Recent studies are providing important new information about drug safety and effectiveness for children. Pediatricians say it’s about time. Most drugs prescribed for children have not been tested in children. Before the Food and Drug Administration initiated a pediatric program, only about 20 percent of drugs approved by the FDA were labeled for pediatric use. By necessity, doctors have routinely given drugs to children "off label," which means the drug has not been approved for use in children based on the demonstration of safety and efficacy in adequate, well-controlled clinical trials.

To be well-controlled, a study should have an adequate number of patients who receive the study drug and a control group--people who are similar to the group taking the drug being studied, but who are receiving some different type of treatment, such as another drug or an inactive pill (placebo).

Experts say the historical lack of pediatric drug testing is due to a combination of reasons. The primary reason is that pharmaceutical companies generally have viewed children as a market that would bring only small financial benefits. The drugs that have been adequately studied in children--vaccines, some antibiotics, and some cough and cold medicines--have a large market.

"It's also harder to carry out studies in children," says Dianne Murphy, M.D., director of the FDA's Office of Pediatric Therapeutics. "You need child-friendly environments in every sense, from age-appropriate equipment and medical techniques to pediatric specialists who are sensitive to a child's fear."

Jeffrey Blumer, M.D., Ph.D., chief of pediatric pharmacology at Case Western Reserve University in Cleveland, says technical procedures that seem simple for adults, such as drawing blood or getting a urine sample, can be difficult with children. The ethical issues are also stickier. For example, while adults can give informed consent to participate in a clinical trial, children can't because "consent" implies full understanding of potential risks and other considerations. Parents are involved in the decision to enroll children in a study, and children ages 7 or older can "assent" or "dissent," meaning they can agree or disagree to participate in a study.

Blumer says, "I've had parents who are enthusiastic about a study and then a 7-year-old who hears everything involved and says, 'No way!'"

Children Aren't Small Adults

Rather than avoiding pediatric research because of the challenges, experts say it's more important to build the foundation and resources needed to conduct the studies. Without them, children face significant risks.

In the absence of data, doctors use their medical judgment to decide on a particular drug and dose for children. "Some doctors stay away from drugs, which could deny needed treatment," Blumer says. "Generally, we take our best guess based on what's been done before."

A common approach has been to use data from adults and adjust the dose according to a child's weight. Experimenting over the years has taught doctors to use many drugs in children safely and effectively. But this trial-and-error approach has also resulted in
tragedy, indicating that adult experiences with a drug aren't always a reliable predictor of how children will react.

For example, in the 1950s, the antibiotic chloramphenicol was widely used in adults to treat infections resistant to penicillin. But many newborn babies died after receiving the drug because their immature livers couldn't break down the antibiotic.

"Experience has shown us that we need to study drugs in children because they aren't small adults," says Ralph Kauffman, M.D., director of medical research at Children's Mercy Hospital in Kansas City, Mo. "It's not just about smaller weight," he says. "There are dynamics of growth and maturation of organs, changes in metabolism throughout infancy and childhood, changes in body proportion, and other developmental changes that affect how drugs are metabolized."

**Proof Is in the Data**

Fortunately, recent legislative changes that provide both a voluntary and a mandatory mechanism to conduct drug studies in children have resulted in a dramatic increase in pediatric drug trials. "There have been more studies conducted in children in the last five years than in the previous 30 years combined," Kauffman says.

The information coming out of those studies has added pediatric information to the drug labeling for more than 80 drugs, and more changes are coming. Drug labeling is the guidance to doctors and other health care providers on how to use a drug. "We knew that we needed science to determine proper dosing for children the same way we do with adults," says Murphy. "Now, we have confirmed it."

Ibuprofen, one of the most common over-the-counter drugs on which parents rely to reduce children's fevers, carried no dosing information for children younger than 2 years old until recently. Now, because of studies in thousands of young infants, the dose considered to be safe and effective for over-the-counter use has been established for children ages 6 months to 2 years.

The labeling has also been changed for Zantac (ranitidine), a drug used to treat gastroesophageal reflux. This condition can be life-threatening in infants. When reflux occurs, the stomach contents can flow up the esophagus and be aspirated into the lungs. This can harm the lungs of infants and result in breathing problems.

Studies have given doctors accurate dosing information for safer and more effective use of the drug to manage reflux in seriously ill infants. Richard Gorman, M.D., chairman of the Committee on Drugs at the American Academy of Pediatrics (AAP), a member of the FDA's Pediatric Advisory Committee, and a pediatrician in Maryland, says, "Now I can use ranitidine with as much information as doctors who use it in adults. I know the dose. I know the dosing interval."

New discoveries have revealed underdosing, overdosing, ineffectiveness, and safety problems. Gorman says, "Even though the best and brightest pediatric minds have helped us establish dosages for children, we're finding out that the dose is different than we thought in some cases. And that probably came as a surprise to most of us."

The FDA is working with the AAP to educate pediatricians about new physician labeling changes through an online continuing medical education program called PediaLink.
What's Spurring the Research?

The FDA has taken a carrot-and-stick approach to encourage pediatric studies, says William Rodriguez, M.D., the FDA's science director for pediatrics. The carrot is the voluntary pediatric exclusivity provision of the Food and Drug Administration Modernization Act of 1997 (FDAMA), which was reauthorized in January 2002 and extended through 2007 as the Best Pharmaceuticals for Children Act (BPCA). The stick is the Pediatric Research Equity Act (PREA), which allows the FDA to require pediatric studies. Here's an overview of each initiative:

The Pediatric Exclusivity Provision of the BPCA. The pediatric exclusivity provision has done more to spur pediatric studies than any other regulatory or legislative initiative so far. The provision allows companies to qualify for an additional six months of marketing exclusivity if they do the studies in children as requested by the FDA.

Patents protect a company's investment by giving it the sole right to sell a drug while the patent is in effect. When patents or other periods of exclusive marketing for brand-name drugs are close to expiring, other drug companies can apply to the FDA to sell generic versions, without having to repeat the original developer's clinical trials. So the trade-off is that by companies qualifying for an additional six months of exclusivity, there is a delay in the availability of lower-cost generic drugs.

The FDA has interpreted the provision so that the six months of exclusivity isn't added only to the drug that was studied in the pediatric population, but also to any of the drug company's formulations, dosage forms, and indications that contain the same active part of a molecule (moiety) and have existing marketing exclusivity or patent life. So if a company markets an oral formulation and a topical cream containing the same moiety, the six months of marketing exclusivity will be added to any existing exclusivity or patent protection for both products.

The process can be initiated either by a drug company or the FDA. A drug company may submit a proposal to the FDA to conduct pediatric studies. If the FDA agrees that studying a drug may produce health benefits for children, the agency will issue a "Written Request" addressing the type of studies to be conducted, study design and goals, and the age groups to be studied. Or the agency may issue a Written Request on its own initiative when it identifies a need for pediatric data. No matter how the studies are initiated, if the FDA determines that the data submitted fairly respond to the Written Request, then the company will be granted six months of pediatric exclusivity.

More than 100 drugs have been granted exclusivity so far. As of Dec. 31, 2004, 691 studies had been requested and 298 Written Requests issued. The FDA estimates that about 80 percent of the studies outlined in Written Requests will be conducted. Kauffman says the exclusivity is proof that economics plays a large role in the lack of pediatric studies. "Once the economic disincentive was removed," he says, "the dam broke completely open."

