WILMERHALE®

WILMER CUTLER PICKERING HALE AND DORR LLP ®

WEBINAR

Navigating Antitrust Issues in the Life Sciences Industry

APRIL 25, 2019

Presenters: Andrew Bonnes, Mark Ford and Hartmut Schneider

Attorney Advertising

Webinar Guidelines

- Participants are in listen-only mode
- Submit questions via the Q&A feature
- Questions will be answered as time permits
- Offering CLE credit in California and New York*

**WilmerHale has been accredited by the New York State and California State Continuing Legal Education Boards as a provider of continuing legal education. This program is being planned with the intention to offer CLE credit in California and non-transitional CLE credit in New York. This program, therefore, is being planned with the intention to offer CLE credit for experienced New York attorneys only. Attendees of this program may be able to claim England & Wales CPD for this program. WilmerHale is not an accredited provider of Virginia CLE, but we will apply for Virginia CLE credit if requested. The type and amount of credit awarded will be determined solely by the Virginia CLE Board. Attendees requesting CLE credit must attend the entire live program. CLE credit is not available for those who watch on-demand webinar recordings.*

WEBINAR

Speakers

Andrew Bonnes
Partner
WilmerHale

Mark A. Ford
Partner
WilmerHale

Hartmut Schneider
Partner
WilmerHale

Antitrust Issues for Life Science Companies

	Product Development	Transformative Transactions	Sales Practices	Litigation & Adversity
Context	• Licensing • Collaborations	• M&A • Exclusive options	• Marketing of successful drugs	• Generic challenges • Lifecycle Management
Goals (e.g.)	• Leverage complementary R&D skills • Ensure focus	• Growth • Monetization of R&D results	• Monetization of R&D results	• Preserve product viability
Potential Issues (e.g.)	• Non-competes • Combination of limited number of R&D efforts	• Overlaps • Consolidation of R&D	• Pricing • Bundling • Exclusive supply	• REMS (samples, SSRS) • Citizens petitions • Lit. settlements • Product transitions

Antitrust Issues for Life Science Companies

1. Antitrust: issues in product development, transformative transactions, and sales practices

2. Practice Implications: how do these issues affect transaction agreements and process

Antitrust: Good First Questions to Ask

No magic list, but a few questions can go a long way

Issue	Question	Potential Red Flag
Rationale	Why are we doing this?	To avoid competition; or difficult to articulate customer benefits
Market Conditions	Market share?	> 35%
	Number of competitors?	3 or fewer
	Competitive conditions?	High barriers to entry; few players; stable market shares
Evidence	What's in the business documents?	Emphasize market concentration or benefits of elimination of competition
	Who might complain?	Customers concerned about prices, innovation, or quality; Competitors concerned about access to inputs or distribution channels

Antitrust: Technology Transfer (Licensing)

Product Development

Virtually always present in life sciences collaborations

Three widely recognized principles:

Licensing is generally procompetitive

- Usually combines complementary strengths
- Allows innovators to recoup investments
- E.g., small biotech exclusive license to large pharma with better path-to-market capabilities

Patents not presumed to convey market power

- Power to exclude from specific product does not create a competition free zone
- E.g., multiple drugs for the same indication may be patent protected, but still compete with each other

Normal antitrust principles apply to licensing restraints

- Usually "rule of reason"
- Must define markets and weigh pro- and any anticompetitive effects
- E.g., fields of use; exclusivities; restrictions on R&D

Technology Transfer: Potential Issues

Product Development

Potential Red Flags (e.g.)
Consolidation of IP among companies that would have competed using different technologies • E.g. acquisition of IP to most promising new drug
Restraint of parties' ability to exploit their own technology
Restraints beyond the scope of patents
Concerted refusals to license • (And certain unilateral refusals to license, especially outside of US)
Provisions that set prices or limit output of products made with the licensed technology • Standards vary internationally
• Provisions that might harm competition outside of the collaboration

Antitrust: R&D Collaborations

Product Development

Typically subject to the rule of reason and often procompetitive

- In the US, rarely challenged where 3+ comparative independent research efforts remain
- EU Guidelines (and related Block Exemption) provide additional guidance, much of which is also relevant elsewhere

Bristol-Myers Squibb

SANOFI

Plavix

Clopidogrel 75mg / 300mg

NOVARTIS

Roche

LUCENTIS

RANIBIZUMAB

R&D Collaborations: Potential Issues

Product Development

Potential Red Flags (e.g.)
Collaborations that combine two of a very small number of promising R&D efforts
Collaborations that involve at least one party that has market power in products that may be affected by the R&D efforts
Collaboration that restrict independent R&D, especially after termination
Collaboration that “spills over” into unrelated areas where the parties compete • E.g., through information exchanges

