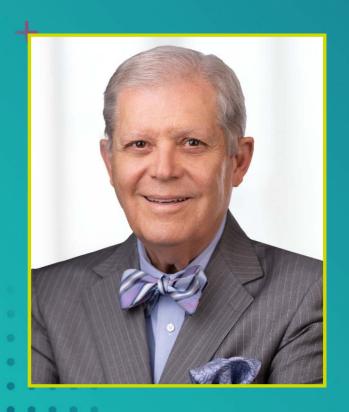


WEDNESDAY, SEPTEMBER 28 | 9:30 a.m. - 4:00 p.m. CYTO PHL | PHILADELPHIA, PA







# Opening Remarks Edward John Allera Co-Head, Buchanan Life Sciences



#### **Summit Emcees**



Lloyd Smith Shareholder, IP Litigation



Tina Hu-Rodgers
Counsel,
FDA Regulatory



+

- Make sure you are properly signed in at the registration table and have received your form
- You will leave the bottom copy of your form at the registration table to receive your credit
- Staff will assist



#### **WIFI INFORMATION**

Network: cytophl Password: ELEMENTS

#### QR Codes and WIFI



**Q&A Portal**Pollev.com/buchanan



Events Page (Bios, Feedback Form, Slides)



#### **Breakfast Keynote**



Election Year Presentation:

Issues Impacting Life Sciences Companies
and their Portfolios

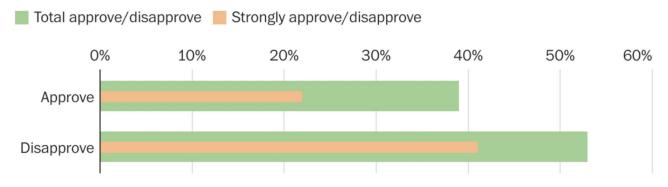
Michael Strazzella Chair, Federal Government Relations Healthcare & Life Sciences



#### 2022 Mid-Term Elections: Biden's Approval Rating

#### Biden's approval rating remains underwater

Q: Do you approve or disapprove of the way Joe Biden is handling his job as president? Do you feel that way strongly or somewhat?



Note: "No opinion" not shown.

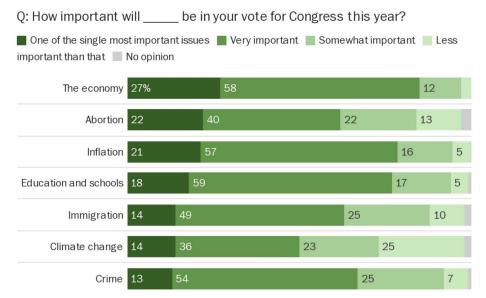
Source: Sept. 18-21, 2022, Washington Post-ABC News poll of 1,006 U.S. adults with an error margin of +/- 3.5 percentage points.

EMILY GUSKIN / THE WASHINGTON POST

➤ Based on historical mid-term gains for the President's opposition party, Republicans are confident in winning the House majority in the mid-term elections. In Gallup's polling history, presidents with job approval ratings below 50% have seen their party lose 37 House seats, on average, in midterm elections.

#### + 2022 Mid-Term Elections: Top Issues for Voters

#### Economy, abortion and inflation top issue list for voters this fall

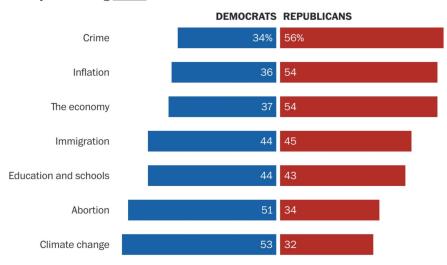


Source: Sept. 18-21, 2022, Washington Post-ABC News poll of 908 registered voters with an error margin of +/- 4 percentage points for the economy, abortion and climate change and 449-459 registered voters with an error margin of 5.5 points for crime, inflation, immigration and education.

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#### Which party do voters trust more to handle major issues?

Q: Which political party, the Democrats or the Republicans do you trust to do a better job handling \_\_\_\_\_?



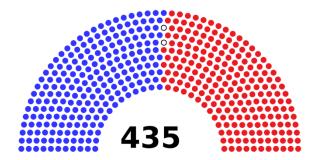
Note: "Both," "Neither," and "No opinion" not shown.

Source: Sept. 18-21, 2022, Washington Post-ABC News poll of 908 registered voters with an error margin of +/- 4 percentage points for the economy, abortion and climate change and 449-459 registered voters with an error margin of 5.5 points for crime, inflation, immigration and education.

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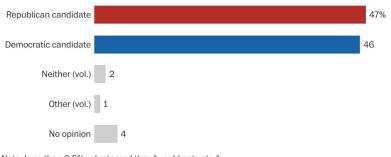
#### + 2022 House Mid-Term Elections

#### **U.S.** House of Representatives



#### **Voters closely divided in support for Congress**

Q: If the election for the U.S. House of Representatives were being held today, would you vote for the Democratic candidate or the Republican candidate in your congressional district? Would you lean toward the  $\dots$ 



Note: Less than 0.5% volunteered they "would not vote."

Source: Sept. 18-21, 2022, Washington Post-ABC News poll of 908 registered voters with an error margin of +/- 4 percentage points.

EMILY GUSKIN / THE WASHINGTON POST

#### **House Current Party Breakdown:**

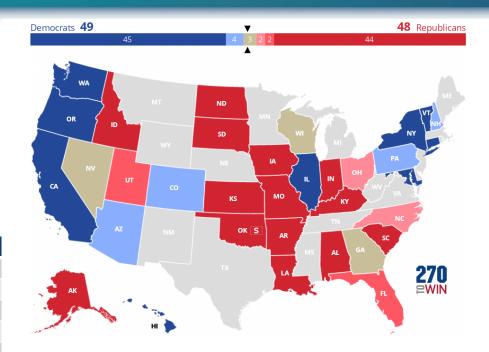
#### 221 Democrats, 212 Republicans, 2 Vacancies

- Democrats are defending only a five-seat majority in the House
- ➤ 30 Democrats are not running for reelection (or are running for other offices); 6 Democrat incumbents were defeated in primaries
- ➤ 20 Republicans are not running for reelection; 8 Democrat incumbents were defeated in primaries
- Cook Political Report, to date, lists 32 Democratic seats as "Toss-Up", "Lean Republican", or "Likely Republican"; lists only 12 Republican seats as "Toss-Up" or "Lean Democratic"
- Recent generic congressional ballot show a tightening for the battle for control of the House
- So, instead of a "red tsunami" or "red wave" prediction earlier this year of a 20-seat Republican majority, Republicans are now projected to win control with a 10-20 seat majority or even in the single digits

