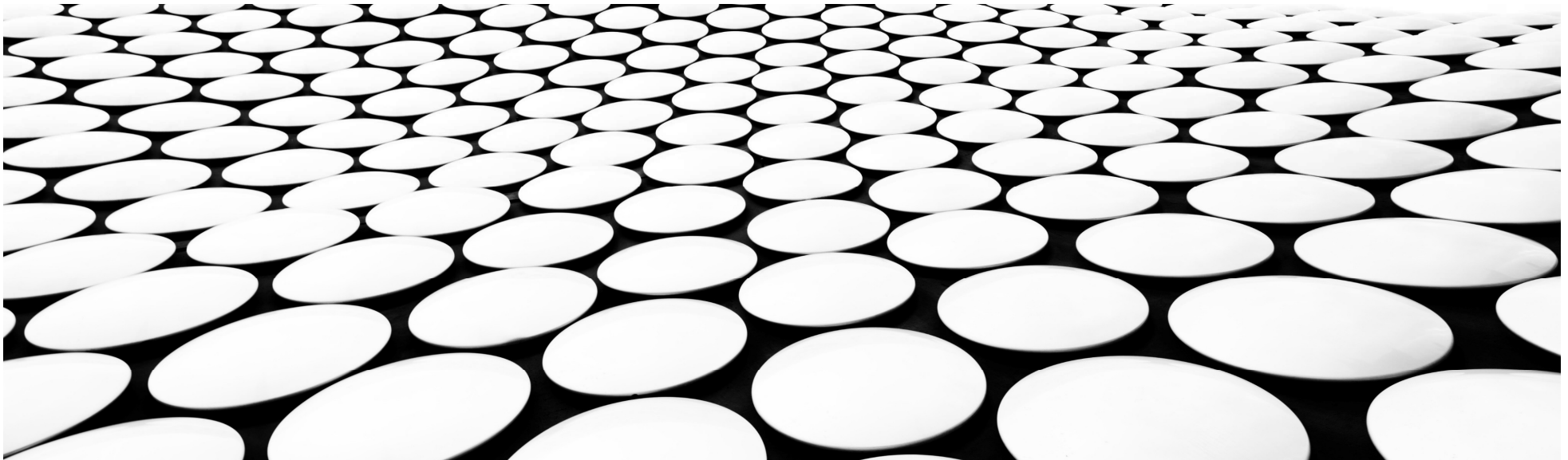

THE GLOBAL CONCERTA® SUPPLY CASE

JOHNSON & JOHNSON

CHRYSMALLOU IOANNA – KARAGEORGOPOULOU FANNY



ATTENTION-DEFICIT/HYPERACTIVITY DISORDER (ADHD)

- **Definition:** Attention-Deficit/Hyperactivity Disorder (ADHD) is a neurodevelopmental disorder characterized by persistent patterns of inattention, hyperactivity, and impulsivity that interfere with functioning or development.
- **Prevalence:** ADHD affects approximately 5-7% of children worldwide, with symptoms often continuing into adolescence and adulthood. A study by the Centers for Disease Control and Prevention (CDC) reported that as of 2021, about 6.1 million children in the United States have been diagnosed with ADHD.
- **Demographics:** ADHD is more commonly diagnosed in boys than girls, with a ratio of approximately 2:1 or 3:1. It can affect individuals across all socio-economic, racial, and cultural backgrounds.

ATTENTION DEFICIT HYPERACTIVITY **DISORDER**

Mental illness is not a personal failure.

@DR. MURUGAPAN



CONCERTA® IN ADHD

Mechanism of Action: Concerta (methylphenidate extended-release) is a central nervous system stimulant that helps to increase attention and decrease impulsiveness and hyperactivity in patients with ADHD.

Usage: Indicated for the treatment of ADHD in children ages 6 and older, teenagers, and adults. Concerta is designed to provide a controlled release of medication over an extended period, often allowing for improved adherence to a once-daily dosing schedule.

MARKET ALTERNATIVES

Ritalin (Methylphenidate) - Novartis

- A short-acting form of methylphenidate.
- Available in various formulations, often requiring multiple doses throughout the day.

Adderall (Amphetamine/Dextroamphetamine) - TeVa

- A combination of amphetamine salts used to treat ADHD.
- Available in both immediate-release and extended-release formulations.