Since the incentive under FDAMA did not apply to old antibiotics and other drugs that lack marketing exclusivity or patent protection, some categories of drugs have remained inadequately studied. For these products, BPCA provides a contract mechanism through the NIH to fund pediatric studies. In addition, if a company that has a drug with existing exclusivity or patent protection chooses not to conduct the requested pediatric studies, the FDA can refer the Written Request to the Foundation for the National Institutes of Health to award grants so that third parties can conduct the needed studies.
The NIH, in consultation with the FDA and other pediatric experts, publishes an annual List of Drugs for Which Additional Pediatric Studies Are Needed in the Federal Register. Since BPCA went into effect, the FDA has issued 11 Written Requests for off-patent drugs and the NIH has published four requests for contracts.
PRESA. In the early 1990s, the FDA implemented voluntary measures to encourage pediatric studies, but they were mostly unsuccessful. In 1997, the FDA published a proposed regulation that for the first time required manufacturers of new drug and biological products to conduct pediatric studies in some circumstances. The rule was finalized in 1998, and the first studies were required to be submitted starting December 2000.
The rule, however, had its critics. In December 2000, the Association of American Physicians and Surgeons, the Competitive Enterprise Institute, and Consumer Alert filed a lawsuit against the pediatric rule, challenging the FDA's legal authority to require pediatric studies. And in October 2002, a federal district court concluded the FDA did not have that authority and the rule could not be enforced.
Former HHS Secretary Tommy G. Thompson responded in mid-December 2002 by announcing that his department would push for rapid passage of legislation that would give the FDA authority to require pharmaceutical manufacturers to conduct appropriate pediatric clinical trials on drugs.
"The fastest and most decisive route for establishing clear authority in this area is to work with Congress for new legislation," Thompson said in a prepared statement.
"Children need to have access to drugs that can benefit them, and these drugs need to be properly tested for pediatric use, not prescribed and sold without testing. Congress alone can speak clearly on the authority that FDA needs ..."
On Dec. 3, 2003, President George W. Bush signed the PREA into law. This act basically mimics the old pediatric rule with a few additional provisions.
As was true with the pediatric rule, the PREA will address some of the gaps left by the pediatric exclusivity provision. Unlike the exclusivity provision, the new act requires pediatric studies and covers both drugs and biologics--medical products derived from living sources, such as vaccines, blood, and blood derivatives.
Under the PREA, the FDA can require pediatric studies of a drug submitted in a new drug application if the FDA determines the product is likely to be used in a substantial number of pediatric patients, or if the product would provide a meaningful benefit in the pediatric population over existing treatments. At the same time, the PREA does not delay the availability of drugs for adults.
"The BPCA and PREA have worked in tandem," says Murphy. "We have told sponsors who submit a new drug application and who are required under PREA to conduct pediatric studies that they also may qualify for pediatric exclusivity."

**Building the Foundation**

"There was no infrastructure for the research before," says Floyd R. Sallee, M.D., Ph.D., a child psychiatrist and director of the pediatric pharmacology research unit at Cincinnati Children's Hospital Medical Center. "I see the culture changing in industry and at FDA," he says. "Drug companies have hired pediatric experts and there is a larger network of expertise to draw from."
Sallee's center is part of the Pediatric Pharmacology Research Unit (PPRU) Network, a group of centers that conduct pediatric drug trials with support from the National Institute of Child Health and Human Development (NICHD). The network was established in 1994 and now includes 13 PPRUs.

Shirley Murphy, M.D., (no relation to Dianne Murphy), joined the FDA in September 2002, as director of the Division of Pediatric Drug Development. She says linkages between the FDA, NICHD, AAP, and other organizations have been important for building a foundation for pediatric research, and children are getting more and better drugs as a result.

"What it means for parents is that they can feel more secure knowing that their children are being treated appropriately," Shirley Murphy says. "FDA remains committed to keeping pediatric drug research a high priority."

Several areas that will continue to receive the agency's attention include the ethics involved with studying drugs in children. The FDA's Pediatric Advisory Subcommittee has concluded that, generally, pediatric studies should be conducted in subjects who may benefit from participation in the trial. This means the subject has or is susceptible to the disease under study.

Shirley Murphy cites pediatric oncology as another important area for the agency. "The development of cancer drugs needs special consideration," she says. Differences in the biology of tumors in children and adults usually make it difficult to prescribe children drugs based on adult data. And it has been typical for new cancer drugs to reach children late—only after they have been tested in adults.

As a result of pediatric initiatives, there have been about 30 studies initiated on cancer drugs, which will help researchers gain access to potential new cancer therapies for children.

While it may be challenging to enroll children in clinical trials for some diseases, that's not the case with cancer. Most children receive their cancer therapy as part of a clinical trial. "Parents are desperate to have their children in these studies," says Patrick Reynolds, M.D., Ph.D., a pediatric oncologist with Children's Hospital Los Angeles. "They know very well what the odds are and they want to take a chance to find life-saving treatment. They also want to help other children. They don't want to do nothing."

Reynolds is a member of the FDA's Pediatric Oncology Subcommittee, a group of outside experts who have met several times since 2000 to advise the agency on such questions as: In what phase of a drug development program should pediatric cancer studies begin? What trial designs should be used? How may data from adult studies be used in pediatric studies? How should adult and pediatric studies be coordinated when studying life-threatening diseases?

Reynolds calls both the pediatric rule and the exclusivity provision essential. "Children don't have a voice in this," he says. "Somebody has to stand up for them."

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**Changing Drug Labels**

Recent pediatric drug studies have resulted in the addition of pediatric information to the labeling for more than 80 drugs. The drug labeling provides guidance for doctors and
other health care providers on how to use a drug. Here are examples of several changes that are considered significant for dosing and risk:

- **Claritin (loratadine) syrup.** Used to treat allergy and hives. Patients ages 2 to 5 years require a lower dose (5 milligrams) compared to a 10-milligram dose in older children and adolescents.

- **Duragesic (fentanyl) transdermal patch.** Used to manage chronic pain. It is now only to be used in patients older than 2 years who have been on opioids and are used to them. This medication is administered through a patch placed on the skin.

- **Luvox (fluvoxamine maleate) tablets.** Treats obsessive-compulsive disorder. The dose of the drug may need to be increased to the recommended adult dose in adolescents, but girls ages 8 to 11 years may need lower than the recommended dose.

- **Midazolam hydrochloride syrup and injection.** Used as a sedative. The drug was shown to have a higher risk of serious and life-threatening adverse events for children with congenital heart disease and pulmonary hypertension. Research identified the need to begin therapy with doses at the lower end of the dosing range to prevent respiratory problems in this special pediatric population.

- **Neurontin (gabapentin) capsules, tablets, and oral solution.** Used as adjunctive therapy in the treatment of partial seizures in pediatric patients ages 3 to 12 years. Neuropsychiatric adverse events were identified in 3- to 12-year-olds.

- **Pepcid (famotidine) tablets, injection, and oral suspension.** Used to treat gastroesophageal reflux disease. Patients up to 3 months of age require a lower dose because their ability to get rid of the drug is less than that of older children and adults.

- **Ultane (sevoflurane) volatile liquid for inhalation.** Used in general anesthesia. Pediatric studies revealed rare reports of seizures in pediatric patients given this drug.
Youth Perception of Marijuana Harm Decreases as “710” Becomes More Potent

Although marijuana use among youth poses a risk to health, nationally only 1 in 5 adolescents perceived it as such. According to SAMHSA’s 2014 National Survey on Drug Use and Health, this misperception among youth exists at a time when marijuana concentrates continue to become more potent, which is cause for public concern. This demonstrates the need to educate young people about various forms of marijuana and their related health consequences and harms.

Marijuana Use

According to SAMHSA’s Short Report, “State Estimates of Adolescent Marijuana Use and Perceptions of Risk of Harm from Marijuana Use: 2013 and 2014,” in the 12 to 17 age group, approximately 1.8 million youth reported using marijuana in the past month.

Health risks associated with youth marijuana use include poorer education/employment outcomes, cognitive problems, increased likelihood of vehicle crashes, and increased addiction risk.

Marijuana Concentrates

The Drug Enforcement Agency describes marijuana concentrate as a substance containing highly potent THC (tetrahydrocannabinol, the psychoactive component of marijuana). This concentrate is often referred to as oil or “710” (“OIL” spelled upside down and backwards). THC levels in this oil could range from 40 to 80 percent, which is about four times stronger than what is found in a “high grade” marijuana plant.

Using marijuana concentrates is different from smoking marijuana in several ways:

- **Oil is harder to detect.** When marijuana is smoked it causes a distinctive smell. But when oil from the marijuana plant is extracted and concentrated, it is odorless, making it harder to detect, for example, in e-cigarettes or foods. Because of this particular characteristic, it could be harder for parents, teachers, and law enforcement to know when marijuana is being used.

“Vaping is much easier to conceal and it is harder to tell if kids are vaping and getting high,” said David Dickinson, M.A., SAMHSA’s Region 10 Administrator. “Teachers may not have a full awareness of what’s happening and THC overdose is a real concern.”

Street Names for Cannabis Extracts & Oils

- Hash Oil
- Butane Honey Oil (BHO)
- Shatter
- Dabs
- Honeycomb
- Honey Oil
- Budder
- Crumble
- Sap
- Ear Wax
- Pull-and-Snap or Snap-and-Pull
- Black Glass
- Erk
- 710 (“OIL” spelled upside down and backwards)

- **Oil can be mixed into other products.** Oil is also sometimes mixed with other drugs including alcohol, cocaine, methamphetamine, and phencyclidine (PCP), creating an even stronger psychoactive response. It is also commonly added to sweet drinks and foods like brownies that appeal to youth, which can lead to high levels of exposure and can have toxic consequences when accidentally ingested.