#### + 2022 Senate Mid-Term Elections

- 35 Senate seats are up for election in 2022:
- ➤ 21 Republican seats (16 safe; 5 Lean Republican, Toss Up, or Lean Democrat)
- ➤ 14 Democratic seats (9 safe; 5 Lean Democratic or Toss Up)

State	Republican	Democrat	Rating
Arizona	Blake Masters	Sen. Mark Kelly	LEAN DEM
Colorado	Joe O'Dea	Sen. Michael Benet	LEAN DEM
Florida	Sen. Marco Rubio	Rep. Val Demings	LEAN REP
Georgia	Herschel Walker	Sen. Raphael Warnock	TOSS-UP
Nevada	Adam Laxalt	Sen. Catherine Cortez Masto	TOSS-UP
N.H.	Don Bolduc	Sen. Maggie Hassan	LEAN DEM
N.C.	Ted Budd (Sen. Burr's seat)	Cheri Lynn Beasley	LEAN REP
Ohio	J.D. Vance (Sen. Portman's seat)	Rep. Tim Ryan	LEAN REP
Pennsylvania	Mehmet Oz (Sen. Toomey's seat)	John Fetterman	LEAN DEM
Wisconsin	Sen. Ron Johnson	Mandela Barnes	TOSS-UP



#### + 117<sup>th</sup> Congress: Relevant Committee Leadership

Senate Committee	Democratic Chair	Republican Ranking Member
Appropriations Committee -Labor, HHS, Education Subcommittee	Sen. Pat Leahy (D-VT) -Sen. Patty Murray (D-WA)	Sen. Richard Shelby (R-AL) – RETIRING -Sen. Roy Blunt (R-MO) – RETIRING
Finance Committee	Sen. Ron Wyden (D-OR)	Sen. Mike Crapo (R-ID)
Health, Education, Labor, and Pensions	Sen. Patty Murray (D-WA)	Sen. Richard Burr (R-NC) – RETIRING

House Committee	Democratic Chair	Republican Ranking Member
Appropriations Committee -Labor, HHS, Education Subcommittee	Rep. Rosa DeLauro (D-CT) -Rep. DeLauro	Rep. Kay Granger (R-TX) -Rep. Tom Cole (R-OK)
Energy & Commerce -Health Subcommittee	Rep. Frank Pallone, Jr. (D-NJ) -Rep. Anna Eshoo (D-CA)	Rep. Cathy McMorris Rodgers (R-WA) -Rep. Bret Guthrie (R-KY)
Ways and Means -Health Subcommittee	Rep. Richard Neal (D-MA) -Rep. Lloyd Doggett (D-TX)	Rep. Kevin Brady (R-TX) – RETIRING -Rep. Vern Buchanan (R-FL)

#### Senate Appropriations Committee

#### Patrick Leahy (D-Vt.) is retiring

- He's served as the panel's top Democrat since 2017
- Patty Murray (D-Wash.) is next by seniority; she would need to give up her current top spot on the Health, Education, Labor & Pensions Committee to lead Appropriations in the 118th Congress

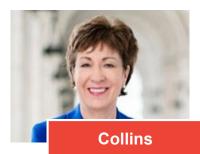
### Richard Shelby (R-Ala.) also is retiring

 Susan Collins (R-Maine) is next in seniority and a likely option to succeed Shelby









#### Senate HELP Committee

- Patty Murray (D-Wash.) is likely to relinquish the Health, Education, Labor & Pensions top spot to lead Appropriations
  - She's served as panel's top Democrat since 2015
  - Bernie Sanders (I-Vt.) would be the most senior Democrat on the panel if Murray goes to Appropriations
- Richard Burr's (N.C.) retirement sets up a potential shift for Republicans
  - Rand Paul (Ky.) is next in line to serve as the top Republican, but also has seniority on Homeland Security
  - Bill Cassidy (La.) is the next most senior Republican on the panel after Paul











#### Outgoing House Committee Leaders

 Four Democratic and three Republican current committee leaders have announced their retirements or lost re-election









Budget: John Yarmuth (D-Ky.)

Homeland Security: John Katko (R-N.Y.)

Oversight & Reform: Carolyn Maloney (D-N.Y.)

Science: Eddie Bernice Johnson (D-Texas)

Transportation: Peter DeFazio (D-Ore.)

Ways & Means: Kevin Brady (R-Texas)





**Johnson** 



#### House Ways and Means Committee

- Richard Neal (MA) is the top Democrat on the panel
- Kevin Brady (TX) is retiring
  - Brady said GOP committee term limits factored into his retirement decision
  - Vern Buchanan (FL) has the most seniority on the panel
  - Adrian Smith (NE) and Jason Smith (MO) are also running to succeed Brady





#### Inflation Reduction Act (PL117-169)

- Requires Medicare to negotiate prices for 'some' drugs under Part B & D with highest spending
- Requires Rx companies to pay rebates to Medicare if prices rise faster than inflations for Medicare covered drugs
- Caps beneficiary out-of-pocket spending for Medicare Part D
- \$35 insulin cap for Medicare monthly costs
- Expand eligibility for full benefits under the Medicare Part D Low-Income Subsidy Program
- Eliminate cost sharing for adult vaccines covered under Medicare Part D and improve access to adult vaccines in Medicaid and CHIP

#### Inflation Reduction Act | Timeline

Figure 1

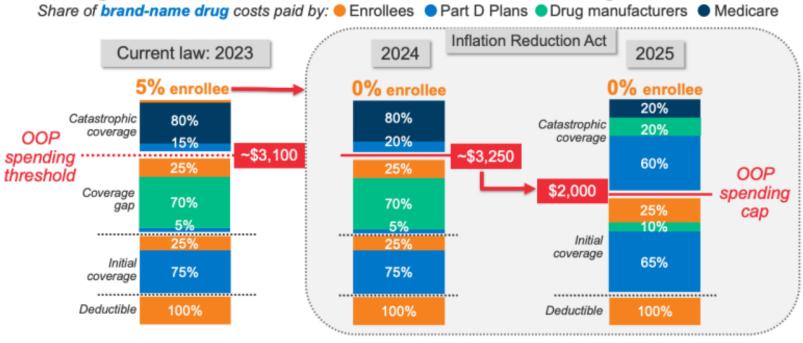
#### Medicare Drug Price Negotiation Timeline for 2026 & 2027





Figure 2

#### Changes to Medicare Part D for Brand-Name Drug Costs



NOTE: OOP is out-of-pocket. The out-of-pocket spending threshold will be \$7,400 in 2023 and is projected to be \$7,750 in 2024 and \$8,100 in 2025, including what beneficiaries pay directly out of pocket and the value of the manufacturer discount on brand-name drugs in the coverage gap phase. These amounts translate to out-of-pocket spending of approximately \$3,100, \$3,250, and \$3,400 (based on brand-name drug use only).



