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Legal Challenges to State Drug Pricing Laws

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Jonathan D. Janow

Matthew D. Rowen

Kirkland & Ellis LLP

Notable Legal Challenges to State Pricing Laws

- **Maryland: *AAM v. Frosh* (D. Md. and 4th Cir.)**
  - Dormant Commerce Clause and Due Process Vagueness challenge to HB 631, recent Maryland generic "price gouging" law.
- **California: *PhRMA v. Brown* (E.D. Cal.)**
  - Dormant Commerce Clause, Due Process Vagueness, and First Amendment challenge to SB 17, recent California pricing transparency law.
- **Nevada: *PhRMA and BIO v. Sandoval* (D. Nev.)**
  - Preemption, Takings, and Dormant Commerce Clause challenge to SB 539, recent Nevada drug transparency law targeting diabetes drugs.

Maryland: AAM v. Frosh Overview

- House Bill 631 -- “Prohibition Against Price Gouging For Essential Off-Patent Or Generic Drugs”
  - Prohibits “price gouging” in the sale of “essential” generic drugs
  - Targets manufacturers and distributors; does not apply to retailers
  - Authorizes broad investigations into manufacturers’ pricing decisions
  - Opens manufacturers and distributors up to potential civil liability
- Passed 38-7 in Senate, 137-2 in House
- Governor Hogan allowed bill to become law, but did not sign
  - Cited concerns that HB 631 violated dormant Commerce Clause and was unconstitutionally vague, in violation of Due Process Clause

AAM v. Frosh: Key Provisions of HB 631

- Section 2-802: prohibits "***price gouging***"
  - "Price gouging" = an "unconscionable" price increase, or one that:
    - Is "excessive" and not cost-justified; and
    - Results in patients having "no meaningful choice" about buying a drug at an "excessive" price
  - Applies only to manufacturers and wholesale distributors, *not* retailers
  - Applies only to prescription drugs that are:
    - Not covered by a patent;
    - Actively manufactured and marketed in the US by ≤ 3 manufacturers;
    - *Made available* for sale in Maryland; and
    - "Essential," which means that the drug is *either*
      - On the WHO's List of Essential Medicines; *or*
      - Designated "essential" by the Md. Secretary of Health and Mental Hygiene

AAM v. Frosh: Key Provisions of HB 63 (cont.)

- Section 2-803
  - Authorizes the Maryland Medical Assistance Program (MMAP) to notify the Attorney General of an increase in the price of a generic drug, if it:
    - Would result in a ≥ 50% increase in the 1-year WAC for the drug; *or*
    - Would result in a ≥ 50% increase in the price MMAP pays for the drug; *and* a 30-day supply or a full cost of treatment would cost > $80 at the WAC
  - Authorizes AG to request written statements from manufacturers explaining the basis for price increases;
    - Itemize the cost components of producing a drug;
    - Identify increases in manufacturing costs; and/or
    - Identify and explain expenditures made to expand access to the drug
  - Authorizes AG to petition state courts to:
    - Enjoin violations of the law;
    - Order disgorgement of profits from price increase; and/or
    - Impose penalty of up to $10,000 per violation
  - The AG's authority to file suit is ***not*** tied to the MMAP benchmarks,

The Generic Drug Marketplace

- Vast bulk of market and pricing conduct is outside Maryland
  - Most AAM members do not reside in Maryland
  - None of the "Big Three" wholesalers *or* the national self-warehousing retailers resides in Maryland
  - So only involvement manufacturers have to transactions in Maryland is via upstream sale that occurred wholly outside of the state
- Pricing decisions made nationally; omnibus agreements
- Even HB 631 itself looks to *national* marketplace
  - Reporting requirements keyed off federal Medicare statute
    - Section 2-801(g): defines WAC to have meaning in 42 U.S.C. §1395w-3A
    - ("the manufacturer's list price for the drug … to wholesalers or direct purchasers in the United States … as reported in wholesale price guides or other publications of drug or biological pricing data.")