“It’s not just smoking that concerns us, edibles and drinkables are also really popular with teens and young adults,” said Charles Smith, Ph.D., SAMHSA’s Region 8 Administrator. People eating a brownie containing marijuana, vaping the oil from an e-cigarette, or mixing it with other drugs may not fully realize the potency or effects until they are feeling unwell or even at a point of crisis from overdose.

There are other problems with marijuana use to consider as well:

- **Additives and other chemicals may be toxic.** According to Charles LoDico, MS, F-ABFT, a chemist in SAMHSA’s Division of Workplace Programs, marijuana concentrate can be extracted by using liquid butane, which is a highly flammable carcinogen. In many cases, trace butane remains and, when inhaled, can lead to long-term cognitive impairment and can affect nervous system functioning. And butane isn’t the only potential chemical exposure – pesticides used when growing the plant are also cause for concern.

**The Need for More Research**

Jon Perez, Ph.D., SAMHSA’s Region 9 Administrator, said “In the case of marijuana, the science lags behind policy and access. That means we do not yet have a full understanding of the health consequences of marijuana, hash concentrates, or what happens when it’s consumed through e-cigarettes.”

Douglas Tipperman, M.S.W., SAMHSA’s Tobacco Policy Liaison, noted that the record growth of smoke shops in recent years coincides with the emergence of the e-cigarette and the legalization of marijuana. He said, “While research is still needed to fully understand the health effects of e-cigarettes at the individual and population level, we also need to consider how marijuana concentrates in e-cigarettes may also pose additional significant health risks.”

Although more data are needed on the impact of marijuana concentrates, it is clear that in order to prevent use by youth, public education and awareness of the potential health risks are critical.

**Related Articles**
- Not for Human Consumption: Spice and Bath Salts
- E-Cigarettes Pose Risks

Resources

- Youth Marijuana Use: Consumption, Consequence, and Risk and Protective Factor Data Resources
- Risk and Protective Factors Associated with Youth Marijuana Use
- Strategies and Interventions to Prevent Youth Marijuana: An At-a-Glance Resource Tool
- Prevention Programs that Address Youth Marijuana Use
- SAMHSA: Cannabis
- ONDCP: Answers to Frequently Asked Questions about Marijuana
I’ll Address...
- Maturational and developmental issues regarding response to medication in youth
- Mental disorders that typically emerge during childhood and adolescence – depression, bipolar disorder, anxiety, ADHD
- Medications used to manage these disorders
- What symptoms to look for and how to differentiate one disorder from another

Special Aspects of Child Psychopharmacology
- In the U.S., any psychiatric medication prescribed for adults can be prescribed for children
- Safety studies for psychiatric medication use in youth were not mandated until 1998.
- Medications are being prescribed to children for symptoms that are within the spectrum of normal behavior, particularly preschoolers
- Many medications are rapidly metabolized by children. Toxic effects vs. therapeutic effects?

Assessing Children and Adolescents
- When possible, observe the child in multiple settings. Children may behave differently in social situations - compared to their actions in school or at home
- Assessment is a team effort. Input from teachers, coaches, other school officials is important to confirm observations
- Conduct interviews with the affected child and at least one parent. Responsible parents or primary caretakers are our de-facto specialists
- Do a thorough review of the child’s medical history, particularly when the behavior is violating others or is outside accepted social norms
- Obtain a thorough family history of psychiatric disorders. Understanding family genetics can be a major ally

Mood Disorders in Children

Depression - The Big Picture
Symptoms of Pediatric Depression:
- Persistent mood disturbance that is a change from prior functioning
- Diurnal variation in mood
- Lack of energy, motivation or enthusiasm
- Changes in sleep or eating patterns
- Irritability, agitation, unwarranted crying
- Pervasive anhedonia
- Sad or morbid play that concentrates on harming themselves or others
Manifestations of Depression in Children

- Demoralization
  - I see many, many kids meeting diagnostic criteria for major depression, but largely their disturbed mood and unhappiness are related to challenging life circumstances: bad schools, family chaos, poor peer relationships, poverty, etc.
  - They appear more dispirited and disheartened than clinically depressed from a physiological perspective.
  - Demoralized kids want to feel better, but life is getting in the way; clinically depressed kids require pharmacological help.
  - The number of kids suffering from clinical depression is small compared to those who are demoralized.
  - I’ve found that demoralized children don’t necessarily have poor esteem and image issues, but all children with poor esteem and low image are demoralized.

- Physiological
  - A clearly defined episode onset that includes a change from prior functioning is present:
    - Psychomotor slowing
    - Attention and concentration problems (clear onset to others in the child’s life)
    - Usual onset age: 15-18
    - If I see an unhappy 6 or 7 year old, I’m going first to demoralization or anxiety
    - Diurnal variation in mood - which is a worse mood in the morning, but improving throughout the day involves “phase shifting” and often sleep deprivation
    - Pervasive anhedonia - important
    - Medical conditions (asthma); Drugs: (substance abuse, steroid inhalers)

Case Example: Demoralization

During the past two months, 11 year old Kyle has appeared distracted, agitated and irritable throughout the school day. His grades have fallen off somewhat, but he’s in no danger of failing. He interacts with other students and school personnel and is engaged, confident and assertive in class and recreational activities, but seems demoralized. When you approach him regarding your observations and ask him what’s been going on, he responds, “my dad lost his job and he and my mom are fighting all the time.” “It makes me mad and unhappy to hear them fighting and I want it to stop, but I don’t know what to do.”

What To Look For

Notice first that Kyle is willing to express his concerns about how difficult the situation between his mom and dad has become for him. This is a huge step when it comes to making progress. Also important is that Kyle is coming to school every day and is engaged. His grades have fallen off somewhat, but this is likely a by-product of the frustration he’s feeling, which in turn is affecting his concentration and desire to apply himself.

How To Proceed

Demoralized youth will better respond to time-honored problem-solving techniques, so take medication off the table for now. Kyle seems willing to talk, so ask him for some more details about the situation and what really bothers him about the discord between his mother and father. Then use Kyle’s confidence and assertiveness as strengths to help him confront his parents about what’s happening and how it makes him feel. Assist him with developing a script he can try out - “mom and dad, it upsets me when you constantly fight and I wish you would stop, please don’t do it in front of me.” Then role play the script with him to determine his competence at delivering his message. Also, mindfulness techniques work well with demoralized kids, and if need be, notifying Kyle’s parents may be warranted. If professional help outside of school is pursued, parents should be encouraged to seek a professional who routinely works with or specializes in treating mood disorders in children.
Treatment

- Medication
- Counseling (Cognitive-behavioral, Mindfulness)
- Diet
- Exercise

Demoralization: What Works

- Psychotherapy is the treatment of choice, any of the models already mentioned can be quite effective.
- Work from the position that the child is NOT damaged by utilizing sound problem-solving techniques.
- Direct efforts toward building on the child's strengths instead of shoring up weaknesses.
- If teens are aware that their low mood is related to their life circumstances, a medication trial may demoralize them further.
- “I’m having it tough and all I get is this stupid pill.”

Physical Depressions

- Medication IS the mainstay of treatment for melancholic, vegetative, depressed manifestations
- Important: Don’t separate the depression help from treatment for the medical disorders, because they are comingled
- Psychotherapy, diet, exercise serve as adjuncts to care

Most Frequently Prescribed Antidepressants

- Prozac - FDA approved for kids 8 and older
- Zoloft
- Paxil
- Celexa
- Lexapro - FDA approved for kids 12 and older
- Effexor
- Wellbutrin

Antidepressant Use

What to expect:
- Increased energy, feeling “brighter,” less “phase shifting,” improved ability to experience pleasure

What they won’t do:
- Change behavior
- Teach children how to cope
- Make them happy
- Take troubles away
- None of these are physiological

Bipolar Disorder
Bipolar Disorder Facts

- Historically referred to as manic-depressive illness
- Cyclic pattern of mood, behavior and thought processes alternating between mania and depression
- Investigated in children as young as age five

Mania is characterized by:
- Racing thoughts
- Pressured speech
- Grandiosity
- Distractibility
- Insomnia
- Decreased need for sleep
- Flight of ideas
- Increase in goal-directed activity
- Increase in risk-taking behavior

Depression is characterized by:
- Low energy
- Sleeping too much
- Increased Appetite

Assessing a Child for Bipolar: The 3 Best Questions to Get Started

1. Has there been a time when you can remember having lots of energy for getting things done, where you needed little sleep, and people noticed this and thought you were acting strange or different?
2. Has there been a time when you felt sad and down and isolated yourself, and people noticed that you were absent?
3. Is there anyone in your family as far back as you can remember who has been treated for what I just asked you?