#### Executive Order: Biotechnology & Biomanufacturing

- Executive Order signed on September 12, 2022
- Goal: Create jobs, build supply chain, lower prices
- Includes:
  - ✓ Grow domestic biomanufacturing capacity via regional innovation and enhanced bio education.
  - ✓ Expand R&D with government support for medical breakthroughs
  - ✓ Improve access to quality federal data
  - ✓ Train a diverse skilled workforce
  - ✓ Streamline regulations for biotech products
  - ✓ Advance biosafety to reduce risk
  - ✓ Protect US biotech ecosystem

#### + PDUFA and GDUFA

- Needs to be reauthorized by September 30, 2022
- Senator Burr (R-NC), ranking member of HELP Committee held up movement
- Will be attached to Continuing Resolution that punts FY23 federal spending levels
- Will be "mostly clean"
- Items for later: regulating diagnostics, cosmetics, and dietary supplements
  - Concerns by Senator Burr
- Challenge will be issues of the Continuing Resolution

#### Pharmacy Benefit Transparency Act of 2022 (S. 4293)

- Introduced by Senators Maria Cantwell (D-WA) and Chuck Grassley (R-IA)
- Illegal to engage in "spread pricing"
- Clawback \$\$s to pharmacies
- Forces PBMs to pass along 100% of rebates to health plans or payors
- Disclosure of cost/price/reimbursement of Rx to health plans or payors
- Disclosure of fees, markups, discounts charges or imposed on health plans/payors
- Disclosure of aggregate remuneration fees received from Rx makers to health plans, payers, and any federal agency
- Requires annual report to FTC on differences between health plan costs and PMB's pay to pharmacies

#### + What's Next?

- Implementation of Medicare Rx Negotiation
- **\$237B** over ten years (2022-2031)
- Expansion of insulin caps (what drug is next?)
- Continued expansion of transparency across the delivery system.
- Republican messaging lower prices with transparency and competition, less dependence on China (does this include API?). Medicare Rx is the beginning of socialized medicine.
- Democrat messaging highlight Rx pricing, MH & SA, eliminate racial, gender and geographic health inequities.

#### **Breakfast Keynote**



#### **Q&A/Discussion**





## Crossing the Approval Divide: Cohesive Strategies From Concept Through Reimbursement



Tom Evegan
Principal, Strategy &
Management Consulting
RSM



Sharon Small
Director, Market Access
Novartis



Sandy Loreaux
US President
Covis



Edward Allera
Shareholder, Co-Head
Buchanan Life Sciences

"The views, opinions, and positions, expressed by the panelists are theirs alone, and do not necessarily reflect the views, opinions or positions of their employers or affiliated organizations. This program is for educational purposes only. Nothing in this discussion is intended to provide legal, business or regulatory advice."



# **LUNCH BREAK: RESUME AT 12 PM** Buchanan Ingersoll-Rooney LIFE SCIENCES

## Recruiting & Retaining Diverse Life Sciences Talent: Solutions that Work



Kate Eisenmann
Director, Corporate
Counsel,
Otsuka America
Pharmaceutical, Inc.



Manoj Raghunandanan President, Global Self Care and Consumer Experience Organization, Johnson & Johnson Consumer Health



Joel C. Trotter
Assistant General Counsel
GSK



Lloyd Freeman
Chief Diversity & Inclusion
Officer
Buchanan Ingersoll & Rooney PC



## Leveraging Your Pharmaceutical Product Portfolio: Driving M&A and Target Identification



Barbara Binzak Blumenfeld, Ph.D. Shareholder, FDA Regulatory Buchanan Ingersoll & Rooney PC



Michael Daley, Ph.D.

Principal Consultant
Cognate Consultants, LLC



Matthew Fedowitz
Shareholder, Intellectual
Property
Buchanan Ingersoll &
Rooney PC



Mythili Markowski, Ph.D.

Counsel, Intellectual

Property

Buchanan Ingersoll &

Rooney PC



#### Driving M&A and Target Identification

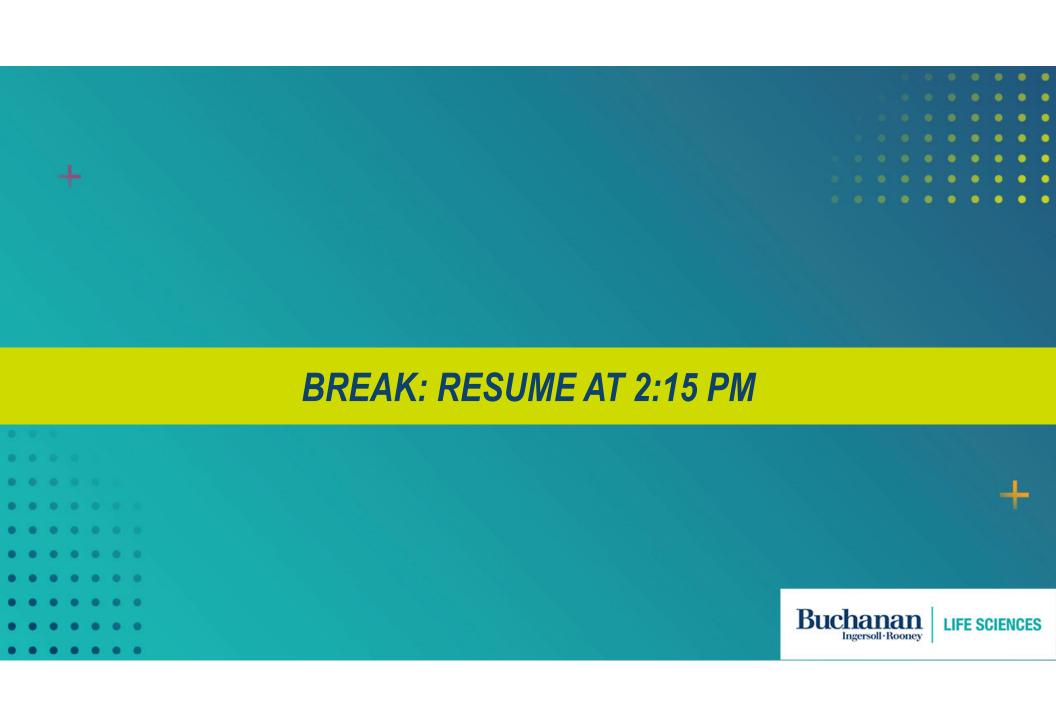
#### **Key Factors Driving Deal Value**

- Intellectual Property
- FDA Regulatory
- Reimbursement

#### **Acquisition and Divestiture of Products or Portfolios**

- Strategy Planning
- Targeting Buyers and Sellers
- Brand vs. Generic Considerations
- Competitive Landscape





## Compliance and Enforcement Trends: Mitigating Risk in Commercializing Your Product



Laurie Levin Goodstine Senior Counsel, US Commercial Legal AbbVie



Jill Fallows Macaluso Corporate VP and Chief of Ethics, Compliance & Privacy Officer NovoNordisk, Inc.



