

HPS Newsletter

Hospital Pharmacy Management

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Alcohol Dependence: What Pharmacists Need to Know

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The term alcohol dependence is synonymous with alcoholism. A growing consensus views alcoholism as a chronic disease characterized by craving for alcohol, loss of control of use, physical dependence (presence of withdrawal symptoms, such as nausea, sweating, shakiness, and anxiety after stopping drinking) and tolerance to alcohol. According to the CDC, 13,050 Americans die from alcoholic-related liver disease. The number of alcohol-induced deaths, excluding accidents and homicides, is 22,073. Alcohol dependence and abuse cost the US approximately \$220 billion annually. Drinking excessively over time has numerous medical consequences including pancreatitis, increased risk of various malignancies, a worsening of hypertension, fetal damage during pregnancy, and cirrhosis of the liver. The psychosocial consequences of alcoholism can devastate the individual and family. An estimated 43% of US adults have had someone related to them who is a current or recovering alcoholic. While estimates vary, approximately 14 million US residents battle an alcohol addiction.

Pharmacists should remind patients that alcohol dependency treatment, such as counseling and/or medications are effective, leading to greater than 60% reductions in alcohol-related problems, 50% reductions in consumption, and 30% abstinent or decreasing to moderate drinking. Unfortunately, only 10% of those with alcohol dependence receive appropriate treatment. Effective, comprehensive management of alcoholism is complex, ranging from acute detoxification to marital and family counseling. In addition, many patients need access to psychological, medical/psychiatric, employment, legal, and social

services during the recovery process. While supervised 12-step self-help programs, such as Alcoholics Anonymous, are the cornerstone of treatment, the addition of pharmacotherapy can help reduce drinking, reduce relapse to heavy drinking, and maintain abstinence.

Several medications are FDA approved for maintenance therapy as adjuncts for treating alcoholism, each having specific advantages depending upon the patient being treated. Acamprosate reduces cravings for alcohol by decreasing the physiological arousal associated with prolonged alcohol withdrawal. Data from recent studies suggest that drinkers with 7-10 days abstinence are more likely to benefit from this medication. Patients who are unable to tolerate naltrexone or who show little response to naltrexone may benefit from a course of acamprosate. Disulfiram can provide a strong deterrent to drinking because of the intense aversive reaction caused when mixed with alcohol. This medication is likely to provide the greatest benefit when combined with a psychosocial treatment that emphasizes disulfiram compliance. Immediate release, sustained-release, and depot injection of naltrexone provide some relief from cravings and may blunt the pleasurable effects of drinking. Non-compliance with naltrexone greatly reduces the efficacy of this medication, making the once-monthly depot injection more appropriate for those with poor adherence.

Pharmacists are well-aware of the numerous and important drug interactions involving alcohol and should counsel patients accordingly. Since alcohol is a CNS depressant, drugs with sedating properties can potentially interact with alcohol causing increased sedation. Examples include benzodiazepines, tricyclic antidepressants, barbiturates, antihistamines, opiates, muscle relaxants, antipsychotics and anticonvulsants. Sedating drugs can interact in patients with alcohol dependence putting patient at increased risk for ataxia, somnolence, respiratory depression, and motor impairment that can lead to falls, accidents, and injury. Excessive use of acetaminophen with regular intake of

alcohol increases one's risk for liver toxicity. A disulfiram reaction (facial flushing, vomiting, tachycardia) can occur if alcohol is ingested with drugs such as metronidazole, sulfonyleureas or isoniazid; thus, patients must also be warned about this too.

In addition to routine screening for drug-alcohol interactions, pharmacists with direct patient care should screen patients they suspect for alcohol abuse or dependency. The most widely used tool is called the CAGE questionnaire, whereby the pharmacist can ask the following questions:

- **C** - Have you ever felt you should Cut down on your drinking?
- **A** - Have people Annoyed you by criticizing your drinking?
- **G** - Have you ever felt bad or Guilty about your drinking?
- **E** - (Eye opener question) Have you ever had a drink first thing in the morning to steady your nerves or to get rid of a hangover?

In situations where two or more "yes" answers are given, it is likely that a problem with alcohol exists and pharmacists should consider referring patients back to their primary care physician for diagnosis, or possibly refer patients to self-help programs.