Case Example: Mania and Depression

Leo is a bright, energetic 9-year-old who tends to act in a dominating way toward peers and even authority figures. He likes to be in charge and take over a situation regardless of the setting or circumstance. His overbearing nature and attitude stirs anger in those around him. He can be mean-spirited and aggressive to the point of starting fights and perpetrating harm on peers, expressing no remorse afterwards. Leo is also quite imaginative and curious, making him prone to speaking in highly sexualized language directly in front of you. But in a perplexing twist, you notice periods where he acts withdrawn, falls asleep in class and does not want to talk to anyone or do any of the activities he usually enjoys.

What to Look For

Leo is showing symptoms of mania and depression. Instead of grandiosity, Leo is exhibiting bullying-type behavior and aggressiveness which is off-putting to other students and faculty. He is mean to others leading to fights and disruption and is not sorry for his actions. Although such behavior may be symptomatic of a conduct problem, Leo is not truant, has not encountered problems with the law, and is not into destroying property or perpetrating serious harm indicative of cruelty. He does however have a fertile imagination which is stimulating his curiosity toward sexual matters. But he also is prone to demonstrate symptoms which are the polar opposite of those just discussed when he shuts down, isolates himself and becomes withdrawn.

How to Proceed

Leo is typical of classic bipolar disorder. He exhibits manic symptoms which periodically switch to depression. All responsible parties interacting with Leo should be made aware of his mood and actions. Treatment should be coordinated with true bipolar symptoms in mind, as Leo demonstrates both ends of the bipolar spectrum. Because bipolar is a brain-based mental disorder, he may very well require medication to truly “stabilize” him because he switches from mania to depression and vice versa. And when a medication regimen has taken shape, adding behavioral treatment would be a major plus to support and provide back-up for the drug treatment.
Treatment

- Bipolar illness is a brain-based illness
- Most common treatment is pharmacological intervention
- Psychotherapy as an adjunct to care

Medications for Bipolar Disorder

- Lithium
  - Treats acute mania
  - Produces “normalizing” effect by smoothing out manic highs and depressive lows
  - Most effective single agent for bipolar disorder
  - Used to treat aggression or self-injury in children and adolescents with conduct disorder, autism and intellectual disability
  - FDA approved in children at least 12 years of age

- Depakote
  - Effective for mania, but not as effective as lithium
  - Treats seizures
  - Treats rage reactions and extreme mood instability
  - Lithium/Depakote combination optimal in mania prevention
  - Side effects: birth defects; PCOS

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Bipolar Disorder in Youth

- Enormously controversial
- There was an epidemic of bipolar diagnosing in youth over the last several years
- Many diagnoses are now made by PCPs with little expertise in psychiatry, less time with each child, and intolerant of unruly behavior
- Children are often shuffled from one clinician to another

Other Issues

- Many kids getting the diagnosis today have temper outbursts and irritability; classic swings between mania and depression are being largely ignored
- The boundaries of pediatric BPD have pushed far into unfamiliar territory
- Because of its fad status, the DSM-5 created a new diagnosis - Disruptive Mood Dysregulation Disorder to create a less harmful diagnosis for kids who shouldn’t have even been diagnosed in the first place
Anxiety Disorders in Children and Adolescents

Generalized Anxiety
- Chronic low-level anxiety
- Resolved worries are quickly replaced with new ones, consuming excessive amounts of time
- These are children who: worry all the time; worry about what they worry about; worry if they’re not worrying
- Common in children and adolescents, not just adults

Understanding GAD
- We’re all often very competent at handling real, identifiable problems...because
- An unambiguous problem invites an unambiguous solution
- So, a clear plan of action settles the anxious mind
- Worriers have trouble distinguishing what is a problem from what might be a problem

Take Action by...
- Sorting out what is real and what can be controlled
- Turning worry into a combination of planning and thought-stopping by printing out the biggest, reddest STOP sign from Google images
- Medication: Will numb symptoms only, not extinguish them; provide short-term relief from worry by reducing the “excitability” factor
- The benzodiazepine Klonopin is the best option
- Again, if at all possible, avoid such medication use in youth

Obsessive-Compulsive Disorder... I Get Lots of Questions
“...My 12-year-old son is adamant about toilet tissue being placed on the roller so that the tissue dispenses from the top of the roll, not the bottom. When other family place it on the roller in reverse, he becomes irritated and immediately changes it back. Does this mean he has OCD?”

Obsessive-Compulsive Disorder
- We all have eccentricities, oddities, habits
- The full-time companion
- A disorder of excessive carefulness accompanied by an exaggeration of possible danger
- Persistent thoughts and compulsions accompanied by shame and guilt
- Often incapacitating
- Emerges in late childhood, prevalent in children and adolescents
- If untreated, symptoms remain remarkable throughout life
What Else To Look For

- Writing a sentence or phrase, erasing it or lining through it, and then writing the same thing again
- Slow to complete tests and other exercises
- Checking work repeatedly before actually turning it in
- Becoming upset when rules aren’t followed by other kids, as on the playground
- Being precise, meticulous, demonstrates a need for near perfect order; fastidious about appearance; need for symmetry
- Examining backpacks and gym bags for needed items repeatedly, particularly when leaving school for the day

Best Practices for Managing OCD

- Use of logic results in abject failure
- Expose and prevent; expose and prevent – THIS IS HOW AFFECTED CHILDREN GET BETTER
- Example: A child with an excessive “checking” type of OCD
- Visual and audio confirmation
- For those who stick with E&P and practice regularly – 85% improve
- Serotonin antidepressants such as Prozac may be helpful but often impede progress. As such, I don’t consider them treatment mainstays

Medicating Children for Anxiety

- Medication management studies are virtually non-existent and inconclusive
- Mood stabilizer, antipsychotic use on the rise for the treatment of violent outbursts, severe aggression, tantrums, destructive behavior

Antihistamines

- Reduce anxiety through their sedative effects and are used to treat children with insomnia
- Not habit-forming
- Can produce “hangover” effect
- Benadryl used for more than 40 years to treat anxious children

ADHD

- CDC: Nearly one in five high school age boys in the U.S. and 11% of school-age children have received a diagnosis of ADHD
- 53% rise in diagnosis in those ages 4-17 in this past decade
- Some diagnosticians are hastily viewing any complaints of inattention as ADHD and are diagnosing it haphazardly
- Slipshod diagnosis accompanied by stimulant prescribing will have kids using these drugs as mental steroids
- Increases in diagnosis = more pills = an increased risk for abuse and drug diversion
- Parents are pressuring doctors for pills, instead of challenging and questioning this diagnosis
What to Look For

Consider the possibility of ADHD if:

- It is obvious that in multiple milieus (school, play, home) it seems impossible for the child to sit and focus without becoming easily distracted and inattentive within a few minutes
- The child has much difficulty following directions and playing by the rules - for example, when “quiet time” is required
- The child is being shunned and is being treated like an outcast by teachers, peers and even family members because he or she is so difficult to be around

- The child has never done well academically and is consistently failing
- The child is often placed in “time-outs” or in some type of “punish hall”
- The child is not responding to multiple attempts at redirection

ADHD Medications

The 5 Ps

The Pills:
- Ritalin; Focalin; Adderall

The Pump:
- Concerta

The Pellets:
- Ritalin LA; Focalin XR; Adderall XR

The Patch:
- Daytrana

The Pro-Drug
-Vyvanse

Thanks for Attending!