David Sandoval
Chief Legal Officer
Chief Compliance Officer
Leadiant Biosciences



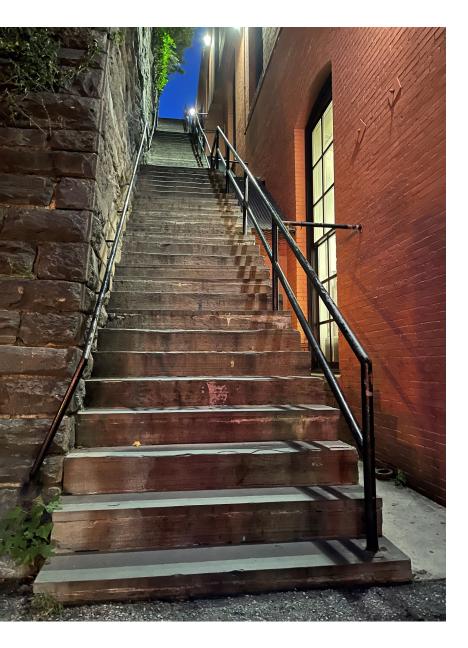
Joel Trotter
Assistant General Counsel
GSK



Linda Pissott Reig Shareholder, FDA Regulatory Buchanan Ingersoll & Rooney PC







Compliance officers and in-house lawyers are expected to provide guidance on legal restrictions while also helping the company achieve its revenue targets.

It is essential to strike the right balance in guiding the commercial efforts of the company.

Failure to do so can cause a perception that the In-House Legal or Compliance Departments are operating as the

"Department of 'No"

"Cop in My Living Room" or

"Sales Prevention Department"

This can lead to hesitation or even a refusal to engage proactively with the Legal & Compliance Departments . . .



How do you thwart the "end run" or the "don't ask permission, ask forgiveness" approach) and encourage consultation and collaboration?

How do you secure a "seat at the table" when commercial strategies are being determined?

How can an In-House Lawyer or Compliance Officer overcome being perceived as the "Sales Prevention Department" and instead be viewed as a trusted team member?

#### Securing a seat at the table...







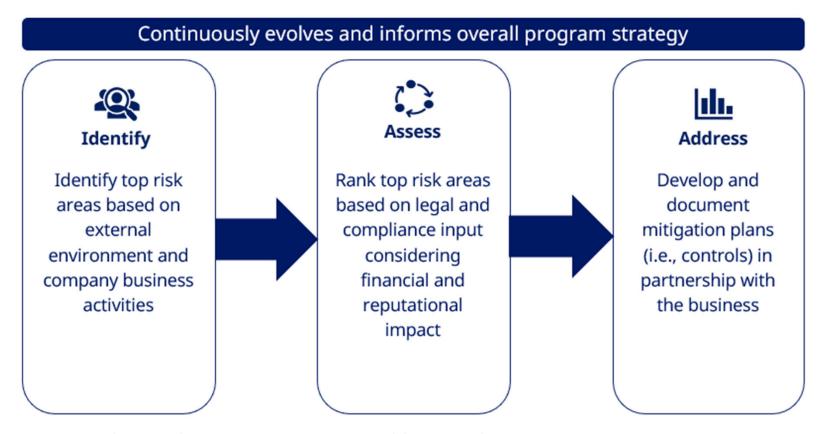
## Proactive business partner model enables company success while managing risk



Ethics & Compliance
Business Partners

- Project management approach to risk mitigation
- Partner closely with Legal
- Operationalize relevant controls
  - e.g., policies, training, monitoring
- Identify and communicate trends & insights
- Promote a "principles-based" approach (vs. rules)
- Build trust and foster a culture of ethics

A well-designed risk management process meets government expectations and automatically leads to a seat at the table



See the U.S. Department of Justice Criminal Division Evaluation of Corporate Compliance Programs (Updated June 2020)



# Kim Kardashian Instagram post draws FDA warning

Zack Guzman I @ZGuz Tuesday, 11 Aug 2015 I 3:27 PM ET

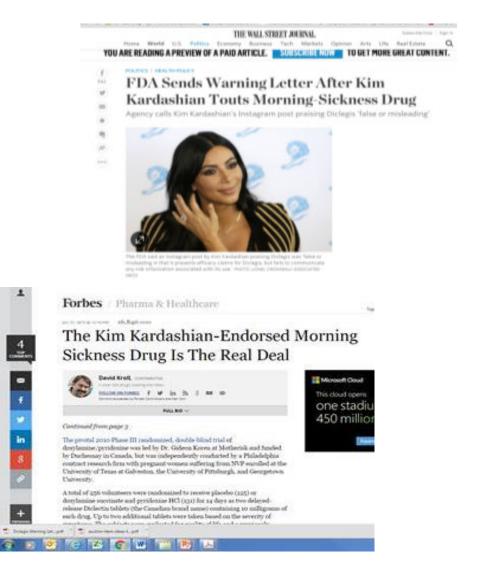




Kim Kardashian may be famous for her selfies, but the Food and Drug Administration wasn't a fan of her latest one.

An Instagram picture featuring Kardashian, morning sickness drug Diclegis and accompanying text promoting the drug's benefits garnered more than 450,000 "likes" but brought about a formal FDA warning letter for the drug's manufacturer. (Tweet This)

Part of the letter says, "The social media post is misleading because it presents various efficacy claims for Diclegis, but fails to communicate any risk information."



Instagram

Diclegis'

kimkardashian OMG. Have you heard about this? As you guys know my

#morningsickness has been pretty bad. I tried changing things about my lifestyle. like my diet, but nothing helped, so I talked to my doctor. He prescribed me #Diclegis, I felt a lot better and most importantly, it's been studied and there was no increased risk to the baby. I'm so excited and happy with my results that I'm partnering with Duchesnay USA to raise awareness about treating morning sickness. If you have morning sickness, be safe and sure to ask your doctor about the pill with the pregnant woman on it and find out more www.diclegis.com: www.DiclegisImportantSafetyInfo.com

gorgeouslifestyle @breshaethemovie\_this what I was telling u about it works hubby ratu170 @fiqqnordin ko sama era ngan dia

leezdoll Interesting @izzy\_31

err\_lika @nicyrus

nicyrus Definitely looking into this @err\_iika love\_gigi24 @k\_\_laflare

s tasha4 @preciouspat5 knew there was a paycheck not too far away.

August 2015 Warning Letter (Office of Prescription Drug Promotion) on DICLEGIS (doxylamine succinate and pyridoxine hydrochloride) delayed-release tablets, for oral use.

