HCV ADVOCATE WEEKLY NEWS REVIEW

Review of HCV, HBV and HIV/HCV Coinfection Related News and Highlights

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Week Ending: March 21, 2009

In This Issue:

- It's time to consider needle exchange program
- Accused Nurse Sparks Dirty Needle Investigation
- Protect your child's liver: Positive Parenting
- Tattoo secrets revealed: What Pamela Anderson wishes she had known
- Telbivudine Better Than Lamivudine for Chronic Hepatitis B
- Digestive and liver diseases: no joking matter
- Music and coffee spread awareness
- Hepatitis B Testing Urged for Non-Hodgkin's Lymphoma Treatment: Presented at NCCN
- Progress Reported Against Gene Involved in Hepatitis C
- Nurse gets injury payout after 36 years
- Have a heart, give a liver
- Vertex Hep C Drug Improves Cure Rate in Study
- Sustained Viral Response Indicates HCV Infection Cure
- FDA issues warning on sharing insulin pens and cartridges
- Syringe scandal could be a wake-up call
- 2-day results predict ultimate response to therapy in chronic hepatitis C
- Human Genome Sciences: Albuferon unlikely to threaten HCV standard of care
- Patients Suffer as a Result of Insurance Pricing Scheme

It's time to consider needle exchange program

http://www.reporternews.com
William Martin

Few images of drug use are more potent than that of the needle -- the needle in the shaky hand of a junkie searching the tracks on his arm or leg for a vein still able to receive one more injection; the needle hanging from the arm of an addict unconscious or dead from an overdose; the contaminated needle passing its deadly load of HIV or hepatitis to the next user and, through him, to his wife or lover and their unborn child.

A contaminated needle is an extremely efficient transmitter of a blood-borne disease. According to the Centers for Disease Control and Prevention, more than a third of AIDS cases in the United States have occurred among injecting drug users (IDUs), their sexual partners and their offspring. Hepatitis C, the most dangerous variant of that disease, is found in the blood of 70 to 90 percent of all adult IDUs.

One may regard such statistics as a matter of just desserts, regrettable effects of an avoidable cause. But those who hold such views should consider the enormous expense of treating people infected with HIV/AIDS or hepatitis C -- more than $300,000 per case for either disease, a high proportion of which is borne by Medicaid and other public funds. Thus, whether driven by compassion, fiscal prudence or self-defense, rational public policy will seek to reduce the incidence of HIV/AIDS, hepatitis and other diseases spread by injecting drug users. Fortunately, the means to such a reduction are well-known and thoroughly proven.

For nearly two decades, public health officials in Europe, Australia and Canada have operated programs that allow addicts to exchange used needles for clean ones. More recently, numerous countries in Asia, Latin America and the developing world have followed suit. This greatly reduces the incidence of blood-borne diseases and limits disposal of needles in places where they can infect children, sanitation or health workers, police and others who might come in contact with them. A 2002 survey of needle exchange programs (NEPs) in 103 cities found that cities with NEPs experienced an average annual decrease in HIV cases of 18.6 percent over the decade of the 1990s; cities without such programs had an average 8.1 percent increase. Findings for hepatitis C were similar.

The science is clear. During the 1990s, the federal government and various major professional organizations funded careful scientific studies of NEPs. Without exception, every independent commission to look at this issue has concluded that these programs dramatically reduce the spread of blood-borne diseases without increasing drug use. Moreover, as a direct result of contact with public health staffers involved in the program, many users voluntarily enter formal treatment programs.

In the United States, IDUs, AIDS activists and public health officials operate needle exchange programs in more than 180 cities. Texas is the only state in the union that still prohibits the purchase or possession of syringes for purpose of injecting illegal drugs. As the state with fourth-highest HIV/AIDS rate in the nation, this is not a lone star of which we can be proud.

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Given the overwhelming evidence, why have policymakers resisted establishment of such proven lifesaving programs? Why have politicians and platforms of both major parties repeatedly vowed, "Not a dime for needle exchange programs!"? The real reason may be fear that any sign of being "soft on drugs" will hurt their standing among people who have not looked at the issue. But the rationale most commonly, often honestly, offered is, "It sends the wrong message."

Before we accept that rationale, we need to think about the message we send to IDUs: "We know a way to dramatically cut your chances of contracting a deadly disease, then spreading it to others, including your unborn children. It would also dramatically cut the amount of money society will have to spend on you and those you infect. But because we believe what you are doing is illegal, immoral and sinful, we are not going to do what we know works. As upright, moral, sincerely religious people, we prefer that you and others in your social orbit die."

The Texas Legislature is considering a bill to permit needle exchange programs. No responsible person wants to encourage drug abuse. No fiscally prudent person wants to waste money simply to satisfy a sense of righteous indignation. No compassionate person wants to consign people unnecessarily to death or a living hell. Fortunately, providing injecting drugs users with access to sterile syringes allows us to be responsible, prudent and compassionate -- admirable criteria for good public policy.

William Martin is a Senior Fellow at the James A. Baker III Institute for Public Policy at Rice University. A fuller version of this article may be found at http://www.bakerinstitute.org/programs/drug-policy .

Accused Nurse Sparks Dirty Needle Investigation

http://cbs4denver.com

BOULDER, Colo. (AP) — A former nurse accused of stealing pain medication intended for surgical patients has been tested for HIV and hepatitis after telling authorities he sometimes used dirty needles on patients.

The Daily Camera newspaper reports that the former nurse at Boulder Community Hospital -- 27-year-old Ashton Paul Daigle -- told police in a taped interview about using dirty needles to replace the drug fentanyl with a saline solution.

The tape was played for victims. The U.S. Attorney's Office in Denver confirmed to the newspaper that Daigle has been tested for HIV and hepatitis and that the tests came back negative.

Still, the office notified the patients.

March 16, 2009

Protect your child's liver: Positive Parenting

By Datuk Dr Zulkifli Ismail
http://thestar.com.my

Your child may have already been given the hepatitis B vaccine, but have you given thought to the other hepatitis diseases that may also harm him? Find out more on what you can do to protect your child.

THE liver is a vital organ in your body. It helps to process nutrients, remove toxins, fight off infections, store energy, and stop bleeding. To allow your liver to keep performing well, you need to protect your liver from various diseases, which can cause liver damage. One of the diseases that may harm your liver is hepatitis.

Hepatitis is an inflammation of the liver, most commonly caused by a viral infection. The five main hepatitis viruses are A, B, C, D, E and G.

Hepatitis A, B and C are the most common types of hepatitis diseases. They vary in terms of severity, means of spread, epidemic features, and preventive measures. Hepatitis can cause the liver to swell and lose its ability to function. It can also lead to cirrhosis (scarring), liver failure or cancer of the liver.