Vyvanse (Lisdexamfetamine) - Takeda

- An amphetamine prodrug that is converted to dextroamphetamine in the body.
- Designed for a once-daily dosing schedule and has a lower potential for abuse.

Strattera (Atomoxetine) – Eli Lilly

- A non-stimulant medication approved for ADHD.
- Works by selectively inhibiting the reuptake of norepinephrine and is an option for those who may not respond well to stimulants.

Intuniv (Guanfacine Extended-Release) - Takeda

- Another non-stimulant option, primarily used to treat ADHD.
- It works by affecting receptors in the brain to help improve attention and reduce hyperactivity.

Kapvay (Clonidine Extended-Release) - Shionogi

- Used to treat ADHD, particularly in children and adolescents.
- Can be effective in addressing hyperactive and impulsive behaviors.

CONCERTA® STRATEGIC MARKET POSITIONING [1]

Medication	Type	Duration of Action	Key Benefits	Side Effects
Concerta	Stimulant	10-12 hours	Long-acting, once-daily dose; effective control of ADHD symptoms throughout the day.	Insomnia, decreased appetite, headache.
Ritalin	Stimulant	3-4 hours	Rapid onset; versatile with immediate and extended-release forms.	Similar to Concerta, may cause anxiety.
Adderall	Stimulant	8-12 hours	Effective for both ADHD and narcolepsy; flexible dosing options.	Risk of insomnia, potential for abuse.
Vyvanse	Stimulant	10-14 hours	Lower potential for abuse; prodrug formulation leads to a smoother onset.	Insomnia, dry mouth, anxiety.
Strattera	Non-Stimulant	24 hours	Non-stimulant option; suitable for those with a history of substance abuse.	Fatigue, stomach upset, decreased appetite.
Intuniv	Non-Stimulant	24 hours	Helps manage symptoms without stimulant effects; suitable for children.	Sedation, fatigue, low blood pressure.
Kapvay	Non-Stimulant	12 hours	Can be used as an adjunct to stimulants; sedative properties beneficial at night.	Sedation, dry mouth, constipation.

