ACC Association of Corporate Counsel
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From Trials to Market: Assessing and Managing Litigation Risks

Presented By

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Introduction

- Litigation is inherently reactive
- Plaintiff's bar leverages element of surprise
- Once sued, a company must prepare for discovery, while at the same time, assessing validity of claims
- Benefits of Litigation Risk Assessment
  - Early determination of risk and level of exposure
  - Develop plan to limit and correct "problems" before litigation is filed

Assessment Benefits

- Preserve Institutional Knowledge
- Identify + Evaluate Potential Witnesses
- Identify Important but Often Hidden Issues
- Analyze Key Documents
- Identify Risk-Shifting Mechanisms
- Help In-House Counsel Make Informed Strategic Litigation Decisions
- Save Costs
- Create a Resource for Future Decision-Making

Overview

- **Pre-Market Risks**
- **Post-Market Risks**

FROM TRIALS TO MARKET: ASSESSING AND MANAGING LITIGATION RISKS

Pre-Market Risks: *Clinical Trials on Trial*

Pre-market Risks:

Litigation can arise in a variety of areas based on numerous aspects of a clinical trial:

Personal Injury to Clinic Trial Subjects
Breach of Contract

Other:

- -Clinical Trial Design
- -Clinical Trial Reporting
- -Licensing and Collaboration Agreements

Personal Injury Lawsuits

- Limited Exposure in Clinical Phase
  - Regulated environment
  - Lack of motivation for plaintiff's lawyers
  - Therapies reach relatively small populations
  - Clinical trial subjects may have higher risk tolerance (novel therapies)

Litigation Risks During Clinical Trials

- *Butler v. Juno Therapeutics*, USDC TX (2021)
  - CAR-T therapy for advanced blood cancers
- *Murthy v. Abbott Labs*, USDC TX (2012)
  - Humira clinical trial
- *Kennke v. Aventis, Meninger Clinic*, USDC KS (2001)
  - Investigational anti psychotic medication

Licensing and Collaboration Agreements

- Used by life sciences companies to share risks, costs, and profits of bringing a product to market
- Typically one party acquiring right to develop, manufacture, distribute, and/or sell a licensed product
- **Advantages:** reduce risks/ costs, prompt innovation, expand portfolios, increase revenues/profits
- **Downsides:** Loss of control; IP issues; litigation and disputes where goals differ or lack of shared understanding of goals

Different Kinds of Agreements

- Joint ventures
- Co-promotion and co-development
- Collaborative research and development
- Material Transfer agreements

Performance Obligations

- Commercially reasonable efforts
- Minimum or annual royalties
- Milestones – performance metrics
- Warranties
- Indemnities

BREACH OF CONTRACT

Commercially Reasonable Efforts Provisions

Efforts Clauses

- Used to manage expectations in a party's performance of contract duties. These standards can apply to any duty within the contract, whether that be completing the transaction, obtaining regulatory approval, or obtaining proper financing.
- Companies developing drugs, biologics, and medical devices, like other industries, are susceptible to uncertainty and disruption in contracting. Licensing costs, outside collaboration, changing landscapes and market fluctuations.

Efforts Clauses: Overview

- Efforts clauses are quite common in commercial agreements and are used to ensure some level of satisfactory result. Traditionally, the most common efforts clause standards were "best efforts," or "reasonable efforts," and "commercially reasonable efforts."
- Many lawyers view these standards as existing in a clear and defined hierarchy, but this does not necessarily reflect case law.
- Differing treatment by courts and the UCC do not support a clear hierarchy, and as a result both a party's and a court's interpretations will vary. Because of this, litigation is common.