As a parent, you definitely want to keep your child healthy and protect him from this dreaded group of diseases. The good news is, vaccines are currently available for the prevention of hepatitis A and B.

Prevent hepatitis A

Hepatitis A is a disease which goes away within a few weeks. It rarely leads to permanent liver damage in healthy people. The hepatitis A virus is found in stools of the infected person. People most commonly get infected when they consume food or drinks that are contaminated with the infected person's stool. Lightly cooked seafood like cockles contaminated by faeces or sewage provides a suitable medium to spread hepatitis A.

There is a chance of an outbreak in day-care centres because many young children wear diapers. If an infected child's stool gets on their hands, they may contaminate the things they touch and transmit the virus to other children who touch these contaminated surfaces. Caregivers may also infect others if they do not wash their hands thoroughly after changing a child's diaper.

Hepatitis can also spread through infected food handlers, consumption of undercooked oysters, clams, or mussels from contaminated waters, traveling to countries with poor sanitation, and injecting-drug users.

The risk of developing symptoms among people infected with hepatitis A is correlated with age. In children below 6 years of age, there are usually no symptoms. Only 10% of the infected children develop jaundice.

On the other hand, infection causes clinical disease among older children and adults, with jaundice occurring in more than 70% of cases. The good news is, once a person gets infected, life-long immunity to the virus is induced.

Prevention is possible through good hygiene practices. However, the best way to protect your child is through vaccination. The hepatitis A vaccine is now available in Malaysia for those above one year of age. Two doses given six months apart are required for full immunity against

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hepatitis A. The duration of protection is 14-20 years for children and at least 25 years for adults. It has also been reported that the vaccine is 85% effective in protecting against the virus.

Keep away from hepatitis B

Hepatitis B can cause chronic liver disease, which is potentially life-threatening. The chance of hepatitis B developing into a chronic disease depends on the age at which a person becomes infected. The younger you are, the higher the risk of a chronic infection. Chronic infection occurs in 90% of infants infected at birth, 30% of children infected at age one to five years and 6% of people infected after age five years.

The hepatitis B vaccine, the first vaccine indirectly related to the prevention of liver cancer, has been a mandatory vaccine under the National Immunisation Schedule since 1989. Since its introduction, there has been a decline in the number of Hepatitis B virus (HBV) carriers in our country. Full immunisation requires an administration of three doses. Hepatitis B vaccine is 90% effective in protecting against the virus, its chronic consequences, and liver cancer. Protection lasts at least 20 years and could be life-long.

Advancements in vaccines for hepatitis

A combination vaccine for hepatitis A and B is now available for those above 16 years of age. It combines inactivated hepatitis A and recombinant hepatitis B.

This combination vaccine consists of three doses. The first dose is followed by the second dose a month later, and the final dose is given six months after the first dose (0, 1, 6 month schedule).

It has been reported that the combination vaccine is more than 99% effective for hepatitis A and 93-97% effective for hepatitis B.

Technology today has made protection against hepatitis A and B available. There will be more hepatitis vaccines to come in the future.

Tattoo secrets revealed: What Pamela Anderson wishes she had known

http://www.examiner.com
Dr. Lissa

Last time I mentioned Tattoo Barbie, the 50 year old toy that teachs girls how cool it will be when they can get a real tattoo. of their own For now they can just practice. Well, tattoos are not child's play. And complications from tattoos are the dirty little secret no one wants to talk about. Sure most people want to think that they're sexy and a sign of creativity or a quirky personality. But like the Sneeches, when everyone has one, isn't it just, well, average?

The evidence has been mounting for the past decade that tattoos are not as safe as most believe- even when done in commercial tattoo establishements.

Tattoo inks are classified as cosmetics, so they aren't regulated or approved by the Food and Drug Administration (FDA).The pigments and dyes used in tattoo inks aren't approved for injection under the skin. Long-term effects of these are unknown. They are also not regulated in

most states. So, the risk those who wish to release their inner creativity is greater than most believe.

Specific risks of tattoos include:

- **Blood-borne diseases.** If the tattoo equipment is contaminated with the blood of an infected person, you can contract a number of serious blood-borne diseases, which include **hepatitis C, hepatitis B, tetanus, tuberculosis and HIV** — the virus that causes AIDS. Pamela Anderson says she contracted hepatitis C this way.
- **Skin disorders.** Your body may form **bumps around tattoo ink**, especially if your tattoo includes red ink. Tattooing can also cause areas of raised, excessive scarring (keloids), if you're prone to them.
- **Infections.** Tattoos can lead to local bacterial infections. Typical signs and symptoms of an infection include redness, warmth, swelling and a pus-like drainage. The Centers for Disease Control and Prevention has linked clusters of potentially serious antibiotic-resistant skin infections to unlicensed tattoo artists who don't follow proper infection-control procedures. Some antibiotic-resistant skin infections can lead to **pneumonia, blood infections and a painful, flesh-destroying condition called necrotizing fasciitis**.
- **Allergic reactions.** Tattoo dyes, particularly red dye, can cause allergic skin reactions, resulting in an **itchy rash** at the tattoo site. This may occur even years after you get the tattoo.
- **MRI complications.** Rarely, tattoos or permanent makeup may cause **swelling or burning in the affected areas during magnetic resonance imaging (MRI) exams**. In some cases — such as when a person with permanent eyeliner has an MRI of the eye — tattoo pigments may interfere with the quality of the image.

If you develop an allergic reaction, infection or other skin disorder, call your doctor immediately. Don't just go on the internet and read about how someone you don't know worked throught it. You may need antibiotics or anti-inflammatory drugs. In some cases, permanent tattoo removal is required to resolve the complication.

Still want one? Well, next time, let's look at things you should consider before you get it.

March 17, 2009

Telbivudine Better Than Lamivudine for Chronic Hepatitis B

www.medscape.com

NEW YORK (Reuters Health) Mar 17 - As a treatment for chronic hepatitis B, telbivudine produces a better therapeutic response than does lamivudine in both HBeAg-positive and -negative patients, according to 2-year follow-up data from the GLOBE trial.

When it became available in 1998, lamivudine revolutionized the treatment of chronic hepatitis B, note Dr. Yun-Fan Liaw, from Chang Gung University College of Medicine, Taipei, Taiwan, and colleagues. The current findings, however, suggest that the newer agent telbivudine has now displaced lamivudine as the treatment of choice.

The GLOBE trial included 921 HBeAg-positive and 446 HBeAg-negative patients who were randomized to receive telbivudine or lamivudine once daily for 104 weeks. Therapeutic

response, the main outcome, was defined as a hepatitis B virus DNA level < 5 log10 copies/mL and HBeAg loss or normalization of the alanine aminotransferase level.

In HBeAg-positive patients, the treatment response rate was higher with telbivudine than with lamivudine: 63% vs. 48% ($p < 0.001$), according to the report in the February issue of *Gastroenterology*. In HBeAg-negative patients, the corresponding rates were 78% and 66% ($p = 0.007$).