Joe Wegmann, PD, LCSW
Services Provided

Drug Testing

- Breath Alcohol (DOT & Non DOT)
- In Office & Onsite Services Adults & Children
- (Urine, Hair, Nails, Oral, Meconium, & Breast Milk)
- Random Selection Generator
- Laboratory Services (Personal testing & Dr. Ordered)
- Service Site for (E screen, Form Fox, DISA, and Quest Diagnostics)
- DOT Physicals by appointment

DNA/ Forensic

- Siblingship
- Paternity (legal and non-legal)
- Grand paternity
- Y Chromosome
- Infidelity
- Prenatal DNA ≥ 14 weeks or greater
- Prenatal Gender Testing

Life/Disability Insurance Physicals

- In Office & Mobile Appointments
- EKG Services
- MD Exam Scheduling
- Trained Examiners
- Status Updates
DCFS Request Form

Circle which Parish:
Calcasieu  Beauregard  Jeff Davis  Allen  Vernon

☐ IN Ofc  ☐ Mobile (add Charges will apply)

Case Worker Name: __________________________

Test Requested:

☐ 5-Panel Hair w/Extended Opiate
☐ 10 panel Urine (Lab)
☐ Urine Alcohol (Lab)
☐ Rapid Urine Alcohol (Non-Lab)
☐ UDS Synthetic Extensive Panel (Lab)
☐ Oral Fluid Synthetic Panel (Lab)
☐ Rapid Urine 10panel (Non-Lab)

☐ Other __________________________

Tested Party Info:

#1 NAME_________________________ D.O.B._________ Tips# _____________________

#2 NAME_________________________ D.O.B._________ Tips# _____________________

Mobile order:
Address: ____________________________________________

If you are sending two clients within the same case & on the same day fill out one form :)  

SPECIAL REQUEST ________________________________

Office Purposes Only ↓

www.ilesenterprise.com
Vendor# 020159170
Fax Date: ________ Invoice # _________
# Hair and Nail Drug Panels

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<th>14</th>
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</tbody>
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## Optional Add-Ons For Hair and Nail

- Buprenorphine
- Diphenhydramine
- High-Potency Opioids (HPOs)
  - 6-B-Naltrexol (naltrexone metabolite)
  - Butorphanol (e.g. Stadol®)
  - Nailbuphine (e.g. Nubain®)
  - Naloxone (e.g. Narcan®)
- EtG (Direct Ethanol Biomarker)
- Propofol Glucuronide
- Zolpidem (e.g. Ambien®)
Choosing The Right Drug Test:
Direct Alcohol Biomarkers and Other Substances of Abuse

When Choosing a Test That's Right For You, Consider These 5 Factors:
1. Substance being tested
2. Desired window of detection
3. Specimen type
4. Level of adulteration potential
5. Notice required before collection

6 months

Other Substances of Abuse

Fingernail
Detection: Up to 6 Months
Adulteration Level: Difficult
Collection: May Need Notice

Hair: Exposure
Detection: Up to 3 Months
Adulteration Level: Moderate
Collection: May Need Notice

Hair
Detection: Up to 3 Months
Biomarker: ETO
Adulteration Level: Moderate
Collection: May Need Notice

Urine
Detection: 2-3 Days
Adulteration Level: Easy
Collection: Requires Notice

Whole Blood
Detection: 1-3 Days
Adulteration Level: Difficult
Collection: No Notice Required

Oral Fluid
Detection: 1-3 Days
Adulteration Level: Difficult
Collection: No Notice Required
*No longer available at USDOT

Alcohol

Fingernail
Detection: Up to 3 Months
Biomarker: ETO
Adulteration Level: Difficult
Collection: May Need Notice

Hair
Detection: Up to 3 Months
Biomarker: ETO
Adulteration Level: Moderate
Collection: May Need Notice

Dried Blood Spot
Detection: 2-3 Weeks
Biomarker: BMA
Adulteration Level: Difficult
Collection: No Notice Required

Urine
Detection: 2-3 Days
Biomarker: ETO & ETS
Adulteration Level: Easy
Collection: Requires Notice
# Specimen vs. Test Requested

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<th>Drug</th>
<th>Urine</th>
<th>Hair</th>
<th>Blood</th>
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</tbody>
</table>
Frequently Asked Questions:

Q: What does a dilute specimen mean?
A: A dilute specimen is a urine that has a greater concentration of water than that of a normal urine specimen. Usually due to oral hydration of fluids and are usually more clear in appearance than that of normal urine.

Q: What is the difference between a "Rapid" screen vs Lab Based Drug Test?
A: A "Rapid" screen will test to see if drug is present in urine, Only (+) or (-) is given. However, a Lab Based drug test can provide quantity of drug present and goes through confirmation processing. If a "rapid" screen shows positive the sample must be forwarded to lab to confirm.

Q: What is the difference between initial screening and confirmation testing at the lab?
A: The initial screening process at the lab separates the negative from non-negative results. GCMS testing is an extremely accurate test that is completed on non-negative results which provides quantitative results for the presence of a specific drug or drug metabolite.

Q: How do I obtain a status for drug test result?
A: Contact our office and we will be glad to update you.

Q: On a hair test under Cocaine, what does benzoylcegonine, cocaethylene?
A: Cocaine is the parent drug and (BE) and (CE) are the metabolites. The presence of (CE) rules out external contamination.

Q: Do clients need to bring in prescription bottles?
A: No, however it does help to have a print out from pharmacy available in the coming days, in the event client is contacted by MRO.

Q: What is the review process for the MRO?
A: Once IMT receives results from lab, the non-negatives are sent to MRO especially for Rx drugs to confirm a valid reason for (+). The MRO's office contacts client to obtain information, then MRO confirms with Dr. Rx was written by and the pharmacy Rx was filled at. Then the MRO determines if the positive result is a verified (+) or (-).

Q: What methods of drug testing are available?
A: Urine/Hair/Nail/Oral/Blood
Q: How far does Hair Testing go back?
A: Hair testing generally uses 1-1/2 inches of hair represents about 3 months of growth. It is generally accepted that in order to test positive, the drug in question must have been used 3 times or more within the window of the test. After a drug is used, it takes about 7-10 days for the hair containing the drug to grow out of the scalp enough to be cut. Consequently, the hair test will not include drugs used in the week prior to the test.

Q: What is "synthetic marijuana"?
A: Synthetic marijuana is a mixture of dried herbs and spices sprayed with chemicals that, when smoked, create a high similar to THC, the main active ingredient in marijuana. "Spice" and "K2" are two popular names for these products.

Q: Are results given to clients?
A: If we are conducting a "rapid" screen, the result is read in front of client. However, we do not provide a paper copy to client unless authorized by case worker. Clients sign authorization to release form prior to testing, the form states without consent from caseworker results will not be provided.

Q: What is lab turnaround time for testing?
A: Normally 24-72 Hrs for Urine, Hair, and Oral samples. Nails take 72-96 hrs.

Q: Which test is most accurate?
A: All test are accurate especially when confirmed by lab. Determine the timeframe you suspect drug was consumed, then choose the right test to fit that timeframe.

Q: Can a hair test be beaten?
A: Drug metabolites stored in your hair are chemically and structurally bonded to the hair shaft core. At this time there are no known successful commercial adulterants for hair test and the use of normal hair care products/procedures (shampoos, dyes, permanents, relaxers, bleaches) do not have a significant effect on results. The effects of these products were reviewed by the FDA as part of labs clearance.
Process Overview

The four main steps involved in the laboratory processing of a drug test result are **Accessioning**, **Screening**, **Extraction**, and **Confirmation**.

**Accessioning** involves the initial processing of a sample into a laboratory’s system. This includes verifying that the sample was sealed and shipped properly, assigning a random LAN (Laboratory Accessioning Number), and completing any additional data entry not provided by an electronic chain of custody system.

**Screening** involves an initial quick check for drugs of abuse. While Screening is a cost-effective way to rule out drug usage on the majority of samples, a positive screen needs to be confirmed to be admissible in court. Any samples that are presumptively positive in Screening do require a secondary confirmation.

If a sample is presumptively positive in the **Screening** stage, more hair is pulled from the initial specimen and prepared for **Extraction**. In this stage, drugs are extracted from hair at a much lower concentration than in other methodologies (ex. urine or oral fluid), which is why hair drug screening is the most difficult methodology to perform.

**Confirmation** of any positive screening result is conducted via GC/MS, GC/MS/MS or LC/MS/MS. All presumptive positive samples are washed prior to confirmation as needed. The entire laboratory process from **Accessioning** to **Confirmation** is reviewed under both the CAP (College of American Pathologists) Hair designation and the accreditation to ISO / IEC 17025 standards.
# Hair Drug Panels & Cutoff Levels

