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Health and Human
Services Commission

Presentation to the House Interim Select Committee on Child Welfare and Foster Care

October 4, 2004

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Presentation Overview

- U.S. Food and Drug Administration (FDA) Review of Antidepressant Medications
- Actions Taken by the Texas Vendor Drug Program
- Antidepressant Use in Foster Children

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FDA Review of Antidepressant Medications

- February 2004 – The FDA Psychopharmacologic Drugs Committee and the Pediatric Advisory Committee recommended that drug labeling should draw more attention to the need to monitor patients being treated with certain antidepressants.
- March 2004 –
  - FDA issues a Public Health Advisory cautioning physicians, patients and caregivers to closely monitor both adults and children with depression.
  - FDA asked manufacturers to strengthen the labeling of 10 antidepressants to include stronger cautions and warnings to monitor patients for the worsening of depression and the emergence of suicidal thoughts.

FDA Review of Antidepressant Medications

- The 10 antidepressants were:
  - **Selective Serotonin Reuptake Inhibitors (SSRI)**
    - Bupropion (Wellbutrin®)
    - Citalopram (Celexa®)
    - Fluoxetine (Prozac®)
    - Fluvoxamine (Luvox®)
    - Paroxetine (Paxil®)
    - Sertraline (Zoloft®)
  - **Serotonin and Norepinephrine Reuptake Inhibitors (SNRI)**
    - Nefazodone (Serzone®)
    - Venlafaxine (Effexor®)
  - **Aminoketones**
    - Escitalopram (Lexapro®)
  - **Alpha 2Receptor Antagonists**
    - Mirtazapine (Remeron®)

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FDA Review of Antidepressant Medications

- September 2004 – The FDA Psychopharmacologic Drugs Committee and the Pediatric Advisory Committee took the following actions:
  - endorsed FDA's approach to classifying and analyzing the suicidal events and behaviors observed in controlled clinical trials;
  - concluded that the finding of an increased risk of suicidality (suicidal thoughts and actions) in pediatric patients applied to all of the 10 drugs studied in controlled clinical trials;
  - recommended that any warning related to an increased risk of suicidality in pediatric patients should be applied to all antidepressant drugs, including those that have not been studied in controlled clinical trials in pediatric patients.

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FDA Review of Antidepressant Medications

- Recommended a "black-box" warning related to an increased risk for suicidality in pediatric patients for all antidepressant drugs;
- endorsed a patient information sheet ("Medication Guide") for this class of drugs to be provided to the patient or their caregiver with every prescription;
- recommended that the products not be contraindicated because the Committees thought access to these therapies was important for those who could benefit; and
- recommended that the results of controlled pediatric trials of depression be included in the labeling for antidepressant drugs.

FDA Review of Antidepressant Medications

- September 2004 – FDA Issues Statement Saying:
  - FDA generally supports the recommendations that were recently made to the agency by the Psychopharmacologic Drugs and Pediatric Advisory Committees regarding reports of an increased risk of suicidality associated with the use of certain antidepressants in pediatric patients.
  - FDA has begun working to adopt new labeling to enhance the warnings associated with the use of antidepressants and to increase the information provided to patients when these drugs are dispensed.

Actions Taken by the Texas Vendor Drug Program

- Vendor Drug Program Actions to Date:
  - The Drug Use Review (DUR) Program educational intervention
  - The ACS/Heritage educational intervention
  - Proposed Pediatric Antidepressant Clinical Edit
- The Vendor Drug Program's interventions were:
  - not specific to foster children
  - included all Medicaid recipients under 18 years of age identified through their medication claim history

Actions Taken by the Texas Vendor Drug Program

- Spring of 2004 - The DUR program in the Medicaid/CHIP division, initiated an educational intervention as a result of the FDA concerns over antidepressant use in children.
- May 2004 - Correspondence was sent to 554 physicians treating 4,877 pediatric patients and included:
  - A letter describing the recent FDA concerns and warnings,
  - A medication profile for each physician's patients under age 18 currently taking one of the 10 drugs in the FDA study, and
  - A response form to be returned to the DUR program

Actions Taken by the Texas Vendor Drug Program

- The DUR program has received responses from 220 physicians to date.
  - 55% reported that the intervention materials they received were helpful.
  - 38% agreed with the intervention materials they received.
  - 12% disagreed with the intervention materials and stated that the information was not helpful.