Under New Law, Kidney Transplant Priorities Will Shift

Written by Sy Kraft, B.A.
Copyright: Medical News Today



Young Patients Waiting for Kidneys May Get Priority

If the new changes pass to the transplant recipient list priorities, organs will be allocated to those who are expected to live longest and to individuals who are within 15 years of the age of the donor. Only around 17,000 Americans actually receive the required transplant they need each year, and nearly 5,000 people die waiting for their transplant. The current established policy disregards age and health status, and only accounts for where the patient is in line, which right now is approximately a 70,000 name list, with over 110,000 on the waiting list.

The nation's organ transplant network is proposing that patients and transplant kidneys be graded and separated into groups. The healthiest and youngest 20% of patients and kidneys would be segregated into a separate pool so that the best kidneys would be given to patients with the

longest life expectancies. However, the remaining 80% of patients would be separated into groups that would limit the age difference between the patient and the organ to 15 years or under. For example, someone who is 60 could only get a donor kidney from someone age 45 to 75.

The principle is used during extreme danger would now apply, meaning resources are allocated to those who are most likely to survive. These new proposed changes are believed to be an improvement, as someone expecting to live just 10 more years, does not need an organ that can adequately function for 40 years or more.

The United Network for Organ Sharing (UNOS) is charged with the difficult task of organ transplant management. When organs are donated, a complex process begins. UNOS maintains a centralized computer network which links all organ procurement organizations (OPOs) and transplant centers. Transplant professionals can access this computer network 24 hours a day, seven days a week.

Every day, the Organ Center handles at least 350 requests from transplant organizations for organ placement assistance, waiting list modifications, policy information, and organ transportation assistance.

In the United States, nearly 90,000 men, women, and children are waiting for kidney transplants for example. Potential recipient's struggle to live depends on a complex and technologically advanced organ allocation system that links patients with organs donated by strangers. The nation's organ-transplant network is considering a change in their Kidney Transplant Policy that will give priority to younger, healthier people over older, sicker patients for the best kidneys.

The National Organ Transplant Act (NOTA) of 1984 called for an Organ Procurement and Transplantation Network (OPTN) to be created and run by a private, non-profit organization under federal contract. UNOS was first awarded the national OPTN contract in 1986 by the U.S. Department of Health and Human Services. UNOS continues as the only organization ever to operate the OPTN.

Did you know that the length of time donated organs and tissues can be kept outside the body vary? Here are the facts by organ:

- Heart: 4-6 hours
- Liver: 12-24 hours
- Kidney: 48-72 hours
- Heart-Lung: 4-6 hours
- Lung: 4-6 hours

In response to the shortage of organs for transplantation, relatives, loved ones, friends, and even individuals with no prior relationship are serving as living donors for the growing number of people on the national organ transplant waiting list.

A living donor can save and/or greatly improve the quality of life of a transplant candidate. However, one should only make a decision about donating an organ after being fully informed of the possible risks and benefits.



How to use Email Effectively & Efficiently at Work

Understanding how to use email effectively will help you be a better communicator at work and convey a professional image. Here are some tips for proper email etiquette.

Email Do's

Make sure it's necessary to send an email. Maybe you could walk over to someone's desk or pick up the phone instead.

Always keep your message to the point. No one has time to waste on long winded emails.

Be careful about attachments. A large attachment can be difficult to pen or can crash someone's computer.

Email Don'ts

Don't use email to discuss confidential matters. Your work email is not private and it can be misdirected easily.

Never send an email when you're angry or upset. Wait at least a day to send your email. You'll be glad you did.

Don't automatically hit "Reply All." Make sure that all the recipients are the people you really want to send it to.

Writing the subject line

Subject lines should be brief. They should summarize the message.

Write a new subject line in a chain of emails. It could help readers quickly get to the point.

Writing the body of the email

Split long blocks of text into separate paragraphs. Your message will be easier to read and understand. Be sure to proofread your email. Always use spell-check before you press the send button.

Remember that effective and to-the-point emails convey a sense of professionalism and are often the ones people respond to first. Communicating effectively in person or in an email is a valuable business skill.

FDA, Drug Makers Reach Drug Review Fee Deal

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Under a proposed new deal, the U.S. Food and Drug Administration will provide quicker, more

predictable reviews of new prescription drugs in exchange for continuing to receive hundreds of millions of dollars in fees from drug companies.

The draft agreement, released ... after months of closed-door meetings between FDA and drug makers, would extend a two decade-old program in which fees paid by the drug industry supplement the FDA's budget. Under the deal, the FDA would provide more frequent updates to drug makers on the status of certain drug reviews. The agreement must be approved and drafted into law by Congress before Oct. 1, 2012.

