

2020 International Law Section
Virtual Annual Meeting

**Impact on Governmental Policy on Pricing
And Access to Prescription Medical Products in the
Market Place**

Wednesday May 27th 11:00am



Presented by the ABA International Law Section
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Speakers 2020 Virtual Annual Meeting

- Maximiliano J. Trujillo – President at MJT POLICY LLC (Moderator)
- Cynthia Stammer – Managing Shareholder at Cynthia Marcotte Stamer PC
- Stephanie Trunk – Partner at ArentFox LLP
- Dan Zavodnick – Senior Regulatory Counsel at Celgene

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Content slide
(additional contentDer slides to be included by panel as needed)

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Dan Zavodnick
Senior Regulatory Counsel - Celgene

"A Drug's Life: The Early Years"



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Overview

- Drug Development Timeline and Cost
- Lead compound identification
- Pre-clinical research (animals)

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Overview

- Launch and Marketing
- Cost and Resources
- Impact of COVID-19

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Overview

- Filing for regulatory status (i.e. FDA)
- Clinical trials in humans
- Regulatory submission and approval

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Cynthia Stamer
Managing Shareholder at *Cynthia Marcotte Stamer, PC*

Prescription Drug Quality, Cost & Availability: Evolving U.S. Policy In The Age Of COVID-19



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Prescription Drug Quality & Pricing: COVID-19 Crisis Adds Fuel To Already Ranging Policy Battles

Prescription Drug Costs Major Component Of Overall US Health Care Costs

- 79 percent of Americans believe the costs of prescription drugs are unreasonable – and 26 percent are worried they cannot afford the prescription drugs they need*
- U.S. payers and consumers pay significantly more for drugs than in other nations, even when accounting for rebates.**
- On average, U.S. drug prices were 3.7 times higher than combined average of 11 other studied countries

*RAND Corporation, Prescription Drug Costs: How High Are They? Robert J. Blendon, Director, Center for Health Policy Studies, RAND Corporation
**RAND Corporation, Prescription Drug Costs: How High Are They? Robert J. Blendon, Director, Center for Health Policy Studies, RAND Corporation

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Prescription Drug Quality & Pricing: COVID-19 Crisis Adds Fuel To Already Ranging Policy Battles

Prescription Drug Cost Containment

- Prescription Drug Costs Major Element Of Overall US Health Care Costs
- Price Gouging & Other Pricing Practices Fueling Growing Scrutiny Of Pharmaceutical Company & Prescription Benefit Management Pricing & Other Business Practices
- Provider, Patients Arguing PBM & Other Payer Cost Management Profiting At The Expense Of Quality Of Care
- Drug Costs/Health Coverage Limitations Or Exclusions A Leading Cause Of Patient Medication Noncompliance
- Cost Containment Interference With Patient/Provider Relationship

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Prescription Drug Quality & Pricing: COVID-19 Crisis Adds Fuel To Already Ranging Policy Battles

- Foreign Prescription Drug Research, Manufacturing & Importation
 - Research & Manufacturing Quality & Reliability
 - Supply Disruptions/Reliability Of Drug Supply
 - Direct Prescribing & Distribution Across Borders Circumvents FDA & Other Protections
 - Privacy & Other Security
 - Anticompetitive Practices
 - Manufacturing Jobs
 - Other

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COVID-19 Prompting Re-Evaluation of Prescription Drug Quality, Cost & Availability Policies

- Worldwide Pandemic Outbreak Highlights Worldwide Connectivity
- Perceived Breakdown In China/WHO Prevention, Containment & Reporting
- International Research Collaboration
- Pharmaceutical Supply Shortages Resulting
- Biomedical Warfare & Other National Security Concerns
- Other



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U.S. Federal Health Care Antitrust Regulatory and Enforcement
 Sherman Act of 1890
 Clayton Act of 1914
 Federal Trade Commission Act
 FDA Regulations
 State Antitrust Laws
 Other Federal & State Laws Impacting Competition
 International Law Impacts Domestically & Internationally

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U.S. Federal Health Care Antitrust Regulatory and Enforcement
 Historical Philosophic Distinctions Between US & Other Countries' Antitrust Policies
 Evolving US Consolidation Of Power In Payers, Hospital Systems As Part Of Effort To Control Cost
 Emerging Backlash To Consolidation

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U.S. Federal Health Care Antitrust Regulatory and Enforcement
 DOJ Health Care Antitrust Division Regulatory and Enforcement
 DOJ, FTC & FDA Collaboration To Advance Competition To Advance Competition In The Biologic Marketplace

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DOJ, FTC, FDA & Other Federal Regulatory & Enforcement Initiatives To Promote Competition & Transparency

- Anti-Competition Policy Applied Differently To Payers, PBMs, Health Care Providers, Employers
- Steering & Other Anticompetitive Managed Care Contracting Practices
- Anticompetitive Mergers
- Boycott, Price Fixing and Other Anticompetitive Conduct

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DOJ, FTC, FDA & Other Federal Regulatory & Enforcement Initiatives To Promote Competition & Transparency