Commercially Reasonable Efforts

- Can provide sense of certainty in commercial agreements by providing flexibility in absence of definable obligations or in anticipation of future commercial realities
- When a company enters a commercial agreement to develop a drug or biologic, provide drug ingredients, or deliver equipment, an obligation to use commercially reasonable efforts is often defined to require a similar level of effort or resource use that similar parties to similar contracts committed

Commercially Reasonable Efforts - Standards

- Depending on the context surrounding an agreement, and a court's interpretation, parties draft CRE provisions around three standards:
  - An outward-facing, objective standard
  - An inward-facing, subjective standard
  - A standard with a mix of both objective and subjective

Outward-Facing Standard

- Applies an **industry-standard** requirement or looks to other members of the industry to define diligence.
- Looks to: the efforts consistent with past practices of similarly sized/staged companies with respect to similar products and agreements.
- **Example**: *S'holder Representative Servs. LLC v. Alexion Pharms., Inc.*, No. 2020-1069-MTZ, 2024 Del. Ch. LEXIS 318 (Del. Ch. Sep. 5, 2024) (Involving efforts clause requiring "efforts and resources typically used by companies like [defendant], developing a product like [drug], taking into account factors typically considered by such companies.").
- This benefits the **manufacturer** or **licensor**, because it allows this party in litigation to point towards steps the distributor or licensee should have taken that other comparable members of the industry would have.

Outward-Facing Application: *InspiRX, Inc. v. Lupin Atlantis Holdings SA*, 554 F.Supp.3d 542 (S.D.N.Y. 2021)

- InspiRX enters into licensing agreement with Lupin to distribute and promote asthma and allergy medication delivery device (A "valved holding chamber" or "VHC").
- Lupin begins advertising and selling the VHC in 2015. Lupin bought advertisements in medical journals and attended several conferences.
- Sales are disappointing, and Lupin disbands the salesforce responsible for selling the VHC, and eventually terminates the contract.
- InspiRX brings suit for breach of contract based on Lupin's "failure to use commercially reasonable efforts."

InspiRX: Efforts Clause

- Efforts Clause: "Lupin shall use Commercially Reasonable Efforts to Distribute the Products… using its current distribution capabilities and resources."
- Definition: "Commercially Reasonable Efforts means…reasonable, diligent, good-faith efforts…which efforts shall not be less than the efforts other **similarly situated companies** would normally use to accomplish a similar task or objective under similar circumstances[.]"
  - Definition also mentions: similar products, similar product life cycle, similar rights and "other relevant factors"
  - Also allowed Lupin to take into account "efficacy, safety, approved labeling, the competitiveness of alternative products in the marketplace, the patent and other proprietary position of the product… and other relevant factors commonly considered in similar circumstances."
  - Finally, the clause recognized that the level of efforts "required to meet the [Commercially Reasonable Efforts] standard **may change over time** if there are changes in the status of the Products or the above criteria applicable to the products."

InspiRX: Analysis

- Court states that a Commercially Reasonable Efforts clause is "not a hell or high water clause" requiring of a party to use "all efforts possible, no matter the cost.
- Lupin's Performance When analyzing Lupin's behavior after the VHC underperformed, court noted that InspiRX failed to point towards **any** facts supporting a similarly situated company would have acted differently.
  - Court notes that no other company was in contact with InspiRX to promote the VHC. ***Other companies had abandoned the pediatrics market*** as a promotional focus entirely.
  - InspiRX argued that Lupin failed to exhibit the product sufficiently, however Lupin attended ***15 sales conferences over five year period***, the court found this to be commercially reasonable.
  - Finally, the court found that Lupin's cost cutting measures in the face of steep losses were a ***reasonable judgement***, and other similarly situated companies would have made the same choice.

Inward-Facing Standard:

- Requires a company to act according to its own internal standards in performing its contractual obligations. Thus, is a **subjective** standard.
- Looks to: The licensee or distributor's own internal standards in determining what is commercially reasonable.
- Pro-licensee or distributor as it tends to be more deferential to the discretion of the party obligated to exercise commercially reasonable efforts. The court is not required to look towards other similarly situated companies to determine if the obligated company met its efforts requirement.