Compared with lamivudine, treatment with telbivudine in the HBeAg-positive group was associated with higher rates of nondetectable viremia and HBeAg loss and with lower rates of viral resistance. In the HBeAg-negative group, telbivudine use also increased the odds of nondetectable viremia and was tied to less viral resistance.

In general, the two drugs had comparable side effect profiles, although telbivudine was more often linked to grade 3/4 increases in creatine kinase levels: 12.9% vs. 4.1% ($p < 0.001$).

Despite these findings, however, the future of telbivudine as a long-term treatment for chronic hepatitis B is uncertain, Dr. Robert J. Fontana, from the University of Michigan Medical Center, Ann Arbor, comments in a related editorial.

"The rising incidence of telbivudine-resistant hepatitis B virus will likely limit its long-term utility in the management of chronic hepatitis B virus," he writes. "Additional drugs that target other steps in the hepatitis B virus replication cycle or host immune response are needed."

Gastroenterology 2009;136:389-403,486-495.

Digestive and liver diseases: no joking matter

http://www.southtownstar.com
Jeffrey Goldman, MD

Maintaining a healthy digestive system is vital to your health and comfort.

But many people ignore the signs of digestive illness and fail to seek relief from their discomfort because they are embarrassed to discuss the symptoms or their own health histories.

Your digestive system is a series of hollow organs joined in a long, twisting tube. It includes the esophagus, stomach and large and small intestines. Your liver, gallbladder and pancreas contribute to the process of breaking down the foods you eat to build and nourish cells and provide energy.

Among the young and healthy, the digestive tract is a remarkably tolerant system, even when challenged with the most reckless diets and lifestyles. But after the age of 40, and especially as you reach age 50, time begins to take its toll and gastrointestinal problems become more common.

Effectively addressing most digestive issues require conversations about topics that many are embarrassed to discuss, including bowel habits, abdominal pain, stool and flatulence. In general,

you should see your doctor if you have:

• Blood in your stool.

• Changes in bowel habits.

• Severe abdominal pain.

• Unintentional weight loss.

• Heartburn not relieved by antacids.

Another digestive disease, hepatitis C, requires discussions about potentially embarrassing aspects of a patient's personal history, including drug use and sexual activity.

Hepatitis C is a serious condition that damages the liver and can lead to potentially fatal liver diseases such as cirrhosis, liver failure and liver cancer. Unlike other common strains, such as hepatitis A and hepatitis B, there is no vaccine to prevent hepatitis C. One of the most common reasons for liver transplants is damage caused by hepatitis C infection. More than four million Americans have been infected with hepatitis C, which is responsible for more than 8,000 deaths each year.

Most people with hepatitis C have no symptoms of the disease. This is why it may persist for years or even decades before it is discovered. In most cases, early diagnosis of hepatitis C depends on the patient's ability to candidly discuss past lifestyle choices.

You can get hepatitis C if your blood comes into contact with blood from someone who already has the virus. The most common cause of transmission is the sharing of needles and other equipment used to inject illegal drugs. The leading risk factors include:

• Past intravenous drug use.

• Tattoos and body piercing using shared needles.

• Past cocaine use.

• High-risk, unprotected sexual activity.

Before 1989 there was a risk of getting hepatitis C from blood transfusions. Now all donated blood is tested for hepatitis C so there is almost no risk of getting the disease from blood transfusions.

Hepatitis C is most often diagnosed by a blood test. However, blood tests conducted in routine physicals do not include tests for hepatitis C. This is why most people with hepatitis C don't know they have the disease, especially since there may be no symptoms.

Some people discover that they have hepatitis C when they donate blood, because all donated blood is tested for hepatitis C virus. Others learn they have hepatitis C when they undergo blood

tests for other medical problems. When blood tests show abnormal liver enzymes, a sign of liver damage, additional tests are conducted to find the cause.

It is during these tests that your physician may delve into potentially embarrassing aspects of your lifestyle. It is important to remember that these conversations are completely private. Your doctor is not sitting in judgment. He or she is merely trying to gather information to more effectively care for you.

If you have hepatitis C, the goal of treatment is to get rid of the virus in your body. In fact, hepatitis C is one of the only viruses that can be cured with medication therapies. The most effective cure for hepatitis C requires patients to take antiviral medications for six months to one year.

The digestive system is the source of countless jokes and embarrassment for some. One of the hardest-working, most complex parts of the body is also the subject of misunderstandings, folklore and old wives tales.

In many cases, the first step to getting relief and treating potential digestive diseases is overcoming embarrassing aspects of the symptoms or your own personal history, ignoring those myths and engaging in frank discussions with your physician.

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Music and coffee spread awareness

http://www.dailytitan.com
Stacey Wang
Daily Titan Staff Writer

When a friend asked her to spread awareness about Hepatitis C, Kelly Zirbes willingly accepted the task and got to work. Unknown to herself when she started, her devotion to the cause led her to become a successful advocate with an effective and contemporary style, speaking through music.

As the founder of the non-profit organization Hepatitis C Awareness Inc., Zirbes incorporates musical performances at her company's events to entice others to learn about the virus.

The upcoming third annual Hepatitis C Awareness for Orange County will be held at Java Joe's in Yorba Linda from 3 p.m. to 11 p.m. March 14. The event will include live musical performances and free Hepatitis C testing.

"I wanted to do things outside of the box using music and doing things that weren't being used," Zirbes, who also created informational postcards to spread awareness, said.

The Orange County event was created in memory of O.C. resident Patrick Eden, who died after contracting Hepatitis C in a blood transfusion. For the past three years, his wife Terri Eden has worked with Zirbes to host the event at Java Joe's.

The Hepatitis C virus affects the liver through blood-to-blood transfer from an infected person. According to the Centers for Disease Control and Prevention (CDC), the virus, although believed to have low transmission, can still be transmitted through sexual contact.

The liver disease can be "acute," which is a short-term illness that occurs within six months of exposure. Or, the disease can become "chronic" in which it is long-term and can stay in the body for a lifetime.

Unlike Hepatitis A and B, there is currently no vaccine for Hepatitis C.

A lack of societal awareness about this fact is one of Zirbes' motivation for the event.

"(The event) makes you more aware of Hep. C. It makes it more personal," Judie Levy, Java Joe's barista, said. The 19-year-old Cal State Fullerton English major worked during the second annual event and felt a stronger connection after she heard Eden speak.

"I think it's a great idea to become aware in a fun way," she added.

For Kindra Chenier, 21-year-old CSUF dance major, the music is what made last year's event enjoyable.

"It was a very interesting way of getting people aware of (Hepatitis C)," Chenier, who plans to attend this year, said. "People were drawn in by the music."