<table>
<thead>
<tr>
<th>Hair 5-Panel (H5P)</th>
<th>Screening Cutoff</th>
<th>Confirmation Cutoff</th>
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<tbody>
<tr>
<td>Amphetamines</td>
<td>500 pg/mg hair</td>
<td>500 pg/mg hair</td>
</tr>
<tr>
<td>Amphetamine</td>
<td></td>
<td>500 pg/mg hair</td>
</tr>
<tr>
<td>Methamphetamine</td>
<td></td>
<td>500 pg/mg hair</td>
</tr>
<tr>
<td>Ecstasy (MDMA)</td>
<td></td>
<td>500 pg/mg hair</td>
</tr>
<tr>
<td>MDA</td>
<td></td>
<td>50 pg/mg hair</td>
</tr>
<tr>
<td>Cocaine</td>
<td>500 pg/mg hair</td>
<td>500 pg/mg hair</td>
</tr>
<tr>
<td>Benzoylecgonine</td>
<td></td>
<td>50 pg/mg hair</td>
</tr>
<tr>
<td>Cocastethylene</td>
<td></td>
<td>50 pg/mg hair</td>
</tr>
<tr>
<td>Norcocaine</td>
<td></td>
<td>50 pg/mg hair</td>
</tr>
<tr>
<td>Opiates</td>
<td>200 pg/mg hair</td>
<td>200 pg/mg hair</td>
</tr>
<tr>
<td>Codeine</td>
<td></td>
<td>200 pg/mg hair</td>
</tr>
<tr>
<td>Morphine</td>
<td></td>
<td>200 pg/mg hair</td>
</tr>
<tr>
<td>6-MAM (Heroin metabolite)</td>
<td></td>
<td>200 pg/mg hair</td>
</tr>
<tr>
<td>Phencyclidine</td>
<td>300 pg/mg hair</td>
<td>300 pg/mg hair</td>
</tr>
<tr>
<td>PCP</td>
<td></td>
<td>300 pg/mg hair</td>
</tr>
<tr>
<td>Marijuana</td>
<td>1 pg/mg hair</td>
<td>0.1 pg/mg hair</td>
</tr>
<tr>
<td>Carboxy-THC</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hair 5-Panel plus Extended Opiates (H5PEO) (In Addition to 5-Panel)</th>
<th>Screening Cutoff</th>
<th>Confirmation Cutoff</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extended Opiates</td>
<td>200 pg/mg hair</td>
<td>200 pg/mg hair</td>
</tr>
<tr>
<td>Oxycodone (OxyContin, Percodan/Percocet)</td>
<td></td>
<td>200 pg/mg hair</td>
</tr>
<tr>
<td>Oxymorphine (Opana, Numorphan, Numophone)</td>
<td></td>
<td>200 pg/mg hair</td>
</tr>
<tr>
<td>Hydrocodone (Vicodin, Lortab/Lorcet)</td>
<td></td>
<td>200 pg/mg hair</td>
</tr>
<tr>
<td>Hydromorphone (Dilaudid)</td>
<td></td>
<td>200 pg/mg hair</td>
</tr>
</tbody>
</table>

*pg/mg = picogram per milligram of hair*

*Please Note: All tests requested as “Confirmation Only” will be run at the levels noted above*
# Oral Fluid Drug Panels & Cutoff Levels

<table>
<thead>
<tr>
<th>Oral Fluid 6-Panel (S6P)</th>
<th>Screening Cutoff (Dilute)</th>
<th>Confirmation Cutoff (Neat)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amphetamine</td>
<td>100 ng/ml</td>
<td>50 ng/ml</td>
</tr>
<tr>
<td><em>Amphetamine (Adderall, Benzedrine, Dexedrine, Vyvanse)</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Methamphetamine</td>
<td>40 ng/ml</td>
<td>50 ng/ml</td>
</tr>
<tr>
<td><em>Methamphetamine, MDM, MDA, MDEA</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cocaine</td>
<td>5 ng/ml</td>
<td>8 ng/ml</td>
</tr>
<tr>
<td><em>Cocaine, Benzoylcegonine</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Opiates</td>
<td>10 ng/ml</td>
<td>40 ng/ml</td>
</tr>
<tr>
<td><em>Codeine, Morphine, Hydrocodone (Vicadin, Lortab/Lorcet), 6-MAM (Heroin)</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phencyclidine</td>
<td>1 ng/ml</td>
<td>10 ng/ml</td>
</tr>
<tr>
<td><em>PCP</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Marijuana (THC)</td>
<td>1 ng/ml</td>
<td>2 ng/ml</td>
</tr>
<tr>
<td><em>THC</em></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Oral Fluid 10-Panel (S10P) (In Addition to 6-Panel)</th>
<th>(Dilute)</th>
<th>(Neat)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxycodone</td>
<td>10 ng/ml</td>
<td>40 ng/ml</td>
</tr>
<tr>
<td><em>Oxycodone (OxyContin, Percodan/Percocet)</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Methadone</td>
<td>5 ng/ml</td>
<td>15 ng/ml</td>
</tr>
<tr>
<td><em>Methadone</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Benzodiazepines</td>
<td>1 ng/ml</td>
<td>5 ng/ml</td>
</tr>
<tr>
<td><em>Diazepam, Nordiazepam (Valium), Alprazolam, Alpha-hydroxylprazolam (Xanax)</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Barbiturates</td>
<td>20 ng/ml</td>
<td>60 ng/ml</td>
</tr>
<tr>
<td><em>Secobarbital (Seconal), Butalbital ( Fioricet, Fiorinal), Pentobarbital (Nembutal), Phenobarbital (Luminal), Amyobarbital (Amytal, Tuinal)</em></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Separate Panels (Offered separate from 6 and 10 panels)</th>
<th>(Dilute)</th>
<th>(Neat)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cotinine (Nicotine Metabolite) (SCOT)</td>
<td>10 ng/ml</td>
<td>10 ng/ml</td>
</tr>
<tr>
<td><em>Cotinine</em></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Neat Vs. Dilute:** Screening cutoff levels listed as Dilute to account for device buffer. Confirmation listed as Neat in accordance with SAMHSA guidelines.

**Validity Testing:** All oral fluid panels include IgG human validity testing.
Top 10 (+)’s

1. Marijuana
2. Amphetamines
3. Methamphetamines
4. Benzodiazepines
5. Opiates
6. Cocaine
7. PCP
8. Barbiturates
9. Alcohol
10. Methadone

*Fact = Drug-induced death rate in Louisiana is higher than the national average... overall trend, rising 74% from 2007.

Drugs on the rise:

*Synthetic THC (K2, Mojo) = Synthetic drug mimics marijuana

*Kratom = Low doses of kratom acts as a stimulant. High doses kratom is a sedative producing opioid-like effects that dull pain.

*Heroin = an opioid pain killer

*Carfentanil = Heroin mixed with animal tranquilizer. 10,000 times stronger than regular heroin.

*Cloud 9 = Synthetic drug mimics the effects of cocaine and meth.
Test(s) Requested: Hair 5 Drug Panel & Extended Opiates

The Hair 5 Drug Panel and Extended Opiates Test includes the testing of the 5 major drug classes screened by ELISA and confirmed by GC/MS or GC/MS/MS.

These include:
- Amphetamines
- Methamphetamine
- Methamphetamines, Ecstasy (MDMA), MDA
- Cocaine, Cocaine Metabolites
- Opiates - Codeine, Morphine, Heroin Metabolite, Hydrocodone
- Oxycodone (Percocet)
- Oxymorphone
- Phenylephrine (Pephine)

Hair 5 Drug Panel & Extended Opiates Test Result: Positive

A positive result indicates that the drug was identified at a level equal to or greater than the listed cutoff and was confirmed by GC/MS.

<table>
<thead>
<tr>
<th>Drugs Tested For</th>
<th>Result</th>
<th>Screening Cut off</th>
<th>Screening Method</th>
<th>Confirmation Cut off</th>
<th>Confirmation Method</th>
<th>Quantitative Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amphetamine</td>
<td>Positive</td>
<td>500 pg/mg</td>
<td>ELISA</td>
<td>500 pg/mg</td>
<td>GC/MS</td>
<td>597 pg/mg</td>
</tr>
<tr>
<td>Methamphetamine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Methamphetamine</td>
<td>Positive</td>
<td>500 pg/mg</td>
<td>ELISA</td>
<td>500 pg/mg</td>
<td>GC/MS</td>
<td>8851 pg/mg</td>
</tr>
<tr>
<td>Cocaine/Metabolites</td>
<td>Negative</td>
<td>500 pg/mg</td>
<td>ELISA</td>
<td>500 pg/mg</td>
<td>GC/MS</td>
<td></td>
</tr>
<tr>
<td>Opiates</td>
<td>Negative</td>
<td>200 pg/mg</td>
<td>ELISA</td>
<td>200 pg/mg</td>
<td>GC/MS</td>
<td></td>
</tr>
<tr>
<td>Extended Opiates</td>
<td>Negative</td>
<td>200 pg/mg</td>
<td>ELISA</td>
<td>200 pg/mg</td>
<td>GC/MS</td>
<td></td>
</tr>
<tr>
<td>Phencyclidine</td>
<td>Negative</td>
<td>300 pg/mg</td>
<td>ELISA</td>
<td>300 pg/mg</td>
<td>GC/MS</td>
<td></td>
</tr>
<tr>
<td>THC Metabolite</td>
<td>Negative</td>
<td>1.00 pg/mg</td>
<td>ELISA</td>
<td>0.10 pg/mg</td>
<td>GC/MS/MS</td>
<td></td>
</tr>
</tbody>
</table>

