Pediatric Focused Safety Review: Vyvanse® (lisdexamfetamine dimesylate) Pediatric Advisory Committee Meeting September 11, 2012

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Outline

Background Information

- Previous Recommendations by the Pediatric Advisory Committee on ADHD Drugs
  - FDA/Agency for Healthcare Research and Quality Study (AHRQ)

Adverse Event Review

- Vyvanse® (lisdexamfetamine dimesylate)

Previous Advisory Committees
ADHD Medications

- February 9, 2006: Drug Safety and Risk Management Advisory Committee (ADHD Medications: Cardiovascular Risk)
- March 22, 2006: Pediatric Advisory Committee (ADHD Medications Class Review)
- January 30, 2012 PAC Recommendations: Daytrana (methylphenidate)
- January 30, 2012: Pediatric Advisory Committee (Focalin & Focalin XR Review)

Drug Safety and Risk Management Advisory Committee February 9, 2006
ADHD Medications: Cardiovascular Risks

- Voted 15 (of 15) in favor (1 abstention) to warn of potential cardiovascular risks with the stimulant class of drugs used for the treatment of ADHD
- No consensus reached regarding boxed warning of the cardiovascular risks with the stimulant class of drugs for ADHD
- Follow-up Advisory Committee meeting March 2006

Pediatric Advisory Committee March 2006
ADHD Medications: Cardiovascular Risks (Continued)

- No need for a boxed warning
- Emphasis on strong warnings for patients with underlying structural cardiovascular defects or cardiomyopathies (to be placed in “Highlights” section of labeling)
- Baseline assessment of family history to improve identification of undiagnosed heart anomalies
- Additional warning regarding use of other medications that elevate blood pressure and/or pulse in patients with underlying cardiovascular disease
- Additional pharmacoepidemiological studies needed to clarify the risk of cardiovascular events in children on ADHD medications.

*FDA/AHRQ Study

- Large retrospective cohort study:
  - 1,200,438 children and young adults (2-24 years)
  - Mean age at baseline was 11.1 years
  - 2,579,104 person years follow-up
  - 373,667 person-years
- No association detected between ADHD medications and serious adverse cardiovascular events
- Myocardial infarction, stroke, and sudden cardiac death

Cooper, et al. ADHD Drugs and Serious Cardiovascular Events in Children and Young Adults. NEJM 2011; 365:20

Pediatric Advisory Committee March 2006 ADHD Medications

Psychosis & Mania (including hallucinations)

- Statistically significant increase in psychosis or mania compared with patients taking placebo
- Some hallucinations appear to be drug-related
- Labeling should include:
  - Quantitative information on rates from clinical trial
  - Description about visual or tactile hallucinations involving insects (e.g. crawling under the skin)

Pediatric Advisory Committee March 2006
ADHD Medications: Aggression

- Clinical trial data suggested an increased frequency of aggression events relative to placebo for some drugs (e.g., Daytrana, Ritalin LA, and Strattera) but not others.
- Labeling should note that aggression can be a feature of ADHD.
- A MedGuide or other form of information should inform patients about the risks of an increase in aggression.
- Parents should notify physicians if changes in aggressive behavior are noted.

Pediatric Advisory Committee March 2006
ADHD Medications: Suicidality & Growth

Suicidality Events:

- For approved ADHD products, no increased suicidality noted in clinical trial analysis other than for atomoxetine
- No labeling changes recommended
- Note: Strattera® (atomoxetine hydrochloride) includes a boxed warning.

Growth

- Agency should consider adding more information about the effects of ADHD medication on growth to labeling.