Accidental Medication Poisonings in Kids on the Rise

Sept. 16, 2011 (HealthDay News)



Despite ongoing prevention efforts, a growing number of young children are being accidentally poisoned with medications. The study, which was based on data reported to the American Association of Poison Control Centers between 2001 and 2008, found that

medication poisoning among children aged 5 and under increased by 22%, although the number of children in the United States in this age group rose by only 8% during the study period.

In conducting the study...the researchers reviewed information on over 544,000 children who landed in the emergency department due to medication poisoning over the course of the seven-year study period.

The vast majority (95%) of emergency department visits were the result of accidental self-ingestion. Prescription drugs were involved in 55% of the emergency visits, 76% of the hospitalizations and 71% of significant injuries. Opioid-containing pain medications as well as muscle relaxants, sleeping pills, and heart medications had the biggest impact.

The researchers suggested that the reason for the trend is likely due to greater availability and easier access to medications in children's homes. They also noted that "poison-proofing" efforts, such as safe guards on packaging and child-proofing in the home, may have declined in recent years. "Prevention efforts of parents and caregivers to store medicines in locked cabinets or up and away from children continue to be crucial. However, the largest potential benefit would come from packaging design changes that reduce the quantity a child could quickly and easily access in a self-ingestion episode, like flow restrictors on liquids and one-at-a-time tablet dispensing containers," said Bond. He added that these types of changes should apply to both pediatric and adult prescription and over-the-counter medications.

Risk Factors for Breast Cancer: BRAC1 and BRAC 2

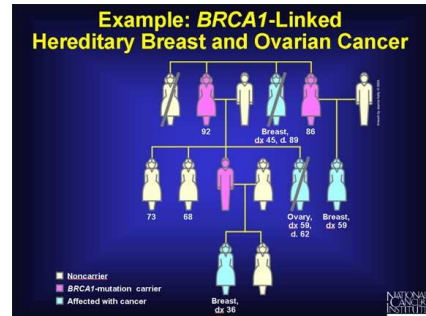
by Karen Siroky, RN, MSN, Clinical Education Director, RxSchool (Source: National Cancer Institute, 2010)

In the United States, breast cancer is the most common non-skin cancer and the second leading cause of cancer-related death in women. Approximately \$8.1 billion is spent each year on treatment of breast cancer. One in eight women will be diagnosed with cancer of the breast during their lifetime. The median age for diagnosis is 61 years of age.

The incidence of breast cancer is highest in whites, but African Americans have higher mortality rates than other racial or ethnic group in the U.S. The gap in mortality between African Americans and whites is wider now than it was in the early 1990s. Although the breast cancer diagnosis rate has increased since the early 1990s, the

overall breast cancer death rate has dropped steadily. This is largely due to increasing awareness of breast cancer resulting in earlier detection, as well as advances in medical technology producing more effective treatment options.

In spite of these advances, in 2009 there were 192,000 estimated new cases and over 40,000 deaths. Commonly known risk factors include age (risk increases with advancing age), previous history of breast cancer, family history, abnormal breast



tissue changes, early onset of menses, late/first pregnancy, nulliparous, late menopause, and certain hormonal therapy. Other less commonly known factors include obesity, lack of physical activity, and increased alcohol consumption. Studies are underway to determine if there are other environmental factors that may also link to breast cancer.

In addition to these risk factors, newer, significant risk factors relate to the identification of two specific genetic mutations: BRAC1 (breast cancer susceptibility gene 1) and BRAC2 (breast cancer susceptibility gene 2). A woman's lifetime risk of developing breast and/or ovarian cancer is significantly increased if she inherits a BRCA1 or BRCA2 mutation. Such a woman has an increased risk of developing breast and/or ovarian cancer at an early age (before menopause) and often has multiple, close family members who have been diagnosed with these diseases. Both mutations also increase the risk of various other cancers. Studies have shown that people who inherit these genes are five times more likely than the general population to develop breast cancer.

If a woman (or man) has a very strong family history with several members who have developed breast cancer, they may pursue genetic testing for the BRAC1 or BRAC2 gene mutations. If the results are negative, the lifetime risk for that person will be the same as the general population – in other words there is no guarantee she will NOT develop breast cancer, especially if she has one or more of the other risk factors.