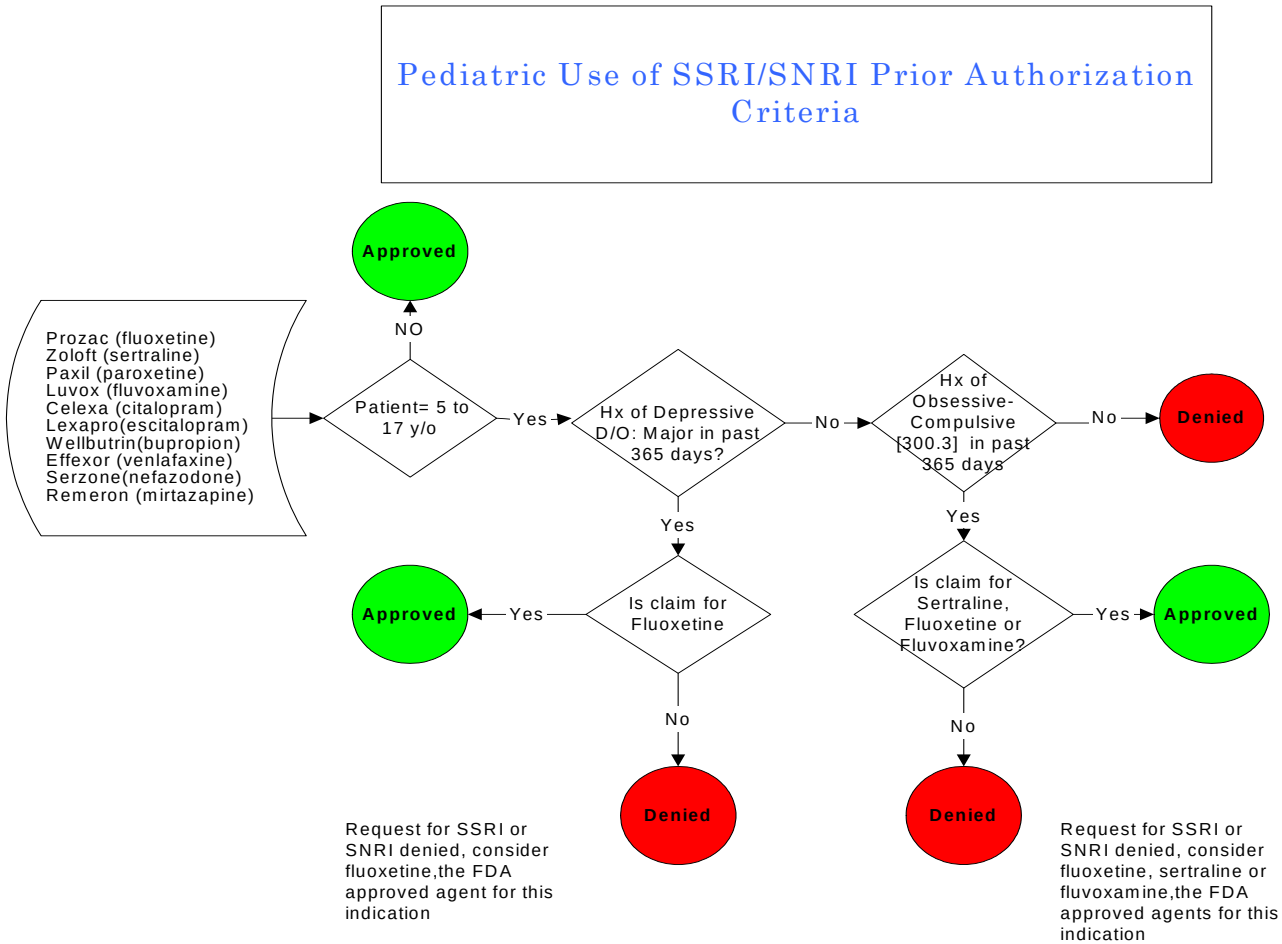
Actions Taken by the Texas Vendor Drug Program