January 30, 2012 PAC Recommendations: Daytrana (methylphenidate)

Psychiatric Adverse events included:

- Suicidal ideation (n=6)
- Suicide attempt (n=2)
- Self-injurious ideation (n=1)
- Intentional self-injury (n=1)
- Aggression (n=5)
- Hallucinations (n=5)
- Confusional state/ disorientation (n=2)
- Paranoia (n=1)
- Abnormal behavior (n=1)

The committee recommended continued standard review

January 30, 2012 PAC Recommendations: Focalin & Focalin XR

Adverse events included:

- Suicide (n=3)
- Suicidal ideation (n=8)
- Hallucinations (n=19)
- Hallucinations (n=19)
- Extrapyramidal symptoms (n=10)
- Angioedema (n=1)

- PAC Agreed with FDA's plan to add angioedema and anaphylaxis to labeling and recommended:
- Strengthen text regarding hallucinations, suicidality, and extrapyramidal symptoms.
- Once labeling revised and labeling for all methylphenidate products harmonized, follow up presentation.

Note: Class labeling is in progress

Pediatric Focused Safety Review: Vyvanse® (lisdexamfetamine dimesylate)

Outline

- Background Information
- Pediatric Studies
- Pediatric Labeling Changes
- Relevant Safety Labeling
- Drug Use Trends
- Adverse Events
- Summary

Background Drug Information Vyvanse® (lisdexamfetamine dimesylate)

- **Drug:** Vyvanse® (lisdexamfetamine dimesylate)
- **Therapeutic Category:** Central nervous system stimulant
- **Indication**: Treatment of attention deficit hyperactivity disorder (ADHD) in adults and children 6 to 17 years of age

Background Drug Information (continued) **Vyvanse® (lisdexamfetamine dimesylate)**

- **Sponsor**
  - Shire Development
- **Formulation**
  - Capsules 20, 30, 40, 50, 60 & 70 mg
- **Dose**
  - Initial dose: 30 mg/day. Maximum dose: 70 mg/day

Background Drug Information (continued)
Vyvanse® (lisdexamfetamine dimesylate)

- **Original Market Approval**

  February 23, 2007: for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) 6 to 12 years of age

- **Pediatric Labeling Changes**

  November 10, 2010: expanded the indication to include adolescents 13 to 17 years of age

*April 23, 2008: Approved for the treatment of ADHD in the adult population

Pediatric Efficacy and Safety Study Vyvanse® (lisdexamfetamine dimesylate)

- Randomized, Double Blind, Placebo Controlled, Parallel Group Trial, 4 weeks
- Adolescents 13 to 17 years (n=314); full analysis set (n=299)
- Fixed-dose with titration: Vyvanse® 30 mg, 50 mg 70 mg & placebo
- Primary endpoint: based on ADHD Rating Scale
- Results:
  - All Vyvanse® treatment groups superior to placebo
  - No deaths. No serious adverse events reported, including suicidality.

Vyvanse® (lisdexamfetamine dimesylate) Relevant Safety Labeling

WARNING: POTENTIAL FOR MISUSE, ABUSE, ADDICTION, AND DIVERSION

VYVANSE® (lisdexamfetamine dimesylate) is a Schedule II controlled substance. Stimulants, such as amphetamines and methylphenidates, are subject to misuse, abuse, addiction, and criminal diversion [*see Drug Abuse and Dependence (9)*].

Misuse of amphetamines may cause sudden death and serious cardiovascular adverse events [*see Overdosage (10)*]

Relevant Safety Labeling (continued)
Vyvanse® (lisdexamfetamine dimesylate)

4 Contraindications:

Known hypersensitivity to amphetamine products

- Anaphylactic reactions
- Stevens-Johnson Syndrome
- Angioedema and urticaria

Concurrent use of monoamine oxidase inhibitors

5 Warnings and Precautions

5.1 Serious Cardiovascular Reactions: Sudden death in children and adolescents with structural cardiac abnormalities or other serious heart problems

5.2 Increased Blood Pressure

Relevant Safety Labeling (continued)
Vyvanse® (lisdexamfetamine dimesylate)

5.3 Psychiatric Adverse Reactions

- Pre-existing Psychosis
- Bipolar Illness
- Emergence of New Psychotic or Manic Symptoms (hallucinations, delusional thinking or mania)
- Aggression

5.4 Long-Term Suppression of Growth

5.5 Seizures

5.6 Visual Disturbance

5.7 Tics

Relevant Safety Labeling (continued)
Vyvanse® (lisdexamfetamine dimesylate)