If the results are positive, several options exist including close surveillance or prophylactic surgery (including hysterectomy, oophorectomy, and/or mastectomy). Other additional steps may include avoiding behaviors that increase risk and possible chemoprevention – taking specific medications that are shown to retard breast cancer growth (e.g. tamoxifen).

The message is clear – great strides are being made against breast cancer, and the added information that genetic testing provides is critical to further reducing the occurrence and deaths from breast cancer. But there is still work to be done to further refine these tests and to provide much needed education, counseling, and increased options when the tests show that a person has this dangerous mutation.

Why your allergies are bugging you

By Aviva Patz, Health.com, September 10, 2011

Every year, sneeze sufferers swear: "This is the worst allergy season ever." And they're right. "Pollen levels are increasing, pollen seasons are getting longer, and more people are developing allergies," says Estelle Levetin, Ph.D., chairwoman of the aerobiology committee for the American Academy of Allergy, Asthma & Immunology.



In fact, this year's fall allergies...will most likely last up to 27 days longer than average in the northernmost parts of North America, going even into November in some spots, a new study suggests. While spring and fall allergies cause the same symptoms (sneezing, itchy eyes, and runny nose), triggers are different.

Spring allergies, which run from February to late July, are brought on by pollen from trees, grasses, and weeds. Fall allergies go from mid-August through the first autumn frost, and are chiefly set off by pollen from the ragweed plant, mold, and dust mites.

The seasons are longer

Thanks to global warming, spring allergies now start sooner and fall allergies end later...says Jeffrey G. Demain, M.D., director of the Allergy, Asthma & Immunology Center of Alaska. We're using more and more carbon-based fuels and generating greenhouse gases (such as carbon dioxide) that trap heat from the sun in our atmosphere. This makes temperatures rise, prompting plants and trees to flower—and release pollen—earlier each spring; in the fall, they delay the death of ragweed plants from frost, extending the pollen season.

There's more pollen than ever

Higher amounts of carbon dioxide not only kick-start pollen production, they also boost the amount of pollen each plant generates, too -- especially in urban areas, where the gas is more plentiful. To add insult to injury, CO2 is making pollen more potent, too. "There's more allergen now in each grain than there used to be," Demain says.

And pollen isn't the only allergen on the rise. Increasingly balmy temperatures mean more moisture in the air, which creates mold. "The higher temperatures and gas may increase not just the growth of mold but also its spore production—which is how it distributes allergens—both indoors and out," Demain says.

More people are developing allergies

The number of Americans with allergies is two to five times higher now than it was about 30 years ago....Genes play a role in your susceptibility, but the blooming allergy boom is most likely due to the longer, more intense pollen seasons — plus these expert-supported theories:

We're too clean. Now that we're exposed to less dirt and bacteria (thanks in part to our obsession with antibacterial everything), and have fewer scourges like polio and parasites to fight, our immune systems are quicker to overreact to otherwise harmless substances like pollen, says Levetin.

At the same time, our environment is too dirty: Studies show that pollution (such as exhaust fumes) can trigger allergic flare-ups. Our modern diet is hurting us. Today's processed, preserved foods lack the tough fibers of the plants and grains our ancestors feasted on, throwing off the delicate balance of bacteria in our guts and setting us up for allergic sensitivity, says University of Michigan professor of internal medicine Gary Huffnagle, Ph.D. Studies suggest, too, that as use of antibiotics — which also disrupt bacteria in the gastrointestinal tract — has surged, so have allergies.

The good news: Even if we're now more prone to sniffing, sneezing, and itchy eyes, "there are many more treatment options on the market now," says Levetin. "The current medications are so much better than they used to be."



Preparing For Wildfires Is Everyone's Responsibility



With an increase in the wildland fire risks across Texas due to extended drought conditions and increasing urbanization, now is the time to be more Firewise.

As a homeowner, you are not powerless in your defense against wildfires. By taking a proactive approach to wildfire prevention and home defense, you can significantly increase your safety and your home's likelihood of survival during a catastrophic wildfire. Unfortunately, these measures cannot guarantee your safety in the face of catastrophic fires. Therefore, it's of paramount importance to "Have an Exit Strategy."

"Have an Exit Strategy" where you live, work, play, and when you're on the road. As the drought continues to intensify, you and all Texans face extreme danger of wildfire this year, so be certain to have an escape plan. Fire propelled by strong winds can move as fast as 60 miles per hour. When told to evacuate, leave the area immediately. Choose a route that leads away from the fire. Stay alert to changes in the speed and direction of fire and smoke.