- July 2004 – HHSC contractor, ACS/Heritage Information Services, implemented an additional educational intervention.
  - Correspondence was sent to an additional 1,765 physicians treating 5,675 pediatric patients with antidepressants
  - ACS/Heritage is currently conducting face-to-face visits with approximately 60 providers with the largest number of pediatric patients currently being treated with the 10 targeted antidepressants

Actions Taken by the Texas Vendor Drug Program

- The Vendor Drug Program is currently requesting stakeholder input on a clinical edit that would be applied to antidepressant prescriptions claims for children at the time the prescriptions are filled.
- Clinical edits check a patient's Medicaid medical and drug claims histories to help determine whether the information on file indicates that the patient's medical condition matches the edit criteria for dispensing the requested drug without need of additional prior authorization.
- The edits are based on evidence-based clinical criteria and nationally recognized peer-reviewed information. The edit would focus on the same 10 drugs reviewed by the FDA.

Actions Taken by Texas Vendor Drug Program



Actions Taken by the Texas Vendor Drug Program

- Claims not meeting the specific approval criteria would be denied and the prescriber would be required to call for prior authorization.
- Approval criteria would include:
  - Age ≥ 18 years of age
  - A diagnosis of Major Depressive Disorder for Fluoxetine
  - A diagnosis of Obsessive Complusive Disorder for Sertraline, fluvoxamine, or fluoxetine
- Denial criteria would include:
  - Age < 18 years of age
  - For Major Depressive Disorder a prescription for SSRI or SNRI other than fluoxetine
  - For Obsessive Complusive Disorder a prescription for SSRI or SNRI other than Sertraline, fluvoxamine, or fluoxetine

Actions Taken by the Texas Vendor Drug Program

- August 12, 2004 - The Pediatric Antidepressant clinical edit was presented by Vendor Drug staff to the Department of Family and Protective Services Advisory Committee on Psychotropic Medications in Foster Children for review and comments.
  - Overall, they were supportive of implementation of the clinical edit
  - Recommended two modifications to the edit:
    - Allowing children currently stable on therapy to remain on that drug therapy, and
    - Design of a system that would have the flexibility to quickly adapt and adjust to any necessary changes.

Actions Taken by the Texas Vendor Drug Program

- August 2004 - The Pediatric Antidepressant clinical edit was presented to the DUR Board, which is an advisory body to the DUR program. No action was taken by the Board at that time due to additional FDA review, in September 2004, of pediatric antidepressant drug classes.
- November 16, 2004 - The edit will be reviewed at the DUR Board meeting.

Antidepressant Use in Foster Children

	Aug. 2004		July 2004		June 2004	
Drug	# Clients	# Rx's	# Clients	# Rx's	# Clients	# Rx's
Bupropion (Wellbutrin®)	532	593	536	564	549	599
Citalopram (Celexa®)	94	109	101	108	111	120
Fluoxetine (Prozac®)	431	485	398	442	440	513
Fluvoxamine (Luvox®)	30	33	28	29	29	35
Mirtazapine (Remeron®)	621	655	625	655	648	700
Nefazodone (Serzone®)	3	3	4	4	7	8
Paroxetine (Paxil®)	39	40	40	43	34	35
Sertraline (Zoloft®)	965	1059	964	1057	1020	1175
Escitalopram (Lexapro®)	876	948	913	1011	897	1041
Venlafaxine (Effexor®)	161	177	185	210	202	226