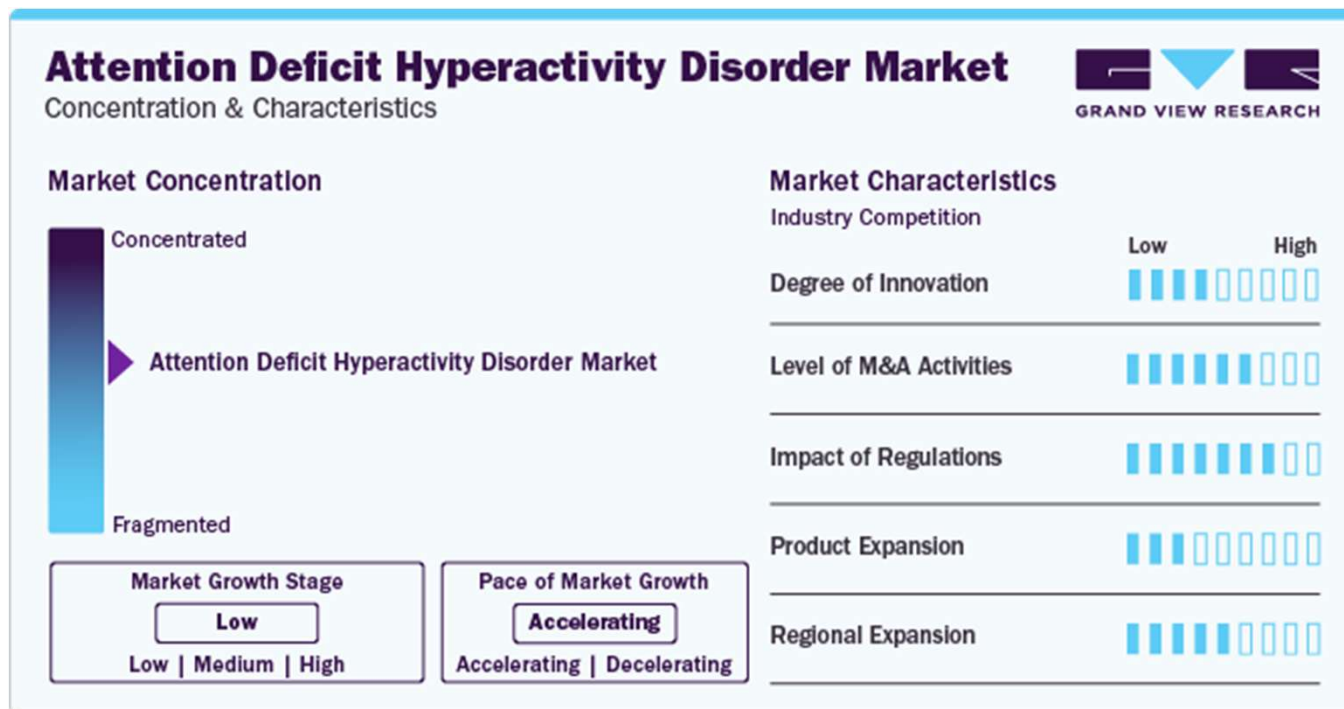


CONCERTA® STRATEGIC MARKET POSITIONING [2]