6 Adverse Reactions

6.1 Clinical Trial Experience

Tics, insomnia, irritability, rash, decreased appetite and vomiting

6.2 Postmarketing Experience

Cardiac: Palpitations, cardiomyopathy

Eye : Mydriasis, diplopia

Hepatobiliary: Eosinophilic hepatitis

Immune System: Anaphylactic reaction, hypersensitivity

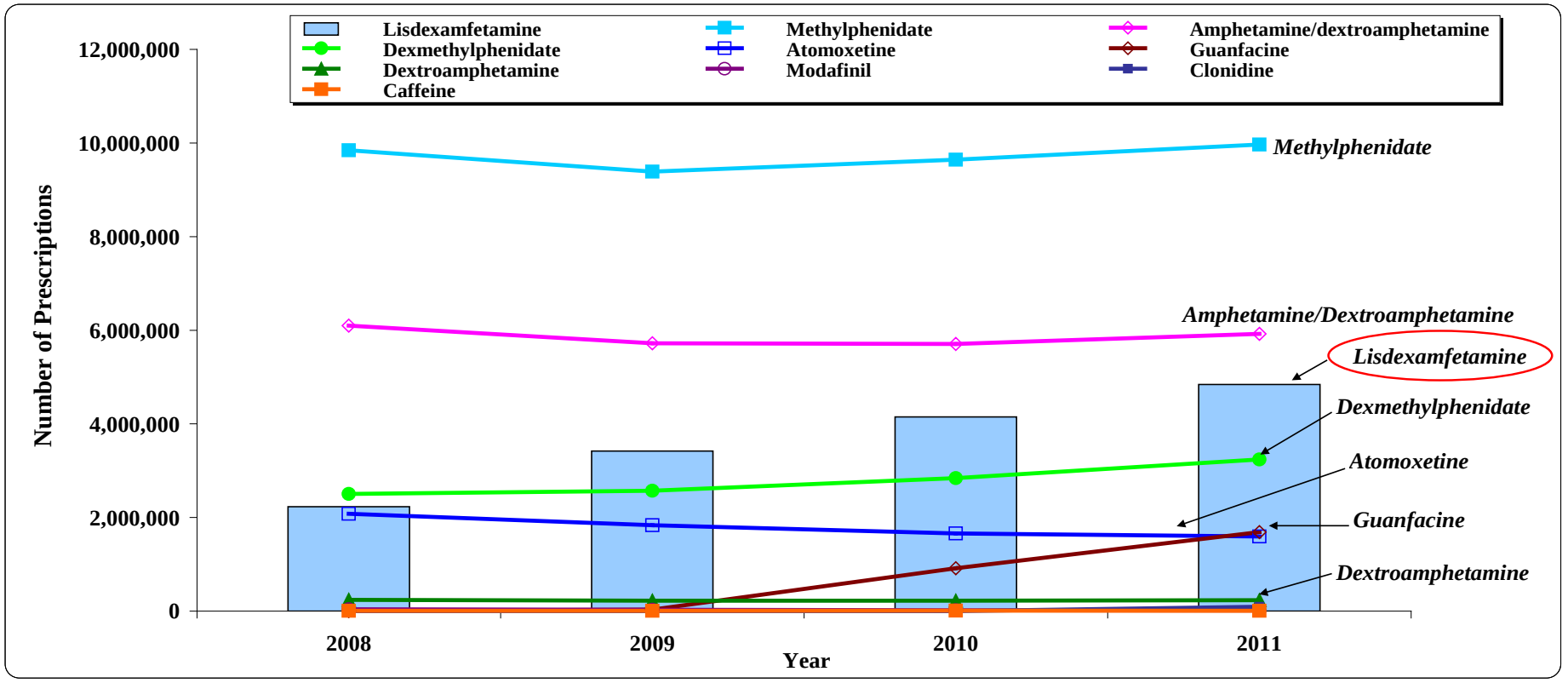
Nervous System: Dyskinesia

Psychiatric: Depression, dysphoria, euphoria, logorrhoea, dermatillomania

Skin and Subcutaneous Tissue: Stevens-Johnson Syndrome, angioedema, and urticaria