Inward-Facing: Drawbacks to Obligated Party

- An inward-facing CREs provision will also put a company's own internal standards and efforts in other agreements under the scrutiny of the courts.
- Can subject a company to additional expenses and time spent in discovery.
- Can potentially reveal sensitive information like internal practices, financial information, and current and future business plans to competitors.
- Can subject key employees and officers to a stressful and time consuming litigation process, forcing them to submit to depositions and to appear as court witnesses.
- Licensees/buyers are unlikely to agree to a subjective inward-facing standard.
- Licensors/sellers prefer to hold licensees/buyers to a subjective standard where it has to exercise the same amount of effort it provides to other programs.

Inward-Facing Application

- Fortis Advisors LLC v. Allergan W.C. Holding Inc., No. CV 2019-0159-MTZ, 2019 WL 5588876, (Del. Ch. Oct. 30, 2019)

Allergan: Facts

- Allergan acquires Oculeve, Inc., the manufacturer of a medical device which induces a person's eyes to tear with a small electric shock.
- The merger agreement includes payments for certain post-closing milestones, including achieving regulatory approval and milestones that track product sales.
- Oculeve receives regulatory approval for "temporary increase in tear production," where regulatory milestone asked for "increase in tear production[.]" As a result, Allergan refused to pay the regulatory milestone and Oculeve (stockholders represented by Fortis) files suit.

Allergan: Efforts Clause

- Efforts Clause was an inward-facing standard: [W]ith respect to the performance of development, regulatory or commercialization activities with respect to the Product, the carrying out of such activities using commercially reasonable, diligent and good faith efforts and expending resources that Buyer would typically devote to, and with respect to, products of similar market potential at a similar stage in development or product life[.]"
- Thus, despite the fact that Oculeve was the aggrieved party in this case, their suit subjected them to an extensive discovery process. Their internal standards were subject to extensive scrutiny.
- Case decided on other grounds

Example Case

- Fortis Advisors LLC v. Johnson & Johnson, No. 2020-0881-LWW, 2024 Del. Ch. LEXIS 315 (Del. Ch. Sep. 4, 2024)

Drafting Considerations: Which Standard?

- Determining whether to use subjective or objective language in drafting an efforts clause is a substantial decision.
- Experienced life sciences corporations might prefer an **internal subjective** standard. This would provide stability and comfort by allowing the corporation to conduct business and manage projects in the way the corporation ordinarily does.
- However, a company may be concerned a subjective standard could expose their own internal practices, subjecting the corporation to intrusive and extensive discovery if the provision is litigated.

Drafting Considerations Cont'd

- Licensees/buyers can gain additional protection by adding specific language to the CRE clause stating that commercially reasonable efforts may include deciding to cease development/commercialization or deprioritize an asset.
  - Company strategy is constantly changing so licensees/buyers will want to retain the ability to shift out of a certain area or decide against moving forward with an asset.
  - The Company should retain discretion to decide whether to cease development.
- Bargaining power can make a difference.
  - Ex. If a company is in-licensing an asset for a rare disease, the Company may be able to get more favorable language about commercially reasonable efforts because the out-licensor does not have many options given the rare disease space.
- For co-development or co-promotion agreements, consider whether different standards should apply to the parties.
  - One party could be held to an objective standard while the other is held to a subjective standard.
  - Different standards might be favored where one company is smaller and inexperienced (hold to objective standard) and the other is larger and experienced (hold to subjective standard).