- Federal Transparency Existing & Proposed Rules
- FDA & Other & State Approval, Licensure, Accreditation, Reimbursement & Other Existing & Emerging Federal & State "Quality" Laws & Impacting On Choice & Price Of Prescription Drugs

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COVID-19 International Law Impacts On Prescription Drug Availability & Pricing

- COVID-19 By The Numbers Around the World
- WHO & Other International Treaties, Conventions & Understandings
- Emerging US Concerns/Policy Arising From COVID Including:
 - Information & Resource Sharing Across Borders
 - Quality, Availability, Safety & Other Growing Concern About Heavy Reliance Upon Importation of Drugs Manufactured In China
- COVID-19 Driving Short & Long Term Policy Changes

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Stephanie Trunk

Partner – ArentFox LLP

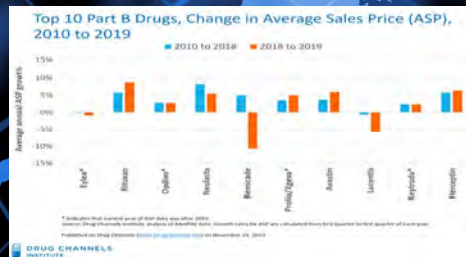
“State Laws on Drug Importation”



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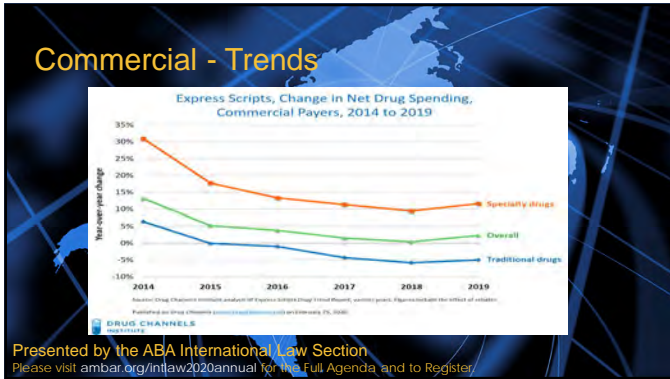
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Medicare Part B Drug Spending Growth



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Talk of Extreme Drug Price Increases- But Not In Reality

Overall recent slow growth in spend

Pharmacy benefit spending grew by only 2.3% in 2019

- Spending on specialty drugs increased by 11.6%
- But spending on traditional drugs dropped -5.0%

Growth not due to increases in net, post-rebate drug costs, but volume

Medicare Part B spending on drugs is increasing because there are more Medicare beneficiaries

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Federal Efforts Related to Drug Pricing

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Senate Finance Committee Bill

S.2543, Prescription Drug Pricing Reduction Act of 2019

Has passed Senate Finance Committee, awaiting vote in full Senate

Several provisions relevant to Medicare Part B drug prices:

- Temporary increase in Part B payment for biosimilar biological products to Average Sales Price ("ASP") + 8% for five years from launch
- Inclusion of value of coupons in determining ASP for drugs/biologicals
- Requiring Part B rebate from manufacturers for drugs/biologicals with prices increasing faster than inflation
- Authority to use all payment to prevent drug shortages

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Senate Finance Committee Bill

Several provisions relevant to Medicare Part D:

- Public disclosure of rebates and Direct and Indirect Remuneration ("DIR")
- Fill in coverage gap and replace Coverage Gap Discount Program with a Catastrophic Discount Program applying to all Part D Drugs
- Require Part D rebate from manufacturers if drug price increases faster than inflation based on Wholesale Acquisition Cost ("WAC")
- Establishment of pharmacy quality measures
- New measures based on access to biosimilar biological products

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CAP 2.0 and the International Pricing Index

2019 Advanced Notice of Proposed Rulemaking Testing International Pricing Index

Followed RFI about potentially reviving the Competitive Acquisition Program ("CAP") as a Centers for Medicare & Medicaid Innovation ("CMMI") demo in 2019 HOPPS Rule

Comment period closed December 31, 2018

Mandatory demonstration through CMMI

Physicians and hospitals in specific geographic regions would be required to utilize a third party CAP vendor; CAP vendor will bill CMS for separately reimbursable Medicare Part B drugs based on established rate based on IPI
CAP vendor would receive

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CAP 2.0 and the International Pricing Index

2019 Advanced Notice of Proposed Rulemaking Testing International Pricing Index

The IPI would be used to establish a target price, phased in over a 5-year demonstration period

CMS sought comments on CAP vendor qualifications, countries to include in the IPA, if certain physicians/hospitals should be excluded, and what drugs to select to include in the demonstration

CMS received a myriad of negative comments

Part B Access for Seniors and Physicians Coalition that includes 339 patient, provider and caregiver groups sent letters to Congress as well particularly concerned about the mandatory nature of the demonstration and the use of international pricing

Administration's goal is clearly to move Medicare Part B away from a buy and bill model

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Incentivizing "Onshoring"- Executive Order in Works

Proposals to provide grants for construction, alteration or renovation of facilities for the U.S.-based production of medicines on a priority drug list (other proposals include tax credits)