ADHD Market: Lisdexamfetamine Pediatric Utilization

Nationally Estimated Number of Prescriptions for Top ADHD Molecules (USC Classes 64500 and 64700) Dispensed to Patients Aged 0-17 years) from U.S. Outpatient Retail Pharmacies, Y2008-Y2011



- Methylphenidate products were the most commonly dispensed medication in the ADHD market among patients aged 0-17 years
- During year 2011, lisdexamfetamine accounted for 17.5% of the ADHD market

[1]IMS, Vector One®: National (VONA). Year 2008 to Year 2011. Data Extracted May 2012.

Lisdexamfetamine Drug Utilization (continued)
U.S. Outpatient Retail Pharmacy Setting
February 2007 – March 2012, cumulative[1]

- **Total population:** 25.9 million lisdexamfetamine prescriptions were dispensed to approximately 3.8 million patients
- **Pediatric population:** 16.5 million lisdexamfetamine prescriptions were dispensed to 2.4 million patients aged 0 to 17 years
  - 97% of pediatric patients aged 6 to 17 years
  - 4% of pediatric patients aged 0 to 5 years

[1]IMS, Vector One®: National VONA and Total Patient Tracker. February 2007 through March 2012. Data Extracted May 2012.

Lisdexamfetamine Drug Utilization (continued)
Prescribing Specialty and Diagnosis
February 2007 – March 2012, cumulative[1]

- Top prescribing specialty for lisdexamfetamine:
  - Psychiatry accounted for 36% of prescriptions
  - Pediatrics accounted for 30% of prescriptions
- Top diagnosis code in pediatric patients aged 0-17 years was “Attention Deficit Disorder”(ICD-9 code 314.0)

[1]IMS, Vector One®: National (VONA) and Encuity Research, LLC., Physician Drug and Diagnosis with Pain Panel.
February 2007 through March 2012. Data Extracted May 2012.

Vyvanse® (lisdexamfetamine dimesylate)

Total Number of Pediatric (0-16 Years) AERS Reports*		
	Non-Fatal Serious†	Fatal
AERS Search Date Range	November 10, 2010§ to April 9, 2012	February 23, 2007¶ to April 9, 2012
N	141	30