REPORT NOTATIONS

1.5 inches (3.81 cm) - Head Hair

Incorporated from

Certified By: Chris Schmidt
Omega Results Report REV US.11.2016
Result Report Version: 2658192.15
- Page 1 of 1 -

David Engelhart, Ph.D.
Laboratory Director

Omega Laboratories, Inc. | 400 N. Cleveland Ave. | Mogadore, OH 44260
Test(s) Requested: Hair 5 Drug Panel & Extended Opiates
The Hair 5 Drug Panel and Extended Opiates Test includes the testing of the 5 major drug classes screened by ELISA and confirmed by GC/MS or GC/MS/MS. These include:
Amphetamines, Methamphetamine, Ecstasy (MDMA), MDA
Cocaine, Cocaine/Cocaine Metabolites
Opiates, Benzodiazepines, Heroin Metabolites, Hydrocodone, Methylmorphine (Dilaudid), Hydromorphone (Dilaudid), Dextromethorphan (Perfext)
Oxymorphone (Opana)
Phencyclidine (PCP)
THC Metabolite (Marijuana)

Hair 5 Drug Panel & Extended Opiates Test Result: Positive
A positive result indicates that the drug was identified at a level equal to or greater than the listed cutoff and was confirmed by GC/MS.

<table>
<thead>
<tr>
<th>Drugs Tested For</th>
<th>Result</th>
<th>Screening Method</th>
<th>Confirmation Method</th>
<th>Quantitative Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amphetamine</td>
<td>Negative</td>
<td>500 pg/ml ELISA</td>
<td>GC/MS</td>
<td></td>
</tr>
<tr>
<td>Methamphetamine</td>
<td>Negative</td>
<td>500 pg/ml ELISA</td>
<td>GC/MS</td>
<td></td>
</tr>
<tr>
<td>Cocaine/Metabolites</td>
<td>Positive</td>
<td>500 pg/ml ELISA</td>
<td>GC/MS</td>
<td></td>
</tr>
<tr>
<td>Cocaine</td>
<td>Positive</td>
<td>500 pg/ml ELISA</td>
<td>GC/MS</td>
<td>3604 pg/mg</td>
</tr>
<tr>
<td>Benzoylecgonine</td>
<td>Positive</td>
<td>200 pg/ml ELISA</td>
<td>GC/MS</td>
<td></td>
</tr>
<tr>
<td>Norcocaine</td>
<td>Positive</td>
<td>200 pg/ml ELISA</td>
<td>GC/MS</td>
<td>745 pg/mg</td>
</tr>
<tr>
<td>Cooxyleone</td>
<td>Positive</td>
<td>200 pg/ml ELISA</td>
<td>GC/MS</td>
<td>164 pg/mg</td>
</tr>
<tr>
<td>Opiates</td>
<td>Positive</td>
<td>200 pg/ml ELISA</td>
<td>GC/MS</td>
<td>304 pg/mg</td>
</tr>
<tr>
<td>Codeine</td>
<td>Positive</td>
<td>200 pg/ml ELISA</td>
<td>GC/MS</td>
<td>261 pg/mg</td>
</tr>
<tr>
<td>Extended Opiates</td>
<td>Positive</td>
<td>200 pg/ml ELISA</td>
<td>GC/MS</td>
<td>2080 pg/mg</td>
</tr>
<tr>
<td>Hydrocodone</td>
<td>Positive</td>
<td>200 pg/ml ELISA</td>
<td>GC/MS</td>
<td></td>
</tr>
<tr>
<td>Oxycodone</td>
<td>Positive</td>
<td>200 pg/ml ELISA</td>
<td>GC/MS</td>
<td>1872 pg/mg</td>
</tr>
<tr>
<td>Phencyclidine</td>
<td>Negative</td>
<td>300 pg/ml ELISA</td>
<td>GC/MS</td>
<td></td>
</tr>
<tr>
<td>THC Metabolite</td>
<td>Negative</td>
<td>1.00 pg/ml ELISA</td>
<td>GC/MS/MS</td>
<td></td>
</tr>
</tbody>
</table>

REPORT NOTATIONS
1.5 inches (3.81 cm) - Head Hair

Certified by: Jessica Lilly
Test(s) Requested: Hair 5 Drug Panel & Extended Opiates
The Hair 5 Drug Panel and Extended Opiates Test includes the testing of the 5 major drug classes screened by ELISA and confirmed by GC/MS or GC/MS/MS.
These include:
- Amphetamine - Amphetamine
- Methamphetamine - Methamphetamine, Ecstasy/MDMA, MDA
- Cocaine - Cocaine/Cocaine Metabolites
- Opiates - Codeine, Morphin, Heroin Metabolite, Hydrocodone (Vicodin, Lornit, Loritab)
- Hydromorphone (Dilaudid)
- Oxydodecene (Oxycet)
- Phencyclidine (PCP)
- THC Metabolite (Marijuana)

Hair 5 Drug Panel & Extended Opiates Test Result: Negative
A negative result indicates that none of the drugs listed were detected at a concentration equal to or greater than their listed cutoff levels.

<table>
<thead>
<tr>
<th>Drugs Tested For</th>
<th>Result</th>
<th>Screening Cut off</th>
<th>Screening Method</th>
<th>Confirmation Cut off</th>
<th>Confirmation Method</th>
<th>Quantitative Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amphetamine</td>
<td>Negative</td>
<td>500 pg/mg</td>
<td>ELISA</td>
<td>500 pg/mg</td>
<td>GC/MS</td>
<td></td>
</tr>
<tr>
<td>Methamphetamine</td>
<td>Negative</td>
<td>500 pg/mg</td>
<td>ELISA</td>
<td>500 pg/mg</td>
<td>GC/MS</td>
<td></td>
</tr>
<tr>
<td>Cocaine/Metabolites</td>
<td>Negative</td>
<td>500 pg/mg</td>
<td>ELISA</td>
<td>500 pg/mg</td>
<td>GC/MS</td>
<td></td>
</tr>
<tr>
<td>Opiates</td>
<td>Negative</td>
<td>200 pg/mg</td>
<td>ELISA</td>
<td>200 pg/mg</td>
<td>GC/MS</td>
<td></td>
</tr>
<tr>
<td>Extended Opiates</td>
<td>Negative</td>
<td>200 pg/mg</td>
<td>ELISA</td>
<td>200 pg/mg</td>
<td>GC/MS</td>
<td></td>
</tr>
<tr>
<td>Phencyclidine</td>
<td>Negative</td>
<td>300 pg/mg</td>
<td>ELISA</td>
<td>300 pg/mg</td>
<td>GC/MS</td>
<td></td>
</tr>
<tr>
<td>THC Metabolite</td>
<td>Negative</td>
<td>1.00 pg/mg</td>
<td>ELISA</td>
<td>0.10 pg/mg</td>
<td>GC/MS/MS</td>
<td></td>
</tr>
</tbody>
</table>

REPORT NOTATIONS

1.5 inches (3.81 cm) - Head Hair

Certified By: Jessica Lilly
Result Report Version: 2655426.5
- Page 1 of 1 -
David Englehart, Ph.D.
Laboratory Director

Omega Laboratories, Inc. | 400 N. Cleveland Ave. | Mogadore, OH 44260
### Laboratory Report

**Specimen Information**
- **Requisition #:**
- **Accession #:**
- **Collected:**
- **Received:**
- **Reported:**
- **Specimen ID:**

**Donor Information**
- **Name:**
- **Primary ID:**
- **Reason:** RANDOM
- **Collection Site:** ZZ

**Client Information**
- **ID:** 65140333
- **Laboratory:** ILES MEDICAL TESTING
- **Address:** 226 WEST PRIEN LAKE RD
  - LAKE CHARLES, LA 70601

---

### Tests Ordered: 27800N (SAP 10-50/2K+MDAS/75)

<table>
<thead>
<tr>
<th>Test Order</th>
<th>Acceptable Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>CREATININE</td>
<td>164.8 mg/dl</td>
</tr>
<tr>
<td>PH</td>
<td>5.6</td>
</tr>
</tbody>
</table>