Award contracts for medicines on the priority drug list to manufacturers making such drugs in the United States for strategic national stockpile

Prioritization of Federal Supply Schedule/National Contracts for generic drugs to those manufactured in the United States

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Ohio Resolution to Congress and FDA

Urge Congress to require manufacturers to alert FDA of manufacturing/supply chain disruptions that might lead to shortages and to take steps to mitigate such shortages

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State Efforts Related to Drug Pricing

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State Drug Pricing and Access Laws

States with Drug Price Transparency Laws

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State Drug Pricing/Access Laws – Trends

WAC

- All drugs marketed in the state – LA, TX, CO*, WV

Transparency

- Advanced Notice of Price Increases – CA, OR, WA
- Justify/explain price increase – CA, CT, ME, NH, NV, OR, VT, WA
- Reporting for new drugs over a \$ threshold – CA, ME, NH, OR, WA
- Drugs specifically identified by the state – CT, ME, NV, VT

* Colorado currently requires manufacturers who are marketing their products to also provide names of at least 3 generics from same therapeutic class to prescribers at the time of any marketing, not report anything to the state, but there is pending legislation that will require reporting upon a price increase, similar to other states.

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State Drug Pricing/Access Laws – Trends

Price Controls

- State affordability boards to set ceiling on price – MA, MD

Biosimilar and Generic Market Entry and Competition

- Notice of a BLA application upon Action Date – CT
- Restrictions on patent settlement agreements – CA

Wholesaler/PBM Reporting

- PBM reporting on rebates received and retained – GA, TX, WA
- Wholesaler/PBM reporting "pricing component data/pricing unit of a drug" – ME

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State Drug Pricing/Access Laws - Trends

Drug Price "Caps"

- Most commonly related to the cost of insulin
- CO and IL have passed laws capping cost of insulin at \$100 for 30-day supply, but applies only to private insurance plans, not Medicare, Medicaid or ERISA plans
- Feb. 2020, KY House passed similar measure
- Feb. 2020, NM passed law capping insulin co-pay at \$25 per 30-day supply for insured patients covered by group health plans

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Importation

States working on legislation to permit importation of drugs from Canada

- 27 states are working on the issue

Some states have passed laws: CO, FL, ME, VT, NM

Only a few have submitted importation plans to HHS: FL and VT

FDA issued NPRM on Dec. 23, 2019

- States or certain other non-federal governmental entities would be able to submit importation program proposals to FDA for review and authorization.

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Importation

Impact on actual pricing

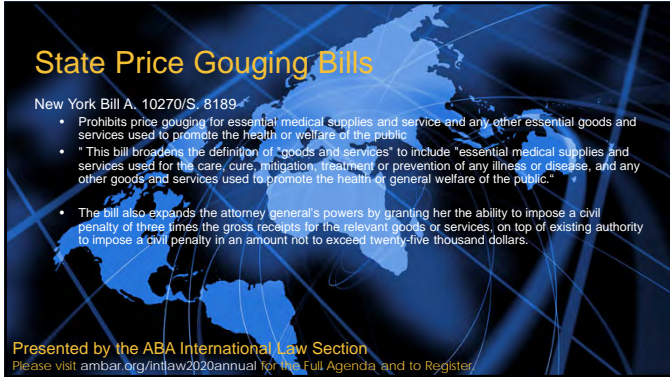
- Is the WAC for an imported drug different than the domestic drug? Report a different WAC? NDC?
- Is reimbursement different for the imported drug than the domestic drug? If so, how is this operationalized?

DSCSA Compliance

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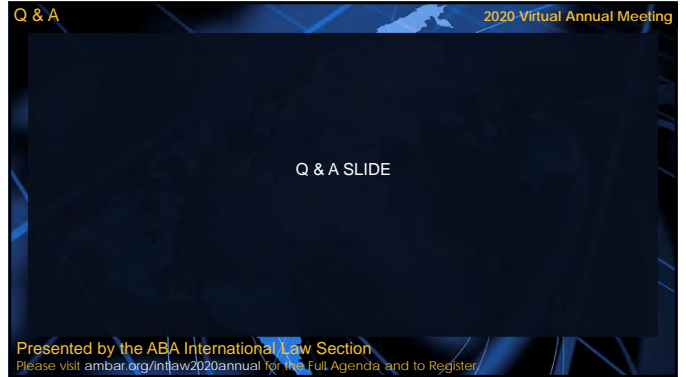
State Price Gouging Bills

New York Bill A. 10270/S. 8189

- Prohibits price gouging for essential medical supplies and service and any other essential goods and services used to promote the health or welfare of the public.
- "This bill broadens the definition of "goods and services" to include "essential medical supplies and services used for the care, cure, mitigation, treatment or prevention of any illness or disease, and any other goods and services used to promote the health or general welfare of the public."
- The bill also expands the attorney general's powers by granting her the ability to impose a civil penalty of three times the gross receipts for the relevant goods or services, on top of existing authority to impose a civil penalty in an amount not to exceed twenty-five thousand dollars.

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Q & A 2020 Virtual Annual Meeting

Q & A SLIDE

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