"OMG. Have you heard about this? As you guys know my #morningsickness has been pretty bad. I tried changing things about my lifestyle, like my diet, but nothing helped, so I talked to my doctor. He prescribed me #Diclegis, and I felt a lot better and most importantly, it's been studied and there was no increased risk to the baby. I'm so excited and happy with my results that I'm partnering with Duchesnay USA to raise awareness about treating morning sickness. If you have morning sickness, be safe and sure to ask your doctor about the pill with the pregnant woman on it and find out more www.diclegis.com; www.DiclegisImportantSafetyInfo.con

### Other FDA Enforcement . . .

- "Facebook Share" social media widget on company website = drug company-created content that viewer can post to FB had claims but <u>no</u> safety (2010)
- **Liking a Customer Post** manufacturer "liked" a customer testimonial on corporate Facebook page for an off-label use = unsubstantiated product claim (2013)
- Instagram Ad colorful fast-paced visuals on benefits & risks minimized or omitted (2022)
- TV DTC Video Lifetime TV's The Balancing Act with Montel Williams (2022): patient video conveys superiority w/o sufficient evidence (e.g. claim that that other drugs did not work but this one did)

Buchanan Ingersoll & Rooney LLP

#### **Draft FDA Guidances Addressing Social Media**

Internet/Social Media Platforms with Character Space Limitations – <u>Presenting Risk</u> and Benefit Information for Prescription Drugs and Medical Devices (*Twitter Guidance*) (June 2014)

Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices (June 2014)

Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media (2253 Guidance) (January 2014)

# FTC Put 700 Businesses on Notice: Endorsements & Testimonials (October 13, 2021) Identifies various offenses (up to \$43,792 per violation):

- 1) Falsely claim an endorsement by a third party
- 2) **Misrepresent** that an endorsement represents **experience**, **views or opinions of users or purported users of the product**
- 3) Misrepresent an endorser as an actual, current or recent user
- 4) Continue to advertise an endorsement unless advertiser has good reason to believe that endorser continues to subscribe to the views in the endorsement
- Use testimonials to make unsubstantiated or otherwise deceptive performance claims even if testimonials are genuine (see 255.2(a) and (b))
- 6) Fail to disclose an unexpected material connection with an endorser
- 7) **Misrepresent** that the experience of endorsers represents **consumers' typical or ordinary experience**

"Notice of Penalty Offenses Concerning Deceptive or Unfair Conduct Around Endorsements and Testimonials" (cites cases from 1941 – 1984)

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#### FTC Guide for Marketers (January 2022)



- Publish all genuine reviews; don't exclude negative ones.
- Don't display reviews in a misleading way, such as by featuring positive ones more prominently.
- Display material connection to company offering product (e.g. if reviewer rec'd \$ or free product for their review) clearly and conspicuously
- Clearly & conspicuously disclose how you collect, process, and display reviews, and how you determine overall ratings, to the extent necessary to avoid misleading consumers.
- Have reasonable procedures to identify fake or suspicious reviews after publication.

# FTC Proposed Endorsements & Testimonials Update

#### FEDERAL TRADE COMMISSION

16 CFR Part 255

Guides Concerning the Use of Endorsements and Testimonials in Advertising

**AGENCY:** Federal Trade Commission. **ACTION:** Proposed changes to guides; request for comments.

**SUMMARY:** The Federal Trade Commission ("FTC" or "Commission") is seeking public comment on proposed revisions to its Guides Concerning the Use of Endorsements and Testimonials in Advertising ("the Guides").

**DATES:** Comments must be received on or before September 26, 2022.

Use of Influencers, Social Media & Other Tactics

How can companies unlock the value of influencers, social media and other tactics, while mitigating legal risk?

#### How influencer marketing impacts consumer behavior



**87%** of shoppers were **inspired** by an influencer **to make a purchase** 



**76%** find content posted by other consumers to be **more honest than brand content** 



**65%** of people **discover a new brand or product** through an <u>influencer at least once</u> a week



**74%** of consumers use 1 or more advertising avoidance tactics, w/ nearly 50% using ad blockers



**61% trust** influencers as category experts and **more credible** than celebrities



**31%** of consumers **recommend** an influencer to **friends and family** at least once a week

#### **Top Marketing Objectives for Influencer Campaigns**

- Increase Brand Awareness
- Improve Brand Advocacy
- Reach new or targeted audiences

#### **Top Social Networks for Influencer Marketing**











Key Factors: # active users, audience engagement, channel adoption w/ target audience, content formats

#### References

- https://influencermarketinghub.com/influencer-marketing-benchmark-report-2020/
- https://www.convinceandconvert.com/influencer-marketing/influencer-marketing-statistics/
- https://oberlo influencer marketing stats, 2020

# **Types of Influencers**

Celebrities: artists, athletes, TV personalities

• Famous personalities with large-scale reach; recognized in mainstream media

**Bloggers** 

- Writers for established blogs w/ many subscribers and readers; often publish multiple articles within a given theme or storyline
- Key Opinion Leaders
   Widely recognized in their area of expertise; have a large following of people interested in their perspective and thought leadership
  - Micro-Influencers
    - Generally defined as having fewer than 50,000 followers; post content about specific categories and have engaged audiences who seek out these influencers because of their expertise on these niche topics

Types 2-4 are not mutually exclusive; similar characteristics may apply across



#### SOME KEY CONSIDERATIONS WHEN USING ENDORSERS AND INFLUENCERS

#### FDA-Related

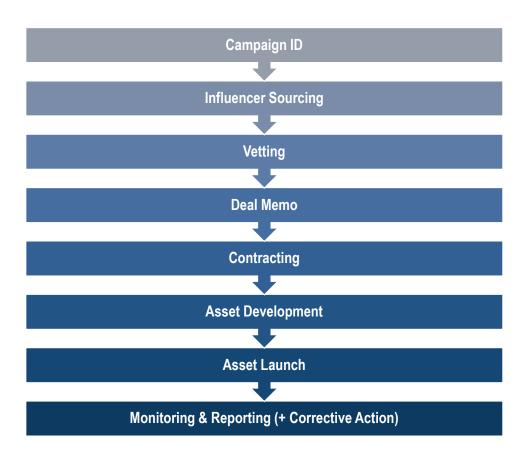
- Branded
  - On/Consistent with label
  - Balanced and not misleading
- Unbranded
  - Disease burden/prevalence
  - Not implicitly branded or product pointing
- Correcting Misinformation
  - Depends on whether company "is responsible for communications that are owned, controlled, created, or influenced, or affirmatively adopted or endorsed, by, or on behalf of, the company."