Scarlet Fever Outbreak: Should we worry?

By Lisa Collier Cool
June 23, 2011

Scarlet fever...is back, with an outbreak in Hong Kong that has killed two children and sickened hundreds. More than 21,000 cases have also been reported in China so far...nearly quadruple the rate for the same period in 2010, while infections have tripled in Macau, prompting the CDC to issue a warning to travelers to China, Hong Kong, and Macau.

What makes the outbreak particularly alarming is that the strain infecting the region is 60% resistant to antibiotics commonly used to treat, compared to 10-30% resistance in previous strains...

Although scarlet fever is no longer as lethal as it was in the 19th century...the disease has never fully disappeared. Between 1999 and 2006 there were 9,400 cases of scarlet fever in the U.S....Hong Kong scientists who isolated the bacteria in a six-year-old patient found a genetic mutation that may make the new strain more contagious than usual, which could explain the dramatic rise in cases in the affected region.

So far, there are no reports of any surge in scarlet fever cases in the U.S. Health authorities warn travelers to Hong Kong, China, and Macau to wash their hands frequently and avoid crowds and places that lack fresh air to reduce the risk of catching the disease.

The same bacteria that cause strep throat trigger scarlet fever: Group A streptococcus. In order to cause scarlet fever, the bacteria must produce a certain toxin, which causes a skin reaction, leading to the characteristic bright red rash that gives the disease its name.

The infection is transmitted through airborne droplets released when an infected person coughs or sneezes. You can also catch it by touching surfaces contaminated by the spray and sharing beverages, food, or eating utensils with an infected person. In *rare* cases scarlet fever can be spread by contaminated food. The incubation period is 12 hours to 7 days and people with the disease can infect others before the symptoms show up.

The hallmark of scarlet fever is a sunburn-like rash with tiny red bumps that makes the skin feel rough. The patient's tongue often resembles a strawberry – or may have a whitish coating. Other symptoms include a fever of 101 or higher, a red sore throat that makes swallowing painful, swollen glands, and less commonly, vomiting or belly pain. After the rash fades, skin on the fingertips and toes may peel.

Scarlet fever is treated with antibiotics, rest, and fluids. Although the Hong Kong strain is resistant to some of the antibiotics used to treat the disease, penicillin still works. Antibiotic resistant bacteria are a growing health threat worldwide, as more and more bacteria are mutated to be resistant to some or all of the common antibiotics.

Texas expert: Addiction science has taken giant steps

By Carlton K. Erickson
SPECIAL TO THE AMERICAN-STATESMAN

Unlike 20 years ago, the quality of addiction science now compares favorably with research on the causes and treatments for cancer, heart disease and other life-threatening illnesses. Because of breakthroughs in genetics, neurobiology, and neuropharmacology, scientists now know that some people who drink or use drugs harmfully can develop a full-blown disease, making them unable to stop without help. It is true that many people drink or use drugs too much because of poor choices. However, significant numbers of drug users develop the disease of chemical dependence, commonly known as addiction.

People who argue over whether alcoholism and addiction are diseases are like blind persons examining an elephant. They believe only the parts they touch. If the only part of addiction one has touched is the pain caused by an alcoholic parent that will shape the belief. Or if they have only been affected by their own use of alcohol or drugs that will limit their understanding.

But the research of the past 20 years has now firmly shown that one type of drinking and drug use — chemical dependence — is a definitive, diagnosable brain pathology in the realm of epilepsy, Parkinson's, and Alzheimer's. This means that what is popularly called "addiction" is a neuropsychiatric problem resulting from "dysregulation" of specific parts of the brain.

In the normal human brain, the "reward pathway" (scientifically known as the mesolimbic dopamine system) enables us to experience pleasure or the feeling of joy that accompanies normal daily rewards — the birth of a new baby, college graduation, a wedding, or the smile of a child. In the "addicted" brain, something goes wrong with the reward pathway so that those pleasurable nerve signals being sent to the frontal lobes (the thinking/processing/judging part of the brain) are misinterpreted as encouragement to continue to use the chemical even though adverse consequences may be looming or actually occurring.