Transformative Transactions

Antitrust: Transformative Transactions

In life sciences, often either traditional M&A or exclusive licensing

- Antitrust test is whether the deal ”substantially lessens competition”
- Example: *Pfizer/Hospira* FTC Settlement (2015)*
  - **Hospira’s clindamycin phosphate injection.** … Without the divestiture, the merger would reduce the number of current suppliers from four to three, making it likely that prices would rise.
  - **Hospira’s voriconazole injection.** … Without the divestiture, the merger would eliminate one of a limited number of firms likely to enter the U.S. market with this product in the near future, thereby delaying beneficial competition and further price decreases.

Can early stage (e.g. pre-Phase III) transactions ever pose problems?

- FTC considers marketing probability as one factor in its review, but has declined to apply bright line cutoffs

* Source: https://www.ftc.gov/news-events/press-releases/2015/08/ftc-requires-pfizer-inc-sell-rights-four-products-condition

Transformative Transactions: Procedural Issues

To file or not to file

- In the US, depends mainly on transaction value (currently $90M)
- Virtually everywhere else in the world, depends on revenues (and sometimes assets or market shares)
  - Often means that exclusive license to drugs in development is not reportable

Filing typically triggers a two-stage review

- Initial stage of approx. 1 month to screen for issues
- In-depth review if initial look reveals potential problems

No filing, no problem?

- Unlike many foreign sister agencies, DOJ/FTC can investigate *any* acquisition of assets or voting securities, regardless of filing

Antitrust: Sales Practices

Sales Practices

Wide range of potential questions, e.g.:

Issue	What Is	Summary Analysis
Bundling	Discounts for purchasers who agree to buy multiple drugs in a manufacturer's portfolio	Generally procompetitive ("more for less"), but can raise issues when discounts make it difficult for outsiders with smaller portfolios to compete
Exclusivities	Appointment of exclusive distributors in certain territories; agreement to buy drugs for certain indications only from one manufacturer	Often procompetitive, but can raise issues when markets are concentrated
Licensor efforts to control price	Licensor wants certainty that licensee prices marketed drug at certain levels, e.g. to protect minimum royalties	Balance between restrictions on resale price maintenance (esp. outside the US) and legitimate interest in protecting royalty base. • Participation in price decision may not be acceptable, but minimum royalties often are

Practice Implications

The practical tools for addressing antitrust issues are generally designed to address two primary concerns:

- Avoiding conduct that would be prohibited under antitrust laws
- Allocating the risk of regulatory approval, where applicable

Regulatory approval is generally limited to transformative transactions, but that is not always the case. For example:

- Grant of exclusive licenses
- Concurrent equity investments

Practice Implications: Planning and Due Diligence

Consider antitrust early in the process—issues can arise long before you sign an agreement

- Preliminary risk assessment
- Information sharing
  - Access restrictions to competitively sensitive information (NDAs, clean teams, data room permissions)
  - Monitoring internal and external communications

Practice Implications: R&D Collaborations

Product Development

Collaboration agreements often include features that could be permitted or prohibited, depending on the circumstances. For example:

- Sharing competitively sensitive information
- Joint governance over development and commercialization activities, including setting prices and dividing markets
- Restraints on the development of competitive products
- Restraints on the use of technology, including licensing to third parties

Practice Implications: R&D Collaborations

Product Development

Do not assume a concept permitted in one context is safely transferrable to another. This is particularly true if:

- The parties to the transaction are competitors
- The agreement restricts or governs matters beyond the collaboration

Allocating Risk in Transformative Transactions

Purchase agreement should stipulate what filings are required

Antitrust covenant

- Efforts standard
- Commitment to offer and accept remedies, including divestitures
- Commitment to litigate and appeal

Reverse termination fee

- Paid if the transaction is unable to close due to antitrust restraints
- The size of the fee is often negotiated in inverse proportion to the Buyer's level of commitment under the antitrust covenant

Outside date

- If antitrust scrutiny is expected, the outside date should allow sufficient time for anticipated actions to facilitate antitrust approval

Interim Period in Transformative Transactions

The period between execution of the definitive agreement and closing raises additional issues

- Operating covenants restrict specified target actions during this period—such restrictions can raise antitrust concerns if they grant too much control of the target's operations
- Integration vs. integration planning
- Timing uncertainty for coordinating the closing