#### SOME KEY CONSIDERATIONS WHEN USING ENDORSERS AND INFLUENCERS

#### FTC-Related

- Disclosure of "material connections"
- Actual user of the product and "honest opinions, findings, beliefs or experience"
- Expert Opinions
  - "endorsement must be supported by an actual exercise of that expertise in evaluating product features or characteristics with respect to which he or she is expert and which are relevant to an ordinary consumer's use of or experience with the product..."
- Reputational concerns
  - Vet your influencer
- Appropriate contract provisions
  - Expectations are clear
    - Conduct and reputation
    - Disclosure of sponsorship
    - Other endorsements or social media activity?
  - Control over content, corrections

# Influencer Engagement and Asset Deployment



# Setting Influencer Engagements Up for Success (5 Ds)

- Design a clear process collaboratively with relevant cross-functional stakeholders and deploy it consistently across TAs
- <u>Develop</u> templates to assist Marketing and Public Affairs colleagues with implementing the engagement and development processes, and train them as well as their agency representatives
  - Example Templates: Deal Memorandum; Influencer Services Workbook; Influencer Training Deck
  - Training Topics: FDA Standards; FTC Guides; company approach to disclosures; company branding requirements; company reputational
    considerations; company-preferred ways of working with respect to contracting, communicating with influencers, asset development and review and
    approval, etc.
- <u>Draft</u> a comprehensive Influencer Services Agreement (ISA) template that is easy for entertainment attorneys (i.e., non-pharma lawyers!) to navigate and an ISA Playbook that is both informational and useful as a reference for in-house contracting teams
- Define non-negotiable terms and hold the line during negotiations
  - Our industry is subject to unique regulatory considerations, and upon explanation, most entertainment attorneys relent when they understand that the company's preferred terms will also be beneficial to their clients
  - Examples of recommended non-negotiables: FDA/FTC required disclosures; cooperation with corrective action; reps/warranties re: bona fide use of
    product and accuracy of statements about influencer's experience with product; company IP ownership of assets (including social posts); safety
    reporting requirement
- Document and file all asset approvals in order to protect the company in the event of a dispute or enforcement action



#### Lawful Pre-Approval Interactions:

- Disease Awareness Campaigns
- Consumer Advocacy Groups
- Physician Organizations
- KOL Identification
- Advisory Boards

- Corporate Website
- Publication Planning (Medical Journal Articles)
- Investigator Meetings
- Poster Sessions
- Scientific Meeting Presentations

#### Lawful Pre-Approval Interactions:

- CME Grants
- Press Releases
- Corporate Awareness / Visibility Campaigns
- Clinical Trial Recruitment
- Investigator-Initiated Trials
- www.clinicaltrials.gov
- Utilization of Medical Science Liaisons
- Managed Care "Dossier" Submission

# Preparing the Market for a High Priced Product

- How do you manage the restrictions against pre-approval promotion restrictions while lawfully preparing the market for a high-priced drug?
  - How can a company best raise awareness with healthcare providers, patients and payors and manage expectations about a new product's anticipated price?



#### SELECTED EXAMPLES: SETTLEMENTS INVOLVING SPEAKER PROGRAMS



GlaxoSmithKline \$3B settlement 07/02/2012

Salix Pharmaceuticals \$54M settlement 06/09/2016 \$108M settlement 09/26/2019

Insys Therapeutics, Inc. \$225M settlement 06/05/2019

# November 2020 OIG Special Fraud Alert: Overview

#### Suspect factors for Speaker Programs may include:

- speaker programs where little or no substantive information is actually presented
- program held at location not conducive to exchange of educational information (e.g. restaurants or entertainment or sports venues)
- large numbers of programs on the same or substantially the same topic or product, especially in situations involving no recent substantive change in relevant information
- alcohol is available or a meal exceeding modest value is provided to program attendees

#### \$900 Million Settlement (2022): Speaker Programs & Consultants

Speaker Training: "Duplicative & Balkanized" – National, Regional, Productspecific

Consultant Meetings – too many and not driven by market research department "Needs Assessment" documents drafted to create optic of a justifiable need

List of 50 high volume prescribers Senior marketing officials told to list all activity against these HCPs (consultant meetings & speaker training)

# Compliance Department alleged to be a "Rubber Stamp"

The Compliance Department expressed concerns about too many meetings, too many consultants, and too many payments . . .

"In theory, [Company's] Compliance Department was supposed to prevent the abusive use of consultant meetings. In reality, it was nothing more than a rubber stamp. Its requirement for an annual consulting plan . . .was ignored. So too were its concerns that there were too many consultants attending too many meetings."

# Physician Speaker Programs & HCPs as Consultants

- How do In-House Lawyers and Compliance Officers best manage physician speaker and HCP consultant programs to mitigate risks?
- How can Legal & Compliance Departments limit the risk that opinions and actions undertaken to protect the company (and mitigate risk) are not used against the company?

# Product Portfolios and Antitrust: Practical Implications of Recent Litigations



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# + Panel Agenda

- Product Hop
- Patent Thicket
- Prescription Drug Pricing
- Reverse Payment Multiple Products



#### **Product Hop Primer:**

- Branded manufacturer introduces a minor change to an existing prescription drug product, shifting sales to the reformulated patented product.
- Intent and effect of inhibiting emerging competition from a generic version of the original branded product.
- Which Switch? Hard Switch vs. Soft Switch
  - Withdrawal of existing product from market vs. preserving product "choice"
    - But Soft Switch precludes automatic generic substitution of newly reformulated product
- Timing of Switch: Before or After Generic Entry?



#### **Namenda** (2d Cir. 2015)

- NYAG case against Forest claiming that Forest implemented a hard switch to move market from twice-daily IR, immediate release, product to once daily XR, extended release product.
  - Forest initially began with soft switch strategy, with both products on market and, heavy promotion of XR product and discounted prices, and a stoppage of active marketing of the IR product.
  - But Forest then moved to a true hard switch, announcing plans to discontinue sales of product prior to patent expiration.
  - Before Forest could follow through with announcement, district court issued preliminary injunction requiring Forest to continue sales of IR product until <u>one month after generics entered</u> market.
- Second Circuit upheld injunction, and concluded that hard switches raise significant monopolization concerns because they remove products from market, but concluded soft switches do not raise the same concerns.

Buchanan

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#### *Doryx* (3d Cir. 2016)

- Mylan, the generic plaintiff, argued Warner Chilcott engaged in a series of product hops by introducing reformulations that merely modified the drug's form, dosage, or score (a groove in tablet intended to allow easier halving of doses).
- With each change, Warner Chilcott eventually ceased promoting the prior formulations and ultimately withdrew them from the market, but generally not before Mylan began selling a generic version.
- Mylan alleged that these reformulations were intended to prevent generic manufacturers from relying on automatic substitution laws because each change required generic manufacturers to re-establish bioequivalence.