Live performances on March 14 will include Kelly's Lot, Onya, Debra Davis, Fuji Minx, Scott Detweiler, Three Car Garage and Acousticconversation.

Although Hepatitis C is most common among intravenous drug users, possible exposure among younger individuals is becoming a concern for Zirbes with the rising popularity of piercing and tattoo parties.

Being careless about cleaning utensils used at these parties could put many individuals at risk, Zirbes said.

Since 2000, Zirbes has devoted her creativity and time in educating others about what she considers a virus the general public knows little about.

"There are so many people who don't know they have it," she said.

For the last decade, Zirbes has struggled to promote Hepatitis C testing because of many misconceptions.

"I realized that was my biggest hurdle – that people thought they were vaccinated," Zirbes said.

Zirbes was first educated and asked to help raise awareness about Hepatitis C from her friend Gioia Siciliano, who was diagnosed with the disease and died after her body rejected a liver transplant.

Affected by Siciliano's death, Zirbes devoted a year on stage with her band Kelly's Lot, discussing Hepatitis C. She received such a positive response that she created Hepatitis C Awareness Inc.

Since its development, Hepatitis C Awareness Inc. has battled the "stigma" of Hepatitis C throughout the country.

According to CDC, about 75 to 85 percent of individuals infected with Hepatitis C virus will have a chronic infection.

Chronic hepatitis, although chances are low, can lead to liver problems like cirrhosis or cancer, CSUF Chief Staff Physician Dr. Richard Boucher said.

Symptoms for Hepatitis C can range from mild flu-like symptoms, such as nausea and abdominal pains when a person is first exposed, or no symptoms at all, Boucher added.

There are an estimated 3.2 million Americans who have chronic Hepatitis C, most of which do not know they have the illness because they don't have symptoms, according to CDC.

While developing events, Zirbes decided to make them a casual environment so that people could learn and get tested in a way "so that it's not in your face."

Although Hepatitis C is uncommon at CSUF, Boucher notes the importance of being educated about the illness.

"Just be aware it's out there and be cautious with those people you come in contact with," Boucher said.

Boucher recommends keeping universal precautions like those practiced in the hospital setting as a key to prevention. If diagnosed with Hepatitis C, the individual is advised to see a gastroenterologist or a liver specialist.

"The sooner you know you have it, the chance of getting rid of it is higher," Zirbes said.

For more information about Hepatitis C Awareness Inc., visit HepCAware.org or e-mail hepatitiscaware@aol.com .

Hepatitis B Testing Urged for Non-Hodgkin's Lymphoma Treatment: Presented at NCCN

http://www.docguide.com
By Ed Susman

HOLLYWOOD, Fla -- March 16, 2009 -- Before initiating treatment for non-Hodgkin's lymphoma, doctors need to determine if the patient has been infected with hepatitis B virus, especially if treatment will be with rituximab-based therapy, according to a presentation here at the National Comprehensive Cancer Network (NCCN) 14th Annual Conference: Clinical Practice Guidelines & Quality Cancer Care.

"Hepatitis B virus can reactivate with immunosuppression," explained presenter Andrew Zelenetz, MD, PhD, Lymphoma Service, Memorial-Sloan Kettering Cancer Center, New York, New York.

Rituximab depletes B cells in patients with B-cell lymphoma, possibly compromising the immune system and allowing the virus to emerge and reactivate, Dr. Zelenetz said in a presentation on March 13.

If patients are found to be positive for the hepatitis B virus -- as determined by hepatitis B surface antigen, core antibody, e-antigen, and/or viral load -- then the treating physician should consult with a hepatologist, he advised. "This is important because more than 5% of patients with acute hepatitis B virus reactivation will die of liver failure," Dr. Zelenetz said.

The US Food and Drug Administration mandated a black box warning regarding rituximab therapy after cases of fulminant hepatitis were reported. The risk of reactivation persists for as long as 6 months following treatment.

The lymphoma algorithm is designed to guide treatment practice among the 21 institutions that make up the NCCN, including Memorial-Sloan Kettering, which releases treatment guidelines that have become standard-of-care for many institutions worldwide.

Dr. Zelenetz said that hepatitis B testing was added to the guidelines as part of the essential work-up for patients.

Other constituents of that work-up include a physical examination with attention to node-bearing areas, including Waldeyer's ring, and with attention to the size of the liver and spleen; the patient's performance status; a chest-abdominal-pelvic computer-assisted tomography (CT) scan; bone marrow and aspirate test to document clinical stage; and pregnancy testing in women of childbearing age if chemotherapy is considered.

"Positron emission tomography [PET] is not an essential part of the work-up," he said, "although PET has been useful in some cases." Also useful in selected cases are hepatitis C testing, discussion of fertility issues and sperm banking, PET-computed tomography scans, neck CT scans, and echocardiogram.

Dr. Zelenetz said the risk of reactivation is higher among young men, in patients with higher hepatitis B virus DNA before treatment, and in patients with prolonged or deep immunosuppression.

[Presentation title: NCCN Non-Hodgkin's Lymphoma Guidelines Update.]

March 18, 2009

Progress Reported Against Gene Involved in Hepatitis C

http://health.usnews.com

Finding could lead to new treatments for the disease, researchers say

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WEDNESDAY, March 18 (HealthDay News) -- Nearly 100 genes that support replication of the hepatitis C virus (HCV) in the human body have been identified by Massachusetts General Hospital researchers.

They also found that blocking several of the genes suppressed replication of the virus.

"We may be a few years away from developing therapies based on these findings, but this study is a proof of principle that targeting host factors is a viable therapeutic strategy," Dr. Andrew Tai, of the hospital's gastrointestinal unit and lead researcher on the study, said in a hospital news release.

Long-term HCV infection can lead to liver failure or liver cancer. Currently, a six- to 11-month regimen of peginterferon and the antiviral drug ribavirin is used to treat HCV, but the therapy can cause serious side effects and is ineffective in many people.

Tai and his colleagues examined whether using small interfering RNAs (siRNAs) to block each of the approximately 21,000 predicted messenger RNA transcripts in the human genome had any effect on HCV replication. The siRNA scan identified 96 genes that appear to play a role in HCV replication, and the researchers took a closer look at several of those genes.

One of the genes encodes for an enzyme called PI4KA, believed to play a role in the formation of membrane structures within the cell that may be the site of HCV replication. Another group of genes contributes to formation of the COPI coat that covers several types of cellular vesicles and plays a role in the replication of poliovirus, the researchers said.

They also zeroed in on the gene for a liver protein (hepcidin) that regulates iron absorption. People with chronic HCV infection experience elevated iron levels in the liver and blood.

Blocking each of these genes prevented HCV replication, as did drugs that inhibit PI4KA and COPI.