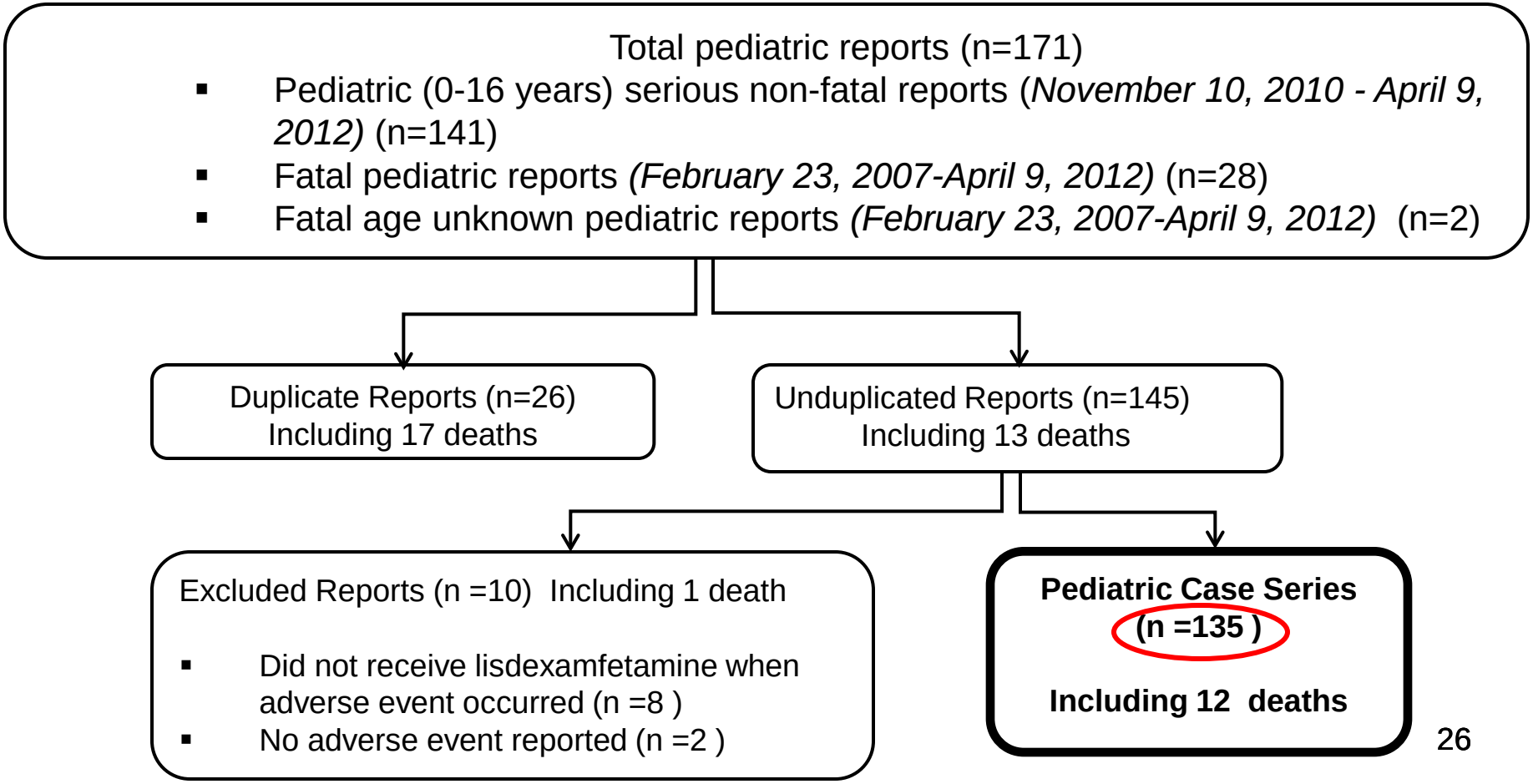
*May include duplicates and have not been assessed for causality

†Serious adverse drug experience outcome per regulatory definition (CFR 314.80)

§Pediatric labeling change date; Requested search dates (11/10/10-4/9/12).

¶Initial FDA approval date for lisdexamfetamine (Vyvanse®); Supplemental search parameter (2/23/07-4/9/12) yielded 30 fatal reports, of which 22 were captured during the requested search dates of 11/10/10-4/9/12.

Vyvanse® (lisdexamfetamine dimesylate) Selection of Serious Pediatric AERS Cases through April 9, 2012



Vyvanse® (lisdexamfetamine dimesylate) Summary of Pediatric Deaths (n=12)

- Suicide (n=6)
- Accidental (n=1)
- Overdose (n=1)
- Toxicity to various agents (n=1)
- Cardiac (n=1)
- Unknown (n=1)
- Aspiration (n=1)

Summary of Shire Reviews of Spontaneous Postmarketing Pediatric Suicide-Related Events for Vyvanse

Shire Global Safety System (SGSS) database†

	Number of patients	*CASA-C Criteria	Pediatric patients	Suicide attempt	Completed suicide
Through May 2008	151	22	13 (6-16 years)	3	0
June 2008 - January 2009	116	15	10 (9-14 years)	0	0

**Columbia Classification Algorithm of Suicide Assessment*

†Suicide-Related Events and Treatment with Stimulant Medications Indicated for Attention Deficit Hyperactivity Disorder. Shire Pharmaceutical Development, December 09, 2008

CDC 2007 Suicide Injury Deaths and Rates per 100,000

Age Group (years)	Deaths*	Population	Crude Rate*
1 to 4	0	20,921,289	0
5 to 9	4	20,054,444	0.02
10 to 14	180	20,318,855	0.89
15 to 19	1,481	21,562,382	6.87
20 to 24	2,659	21,217,108	12.53

