.g.*, Walgreens agreed to pay $7.9 million to settle FCA allegations that it had offered FHCP beneficiaries illegal inducements in the form of $25 gift cards for prescription transfers, despite the fact that the program advertisements stated that the offer was not applicable to government programs.[10]
  - With regard to manufacturers, the Office of Inspector General (OIG) has indicated that coupon programs may become an area of focus of additional guidance and monitoring in the coming years.
    - By fiscal year 2014, the OIG plans to issue manufacturer safeguards to protect against Medicare beneficiaries using co-pay coupons to obtain Medicare Part D drugs.[11]

[10] U.S. Department of Justice, Press Release, *Walgreens Pharmacy Chain Pays $7.9 Million to Resolve False Prescription Billing Case* (Apr. 20, 2012).
[11] Office of Inspector General, *Fiscal Year 2013 Work Plan*, available at https://oig.hhs.gov/reports-and-publications/archives/workplan/2013/Work-Plan-2013.pdf.

How to Respond to the Recent Activity Surrounding Co-Pay Coupon Programs? (cont'd)

- For FHCP beneficiaries (cont'd)
  - However, the relationship of co-pay coupon programs to qualified health plans (QHPs) offered through the state-based exchanges established under the Patient Protection and Affordable Care Act (PPACA) is less clear.
    - Do Exchange QHPs fall within the definition of FHCPs?
      - Definition of FHCP: "any plan or program providing health care benefits, whether directly through insurance or otherwise, that is funded directly, in whole or part, by the United States Government [other than the Federal Employees Health Benefits Plan]."[12]
      - PPACA (i) grants Federal funds to the States for the initial establishment of Exchanges until January 1, 2015; and (ii) requires the Federal government to pay subsidies on behalf of certain low-income individuals directly to QHP issuers.[13]

[12] 42 U.S.C. § 1320A-7b(f).
[13] *See* PPACA, Pub. L. No. 111-148, §§ 1311(a)(1), 1412(c)(2)-(3).

How to Respond to the Recent Activity Surrounding Co-Pay Coupon Programs? (cont'd)

- As drug manufacturers reflect on how to respond to the recent litigation, several factors are worth considering when assessing the level of risk associated with various co-pay coupon programs.
- Where might the greatest areas of risk lie?
  - Extending coupons to FHCP beneficiaries?
  - Creating coupon programs that undermine existing formulary structures?
  - Offering coupons on:
    - Expensive products?
    - Products with lower cost therapeutic alternatives?
    - Products with high utilization, or whose utilization will increase as a result of the co-pay coupon program?

Questions?