Further research is needed to identify the molecular mechanisms in these genes that support HCV replication. That could lead to new treatments for HCV infection, the researchers said.

The study is in the March 19 issue of *Cell Host & Microbe*.

Nurse gets injury payout after 36 years

http://www.thelocal.se

A Swedish nurse who contracted Hepatitis C after coming into contact with an infected needle has had the cause of her sickness recognized by the authorities as a workplace injury after a 36 year wait.

Agneta Bjurman had just qualified as a nurse when she inadvertently pricked herself with a syringe after carrying out tests on a man who was seriously ill.

Shortly afterwards she began to feel unwell, but it took some time before she made the

connection between the deterioration of her health and the incident with the needle.

Many years after the initial accident, in 1994, she was eventually diagnosed with Hepatitis C. But only now has the Swedish Social Insurance Agency (Försäkringskassan) agreed to accept that her illness was work-related, entitling her to some financial compensation.

"It's an incredibly good feeling to be told I was right after all these years," Bjurman told news agency TT.

"I was very sick for many years but I didn't get any help from the Social Insurance Agency because it wasn't possible to verify that I had been infected on that particular occasion," she added.

Bjurman, who currently works within the healthcare service in Skellefteå in northern Sweden, underwent major treatment in 2006 after seeing her condition worsen since the beginning of the decade.

After her treatment, she began to argue her case more forcefully with the assistance of Riksföreningen Hepatit C Vårdnet ('The National Hepatitis C Care Network').

"For me to have my case classified as a work-related injury could be a breakthrough for others who have become infected in the healthcare system," said Bjurman, whose condition has improved considerably since her recent treatment.

According to the Hepatitis C lobby group assisting Bjurman, more than 10,000 care workers accidentally prick themselves with needles and syringes each year, though only a fraction report the incidents as work-related injuries.

"I consider that fact that Agneta Bjurman has had her infection approved as a work-related injury a victory for everybody who has been infected via prick and cut wounds in the workplace," said Kaj Johansson, a spokesman for the Hepatitis C Care Network.

March 19, 2009

Have a heart, give a liver

http://www.yourottawasouth.com
BY Nathan Jahn

Susan Kingston is going to die.

That is, unless she finds a new liver.

Without it, she could have anywhere from two to four years left. Kingston has put out a plea for help after her last visit to doctors at Toronto's General Hospital made it clear that the chances of receiving a new liver in time to survive just isn't likely to happen.

"They said, 'You're O-positive – there's no chance we will be calling you,'" said Kingston in her home near Kemptville. "As the list is long, I would have to be bedridden in the hospital and

airlifted to Toronto before I would be put higher on the list."

Odds are, doctors told her, the 56-year-old will be too sick to survive the surgery by that time. Now she's hoping a kind-hearted Samaritan will step forward and offer up a piece of their liver so she can live.

The fact that Kingston's blood-type is O-positive puts her at a disadvantage because it's one of the most common blood types; that means her name is farther down the lengthy, 306-name transplant list.

Kingston didn't damage her liver with alcohol, drugs or catching a bug through unsafe actions; rather she was pricked with a needle while working as a laboratory technician in the 1970s. Kingston continued to work as a lab tech up until last year, and knew she had been infected with hepatitis B at the time.

What she didn't know – what know no one knew – was that Kingston also had hepatitis C.

"Back then there was hepatitis A or B … or non-A or -B," said Susan. "I didn't know I had it."

It was only in 1989 that doctors and scientists identified hepatitis C specifically. Even now there are six separate, identified strains of hepatitis; but the three most common, accounting for about 90 per cent of all acute cases in Canada every year, are A, B and C, according to Health Canada.

Most people who get the A or B virus, says Health Canada, will recover completely and develop a lifelong immunity to the virus.

Currently in Canada, there are between 210,000 and 275,000 people with hepatitis C. Health Canada estimates 30 per cent actually know they have it, which was exactly Kingston's problem.

The virus went undetected for so long that the damage had been done by the time it was spotted.

The virus has caused Kingston's liver to get cirrhosis, which is when the liver gets so damaged that it slowly deteriorates and stops working. Chronic hepatitis C causes inflammation and damage over time that can lead to cirrhosis.

Doctors have told Kingston she is more than welcome to find her own donor.

No one close to Kingston is the right blood type to offer up a portion of their liver; her husband, Hal, would certainly do it in a heartbeat if he could.

Instead Susan lives every day in pain.

The lack of a fully functioning liver means Susan suffers from ammonia buildup in her abdomen. Her stomach wasn't horribly distended when she spoke to a reporter, but Susan explained that she has to have her midsection drained on a regular basis or else the pain becomes unbearable.

Through the course of her treatment, she's been on interferon, albumin transfusions and quinine for her restless leg syndrome. Interferon is commonly used for chemotherapy patients, but the

drugs within the umbrella of interferon are used by anyone with a weakened immune system as they direct the body to target viruses, bacteria and tumours.

"There's a treatment I went on, and it's a type of chemotherapy used for melanoma patients," Susan said. "The first time I got really, really ill and the second time just about killed me. So it didn't work."

It is illegal for Susan to offer to pay someone straight up for their liver; but she can – and is – offering to pay for any expenses or lost wages for the person who can offer up a portion of their liver.

Please contact nathan.jahn@metroland.com if you or someone you know is willing to be a lifesaver.

Vertex Hep C Drug Improves Cure Rate in Study

http://www.thestreet.com
Adam Feuerstein

Vertex Pharmaceuticals'(VRTX Quote - Cramer on VRTX - Stock Picks) experimental hepatitis C drug telaprevir is capable of significantly improving cure rates in the most difficult-to-treat patients, according to final results from a phase II study released Wednesday afternoon.

The new data come from Vertex's PROVE 3 study, which enrolled 453 patients who had failed prior treatment with the current standard drug regimen for hepatitis C -- a 48-week course of long-acting interferon plus ribavirin. In the phase II study, these patients were randomized to receive either treatment with a combination of telaprevir plus the standard therapy or retreatment with the standard therapy alone.

In all, 51% of patients treated with a 24-week regimen that included 12 weeks of telaprevir reported undetectable levels of the hepatitis C virus six months after treatment. In hepatitis C parlance, that's known as a sustained virologic response, or SVR. Simply stated, these patients are considered cured of hepatitis C.

By comparison, only 14% of the patients retreated with 48 weeks of standard therapy alone achieved an SVR, or cure, six months after treatment.

The final data from the PROVE 3 study was released online Wednesday in a research abstract ahead of next month's meeting of the European Association for the Study of the Liver (EASL), one of two important scientific meetings held each year devoted to hepatitis C research.

Researchers had previously presented the PROVE 3 results from patients treated with telaprevir, but Wednesday's research abstract was the first time data was made public on the patients in the study's control arm retreated with standard therapy alone.