***rates based on 20 or fewer deaths may be unstable**
http://webappa.cdc.gov/sasweb/ncipc/mortrate10_sy.html

Vyvanse® (lisdexamfetamine dimesylate) Fatal Adverse Events

Completed Suicide (n=6)

- 13 year-old male was on Vyvanse® 50 mg for 20 months before committing suicide by hanging. No history of psychiatric illness. No drug or alcohol abuse.
- 10 year old female committed suicide by hanging. No additional information.
- 9 year-old male with possible "bipolar", hung himself at school. No additional information was provided.

All three cases had a history of being bullied at school

Unlabeled adverse events are underlined

Vyvanse® (lisdexamfetamine dimesylate)

Fatal Adverse Events (continued)

Completed Suicide (continued)

- 16 year-old male hung himself. He was on Vyvanse® for five months prior to the incident. No additional clinical information was provided.

- 7 year-old male was on Vyvanse® for 4 months before committing suicide by hanging
  - Concomitant escitalopram, olanzapine, fluoxetine (all labeled for suicidality)
  - Lived in foster care. History of sexual abuse, impulse control, aggression, and self-injurious behavior.

- 16 year-old female committed suicide by taking morphine solution, Vyvanse® and "stimulant laxative."

Vyvanse® (lisdexamfetamine dimesylate)
Fatal Adverse Events (continued)

- Accidental Death (n=1)
  14-year old male was found hanging from a tree, 8 months after initiating Vyvanse® 50 mg. No history of psychiatric illness or suicidal ideation. His death was ruled as accidental by his physician. Autopsy was not performed.

- Overdose (n=1)
  8 year-old female died while on Vyvanse® 100 mg. (dose increased from 70 to 100 mg), for unspecified duration.

- Toxicity to various agents (n=1)
  14 year-old male who died after multiple drug exposure [codeine (primary toxic substance), quetiapine, aripiprazole, valproic acid, Vyvanse®, diphenhydramine, sertraline and clonidine].

No additional clinical information

Vyvanse® (lisdexamfetamine dimesylate)

Fatal Adverse Events (continued)

- "Cardiac problem" (n=1)

  7 year-old male died while sleeping. Structural heart abnormality was found on autopsy. On Vyvanse® 30 mg for 16 months prior to the incident.

  – Concomitant Methylphenidate 10 mg

- Unknown (n=1)

  9 year-old female was on Vyvanse® 30 or 40 mg for a year before she was found dead in bed by her mother. No additional information

- "Aspiration" (n=1)

  8 year-old male with history of unspecified respiratory problem found in asystole by emergency medical services. Patient treated with Vyvanse® 70 mg and melatonin 3 mg.

Vyvanse® (lisdexamfetamine dimesylate) Non-Fatal Adverse Events

- Psychiatric Adverse Events (n=45)
- Cardiac Adverse Events (n=21)
- Neurologic Adverse Events (n=9)
- Movement Disorder (n=9)
- Miscellaneous (n=39)

Vyvanse® (lisdexamfetamine dimesylate) Non-Fatal Psychiatric Adverse Events

- Psychiatric Adverse Events (n=45)
  - Homicidal ideation, Self-injurious behavior, Suicidal ideation, Suicide attempt (n=27)
  - Agitation, Anger, and Violence (n=7)
  - Hallucination, Paranoia (n=6)
  - Other psychiatric adverse events (n=5)

Labeling 5.3 Psychiatric Adverse Reactions: Aggressive behavior, hostility hallucinations, delusional thinking, or mania

Vyvanse® (lisdexamfetamine dimesylate)
Unlabeled Psychiatric Adverse Events (n=27)

- Events abated after Vyvanse® was stopped or dose reduced (n=10)
- Insufficient information (n=9)
- Cases confounded by medical history and/or concomitant medications (n=6)
- Hospitalization (n=2) Minimal additional information for both cases.