Drafting Considerations Cont'd

- Be Objective wherever possible: In certain jurisdictions, courts will only find efforts clauses enforceable if the agreement includes objective criteria against which a party's efforts can be measured.
  - *See Kevin M. Ehringer Enter. v. McData Serv.* 646 F.3d 321, 326 (5th Cir. 2011)
- Negotiate What Standards Apply: Agreeing what effort a "commercially reasonable efforts" clause requires can help avoid ambiguity, and establish a record that can be relied upon if litigation were to commence. This can potentially save costs down the line by clearly establishing what efforts would constitute a material breach of the agreement.
- Be as specific as possible in defining CREs.
- Avoid Ambiguity
  - By providing definitions and staying objective wherever possible, ambiguity will be avoided which could result in litigation in the future. (e.g. *Fortis Advisors LLC v. Johnson & Johnson*, No. 2020-0881-LWW, 2024 Del. Ch. LEXIS 315 (Del. Ch. Sep. 4, 2024) (finding J&J had little discretion over pursuit of efforts because agreement was ambiguous on J&J's discretion)
  - Provide an agreed upon definition for "commercially reasonable efforts" within the agreement. Clarifying any ambiguity in the agreement can effect litigation down the line.
- Consider Limitations on Obligations:
  - Counsel should take steps to review a party's obligations in an efforts provision with clients (or internally).
  - This will provide an opportunity to measure whether the obligations are reasonable and acceptable.
  - It will also allow counsel to seek limitations on the obligations, for example, if an efforts clause requires great expense to the client, affect its solvency, or render benefits under contract moot, Counsel can seek to limit.

FROM TRIALS TO MARKET: ASSESSING AND MANAGING LITIGATION RISKS

Post-Market Risks:

Post-market Risks:

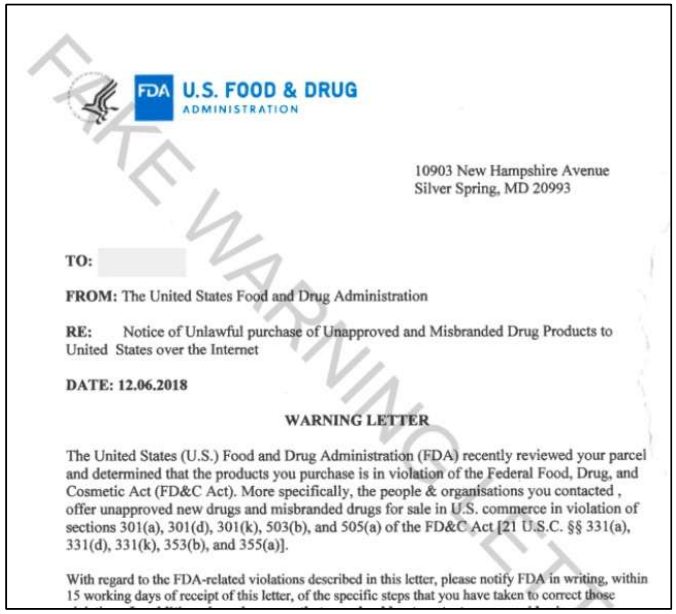
- Lifespan of product – greater exposure
- Many forms: personal injury/ product liability; regulatory and government; commercial-contractual

Litigation Triggers

- FDA Warning Letters
- Citizen Petitions
- Published Studies
- Label Changes
- Recalls
- Qui tam/ whistleblowers
- DOJ investigations
- Third Party Litigation Profiteers

Litigation Triggers: Warning Letters

- "FDA's inspection found that **your firm failed to comply** with the postmarketing reporting requirements under 21 U.S.C. § 355(k)"
- "**Failure to review, evaluate, and submit adverse drug experience** (ADE) reports that are both serious and unexpected to FDA within 15 calendar days of initial receipt of the information"
- "**Misbranding** of investigational drug" by hyperlinking video of scientist discussing safety and efficacy



FDA U.S. FOOD & DRUG ADMINISTRATION

10903 New Hampshire Avenue
Silver Spring, MD 20993

TO:

FROM: The United States Food and Drug Administration

RE: Notice of Unlawful purchase of Unapproved and Misbranded Drug Products to United States over the Internet

DATE: 12.06.2018

WARNING LETTER

The United States (U.S.) Food and Drug Administration (FDA) recently reviewed your parcel and determined that the products you purchase is in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act). More specifically, the people & organisations you contacted , offer unapproved new drugs and misbranded drugs for sale in U.S. commerce in violation of sections 301(a), 301(d), 301(k), 503(b), and 505(a) of the FD&C Act [21 U.S.C. §§ 331(a), 331(d), 331(k), 353(b), and 355(a)].