Simply put, addictions are the result of our brain losing the ability to recognize that it is time to stop using drugs. It is the same as a schizophrenic person losing the ability to dampen "internal voices" without getting some type of help. Addiction, or chemical dependence, is far more serious and in many ways different from the other diagnosable drug overuse condition — called drug abuse — in which people make bad choices and show foolish (and often illegal) behaviors.

Drug abuse is a self-controllable condition that often is reduced by education, punishment, maturity, increased will power, or sometimes simply learning from an embarrassing or costly experience. Drug abusers who won't stop might need a bit of tough love to help them see how they are harming themselves and others.

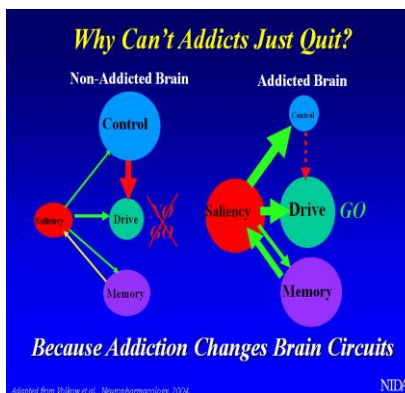
Drug abusers are the ones who are most likely to respond to the "war on drugs" — take away their drugs or punish their use, and they usually give up. People who are chemically dependent, on the other hand, usually require powerful intervention and intensive treatment that can be expensive and prolonged. During Prohibition, from 1920 to 1933, the national ban on alcohol manufacturing significantly reduced the amount of alcohol consumed in the United States. Yet the number of alcoholics — those chemically dependent on alcohol — remained roughly the same.

In desperation, they turned to black-market whiskey and more dangerous forms, such as rubbing alcohol. This illustrates the

extraordinary "need" for the drug caused by dysregulation of the brain in those who are chemically dependent.

Breakthrough research in the addiction field has been massively underreported considering the financial and societal cost of these diseases. For example:

- Practitioners can now specifically diagnose chemical dependence, using research criteria published by the American Psychiatric Association.
- These same criteria clearly discern willful drug abuse from pathological chemical dependence.
- A formidable body of high-quality neuroscience and genetic research literature has determined that a certain percentage of alcohol and other drug users will develop chemical dependence. For example, about 25 percent of heroin users, 32 percent of nicotine users, and 15 percent of alcohol users will become chemically dependent during their lifetimes.
- There is overwhelming evidence that chemically dependent individuals have a brain disease that can develop from early use but also from long-term use of drugs and that genetic vulnerability plus other environmental factors also play a role.
- Drug abuse and chemical dependence respond differently but well to treatments



developed and validated over the past 10 to 15 years, causing an enormous decrease in suffering for those with the disease and those they touch. In fact, several studies show that for every dollar spent for treatment, seven health care dollars are saved because of reduced accidents, medical complications and injuries, and improvements in attendance, performance and behavior in the workplace.

- Alcoholics Anonymous and its many spinoff 12-step programs that have historically saved the lives of "alcoholics" and "addicts" have been researched so thoroughly in the past 10 years that they are considered to be "evidence-based" — that is, research-proven. This means that in

the future, insurance companies may reimburse reputable treatment facilities for using 12-step work as part of their holistic treatment programs.

- Anti-craving and abstinence-enhancing medications, although not magic bullets to "cure" alcohol and other chemical dependencies, are sufficiently effective that they have helped hundreds of thousands of people stay clean and sober, especially by preventing relapse. Continuing genetic studies are expected in the future to provide even better reward medications that target reward systems.

- Most exciting are the recent studies with brain scans, indicating how 12-step programs and addiction therapies work. It appears that they normalize the "dysregulation" of the brain's reward pathway, involving a change in neurotransmitter systems that have gone wrong. Research on addiction has been ongoing for more than 20 years in at least four colleges and several departments at the University of Texas, including the College of Pharmacy. Other academic institutions around the world, many in collaboration with UT, have contributed to our knowledge about the causes of harmful drinking and drugging; the genetics of alcohol dependence; the development of new medications to help individuals in the grip of addiction; and social, psychological and clinical correlates to basic science findings in this area.

UT researchers are especially collaborating with their colleagues in health science and medical centers around the nation. Even more importantly, UT scientists teach undergraduate, professional and graduate students, as well as the public, about these new findings. Great progress is being made in the attack on addiction, through the efforts of UT faculty to change the world. For UT students experiencing problems with alcohol and drugs, help is available through the Center for Students in Recovery.