**Urine Substance Abuse Panel**

<table>
<thead>
<tr>
<th>Substance</th>
<th>Test Level</th>
<th>MS Confirm Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMPHETAMINES</td>
<td>Negative</td>
<td>1000 ng/mL</td>
</tr>
<tr>
<td>BARTIRBITURATES</td>
<td>Negative</td>
<td>300 ng/mL</td>
</tr>
<tr>
<td>BENZODIAZEPINES</td>
<td>Negative</td>
<td>300 ng/mL</td>
</tr>
<tr>
<td>COCAINE METABOLITES</td>
<td>Negative</td>
<td>300 ng/mL</td>
</tr>
<tr>
<td>MARIJUANA METABOLITES</td>
<td>Positive</td>
<td>300 ng/mL</td>
</tr>
<tr>
<td>METHADONE</td>
<td>Negative</td>
<td>300 ng/mL</td>
</tr>
<tr>
<td>METHAQUALONE</td>
<td>Negative</td>
<td>500 ng/mL</td>
</tr>
<tr>
<td>NCA-ANALOGUES</td>
<td>Negative</td>
<td>500 ng/mL</td>
</tr>
<tr>
<td>OPIATES</td>
<td>Negative</td>
<td>2000 ng/mL</td>
</tr>
<tr>
<td>PHENCYCLIDINE</td>
<td>Positive</td>
<td>25 ng/mL</td>
</tr>
<tr>
<td>PROPXYPHENE</td>
<td>Negative</td>
<td>300 ng/mL</td>
</tr>
</tbody>
</table>

**Urine Quantitative Results**

- **MARIJUANA METABOLITE:** >300 ng/mL
- **PHENCYCLIDINE:** 487 ng/mL

**Certifying Scientist:** KSKPD1 (Signature)

**Specimen Received and Processed in the Lenexa DHS Certified Laboratory.**

**Lab:** Quest Diagnostics-Lenexa
- **Address:** 10101 Renner Bivd
  - Lenexa KS 66215

>> END OF REPORT <<
Urine Result

Laboratory Report

SPECIMEN INFORMATION
Requisition #: 
Accession #: 
Collected: 1/14/2017 4:19 PM
Received: 
Reported: 1/14/2017 4:19 PM
Specimen ID:

DONOR INFORMATION
Name: 
Primary ID: 
Reason: RANDOM
Collection Site: ZZ

CLIENT INFORMATION
65140333
ILES MEDICAL TESTING
226 WEST PRIEN LAKE RD
LAKE CHARLES, LA 70601

*** POSITIVE/ABNORMAL REPORT ***

Tests Ordered: 27800N (SAP 10-50/240MDAS/15)

Urine specimen validity testing

<table>
<thead>
<tr>
<th>TEST</th>
<th>ACCEPTABLE RANGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specific Gravity</td>
<td>1.003 - 1.020</td>
</tr>
<tr>
<td>Oxidizing adulterants</td>
<td>Negative</td>
</tr>
<tr>
<td>Creatinine</td>
<td>9.0 mg/dl</td>
</tr>
<tr>
<td>pH</td>
<td>4.5-6.9</td>
</tr>
</tbody>
</table>

Urine Substance Abuse Panel

<table>
<thead>
<tr>
<th>Substance</th>
<th>Initial Test Level</th>
<th>Confirm Test Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amphetamines</td>
<td>Positive</td>
<td></td>
</tr>
<tr>
<td>AMPHETAMINE</td>
<td>1000 ng/mL</td>
<td>500 ng/mL</td>
</tr>
<tr>
<td>METHAMPHETAMINE</td>
<td>500 ng/mL</td>
<td></td>
</tr>
<tr>
<td>BARBITURATES</td>
<td>Negative</td>
<td>300 ng/mL</td>
</tr>
<tr>
<td>BENZODIAZEPINES</td>
<td>200 ng/mL</td>
<td></td>
</tr>
<tr>
<td>COCAINE METABOLITES</td>
<td>Negative</td>
<td>300 ng/mL</td>
</tr>
<tr>
<td>MARIJUANA METABOLITES</td>
<td>150 ng/mL</td>
<td></td>
</tr>
<tr>
<td>METHADONE</td>
<td>Negative</td>
<td>100 ng/mL</td>
</tr>
<tr>
<td>METHAMPHETAMINE</td>
<td>100 ng/mL</td>
<td></td>
</tr>
<tr>
<td>MDA-ANALOGUES</td>
<td>Negative</td>
<td>100 ng/mL</td>
</tr>
<tr>
<td>OPIATES</td>
<td>250 ng/mL</td>
<td></td>
</tr>
<tr>
<td>PHENCYCLIDINE</td>
<td>Negative</td>
<td>2000 ng/mL</td>
</tr>
<tr>
<td>PROPoxyPHENETE</td>
<td>2000 ng/mL</td>
<td></td>
</tr>
</tbody>
</table>

Urine Quantitative Results

<table>
<thead>
<tr>
<th>Substance</th>
<th>ng/mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMPHETAMINE</td>
<td>636</td>
</tr>
<tr>
<td>METHAMPHETAMINE</td>
<td>1419</td>
</tr>
</tbody>
</table>

>> REPORT CONTINUED ON NEXT PAGE <<

CERTIFYING SCIENTIST: KSBR01 (Signature Code)

SPECIMEN RECEIVED AND PROCESSED IN THE LENEXA DHHS CERTIFIED LABORATORY.

LAB: Quest Diagnostics-Lenexa
10101 Remer Blvd
Lenexa KS 66219

>> END OF REPORT <<
Laboratory Report

SPECIMEN INFORMATION
Requisition #: 
Accession #: 
Collected: 
Received: 
Reported: 1/14/2017 11:20 AM 
Specimen ID: 

DONOR INFORMATION
Name: 
Primary ID: 
Reason: OTHER 

Collection Site: ZZ

CLIENT INFORMATION
65140333
ILES MEDICAL TESTING
226 WEST PRIEN LAKE RD
LAKE CHARLES, LA 70601

Tests Ordered: 27800n (SAP 10-50/2K-MDAS/TS)

<table>
<thead>
<tr>
<th>Test</th>
<th>Initial Test Level</th>
<th>MS Confirm Test Level</th>
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</thead>
<tbody>
<tr>
<td>CREATinine</td>
<td>45.9 mg/dL</td>
<td>4.5-8.9</td>
</tr>
<tr>
<td>pH</td>
<td>7.2</td>
<td></td>
</tr>
<tr>
<td>OXIDIZING AGENTERANTS</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td>Urine Substance Abuse Panel</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AMPHETAMINES</td>
<td>Negative</td>
<td>1000 ng/mL 500 ng/mL</td>
</tr>
<tr>
<td>BARRITURATES</td>
<td>Negative</td>
<td>300 ng/mL 200 ng/mL</td>
</tr>
<tr>
<td>BENDODRILPINE</td>
<td>Negative</td>
<td>300 ng/mL 200 ng/mL</td>
</tr>
<tr>
<td>COCAINE METABOLITES</td>
<td>Negative</td>
<td>500 ng/mL 150 ng/mL</td>
</tr>
<tr>
<td>MARIJUANA METABOLITES</td>
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<td>500 ng/mL 150 ng/mL</td>
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<tr>
<td>METHADONE</td>
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<tr>
<td>METHAMPHETILONE</td>
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<tr>
<td>MDA-ANALOGUES</td>
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<tr>
<td>OPIATES</td>
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<tr>
<td>PHENCYCLIDINE</td>
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<tr>
<td>PROPYFENPHINE</td>
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<td>300 ng/mL 200 ng/mL</td>
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CERTIFYING SCIENTIST (KSAX02)

SPECIMEN RECEIVED AND PROCESSED IN THE KENEXA DHHS CERTIFIED LABORATORY.

LAB: Quest Diagnostics-Lenexa
1201 Lenexa Blvd
Lenexa KS 66219

>> END OF REPORT <<
Joe Wright has been a volunteer with our program for just over 2 years. Mr. Joe came to us after hearing a presentation given at University Methodist Church where he is an extremely active member. He is involved in various groups through his church and also out in the community. Mr. Joe is a member of the Krewe C’est Tout Bon. He and his wife Marty live in Lake Charles. Their children live in other states, but Joe and Marty travel often to see them and their grandchildren. Mr. Joe loves fishing and goes as often as he can. Mr. Joe also loves meeting new people. Mr. Joe has worked on 2 cases since he was sworn in as a volunteer. He has worked with 6 children and his current case has 4 children. Mr. Joe has visited with his children more than twice a month with both of his cases. He has been successful in advocating for the children to be in safe and permanent homes. Mr. Joe has dedicated 161.20 hours and 1,463 miles for his CASA children. Mr. Joe has also completed 38.50 in-service hours to learn more about how to help his children. Mr. Joe has gone above and beyond to better the chances for a successful life for his CASA children. We do love our dedicated volunteers!!!

Thank you Mr. Joe for what all you do on behalf of our foster children!!!