With regard to the FDA-related violations described in this letter, please notify FDA in writing, within 15 working days of receipt of this letter, of the specific steps that you have taken to correct those

Litigation Triggers: FDA Citizen Petitions

- A citizen petition is a way for individuals, regulated industry representatives, or consumer groups to petition FDA to issue, amend, or revoke regulations, or take other action related to a product.
  - Influence FDA action and shape agenda
  - 200 annually
  - Public docs - anyone can search
  - Agency must respond
  - Set the table for litigation

CDRH Petitions

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A petition is a way for individuals, regulated industry or consumer groups to petition the agency to issue, change or cancel a regulation, or to take other action. The agency receives about 200 petitions yearly.

Litigation Triggers: Published Studies

- **Key Example:** acetaminophen

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NEWS RELEASES

Media Advisory Wednesday, October 30, 2019

NIH-funded study suggests acetaminophen exposure in pregnancy linked to higher risk of ADHD, autism

What

Exposure to acetaminophen in the womb may increase a child's risk for attention deficit/hyperactivity disorder and autism spectrum disorder, suggests a study funded by the National Institutes of Health and the Agency for Health Care Research and Quality. The study was conducted by Xiaobing Wang, M.D., of the Johns Hopkins University Bloomberg School of Public Health, Baltimore, and colleagues. It appears in *JAMA Psychiatry*.

Attention deficit/hyperactivity disorder (ADHD) is marked by a pattern of hyperactivity and impulsive behavior. Autism spectrum disorder (ASD) is a complex developmental disorder that affects how a person behaves, interacts with others and learns.

Institute/Center

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

Contact

Robert Bock or Meredith Daly
301-496-5133

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Litigation Triggers: FDA Label Changes

- Label changes that relate to "safety" often trigger litigation

Drug Safety-related Labeling Changes

FDA U.S. FOOD & DRUG ADMINISTRATION

Drug Safety-related Labeling Changes (SrLC)

The SrLC database has been updated with the following approved drug safety labeling changes.

Drug Name	Active Ingredient	Application Number	Application Type	Supplement Date	Database Updated
FOSRENOL	LANTHANUM CARBONATE	021468	NDA	08/29/2024	09/04/2024
FOSRENOL	LANTHANUM CARBONATE	204734	NDA	08/29/2024	09/04/2024
POTASSIUM PHOSPHATES	POTASSIUM PHOSPHATE, DIBASIC; POTASSIUM PHOSPHATE, MONOBASIC	212832	NDA	08/30/2024	09/04/2024
PREVYMIS	LETERMOVIR	209939	NDA	08/30/2024	09/04/2024
PREVYMIS	LETERMOVIR	209940	NDA	08/30/2024	09/04/2024
TOUJEO MAX SOLOSTAR	INSULIN GLARGINE RECOMBINANT	206538	BLA	08/29/2024	09/04/2024
TOUJEO SOLOSTAR	INSULIN GLARGINE RECOMBINANT	206538	BLA	08/29/2024	09/04/2024
ZEPOSIA	OZANIMOD HYDROCHLORIDE	209899	NDA	08/30/2024	09/04/2024

Litigation Triggers: Recalls

Recalls, Corrections and Removals (Devices)

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On this page:

- Overview
- Definitions
- Voluntary Recalls - 21 CFR 7
- Mandatory Device Recalls - 21 CFR 810
- Corrections and Removals - 21 CFR 806
- Regulations
- Federal Register Notices