#### Doryx (3d Cir. 2016) (continued)

- Third Circuit found no violation of Sherman Act, for two reasons:
  - First, because Warner Chilcott lacked the monopoly power to destroy competition or deprive consumers of choice.
    - Market Share analysis dispositive: Warner Chilcott's share in the market of *interchangeable* oral tetracycline drugs was only 18 percent, it did not have monopoly power, nor could its product hops achieve such power.
  - Second, Third Circuit held that Warner Chilcott's product hops were not anticompetitive because Mylan
    was not entirely blocked from the market due to generic entry prior to switches.
    - Timing of switch, Mylan 180-day exclusivity and availability of alternative products key to analysis.
    - "Here, there were no patent cliffs on the horizon, and the evidence demonstrates that there were plenty of other competitors already in the oral tetracycline market."
- Court left open possibility that product hops could be anticompetitive and unlawful
  - "To be clear, we do not rule out the possibility that certain insignificant design or formula changes, combined with other coercive conduct, could present a closer call with respect to establishing liability in future cases."



#### Suboxone (E.D. Pa. Aug. 2022)

- Multistate coalition of State AGs sued Indivior (Reckitt) over product hop conduct.
  - Separate prior FTC case and settlement in the W.D.Va over same conduct.
- Allegations that company had executed a planned "generic defense strategy" aimed to switch from tablet product to sublingual film with child proof packaging.
- State plaintiffs alleged that Indivior raised tablet price aggressively after film launched and then withdrew tablet form market prior to generic entry, which then occurred in a weakened product market.
- Further alleged Indivior engaged in conduct that amount to the fabrication and marketing of a "safety story" about the dangers of the tablet.
  - Campaign allegedly included disparaging statements the safety of tablets regarding potential pediatric abuse, misuse, and diversion.

#### Suboxone (E.D. Pa. Aug. 2022) (continued)

- Federal district court here in Philadelphia denied summary judgment motions by Indivior, sending case to jury trial.
  - "Plaintiffs have pointed to evidence that could establish that the "product hop" here was effectuated along with other alleged anticompetitive behavior—a combination the Third Circuit [in Doryx] ... affirmatively recognized could result in antitrust liability."
  - Includes "evidence of extreme coercion of physician prescribing decisions;" "blatant misrepresentation about a generic manufacturer's version of a drug"; and whether a "patent-cliff" is present "especially when a defendant's actions are paired with weak or inconsistent evidence of procompetitive justifications."
- District court also found persuasive Namenda ruling that "while 'neither product withdrawal nor product improvement alone is anticompetitive,' where a defendant 'combines product withdrawal with some other conduct, the overall effect of which is to coerce consumers rather than persuade them on the merits . . . and to impede competition . . . its actions are anticompetitive."



# **Pharmaceutical Patent Thicket**



#### Pharmaceutical Patent Thicket

#### **Patent Thicket Primer**

- Patent thickets refer to a multitude of overlapping patents for the same drug held by a single company, often for strategic business advantage.
- Can apply to biologics and small molecule drugs alike.
- Patent thickets at issue in other industries as well think tech but pharma litigation landscape unique given Hatch-Waxman Act and Biologics Price Competition and Innovation Act (BPCIA) litigation frameworks.
- How thick of a thicket?



### Pharmaceutical Patent Thicket

### Humira (7th Cir. Aug. 2022)

- AbbVie's blockbuster biologic drug a monoclonal antibody with multiple indications including arthritis, Crohn's disease, ulcerative colitis, plaque psoriasis and more.
- Original Humira patent expired in 2016, but AbbVie obtained 132 additional patents related to the drug.
- After the 12-year BPCIA requirement passed, none of AbbVie's competitors chose to launch a biosimilar.
- Instead, competitors settled with AbbVie on terms to enter the US market in 2023. In exchange, AbbVie agreed that enforcement of all 132 of its patents would end in 2023 even if they were not set to expire.



### Pharmaceutical Patent Thicket

#### Humira (7th Cir. Aug. 2022) (continued)

- Drug purchasers sued alleging that AbbVie had prevented manufacturers of competing biosimilars from entering the U.S. market in violation of federal and state antitrust laws.
- Two novel antitrust theories:
  - (1) Patent thicket: AbbVie monopolized the market by creating and asserting a "patent thicket" of invalid and unenforceable patents around Humira
  - (2) Reverse payment: AbbVie and competing biosimilar manufacturers illegally allocated geographical markets and engaged in illegal pay-for-delay arrangements through settlement agreements in which AbbVie granted licenses for manufacturers that allowed them to sell their Humira biosimilars in Europe in 2018 while prohibiting sales in the U.S. until 2023.



### Pharmaceutical Patent Thicket

### Humira (7th Cir. Aug. 2022) (continued)

- On patent thicket claims, Court found that amassing patents by itself is not enough to give rise to an antitrust claim, and plaintiffs would need to prove that the patents were invalid.
  - "But what's wrong with having lots of patents? If AbbVie made 132 inventions, why can't it hold 132 patents? The patent laws do not set a cap on the number of patents any one person can hold—in general, or pertaining to a single subject."
  - "The payors insist that AbbVie's patents are weak—too weak to monopolize the sales of such an important drug. This argument leaves us cold. Weak patents are valid; to say they are weak is to say that their scope is limited, not that they are illegitimate."
- Court found persuasive that there were no claims of fraud on the PTO, and that numerous patents were scrutinized by Patent Trial and Appeal Board (PTAB) through *inter partes* review after which they were left intact. And many other patents were left unchallenged.
  - "The district court observed that AbbVie had a "batting average" of .534, which is stellar in patent practice and unheard-of in baseball."

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### **Kaiser Family Foundation Polling (2021)**

- 62% of adults currently are taking at least one prescription drug
  - 25% of adults currently are taking four or more prescription drugs
- 83% of adults say the cost of prescription drugs is unreasonable
- 78% of adults say pharmaceutical company profits are a major reason for the cost of prescription drugs
- 88% of adults support some version of price controls for prescription drugs



#### **Recent federal actions**

- Nov 2020: Most Favored Nation (MFN) Rule
  - Would have tied Medicare Part B reimbursements for certain, physician-administered drugs to the lowest price charged in other high-income countries
  - Blocked by federal court in December 2020; rule rescinded by CMS in August 2021
- Nov 2020: PBM Rebate Rule
  - Eliminates the anti-kickback safe harbor for rebates by pharmaceutical companies to PBMs in federal healthcare programs
  - Implementation delayed until 2032 by the Inflation Reduction Act



#### Recent federal actions

- Aug 2022: Inflation Reduction Act
  - Requires the federal government to negotiate prices for some higher-cost drugs covered by Medicare
    - Applies to brand-name and biologic drugs without generic or biosimilar competition
      - 10 Part D drugs in 2026; +15 Part D drugs in 2027; + 15 Part B / Part D drugs in 2028; +20
         Part B / Part D drugs in 2029 and later years
  - Requires drug manufacturers to pay rebates to Medicare if prices for drugs used by Medicare beneficiaries increase faster than inflation
  - Caps Medicare beneficiaries out-of-pocket spending under Medicare Part D
    - Eliminates coinsurance above the catastrophic threshold (\$7,050 in 2022) in 2024
    - Adds a \$2,000 cap on spending in 2025
    - Limits annual increases in Part D premiums for 2024-2030
  - Limits cost-sharing for insulin to \$35 per month for Medicare beneficiaries