A host of companies are racing to develop new hepatitis C drugs. Vertex and partner Johnson & Johnson(JNJ Quote - Cramer on JNJ - Stock Picks) are in the lead with telaprevir, which is nearing the completion of patient enrollment in a series of pivotal phase III studies. These studies

are enrolling patients both newly diagnosed with hepatitis C who are being treated for the first time as well as patients like those in PROVE 3 who have failed prior treatment.

To date, telaprevir is the only one of the new crop of experimental hepatitis C drugs that have shown the ability to cure in significant numbers patients who have failed prior treatment.

The commercial market for so-called treatment-failure patients is substantial. An estimated 250,000 to 300,000 hepatitis C patients in the U.S. have failed current interferon-ribavirin therapy and are waiting for something new and more effective to be approved so they can be retreated, and hopefully cured.

Many of Vertex's hepatitis C competitors are still in earlier stages of clinical development, but the drugs pose a threat because many can be dosed once or twice a day -- more conveniently than telaprevir, which requires patients to take the drug three times a day.

Schering-Plough(SGP Quote - Cramer on SGP - Stock Picks), Merck(MRK Quote - Cramer on MRK - Stock Picks), Bristol-Myers Squibb(BMY Quote - Cramer on BMY - Stock Picks), InterMune(ITMN Quote - Cramer on ITMN - Stock Picks), Pharmasset(VRUS Quote - Cramer on VRUS - Stock Picks) and Anadys(ANDS Quote - Cramer on ANDS - Stock Picks), among others, will also be presenting data on their drugs at next month's EASL meeting.

Some of the most highly anticipated, albeit early stage, data will come from a small study treating hepatitis C patients with a combination of InterMune's ITMN-191 and Pharmasset's R7227. (Both drugs are partnered with Roche.) This study, known as INFORM-1, is the first in which two experimental drugs are being used in combination without long-acting interferon and ribavirin.

A research abstract from the INFORM-1 study, also released Wednesday afternoon, reported significant reductions in the amount of hepatitis C virus in patients treated with the ITMN 191/R7227 combination. The data in the abstract was preliminary, however, and more data will be presented at the EASL meeting.

Earlier this month, Vertex acquired ViroChem, a privately held Canadian drug maker, in order to expand its pipeline of hepatitis C drugs. Vertex is planning combination studies of telaprevir with a promising drug from ViroChem, VCH 222, that will also seek to eliminate the need for interferon and ribavirin.

Vertex shares were down 1.5% to $29.06 in recent trading.

Sustained Viral Response Indicates HCV Infection Cure

www.medscape.com

NEW YORK (Reuters Health) Mar 19 - A 4-year follow-up of patients with chronic hepatitis C virus (HCV) infection who achieve a sustained viral response (SVR) to interferon-alpha-2b "strongly suggests" that they are "cured," French investigators report in the April issue of *Liver International.*

Dr. Sarah Maylin and colleagues at Hopital Beaujon in Clichy, France, followed 157 patients with chronic HCV infection who achieved SVR after treatment with interferon-alpha-2b and a control group of 23 patients with detectable HCV RNA and normal serum alanine levels. HCV viral titers and HCV antibodies were measured periodically during 4 years of follow-up.

Serum HCV RNA levels remained undetectable in all patients and HCV antibody titers remained unchanged throughout follow-up.

"This long-term study...demonstrated that SVR...is durable, and HCV antibodies were markedly decreased (mainly those directed against the non-structural proteins), emphasizing an absence of ongoing infection," Dr. Maylin and colleagues write.

"These results strongly suggest that HCV infection (is) cured in patients who achieve an SVR," the researchers say.

The findings show that the humoral immune response to non-structural HCV proteins is short-lived and might be a marker of infected cells," the French investigators say. "A decrease in the antibodies against the (nonstructural) proteins, observed in our study, could reflect a decrease in infected cells, suggesting that there is no antigenic stimulation after viral eradication."

Liver Int 2009;29:511-517.

FDA issues warning on sharing insulin pens and cartridges

http://www.news-medical.net

The U.S. Food and Drug Administration has issued an alert to health care professionals reminding them that single-patient insulin pens and insulin cartridges should not be used to administer medication to multiple patients due to the potential risk of transmitting blood-borne pathogens such as HIV and the hepatitis viruses.

Insulin pens are pen-shaped injector devices that contain a disposable needle and either an insulin reservoir or an insulin cartridge. The devices typically contain enough insulin for a patient to self-administer several doses of insulin before the reservoir or cartridge is empty. All insulin pens are approved only for single-patient use (one device for only one patient).

The FDA is aware of incidents at two undisclosed hospitals involving more than 2,000 people in which the cartridge component of the insulin pens were used to administer insulin to multiple patients, although the disposable needles were reportedly changed among patients.

"Insulin pens are designed to be safe for one patient to use one pen multiple times with a new, fresh needle for each injection," said Amy Egan, M.D., deputy director of safety at the FDA's Division of Metabolism and Endocrinology Products in the Center for Drug Evaluation and Research. "Insulin pens are not designed, and are not safe, for one pen to be used by more than one patient, even if needles are changed between patients due to the risk of transmitting blood-borne pathogens."

Patients exposed to shared insulin pens are being contacted by the two hospitals and are being

offered testing for hepatitis and HIV. Some of the potentially exposed patients have reportedly tested positive for the hepatitis C virus, although it is not known if the virus was spread as a result of insulin pen sharing.

The FDA is working with the Centers for Disease Control and Prevention and professional organizations to address infection control issues related to insulin pens.

http://www.fda.gov

Syringe scandal could be a wake-up call

http://www.chtv.com
Paula Simons
The Edmonton Journal

Health crisis might shine new light on infections in high-risk communities

Early last week, I set out to discover how many of the 1,378 patients from the High Prairie Regional Health Centre who'd been exposed to reused syringes had tested positive for HIV, hepatitis B and hepatitis C.

The official answer that I received from Alberta's acting chief medical officer, Dr. Gerry Predy, and which I reported in last Thursday's column, was that "at least one" person had tested positive for a bloodborne infection.

How many people does "at least one" mean to you? In Alberta, it seems that "at least one" means at least 30.

The Peace Country Health Region has now tracked down 1,270 of the 1,378 patients who received medication via a reused syringe and asked them to come in for testing. So far, they've processed 1,000 of those tests. To date, according to the region, approximately 30 tests have come back positive for HIV, hep B or hep C. The region won't yet reveal who's got what, but it's reporting an infection rate of about three per cent.

Peace Country Health says its final report won't be complete until the end of the month -- it's still waiting for test results from 270 patients. But so far, the health region says it's found found no demonstrated link between those 30 infections and the hospital's practice of reusing the same syringe on multiple patients undergoing either dental surgery or endoscopy.