Export Excel Show 10 entries

			Product Type	Recall Reason Description	Company Name
		ons:	Drugs	Labeled as Eliquis5 mg was found to contain Eliquis 2.5 mg tablets	Baxter International Inc.
		ainer SP			
		g	Drugs	Potential Labeling Issue	Bristol-Myers Squibb
02/08/2018	Amneal Pharmaceuticals LLC	Lorazepam Oral Concentrate, USP 2mg/mL	Drugs	Due to Misprinted Dosing Droppers	Amneal Pharmaceuticals LLC
08/10/2021	SterRx, LLC	Sodium Bicarbonate in 5% Dextrose Injection 150mEq per 1,000 mL	Drugs	Due to waterborne microbial contamination	SterRx, LLC

Litigation Triggers:
Qui Tam/ Whistleblower/ DOJ Investigations

ROB BONTA
Attorney General

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Attorney General Bonta Announces Nearly $60 Million Settlement Against Pfizer-Owned Pharmaceutical Holding Company, Biohaven

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Justice.gov > Office of Public Affairs > News > Press Releases > Athira Pharma Inc. Agrees To Pay $4M To Settle False Claims Allegations Related To Scientific Research Misconduct

PRESS RELEASE

Athira Pharma Inc. Agrees to Pay $4M to Settle False Claims Act Allegations Related to Scientific Research Misconduct

Keeping Fraud Out of Research: Government Grant Whistleblower Awarded Over $200,000

by: Tycko & Zavareei Whistleblower Practice Group of Tycko & Zavareei LLP - *Fraud Fighters*

Posted On Tuesday, January 14, 2025

RELATED PRACTICES & JURISDICTIONS

Criminal Law Business Crimes
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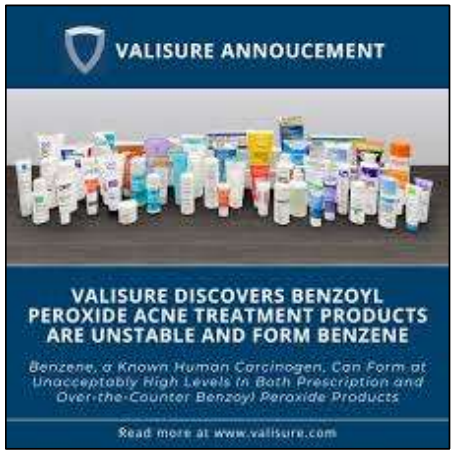
All Federal

Litigation Triggers: Third Party Litigation Profiteers

- Third party litigation funding (TPLF) - process where third party funders provide money to plaintiffs' counsel in exchange for a cut of the proceeds resulting from the underlying litigation or settlement.
- Sometimes there are other outside organizations that can profit from litigations as well.

valisure
the pharmacy that checks



Example Forms of Litigation

- Mass torts: MDLs, State Consolidated Proceedings
- One-off personal injury cases
- Class actions:
  - Sales & marketing practice act claims
  - Third party reimbursement claims
- Government initiated (False Claims Act)
- Commercial/ Contractual

Common Defenses

- Show Cause: Proof of Use and Injury
- Learned Intermediary doctrine
- Label Adequacy as a Matter of Law
- Preemption
- General and Specific Causation
- Statute of Limitations
- State of the Art Defense
- Comment K: Unavoidably Unsafe Products
- Bulk Supplier Defense

Key Issues In Contract Disputes

- Damages Limitation Provisions
- Indemnity Provisions
- Dispute Resolution
- Pros and Cons of Arbitration

Some Risk Mitigation Tips

- **Good document hygiene** – best practices from clinical trials through launch and product life cycle
- **Integrate Legal** – in-house or outside counsel oversight of labeling, marketing, medical information, website communications, warranty programs, *etc.*
- **Regulatory Counseling**– *e.g.*, pre and post-market policies and procedures; post-market surveillance compliance
- **Monitor the marketplace** – especially if scientific controversy develops

Thank you.

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