#### Recent state actions

- Every state has enacted legislation to address prescription drug prices these fall broadly into a few categories:
  - Regulation of PBMs (47 states)
  - Price controls / cost-sharing (22 states)
    - Impose price caps for certain prescription drugs (e.g., insulin)
  - Price transparency (21 states)
    - Require advance notification (to purchasers or state entities) of certain price increases
  - Importation (6 states)
    - Allow wholesale importation from Canada, typically tied to a change in federal law or HHS approval



#### Rutledge v. Pharmaceutical Care Management Association (2020)

- Arkansas Act 900 seeks to address low PBM reimbursement rates that did not cover drug acquisition costs of rural and independent pharmacies
  - Requires timely updates to PBM MAC rates to address wholesale price increases
  - Mandates an appeals process for pharmacies to challenge MAC rates below drug acquisition cost
  - Permits a pharmacy to decline to dispense a drug to a beneficiary if the PBM will reimburse at less than drug acquisition cost
- PBM trade association sued claiming ERIA preemption; district court and 8<sup>th</sup> Circuit agreed
  - ERISA preempts "any and all State laws insofar as they may now or hereafter related to any employee benefit plan"
- Supreme Court reversed, upholding the statute 8-0
  - No impermissible connection or reference to an ERISA plan: "merely a form of cost regulation that does not dictate plan choices"

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#### **Generic Drugs Pricing Litigation (E.D. Pa.)**

- Dozens of lawsuits by state attorneys general, putative classes, and direct action plaintiffs alleging price-fixing and market allocation conspiracies for hundreds of generic drugs plus an industry-wide "overarching conspiracy"
  - Issues originated from price increases for dozens of generic drugs beginning in 2010 due to a variety of factors:
    - API supply and pricing issues
    - Enhanced FDA regulation
    - Buyer consolidation
  - First lawsuits filed in 2016; fact discovery is ongoing; first trials likely in late 2023 or early 2024
  - Plaintiffs' case turns almost entirely on indirect evidence of an alleged conspiracy numerous phone calls and text messages among defendants' employees that roughly correspond with market events
  - May 2022 MTD Opinion: "[T]he Third Circuit has held that the mere exchange of information, in the absence of an agreement, does not violate the Sherman Act."



#### FTC v. Vyera (S.D.N.Y.)

- FTC and a group of seven state attorneys general sued Vyera and others alleging an anticompetitive scheme to preserve a monopoly for Daraprim
  - Defendants acquired the U.S. rights to Daraprim in 2015 and raised the price from \$17.50 to \$750 per tablet
  - To forestall generic competition, Defendants allegedly created a "complex web of contractual restrictions" for the purpose of prohibiting distributors or others from re-selling Daraprim to generic manufacturers for purposes of bioequivalence testing
  - Seven-day bench trial in Dec 2021 before Judge Cote
    - All defendants other than Martin Shkreli settle immediately before trial
    - Verdict for plaintiffs: Shkreli barred for life from participating in the pharmaceutical industry and is ordered to pay \$64.6 million in restitution
- Broadly similar to recent litigation involving EpiPen and insulin arguably inequitable pricing paired with traditional allegations of antitrust, False Claims Act, or RICO violations



# **Reverse Payment**



### Reverse Payment

#### **Reverse Payment Primer**

- FTC v. Actavis (SCT 2015)
  - "Reverse" Payments, AKA "Pay for Delay" vs. "Traditional" settlements
  - "Large and Unexplained" Reverse Payments
- Numerous litigations have followed
  - Cash payments only?
  - Fair value side transactions
  - No Authorized Generic (No-AG) Clauses
- Discrete Issue in Flux: Settlement of Multiple Cases or Different Products at the Same Time
  - Search for "Global Peace" in Patent Litigation with Competitor



#### Humira (7th Cir. 2022)

- Plaintiffs also claimed that AbbVie unlawfully settled patent litigation through reverse payment by settling European patent disputes over Humira at the same time as settlement of U.S. patent litigation over that same biologic product.
  - European biosimilar entry date in 2018; U.S. biosimilar license date 2023.
- Plaintiffs claimed that AbbVie gifted the biosimilar challengers 4+ years of profits in Europe in order to purchase a delayed entry in the U.S., and that constituted an unlawful reverse payment.
- DCT and 7th Cir. rejected that view, holding that that European settlements, standing alone, were precisely the kind of no-payment settlements authorized by Actavis, with royalties paid on specific licensed indications. And settlements in the U.S. litigation, standing alone, also did not include any payment.
- Combining the two together did not create a payment where there otherwise was none.



### Humira (7th Cir. 2022) (continued)

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### *Lipitor* (3d Cir. 2017)

- Pfizer and Ranbaxy settled multiple patent litigations between the companies simultaneously, in the hopes of achieving some semblance of "global peace."
  - Settled U.S. Lipitor (atorvastatin) litigation on a highly significant product with a straightforward licensed entry date
  - Also settled a host of foreign patent disputes relating to Lipitor and several other unrelated products.
     Each of those settlements had straight licensed entry dates before patent expiration in the ex-US jurisdiction.
  - In addition, Pfizer and Ranbaxy also settled a longstanding U.S. patent litigation concerning a different drug, Accupril, with unique context.
    - Ranbaxy had launched its generic Accupril product at-risk and then was preliminarily enjoined from the
      market. At the time of the global settlement, significant open issues remained in the litigation, including claim
      construction, liability, and potential damages flowing both directions both for at-risk launch but also for
      wrongful injunction flowing against Pfizer.

#### Lipitor (3d Cir. 2017) (continued)

- Antitrust plaintiffs alleged that these simultaneous settlements in other jurisdictions and on other products amounted to a reverse payment from Pfizer to Ranbaxy to purchase a delay in the U.S. Lipitor license date.
- District court rejected those claims, finding that they had not been plead with sufficient factual detail particularly as to valuation—to allow for plausible claim of a reverse payment.
- Third Circuit, however, ultimately agreed with plaintiffs at least on a motion to dismiss and allowed the case to proceed into discovery.
  - "For its part, the Supreme Court in Actavis was deliberately opaque about the parameters of reverse payment antitrust claims."
  - "The alleged reverse payment here was 'large' enough to permit a plausible inference that Pfizer possessed the power to bring about an unjustified anticompetitive harm through its patents and had serious doubts about the ability of those patents to lawfully prevent competition."



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