Antitrust Issues for Life Science Companies

1. REMS
2. Litigation Settlements
3. Product Transitions

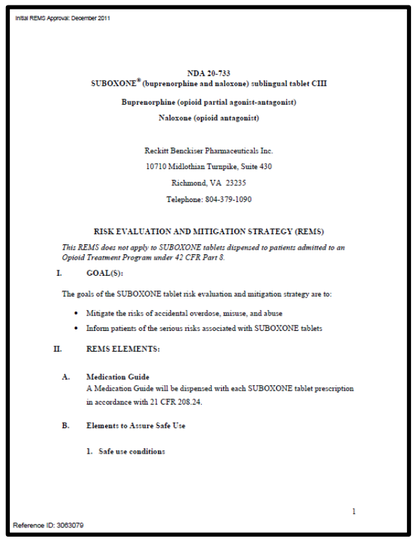
Litigation & Adversity

Aggressive Enforcement

- Focus of FTC enforcement for two decades
- Recent increase in activities from state attorneys general
- Scores of class action lawyers seeking new cases

REMS and Antitrust

Litigation & Adversity



Initial REMS Approval: December 2011

NDA 20-733
SUBOXONE® (buprenorphine and naloxone) sublingual tablet CIII

Buprenorphine (opioid partial agonist-antagonist)
Naloxone (opioid antagonist)

Reckitt Benckiser Pharmaceuticals Inc.
10710 Midlothian Turnpike, Suite 430
Richmond, VA 23235
Telephone: 804-379-1090

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

This REMS does not apply to SUBOXONE tablets dispensed to patients admitted to an Opioid Treatment Program under 42 CFR Part 8.

I. GOAL(S):

The goals of the SUBOXONE tablet risk evaluation and mitigation strategy are to:

- Mitigate the risks of accidental overdose, misuse, and abuse
- Inform patients of the serious risks associated with SUBOXONE tablets

II. REMS ELEMENTS:

A. Medication Guide
A Medication Guide will be dispensed with each SUBOXONE tablet prescription in accordance with 21 CFR 208.24.

B. Elements to Assure Safe Use

1. Safe use conditions

1

Reference ID: 3063079

Approved Risk Evaluation and Mitigation Strategies (REMS)

***Generic's Access to Samples*—"refusal to deal" claims**

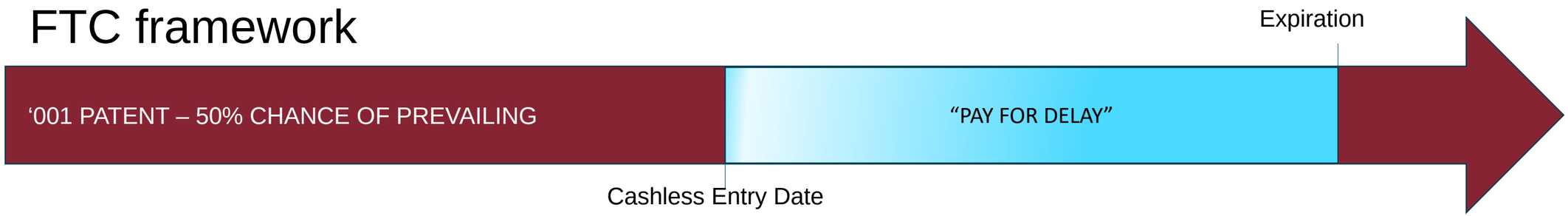
- Case law generally unfavorable if samples *are genuinely unavailable*
- Some protections for liability possible (indemnification, FDA certifications), but outright refusals to sell have been subject to antitrust scrutiny

***Single Shared REMS System*—"refusal to cooperate" claims**

- *Suboxone* (EDPA) – antitrust claim based on alleged efforts to derail SSRS, and thereby delay generic approval
- Legitimate issues: confidentiality, voting structures, cost-sharing, product liability concerns
- Antitrust implications of FDA SSRS waiver procedure?

*Settlements Post-*Actavis / Framework

Litigation & Adversity



- FTC theory:
  - Cashless entry date (“patent splitting”) results in a date reflective of the patent’s “strength” (likelihood of success)
  - Consumers are unharmed because the litigants fairly trade the risk of generic’s success (near term entry) with innovator’s success (patent expiry)
  - Additional “value transfer”—”large, unexplained payment” under *Actavis*—from innovator to generic pushes the date further out, and results in harm to consumers