Vyvanse® (lisdexamfetamine dimesylate)
Unlabeled Psychiatric Adverse Events (continued)

Events abated after Vyvanse® was stopped or dose reduced (n=10)

- 10 year male with aggression, delusion, depression, homicidal and suicidal ideation while on Vyvanse® 30 mg daily. Vyvanse® discontinued and the events resolved.
- 8 year female with homicidal ideation "wanted to hurt or kill her mother" two days after initiating Vyvanse® 30 mg daily. Vyvanse® discontinued and the events resolved.
- 7 year male with depression and suicidal ideation nine days after Vyvanse® dose increased to 30 mg daily. Events resolved with reduced dose.

Vyvanse® (lisdexamfetamine dimesylate)
Unlabeled Psychiatric Adverse Events (continued)

Events abated after Vyvanse® was stopped or dose reduced (n=10)

- 9 year male became depressed, and experienced suicidal ideation while on 30mg . Vyvanse® discontinued and events resolved.
- 11 year male experienced “burst of outrage”, suicidality, and psychotic behavior the day Vyvanse® 30mg initiated. Vyvanse® discontinued and events resolved.
- 12 year male with suicidal ideation and feeling of “spaced out” while on Vyvanse®. Vyvanse® discontinued and the events resolved.

Vyvanse® (lisdexamfetamine dimesylate)

Unlabeled Psychiatric Adverse Events (continued)

Events abated after Vyvanse® was stopped or dose reduced (n=10)

- 6 year female hospitalized for suicidal and homicidal ideation. On Vyvanse® 20 mg and guanfacine 2 mg. Vyvanse® discontinued, guanfacine dose reduced and paliperidone started. Events resolved. Note Paliperidone is labeled for schizophrenia in patients 12 years and older.
- Confounded cases (n=3)

  These cases were confounded by concomitant medications labeled for suicidal ideation, such as (atomoxetine and cetirizine), concurrent depression or anxiety, or a family history of bipolar disorder and depression.

Vyvanse® (lisdexamfetamine dimesylate) Non-Fatal Cardiac Adverse Events

- Cardiac Adverse Events (n=21)
  - Syncope or Loss of consciousness (n=6)
  - Arrhythmia, EKG shortened QT, or Ventricular extrasystoles (n=4)
  - Cardiac arrest (n=2)
  - Chest pain (n=2)
  - Cardiac murmur (n=1)
  - Increased blood pressure, Hypertensive crisis (n=3)
  - Tachycardia (n=3)

Unlabeled adverse events are underlined

Vyvanse® (lisdexamfetamine dimesylate) Cardiac Adverse Events (labeling)

Labeling

5.1 Serious Cardiovascular Reactions:

- *Sudden death has been reported in association with CNS stimulant treatment at usual doses in children and adolescents with structural cardiac abnormalities or other serious heart problems*
- *Unexplained syncope, or other symptoms suggestive of cardiac disease during stimulant treatment should undergo a prompt cardiac evaluation*

5.2 Increased Blood Pressure and heart rate

Vyvanse® (lisdexamfetamine dimesylate) Unlabeled Cardiac Adverse Events

Syncope or Loss of consciousness (n=6)

- 9 year-old male who "passed out" following the first dose of Vyvanse® 20 mg.
  - Diagnosis: "allergic reaction to Vyvanse®"
  - Treatment with Vyvanse® was discontinued and the events resolved.

- 8 year-old male who experienced abdominal pain, irritability, palpitations, and fainting following the initiation of Vyvanse® 50 mg. No additional information on treatment discontinuation and outcome.

- 15-year-old female experienced headache, chest pain, "forceful and bounding pulse", and "passed out" one year after initiating treatment with Vyvanse® 70 mg
  - The patient recovered from event. Vyvanse® treatment continued.

- The 3 remaining cases were confounded.

Vyvanse® (lisdexamfetamine dimesylate) Unlabeled Cardiac Adverse Events (continued)

Arrhythmia (n=4)

- 7 year-old male who developed shortened QT and increased heart rate (160 bpm), 18 months after initiating Vyvanse®, "dose unknown". Treatment was discontinued and the events resolved.