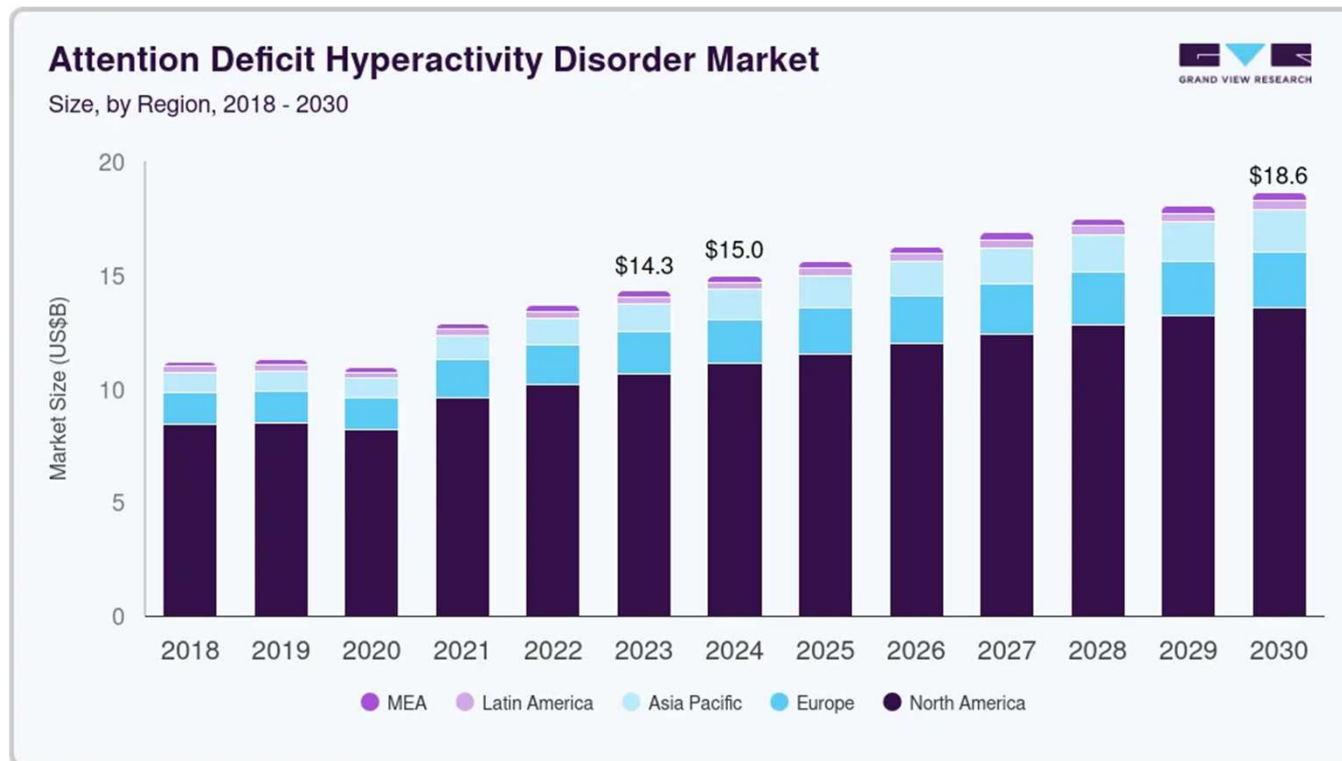
CONCERTA: An ADHD Top Product

- **Extended Release Formula:** Designed for once-daily dosing, providing continuous symptom control throughout the day without the need for multiple doses.
- **Established Efficacy:** Extensive clinical research supports its effectiveness in reducing ADHD symptoms, leading to higher physician prescribing rates.
- **Favorable Pharmacokinetics:** The osmotic-controlled release oral delivery system allows for a gradual release of medication, minimizing peak-and-trough effects that are common with other stimulants.
- **Wide Acceptance:** It is commonly recommended by healthcare providers and has a broad age range for pediatric and adult use, enhancing its market presence.
- **Strong Brand Recognition:** Being a well-known and widely used medication, it builds trust among patients and healthcare providers.

THE ADHD MARKET CHARACTERISTICS



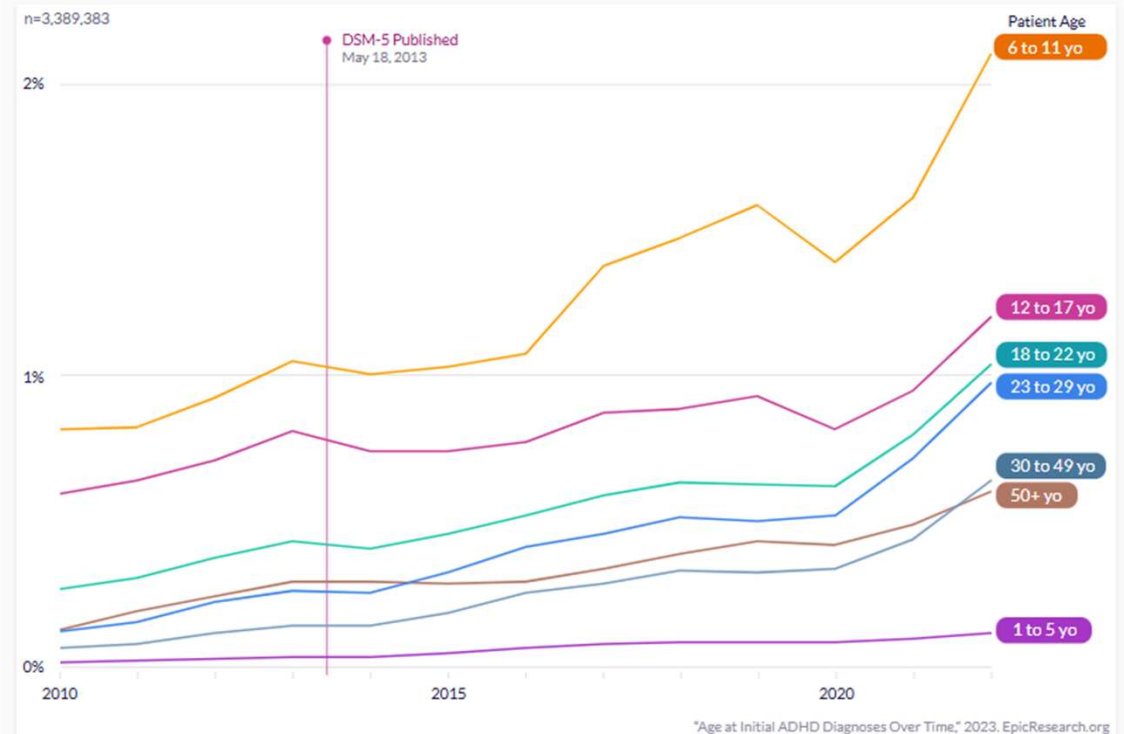
THE ADHD MARKET EVOLUTION



WHY?