Small Doses.....
By Mike Petry, MS, RPh
Clinical Pharmacist

FDA UPDATE
Safety Label Changes for
Simvastatin

Recent review of clinical trials data and submitted adverse event reports on the popular cholesterol lowering drug simvastatin has prompted the Food and Drug Administration (FDA) to modify the label information for simvastatin and simvastatin-containing medications (Zocor[®], Vytorin[®],

Simcor[®]). The data have shown that patients taking simvastatin 80mg had an increased risk of muscle injury compared to patients taking lower doses, or other statin drugs.

The risk of injury is highly associated with:

- use of 80mg of simvastatin within the first year of treatment
- drug-drug interactions with certain medications
- a genetic predisposition for simvastatin-related muscle injury

At this time, the FDA recommends the following:

- Simvastatin 80mg should NOT be prescribed to new patients
- Patients who are unable to adequately lower their level of LDL-C on simvastatin 40mg should NOT be given the higher 80mg dose; instead, they should be placed on alternative LDL-C lowering treatment(s)
- Simvastatin 80mg should be used only in patients who have been taking the dose for at least 12 months or more, and have not experienced any muscle toxicity
- Simvastatin should not be used with certain medications which can raise the level of simvastatin in the body and increase the risk of myopathy.

The maximum daily dose of simvastatin should not exceed 10mg if the patient is also taking any of the following drugs:

- Amiodarone (Cordarone[®]/Pacerone[®])
- Verapamil (Calan[®]/Isoptin[®])
- Diltiazem (Cardizem[®])

The maximum daily dose of simvastatin should not exceed 20mg if the patient is also taking any of the following drugs:

- Amlodipine (Norvasc[®])
- Ranolazine (Ranexa[®])

Simvastatin is contraindicated with any of the following drugs:

- Itraconazole (Sporanox[®])
- Ketoconazole (Nizoral[®])
- Posaconazole (Noxafil[®])
- Erythromycin (EryTab[®])
- Clarithromycin (Biaxin[®])
- Telithromycin (Ketec[®])
- HIV protease inhibitors Nefazodone (Serzone[®])
- Gemfibrozil (Lopid[®])
- Danazol (Danocrine[®])
- Cyclosporine (Sandimmune[®]/Neoral[®]/Gengraf[®])

Patients taking simvastatin should be advised to contact their health professional if they experience any of the following symptoms:

- Muscle pain, tenderness or weakness
- Dark or red-colored urine
- Unexplained fatigue

Patients should also be advised to avoid drinking large quantities of grapefruit juice (>1 quart daily)

Discontinued Acetaminophen Combination Products

In an attempt to reduce the risk of liver toxicity, the FDA announced in January that by 2014 all acetaminophen containing prescription combination products will be limited to a maximum of 325mg of

acetaminophen per dosage form. All manufacturers will also be required to update combination product labels to warn of the potential risk for severe liver injury and allergic reactions. The three year implementation period should allow enough time for product reformulations to be completed and therefore avoid any drug shortages. At this time, the FDA has exempted any acetaminophen containing OTC products.

Hospital pharmacy formularies will need to be updated, and Pharmacy and Therapeutics Committee therapeutic interchange protocols for acetaminophen combination products will need to be updated and/or developed.

Please sign and date for pharmacy nursing in-service.

Sign _____

Date _____

Do You Have Your NABP e-Profile ID Number Yet?

All pharmacists and pharmacy technicians will be required to use this new NABP e-profile ID number and the month and day of their birth for all CE programs, both live and correspondence,*beginning Fall 2011.

The new system will authenticate and store all CPE units received from ACPE-accredited providers. ACPE providers will no longer issue paper or electronic certificates, after a transition period. The CPE units will be made available to the state boards of pharmacy where the pharmacist or pharmacy technician is licensed or registered.

To get your NABP e-profile ID number, go to www.nabp.net <<http://www.nabp.net>> and select the CPE Monitor Program or to www.CPEmonitor.net <<http://www.CPEmonitor.net>>. There will be a hyperlink within the text. Once your information has been entered, you will receive an e-mail message from NABP that contains your NABP e-profile ID number. You will need this number for all your future CPE programs.

Once you have your ID number, you can log on to www.MyCPEmonitor.net

<<http://www.MyCPEmonitor.net>> or the CPE Monitor section of the NABP website to monitor your CE credits.

<http://www.nabp.net/programs/cpe-monitor/cpe-monitor-service/index.php>