AAM v. Frosh: Dormant Commerce Clause Claim

- DCC Extraterritoriality Principle: State laws that directly regulate out-of-state commerce are invalid, even if they also regulate in-state commerce
  - *Healy v. Beer Institute, Inc.*, 491 U.S. 324 (1989) ("A statute that directly controls commerce occurring wholly outside the boundaries of a State exceeds the inherent limits of the enacting State's authority and is invalid, regardless of whether the statute's extraterritorial reach was intended by the legislature.")
  - *PhRMA v. Walsh*, 538 U.S. 644 (2003) (Maine Rx program made mfr's negotiate a rebate for sales in Maine, or else be subject to prior authorization requirement. Court upheld because program directly applied only to in-state sales.)
    - A State may not "insist that manufacturers sell their drugs to a wholesaler for a certain price" when those sales take place out of state, even if the drugs are later resold in the State.
    - Anti-profiteering provision similar to HB 631 struck down by Dist. Ct. under Dormant Commerce Clause not appealed.
- HB 631's "price gouging" prohibition applies to *any* price increase for covered drugs that are merely "*made available* for sale in" Maryland
  - Regulates transactions and prices in sales between manufactures and wholesalers outside of Maryland.

AAM v. Frosh: Void for Vagueness Claim

- "Fair notice" requirement
  - All laws must give people of ordinary intelligence a reasonable opportunity to know what is forbidden or required under the law
    - But HB 631's "price gouging" prohibition turns on undefined terms like "excessive," cost-"justified," and "no meaningful choice"
- Rule against "arbitrary and discriminatory enforcement"
  - Laws that delegate too broadly to officials are invalid
    - But here, given the vague terms ("excessive," "meaningful," etc.), the AG has very broad discretion to decide whether to file suit against a manufacturer or distributor for price increases

AAM v. Frosh: District Court

- District Court dismissed Dormant Commerce Clause claim, but declined to dismiss Vagueness claim.
- District Court concluded that regulation sufficiently targeted, or was linked to, later in-state sales.
  - "To the extent that HB 631 may affect the prices charged by out-of-state distributors or producers, the effect would be applicable only to prices charged on drugs to be sold within Maryland."
  - "Under HB 631, a sale of drugs between an out-of-state manufacturer and an out-of-state distributor – regardless of the price – does not give rise to liability. Only if those drugs are then made available for sale in Maryland would the provisions of HB 631 apply to the transaction."
- Vagueness claim plausible but in need of further record development
  - Focus on qualifiers for what constitutes an "unconscionable" price increase – "excessive," "not justified," and "appropriate"
- Fourth Circuit granted expedited appeal on both issues

AAM v. Frosh: Fourth Circuit

- Reversed district court's dismissal of AAM's dormant commerce clause claim with instructions to enter judgment in favor of AAM.
  - "We hold that the statute violates the dormant commerce clause because it directly regulates the price of transactions that occur outside Maryland."
- Reaffirmed breadth of DCC extraterritoriality principle:
  - "The principle against extraterritoriality as it relates to the dormant commerce clause is derived from the notion that 'a State may not regulate commerce occurring wholly outside of its borders.'" *Star Sci., Inc. v. Beales*, 278 F.3d 339, 355 (4th Cir. 2002).
  - Rejected Maryland's argument that extraterritoriality principle was narrow and limited only to "price affirmation" statutes.

AAM v. Frosh: Fourth Circuit (cont.)

- Act not limited to sales within Maryland
  - "'[M]ade available for sale' language does not limit the Act's application to sales that actually occur within Maryland, nor does it restrict the Act's operation to the context of a resale transaction with a Maryland consumer. Indeed, Maryland acknowledges that the Act is intended to reach sales upstream from consumer retail sales."
- Even if directed at Maryland sales, still improperly controlled prices in out of state transactions
  - "[T]he lawfulness of a price increase is measured according to the price the manufacturer or wholesaler charges in the initial sale of the drug….. Significantly, the retailers that sell the drug directly to the consumer cannot be held liable under the Act "
  - "This structure makes clear that the conduct the Act targets is the upstream pricing and sale of prescription drugs, and the parties agree that nearly all of these transactions occur outside Maryland."
  - "[T]he Act effectively seeks to compel manufacturers and wholesalers to act in accordance with Maryland law outside of Maryland. This it cannot do."

AAM v. Frosh: Fourth Circuit (cont.)

- Rejected argument that Act merely created minor upstream pricing impact from in-state regulation
  - "[T]he Act aims to override prescription drug manufacturers' reaction to the market and to regulate the prices these manufacturers charge for their products. This is more than an 'upstream pricing impact' -- it is a price control."
- Concluded Act impermissibly burdened interstate commerce in prescription drugs.
  - "Because the Act targets wholesale rather than retail pricing, an analogous restriction imposed by a state other than Maryland has the potential to subject prescription drug manufacturers to conflicting state requirements."
  - "[T]he Act requires manufacturers and wholesale distributors to do more than alter their distribution channels. It sets prescription drug prices in a way that 'interfere[s] with the natural function of the interstate market' by superseding market forces that dictate the price of a good."