- 1. Rising Awareness and Diagnosis:**
 - Increased Public Awareness
 - Improved Diagnostic Criteria
- 2. Changes in Educational Environments:**
 - Academic Pressures
 - Special Needs Services
- 3. Increased Telehealth Services:**
 - Accessibility
- 4. Growing Acceptance of Mental Health Issues:**
 - Stigma Reduction:
- 5. Population Trends:**
 - Population Growth
 - Longer Lifespans:
- 6. Increased Research and Treatment Options:**
 - Emerging Treatments
 - Prominent Marketing

Age at Initial ADHD Diagnosis Over Time



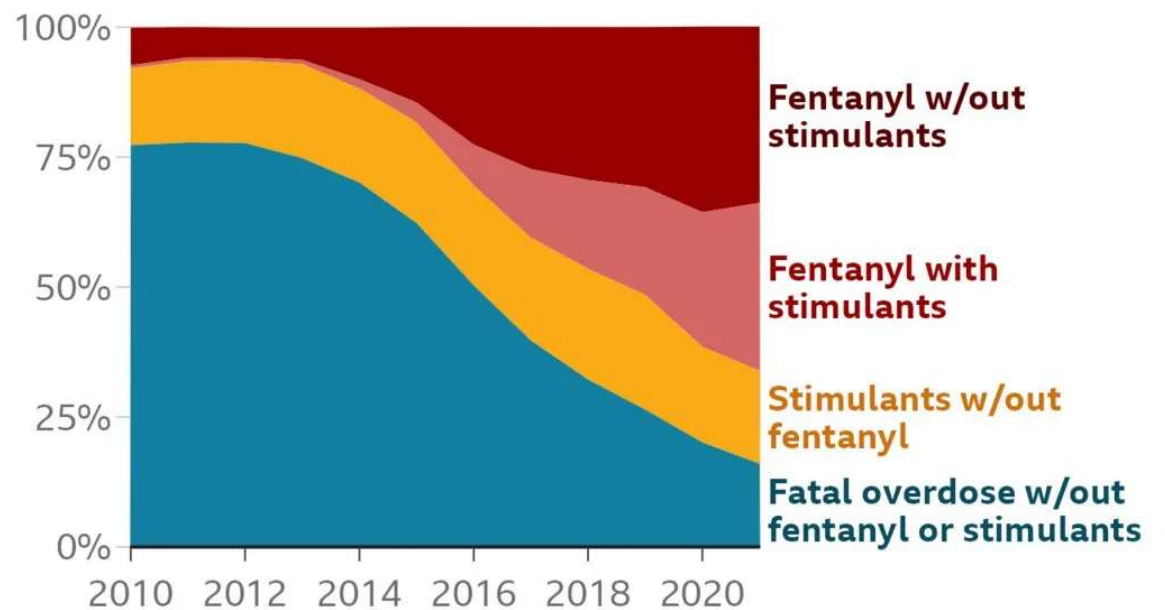


BUT...

THE US OPIOID CRISIS

Fentanyl is a growing problem in the US

% of all overdose deaths by fentanyl and stimulant presence



Source: Charting the fourth wave, Friedman/Shover 2023

BBC

MARKET REGULATIONS IMPACT

1. **Increased Scrutiny:** The opioid crisis has led to heightened scrutiny of all controlled substances, including ADHD medications like Concerta and Adderall. Regulatory bodies are more vigilant about prescribing practices and monitoring potential misuse.
2. **Manufacturing Regulations:** The Drug Enforcement Administration (DEA) closely regulates the manufacturing and distribution of stimulant medications due to concerns about abuse potential. Changes in quotas, inspections, and production limits can impact the availability of these medications.
3. **Resource Allocation:** Since the opioid crisis has driven a significant focus on opioids, resources from pharmaceutical companies, regulatory agencies, and healthcare providers may be more heavily allocated toward managing opioid prescriptions, potentially affecting other classes of medications.
4. **Economic Factors:** The legal and compliance costs for pharmaceutical companies due to increased regulations may lead to fewer manufacturers being willing to produce stimulant medications, which can contribute to shortages.



AND SO...

Psychiatric Times

Peer-Reviewed Practice-Oriented August 2023 • Vol. 40, No. 08

Rx Crisis The Impact of Ongoing ADHD Medication Shortages

Leah Kurtz

Class is now in session, but young patients with attention-deficit/hyperactivity disorder (ADHD) might not be ready to face the classroom. Thousands—if not millions—of them may not have their medication.