The region says that since none of the infected patients was seen on the same day, there's no evidence that one patient passed on an infection to another.

So how does the health region account for those 30-odd positive tests? Deb Guerette, who speaks for Peace Country, says that's simply the normal background rate of infection in the community. If that's so, it well may signal a much broader public health crisis.

According to a report on infectious disease rates, published on the Alberta Health website, the incidence of hepatitis B in this province in 2004, the last year for which data is available, was

1.41 cases per 100,000.

The incidence of hepatitis C was 46 cases per 100,000. And the incidence of HIV was 5.4 cases per 100,000.

Add them all up and assuming, for a moment, that there's no overlap, that no one has two or three of these diseases at the same time, and you get about 53 cases per 100,000.

That translates to an aggregate rate of about 0.5 per cent -- six times less than three per cent.

And according to Alberta Health, the incidences of all these diseases in the Peace Country health region were actually at or below the provincial average.

Now, it's important that we don't mix up the incidence rate with the prevalence rate. The incidence rate measures the number of cases found in any one year. The prevalence rate measures the total number of cases in a population. Obviously, the prevalence of a disease in a community is likely going to be significantly higher than the incidence of new diagnoses in any one year.

But even then, the numbers from High Prairie seem out of whack. According to the Public Health Agency of Canada, the prevalence rate for hepatitis B in Canada is 0.8 per cent. For hepatitis C, it's between 0.7 and 0.9 per cent, and for HIV/AIDs it's 0.18 per cent.

"Three per cent is a very high rate of infection, at least compared with the rest of Alberta," says Dean Eurich, a professor of epidemiology with the University of Alberta's school of public health. "If the background rate of infection really is that high, it suggests we need to be doing a lot more about prevention."

To say the least.

Let's accept, at least for a moment, that no one was infected through the syringe reuse at the High Prairie hospital, that a three-per-cent infection rate is normal in the High Prairie area.

If that's really the case, the hospital and the health region got damned lucky. In a patient community with such a high prevalence of bloodborne diseases, it was all the more foolhardy to use the same syringes over and over again. A hospital treating a community with an unusually high rate of infection owed its patients a far higher duty of care.

But this problem goes well beyond the walls of the hospital. The numbers released by Peace Country Health suggest that the community around High Prairie, which has a large aboriginal population, has a disproportionate rate of these serious infectious diseases -- and that's a deeper public health problem that must be addressed.

We know that such diseases spread primarily through IV drug use, unsafe sex and maternal transmission. A community can fight back with needle exchange programs, drug treatment programs, sex education campaigns and improved prenatal care and testing -- but only if it acknowledges the scope of the problem in the first place.

The syringe scandal may yet turn out to be a blessing in disguise -- if it shines a fresh, harsh light on the chronic problem of HIV and hepatitis infections in high-risk northern communities. It's a health crisis that's all too easy to ignore, until something happens to rub our noses in it. Maybe the syringe debacle is just the wake-up call this province needs.

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March 20, 2009

2-day results predict ultimate response to therapy in chronic hepatitis C

http://www.eurekalert.org

A new study suggests that previously noted low rates of successful hepatitis C virus (HCV) therapy in African Americans are in large part due to very early differences in the antiviral activity induced by interferon. The study is published in the April 15 issue of the *Journal of Infectious Diseases*, now available online.

More than 3 million Americans are infected with HCV, and in some countries more than 10 percent of the population is infected. Chronic HCV infection is the leading cause of liver failure worldwide. Response to standard therapy with peginterferon and ribavirin varies widely. Those infected with one strain of the virus—genotype 1—are the least likely to have a successful response to therapy, known as a sustained virological response (SVR). About one-half of patients infected with genotype 1 do not achieve SVR.

Studies have shown that African Americans have consistently lower rates of SVR to interferon-based therapy, compared to Caucasian Americans. A recent study of those with chronic genotype 1 HCV infection found that only 28 percent of African American patients attained SVR, compared with 52 percent in Caucasian Americans. This new study shows that the variation in therapy responsiveness between African Americans and Caucasian Americans can be partly explained by differences in viral response noted as early as one to two days after the first dose of peginterferon.

The study, conducted by a collaborative group of eight medical centers throughout the United States, monitored 341 patients with chronic HCV, genotype 1, who underwent therapy with peginterferon and ribavirin for at least 24 weeks. It focused on response rates to interferon therapy within the first 28 days of therapy, noting viral factors such as HCV RNA levels and host factors such as race, gender, and weight.

Results showed that HCV RNA levels decreased in almost all patients, and that the degree and pattern of decrease, as expected, was different between African and Caucasian Americans. Most important was the new finding that these differences were statistically significant by day 2 of treatment, and that this early viral kinetic measurement was a reliable predictor of ultimate SVR rates. After 28 days of treatment, 22 percent of Caucasian Americans, but only 12 percent of African Americans, were HCV RNA negative.

These findings are particularly important because they point toward the presence of some block or defect in the immediate antiviral response of those who do not respond to therapy. As the

authors summarize, "The underlying cause of virological non-response and the reasons why it is more common among African Americans than Caucasian Americans are not clear. [But] the current analyses demonstrated that these differences are fundamentally biologic and become apparent within 24 to 48 hours of starting therapy." As a next step, future research should focus on these host biologic factors that are induced by interferon in an attempt to improve therapy response rates.

In an accompanying editorial, Andrew W. Tai, MD, PhD, and Raymond T. Chung, MD, of Massachusetts General Hospital agree that the findings will prove vital for future research into HCV, remarking, "[this study] demonstrates that the low rates of SVR in African American patients in response to IFN-based therapy appear to result, in large part, from impaired early viral kinetics. Further studies are necessary to uncover the relevant mechanisms that underlie this defect in IFN signaling… with the hope that such mechanisms can be manipulated to restore interferon responsiveness in the otherwise nonresponsive host."

Human Genome Sciences: Albuferon unlikely to threaten HCV standard of care

http://drugdiscovery.pharmaceutical-business-review.com/
By Datamonitor staff writer

Human Genome Sciences' Albuferon has demonstrated non-inferiority to the current standard of care in a Phase III trial in treatment-naive genotype 1 hepatitis C patients. Although Albuferon's less frequent dosing schedule is an advantage, the fact that it did not show superior efficacy in this area of high unmet need suggests that the drug is unlikely to threaten existing interferon therapies.
Albuferon meets non-inferiority endpoint but fails to offer major benefits over existing treatments.

Human Genome Sciences (HGS) has announced results from Phase III trials for its investigational interferon therapy for the treatment of hepatitis C infection. Albinterferon alfa-2b (Albuferon) is a long-acting, injectable interferon therapy given once every two weeks which is being developed by HGS and Novartis.