AAM v. Frosh: Fourth Circuit (cont.)

- Court declined to reach vagueness claim.
- Judge Wynn issued vigorous dissent:
  - "At the end of the day, AAM argues—and the majority opinion concludes—that, absent federal regulation, its members are constitutionally entitled to impose conscience-shocking price increases on Maryland consumers, so long as AAM's members sell their essential generic drugs to Maryland consumers through out-of-state intermediaries."
- Petition for Rehearing denied 9-3, with additional Wynn dissent.
- Petition for Certiorari appears likely.

California: PhRMA v. Brown

- Senate Bill 17
  - Enacted in 2017
  - Declares that it is “the intent of the Legislature to permit a manufacturer of a prescription drug to voluntarily make pricing decisions regarding a prescription drug, including any price increases.”
  - Imposes price-disclosure and reporting requirements on prescription drug manufacturers.
  - Contains three separate substantive reporting requirements:
    - Section 127677
    - Section 127679
    - Section 127681

California: PhRMA v. Brown

- Section 127677
  - (a) “A manufacturer of a prescription drug with a wholesale acquisition cost of more than $40 for a course of therapy shall notify each purchaser [listed below] if the increase in the wholesale acquisition cost of a prescription drug is more than 16%, including the proposed increase and the cumulative increases that occurred within the previous two calendar years prior to the current year.”
  - (b) The notice must be provided “at least 60 days prior to the planned effective date of the increase.”
  - The “purchasers” this provision reaches are:
    - (1) the State; (2) licensed health care service plans; (3) health insurers; and (4) PBMs.
  - This provision applies only if such a purchaser actually buys or reimburses the drug in question, and only if it registers for notification with the State.
  - Finally, this provision does not contain a penalty provision for noncompliance.

California: PhRMA v. Brown

- Section 127679
  - Manufacturers “shall report” certain information specified below on a quarterly basis to the State “for each drug for which an increase in wholesale acquisition cost is described in Section 127677.”
    1) The information required to be reported includes:
    2) the “specific financial and nonfinancial factors used to make the decision to increase” the WAC;
    3) the amount of the increase in the WAC; “an explanation of how these factors explain the increase in” the WAC;
    4) a schedule of WAC increases for the drug over the previous 5 years;
    5) a “description of the change or improvement in the drug, if any, that necessitates the price increase”; and
    6) “volume of sales of the manufacturer’s drug in the United States for the previous year.
- The State will publish the information online “on a per-drug basis.”
- A manufacturer that fails to report “is liable for a civil penalty of $1,000 per day.”

California: PhRMA v. Brown

- Section 127681
  - Within three days of releasing a new drug, a manufacturer of a prescription drug "shall notify" the State if it is introducing a new drug at a WAC greater than the threshold set for a specialty drug under Medicare Part D.
  - Within thirty days after that initial notification, manufacturers shall report" the following information to the office in a format prescribed by the office":
    1) a description of the marketing plan; a description of the pricing plan;
    2) the estimated number of patients who may be prescribed the drug;
    3) whether the drug has a breakthrough therapy designation; and
    4) if the drug was not developed by the manufacturer, the date and price of acquisition of the drug.
- As with Section 127679, non-compliance may trigger $1,000 per-day civil penalties.

California: PhRMA v. Brown

- Commerce Clause claim:
  - Alleged to regulate commerce beyond California:
    - "The Act will prohibit manufacturers from lawfully increasing the list price of their qualifying products in other states"
    - "It will also curtail lawful pricing activities conducted entirely outside California"
  - Alleged to impose unconstitutional burdens on interstate commerce:
    - "The Act creates a significant risk of drug stockpiling, price stabilization, and distortion of the national pharmaceuticals market"

California: PhRMA v. Brown

- First Amendment compelled speech claim:
  - Alleged to violate the First Amendment by compelling manufacturers to speak "even when they prefer to remain silent"
    - The Act allegedly forces manufacturers to disseminate "the State's designated message about their pricing": that "manufacturers charge inflated prices for drugs"
    - The Act "discriminates on the basis of content, viewpoint, and speaker"
  - Also alleged to constitute "an impermissible effort by California to mandate speech to regulate drug prices that the State cannot regulate directly"