Settlements Post-Actavis / Common Issues

Litigation & Adversity

Royalties from generic *Generic pays royalty on sales of generic at issue*	• Common and accepted, usually procompetitive
Acceleration clauses *Generic's entry data accelerates if there is additional entry or patent invalidation, etc.*	• Some challenges, but unsuccessful and widely included in settlements, usually procompetitive
Litigation cost avoidance *Reflects value of innovator's savings*	• Expressly recognized by FTC and *Actavis* court as permissible
Contemporaneous settlement *Another litigation settlement with same generic company (early entry on another drug; settlement of damages exposure)*	• Have been challenged with mixed success (compare *Nexium* to *Actos*)
"Fair value" transactions *Paying fair value in a contemporaneous transaction*	• Expressly recognized by *Actavis* court but standards are unclear, and subject to challenge as "overpayment" or "inducement"
No-AG provisions *Innovator agrees not to launch AG (usually during generic's exclusivity period)*	• Have been successfully challenged

*Settlements Post-*Actavis / Screening

Litigation & Adversity

Inducement

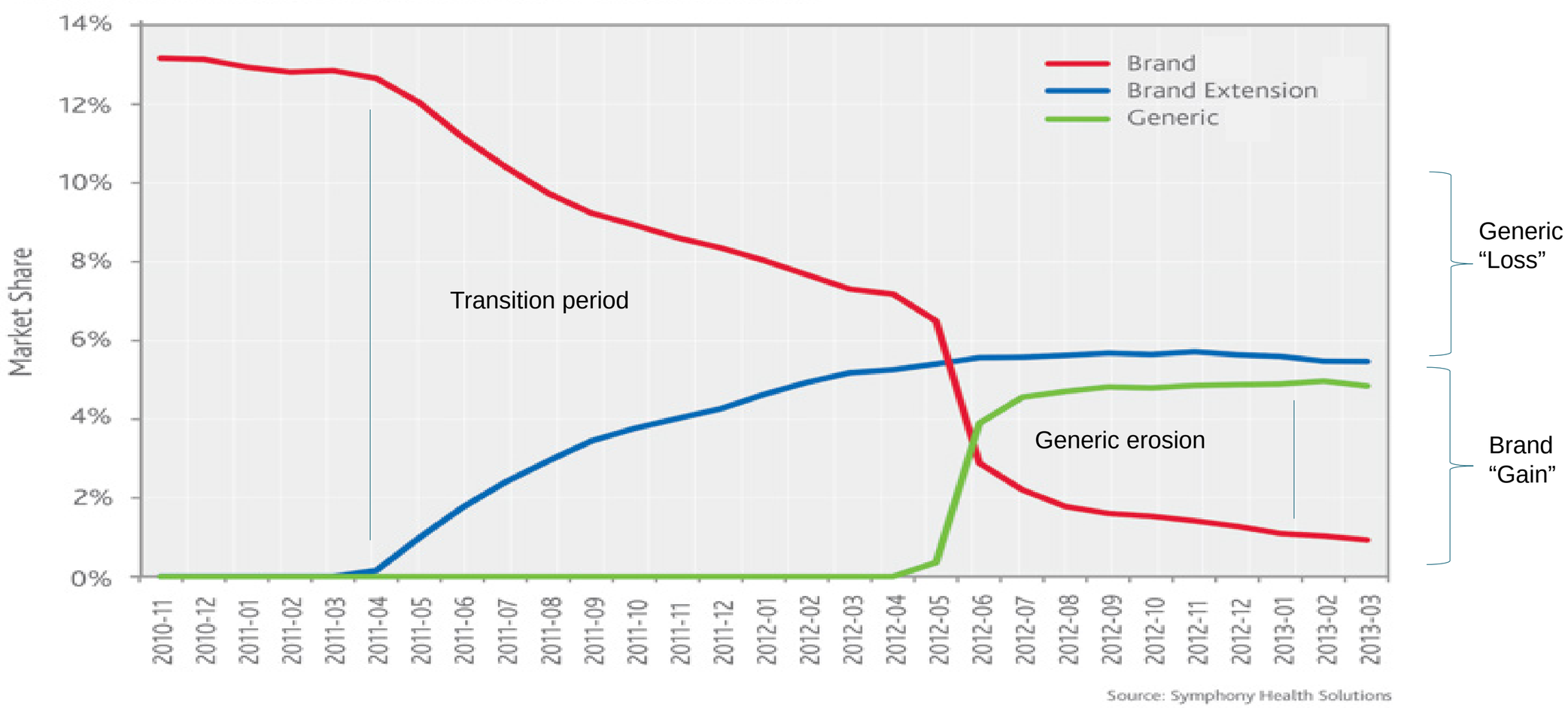
- Would the provision provide the generic company an incentive to accept a later entry date than it would have in a cashless settlement

Justification

- Does it facilitate entry or earlier entry?