Continued on page 95

97%

of independent pharmacy owners reported shortages in early 2023, with shortages predicted through December 2023

The Delivery of Psychiatric an Era of Rapid Therapeutic

Michael Asbach, DMSc, PA-C, Psych-CAQ

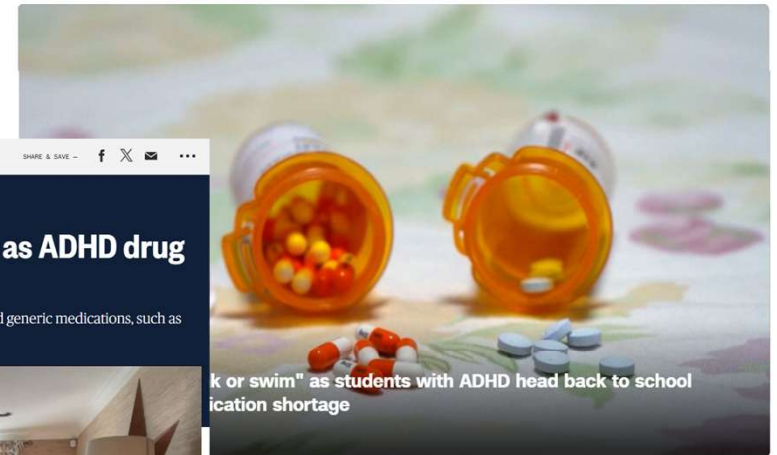
Psychiatry is a field of medicine that is constantly evolving. Innovations in psychiatric treatment have historically driven changes

in how care is: psychoanalysis, mental illness, in the mid-20th-century, antipsychotics

ADHD drug shortage stresses families during back-to-school season

By Meg Tirrell and Amanda Sealy, CNN

5 minute read • Updated 2:52 PM EDT, Mon September 4, 2023



"Sink or swim" as students with ADHD head back to school amid medication shortage

NBC NEWS

'I'm fed up': Frustrations grow as ADHD drug shortage continues

SHARE & SAVE — f X E ...

HEALTH NEWS

'I'm fed up': Frustrations grow as ADHD drug shortage continues

The supply of Adderall has improved, but other brand name and generic medications, such as Ritalin, are still hard to come by, doctors say.



MEDICATION
SHORTAGE

SOME PATIENTS "FED UP" AS YEARS-LONG
AS ADHD DRUG SHORTAGE CONTINUES

NBC
NOW

4/7/2025

HOW CAN INDUSTRY COPE WITH THIS BURDEN?

PROPOSALS [1]

1. Improve Manufacturing Capacity:

- Incentives for Production: Regulatory agencies could provide incentives for pharmaceutical companies to increase their manufacturing capacity for ADHD medications.
- Invest in Automation: Encourage investment in automated manufacturing technologies to boost efficiency and output.

2. Streamlined Regulatory Processes:

- Fast-Track Approvals: Implement policies to expedite the approval process for new formulations or alternative manufacturers for ADHD medications.
- Flexible Quotas: Adjust DEA quotas or scheduling to allow for greater production of stimulant medications when there is a demonstrated need.

3. Enhanced Communication:

- Supplier Collaboration: Improve collaboration between manufacturers, pharmacies, and healthcare providers to better anticipate demand and manage inventory more effectively.
- Transparent Reporting: Encourage pharma companies to provide clearer forecasts about production timelines and potential shortages, allowing for proactive measures.

PROPOSALS [2]

4. **Alternative Formulations:**


- **Development of New Products:** Invest in research and development of alternative dosing forms or non-stimulant medications that could provide similar therapeutic effects.
- **Generic Options:** Promote the production of generic alternatives to existing formulations, which can help mitigate shortages.

5. **Education for Healthcare Providers:**

- **Guidelines on Alternative Treatments:** Provide educational resources to healthcare providers about alternative treatments and management strategies for ADHD during shortages, ensuring continuity of care.

6. **Policy Recommendations:**

- **Stakeholder Involvement:** Foster involvement of all stakeholders, including manufacturer representatives, healthcare providers, and patient advocacy groups, in discussions about addressing shortages.
- **Federal Support:** Advocate for governmental or federal support to address the systemic issues causing shortages, including funding for research on ADHD treatment alternatives.



Thank You All!