- 13 year-old male complained of chest pain 3 days following the initiation of Vyvanse® 30 mg. Diagnosed with "irregular heart beat." No additional relevant information was provided.

- 14 year-old male experienced shortness of breath, chest pain, palpitations, and syncope one week after initiating Vyvanse® 30 mg
  - EKG: premature ventricular contractions (PVCs)
  - PVCs continued despite stopping treatment.

- 14 year-old male experienced two episodes of "heart pounding out of chest" lasting for a minutes while on Vyvanse® 40 mg. EKG: "Arrhythmia". Arrhythmia persisted after treatment discontinuation.

Vyvanse® (lisdexamfetamine dimesylate) Unlabeled Cardiac Adverse Events (continued)

- Cardiac arrest (n=2)
  - 8 year-old female with a past medical history of "abnormal" EKG. Vyvanse® dose was increased to 30 mg. The patient developed cardiac arrest while playing basketball. Vyvanse® was discontinued.
  - 15 year-old male, was on Vyvanse® 60 mg, developed cardiac arrest, and was taken to the emergency room. Vyvanse® was discontinued.

Vyvanse® (lisdexamfetamine dimesylate) Unlabeled Cardiac Adverse Events (continued)

- Cardiac murmur (n=1)

  11 year-old male with heart murmur detected on exam two years after initiating treatment with Vyvanse® 70mg. Vyvanse® continued and the event persisted.

- Chest pain (n=2)
  - 6 year-old male experienced itchy skin, constant headaches and chest pain two weeks after initiating treatment with Vyvanse® 20 mg. Treatment was discontinued and events resolved.
  - 15 year-old male experienced chest pain, left arm and back pain when breathing. In addition, the patient complained of sore jaw and pain on the roof of his mouth, two months after initiating treatment with Vyvanse® 50 mg. Treatment was discontinued and events resolved.

Vyvanse® (lisdexamfetamine dimesylate) Non-Fatal Neurologic Adverse Events

- Seizures (n=9)
- Movement Disorders (n=9)
  - Dyskinesia (n=5)
  - Tics (n=3)
  - Involuntary Muscle Contractions (n=1)

Labeling
Warnings and Precautions 5.5: Seizures and 5.7: Tics
6.2 Postmarketing Experience: Dyskinesia

Vyvanse® (lisdexamfetamine dimesylate) Non-Fatal Neurologic Adverse Events (continued)

- Involuntary muscle contractions (n=1)
  14-year-old female experienced lethargy, dizziness, difficulty breathing, confusion, hallucinations, panic attack, "muscle tensing in her jaw and tongue", tingling in hands and feet on the same day as initiating Vyvanse® 40 mg. Vyvanse® was discontinued. Treated with intravenous lorazepam and events resolved.

Vyvanse® (lisdexamfetamine dimesylate) Unlabeled Miscellaneous Adverse Events

- Single reports (n=13):

  Chromatopsia, headache, hypoesthesia, pruritus, apnea, increased weight , skin exfoliation, scleroderma, increased intraocular pressure, ANA positive, increased bilirubin , retinal detachment, and type I diabetes mellitus.

- Dyspnea (n=2)

  Both cases are likely related to underlying illness.

- Alopecia (n=4)

Summary Pediatric Focused Safety Review Vyvanse® (lisdexamfetamine dimesylate)

- This concludes the pediatric focused safety review.
- While reports of suicidality were noted in the Pediatric focused safety review, epidemiological data from CDC and controlled data from clinical trials do **not** suggest increased suicidality rates compared to the general population, or in patients taking stimulants compared to placebo.
- While the Pediatric focused safety review revealed other unlabeled adverse events, the Agency does not believe the adverse events identified during this review warrant labeling changes at this time.

Summary Pediatric Focused Safety Review Vyvanse® (lisdexamfetamine dimesylate) (continued)

- FDA is in the process of harmonizing labeling for ADHD medications.
- After class labeling for ADHD medications is completed, FDA will present the changes to the PAC.
- FDA recommends return to routine monitoring.
- Does the Committee concur?

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