"Product Hopping": Enforcers' Theory

Litigation & Adversity



"Product Hopping": Critique

Predicated on two features of pharmaceutical markets

Automatic substitution (AB-rated generics)

- Claim that generics are not incentivized to promote because of "free rider" issues
- Generics cannot "passively" gain as much in sales as they would have had they eroded the legacy drug's pre-transition market
  - **But does that really offend antitrust principles?**

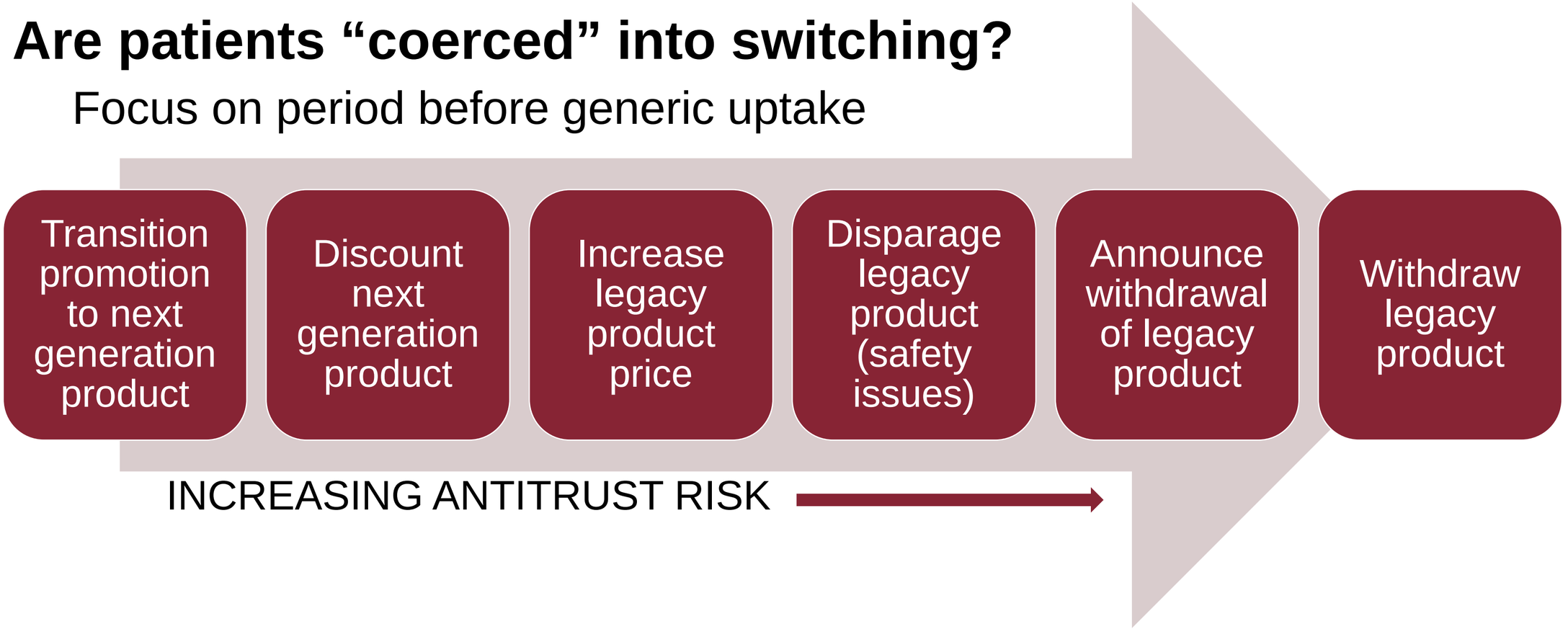
"Price disconnect"

- Party that makes "choice" (physician) is not the party that pays (TPP, patient)
- Less incentive actively to select lower cost generic of legacy product over promoted next-generation product
  - **But is this true in all cases? E.g., formulary influence**

"Product Hopping": State of the law

Are patients "coerced" into switching?

Focus on period before generic uptake



Questions

Andrew Bonnes
Partner, WilmerHale

+1 617 526 6136
Andrew.Bonnes@wilmerhale.com

60 State Street
Boston, MA 02109

Mark A. Ford
Partner, WilmerHale

+1 617 526 6423
Mark.Ford@wilmerhale.com

60 State Street
Boston, MA 02109

Hartmut Schneider
Partner, WilmerHale

+1 202 663 6948
Hartmut.Schneider@wilmerhale.com

1875 Pennsylvania Ave NW
Washington, DC 20006