California: PhRMA v. Brown

- Due Process vagueness claim:
  - Alleged that it is "impossible to discern from the Act's plaint text whether increases in the WAC list price from January 1, 2016, through December 31, 2017, are retroactively included in determining whether the list price for those drugs has increased by 16 percent or more 'the previous two calendar years,'" "thereby triggering" section 127677(b)'s "60-day notice requirement."
  - Alleged that it is "also unclear whether price increases taken in the first 60 days of 2018 are subject to the 60-day notice requirement"

California: PhRMA v. Brown

- PhRMA filed complaint in E.D. Ca. on 12/8/2017, seeking:
  - a declaration that sections 127677, 127679, and 127681 are unconstitutional;
  - a permanent injunction prohibiting the State from enforcing those sections;
  - attorneys' fees and costs; and
  - any other relief the Court deems appropriate
- PhRMA did not move for a preliminary injunction.
- Court dismissed without prejudice for lack of standing on 8/30.
  - PhRMA will likely re-file, adding new allegations that support imminent injury.

Nevada: PhRMA v. Sandoval Overview

- Senate Bill No. 539 – Pricing transparency law targeting diabetes drugs
  - Directs the Nevada Department of Health and Human Services to compile list of prescription drugs "essential" for treating diabetes
  - Directs manufacturers to report annually to the Department:
    1) costs of producing the drug;
    2) marketing and advertising costs associated with the drug;
    3) profit earned from the drug and total profit attributable to it;
    4) the amount spent on patent prescription assistance programs;
    5) the cost of coupons provided directly to consumers;
    6) the wholesale acquisition cost (WAC) of the drug;
    7) history of price increases for prior five years;
    8) aggregate amount of all rebates in Nevada; and
    9) any other information prescribed by regulation for the purpose of analyzing the cost of the listed prescription drugs.

Nevada: PhRMA v. Sandoval Overview (Cont.)

- SB 539 – Pricing transparency law targeting diabetes drugs
  - Directs Department to compile a second list of essential diabetes drugs for which the manufacturer raised WAC by more than the prescribed benchmark – CPI for Medical Care or double the % increase in CPI for Medical Care over previous 2 years
  - Manufacturers of such drugs required to disclose to Department information on the methodology used to price drugs, subject to administrative penalty of up to $5000/day for failure to disclose:
    1) list of each factor that has contributed to the increase
    2) percentage of the total increase attributable to each factor;
    3) an explanation of the role of each factor;
    4) any other information prescribed by regulation.
  - Modifies definition of trade secret under Nevada law to carve out information required to be reported under the law.
- Prior iteration of law– SB 265 had contained a price control provision requiring reimbursement to patients and consumers if price increases exceeded threshold levels.

PhRMA v. Sandoval Legal Challenge

- PhRMA and BIO brought suit challenging SB 539 on four grounds:

1) Preempted by Federal Patent Law
    - Burdens the federal patent right by requiring disclosure of trade secrets if prices are raised, thereby restraining prices and the diminishing the reward granted to patentees
2) Preempted by Federal Trade Secret Law
    - Requires disclosure of confidential and proprietary information protected under the Defend Trade Secrets Act of 2016 (DTSA)
3) Unconstitutional Taking
    - Categorical taking of IP rights by requiring disclosure of trade secrets, or alternatively regulatory taking creating severe economic impact.
4) Dormant Commerce Clause
    - Burdens interstate commerce in a manner excessive to putative local benefits by imposing requirements tied to national list price, thereby creating an “effective national cap on prices,” and overriding trade secret laws of other states.

PhRMA v. Sandoval Legal Challenge

- Trade Secret concern at the heart of the legal challenge.
- In late May 2018, Nevada Department of Health and Human Services accelerated the adoption of additional regulations creating protections for trade secrets.
- Regulations permit pharmaceutical manufacturers to request that information submitted to Department be kept confidential as trade secrets under DTSA.
- PhRMA and BIO thereafter agreed to dismiss their lawsuit without prejudice and with full reservation of rights.

Legal Challenges: Key Takeaways

- State drug pricing laws intersect with complex multilayer interstate marketplace – easy to overstep constitutional limits on interstate regulation
- Laws creating price controls – express or implicit – may be most vulnerable to challenge
- Legal challenges may force States to expressly narrow the scope of laws' potential reach – either through legal argumentation or regulation – in an effort to preserve them
- Aggressive transparency laws may run afoul of First Amendment protections against compelled speech

Questions?

Jonathan D. Janow
Partner
Kirkland & Ellis LLP
jonathan.janow@kirkland.com
(202) 879-5203

Matthew D. Rowen
Associate
Kirkland & Ellis LLP
matthew.rowen@Kirkland.com
(202) 879-5931