The ACHIEVE 1 study investigated Albuferon and ribavirin in 1,278 treatment-naive patients with chronic hepatitis C genotype 1 for 48 weeks. The primary endpoint was the sustained virological response (SVR) rate, 24 weeks after the end of treatment. Top line results demonstrate that Albuferon met its primary efficacy endpoint of non-inferiority to peginterferon alfa-2a (Roche's market leading Pegasys), with 48.2% of patients achieving SVR in the 900-mcg Albuferon arm, versus 51% in the Pegasys treatment group in an intention-to-treat analysis. Importantly, the rate of Albuferon treatment discontinuations due to adverse events was more than double that of Pegasys, at 10.4% versus 4.1%. Adverse events observed were those typically associated with interferon therapy.

The standard of care in hepatitis C virus (HCV) therapy currently comprises pegylated interferon alpha in combination with ribavirin. There are two pegylated interferon therapies available, Schering Plough's PegIntron and Roche's Pegasys. Despite the ability of current HCV therapies to cure the infection in some patients, there remains significant room for improvement. Limited

efficacy in patients infected with genotype 1 HCV is the greatest unmet need for this class; other drawbacks include high incidence of adverse events, long duration of treatment and consequently suboptimal patient compliance.

Although Albuferon has demonstrated efficacy in genotype 1 patients, the number achieving SVR in ACHIEVE 1 was similar to the current standard of care. Since the drug did numerically, albeit not statistically, slightly worse than Pegasys in genotype 1 patients, it does not address this unmet need any better than its marketed competitors. Moreover, the higher rate of discontinuations in the Albuferon arm indicates that it does not offer any benefits in terms of tolerability either.

Consequently, Datamonitor believes that while Albuferon reduces the dosing frequency, the lack of efficacy compliance benefits in genotype 1 patients makes it unlikely to threaten currently marketed interferon therapies. Therefore, Datamonitor forecasts annual peak sales of just over $200 million in the seven major markets by 2017.

Patients Suffer as a Result of Insurance Pricing Scheme

http://www.newswise.com

Newswise — Millions of patients suffering from diseases such as rheumatoid arthritis, multiple sclerosis, hemophilia, hepatitis C and certain types of cancer are at risk of incurring thousands of dollars in medical expenses due to a new pricing system being implemented by many insurance companies across the United States.

Health insurance companies are rapidly adopting this new system, commonly called **Tier IV**, for many of the expensive drugs used in the treatment of several diseases – asking patients to pay hundreds and even thousands of dollars a month for needed prescriptions. Blue Cross Blue Shield of Mississippi was one of many insurance companies to adopt this system, forcing its policyholders to shoulder 20 to 40 percent of the costs of their medication.

Traditionally, individuals and families pay reasonable co-pays for medications as part of their health insurance coverage, such as $15 for generic, $20 for brand name, or $30 for off formulary. Tier IV pricing goes above-and-beyond the traditional co-pay, forcing patients to pay hundreds or thousands of dollars out-of-pocket each month. For many rheumatology patients affected by Tier IV pricing, these costs are staggering, and because Tier IV often applies to the most expensive medications (such as infusions) these patients often consider other options, including stopping treatment.

"The Tier IV pricing system essentially represents discriminatory pricing for certain patients," explains Charles King, MD, a rheumatologist in Tupelo, Miss. "Asking my patients to pay 20 to 40 percent of their drug costs out-of-pocket (often up to $600 each month) means they will not have access to these life-altering therapies. My office has been flooded with calls from worried patients since the Tier IV system took effect. They are fearful of losing access to medicines that afford them the ability to lead independent, productive lives, and this is of great concern to me as their rheumatologist."

Robin Bates, a 34 year-old patient of Dr. King's has suffered from rheumatoid arthritis since she

was 21, and was faced with the challenge of purchasing her expensive Tier IV treatment from a specialty pharmacy assigned to her by her insurer. Her treatments were costing her well over $1,000 per year on top of her insurance premium, leaving her baffled as to why this was happening.

"I can't function without my medication, and I have four small children and a husband who need me; I have to be able to get up and go," says Bates. "But, this Tier IV pricing system made me wonder if I could find a cheaper medication—which I couldn't—and for a moment, I stopped considering the best option for my treatment, and started looking for the most affordable one."

Charged by this kind of fear and frustration, physicians, health care professionals, patients and caregivers in Mississippi recently rallied together and overwhelmed phone lines and message boards demanding fair pricing and appropriate access-to-care, and their efforts worked. As a result of this action, Blue Cross Blue Shield of Mississippi has lowered out-of-pocket expenses for Tier IV drugs to 10 percent of the cost of the drug – with a $200 maximum co-pay per month.

"I am pleased that BCBS of Mississippi has realized the importance of assuring access to these medicines, and has taken the lead in putting patient's needs first. My hope is that other insurance companies nationwide will follow the example set by BCBS of Mississippi," says Dr. King.

It is important for physicians, patients and caregivers in all states to come together and fight this unfair pricing system, which has lead to a severe access-to-care issue. For the Mississippians who rallied against Tier IV pricing, the results were great – they influenced change in one of the biggest insurance companies in the United States.

According to the American College of Rheumatology's President, Sherine Gabriel, MD, this type of grassroots action is what causes change. "Picking up the phone and making a call to your insurance company, contacting members of Congress, contacting local news outlets, and simply learning more about Tier IV pricing can make a huge impact in your state, just as it did in Mississippi," explains Dr. Gabriel.

The action taken after local news coverage of this issue in Mississippi led to the reform of an insurance policy that was damaging to the health of many residents, and Dr. Gabriel believes that this groundswell of action is what caused the change in policy. "Insurance policyholders have the right to question unfair pricing and should fight for reasonable pricing for their treatment and the treatment of their loved ones," she says. "Patients acquire insurance so they won't have huge out-of-pocket expenses, and Tier IV pricing makes that protection null-and-void."

Being positively affected by BCBS's recent policy reform, Bates urges other patients to take a stand. "If everybody sits back quietly, nothing will change. If nobody calls, they [the insurers] will continue to do this, and the prices could go up even more," she says.

Those concerned about Tier IV pricing in their state can take two simple steps:

• Call your insurance company and make an official request that they do not adopt this pricing structure, or request that they do away with their current Tier IV pricing structure.
• Ask your lawmakers to take a stand against Tier IV pricing that places an unfair burden on many constituents with serious health conditions. Reach your lawmakers through American

Medical Association's toll-free grassroots hotline at (800) 833-6354.

To learn more about Tier IV pricing, how it can cause major out-of-pocket expenses for you or someone you love, and how to fight it in your state, www.rheumatology.org.

The ACR is an organization of and for physicians, health professionals, and scientists that advances rheumatology through programs of education, research, advocacy and practice support that foster excellence in the care of people with or at risk for arthritis and rheumatic and musculoskeletal diseases.

Source: American College of Rheumatology (ACR)