HEPATITIS C SUPPORT PROJECT

HCV Advocate

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Celebrating 15 years of Living Positively—Being Well!

Drug Development News

—Alan Franciscus, Editor-in-Chief

April has been a month that has been jam-packed with news about drugs that are being developed to treat chronic hepatitis C. This article will focus on various news items that were released in April from ABBVIE, Gilead, Janssen and Jennerex. For information about the latest data released from the European Association for the Study of the Liver (EASL) conference see Liz Highleyman's comprehensive review in this newsletter.

ABBVIE

The Food and Drug Administration (FDA) has designated ABBVIE's drug combination—ABT-450/r plus ABT-267 and ABT-333 (with and without ribavirin)—as a 'Breakthrough Therapy'—the first drug(s) in HCV that have been given that important designation. The FDA designates a drug as 'Breakthrough Therapy' when there is a substantial improvement in therapy for serious or life-threatening diseases. Breakthrough therapy means that, in addition to the drug(s) being given expedited review, the FDA will also provide additional guidance to help with ABBVIE'S drug development program. This is based on the data from the Aviator study that reported cure rates of 99% in treatment naïve patients and 93% in prior null responders. Patients were treated for 12 or 24 weeks. ABBVIE's interferon-free combination is currently in Phase 3 development.

GILEAD

Gilead's investigational HCV medications continue to show impressive results in their HCV drug development programs. On May 02, 2013 Gilead released interim top-line results from their LONESTAR Phase 2 study. The study included people who were treatment-naïve and treatment-experienced. The treatment duration was 8 or 12 weeks. The

Treatment-naïve:		
SOF/LED	8 weeks	SVR8 - 95% (19 of 20 pts)
SOF/LED/RBV	8 weeks	SVR8 - 100% (21 of 21 pts)
SOF/LED	12 weeks	SVR4 - 100% (19 of 19 pts)
Treatment-experienced:		
SOF/LED	12 weeks	SVR 4 - 95% (18 of 19 pts)
SOF/LED/RBV	12 weeks	SVR4 – 95% (20 of 21 pts)

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EASL 2013: DAAs Look Good, but Challenges Remain—*Part 1*

—Liz Highleyman

Note: ***Due to the extensive EASL conference coverage in this month's issue, the SnapShots column will not be included in this issue.***

The European Association for the Study of the Liver (EASL) International Liver Congress, held April 24-28 in Amsterdam, confirmed expectations that the next generation of direct-acting antiviral agents (DAAs) will be more effective, easier to take, and better tolerated than current options, both as add-ons to interferon/ribavirin and in interferon-free regimens. Some patients, however, remain more difficult to treat.

INTERFERON-FREE GENOTYPE 2 VS 3

Interferon-sparing regimes have received the most attention at recent conferences, and EASL 2013 was no exception. Some combinations under study also dispense with ribavirin, which can cause anemia and other side effects.

Gilead Science's NS5B HCV polymerase inhibitor sofosbuvir (formerly GS-7977) is furthest along in the interferon-free pipeline, having been submitted in late March for Food and Drug Administration (FDA) approval for use with ribavirin for people with presumed "easier-to-treat" HCV genotypes 2 or 3.

A 12-week dual regimen of sofosbuvir/ribavirin previously demonstrated 100% sustained virological response (SVR) for previously untreated, non-cirrhotic people with genotypes 2 or 3 in the Phase 2 ELECTRON trial. But cure rates proved lower in larger Phase 3 trials that included 15% to 30% of participants with liver cirrhosis.

Edward Gane (*abstract 5*) presented final results from the FISSION trial, which looked at a 12-week regimen of sofosbuvir/ribavirin in 499 previously untreated patients, 72% with genotype 3 and 28% with genotype 2. A majority (57%) had unfavorable IL28B gene patterns and 20% had compensated cirrhosis. Participants received either 400 mg once-daily sofosbuvir plus 1000-1200 mg/day weight-based ribavirin for 12 weeks, or else pegylated interferon plus 800 mg/day ribavirin for 24 weeks, the current standard of care (SoC) for genotypes 2/3.

In both arms, 99% of patients had undetectable HCV RNA at the end of therapy and treatment failure rates were also the same, resulting in 12-week post-treatment sustained response (SVR12) rates of 67%.

But the most interesting finding was the divergence in response by genotype. Among genotype 2 patients, the SVR12 rate was 97% with sofosbuvir/ribavirin compared with 78% in the SoC arm. Among those with genotype 3, the corresponding rates were just 56% vs 63%, with the DAA regimen performing no better than interferon. The difference was even more pronounced among people with cirrhosis. Genotype 2 patients taking sofosbuvir/ribavirin had high SVR12 rates whether they had cirrhosis (91%) or not (98%). But for those with genotype 3, only 34% of cirrhotics were cured compared to 61% of non-cirrhotics.

Turning to treatment-experienced patients, the FUSION trial (*abstract 6*) compared sofosbuvir plus weight-based ribavirin for 12 or 16 weeks in 201 patients (63% with genotype 3, 37% with genotype 2) who were not cured with prior interferon-based therapy. Most (75%) were prior relapsers, 70% had unfavorable IL28B patterns, and one-third had cirrhosis.

All patients in both arms had undetectable HCV RNA at the end of treatment, but relapse was common, resulting in SVR12 rates of 50% for people taking the 12-week regimen and 73% for those treated for 16 weeks. Again, genotype 2 patients had high sustained response rates with both durations (86% and 94%), but for those with genotype 3 rates fell to 30% and 62%. Almost all non-cirrhotic genotype 2 patients were cured with either treatment duration (96% and 100%), falling to 60% and 78% for those with cirrhosis. But among people with genotype 3, the non-cirrhotic SVR12 rates for 12- and

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16-week treatment were 37% and 63%, falling to 19% and 61% for cirrhotics.

Ira Jacobson (*abstract 61*) reported data from POSITRON, another Phase 3 trial with 278 participants, split evenly between genotypes 2 and 3, who were ineligible, intolerant, or unwilling to take interferon. About 55% had unfavorable IL28B variants and about 16% had cirrhosis. They were randomized to receive sofosbuvir plus weight-based ribavirin for 12 weeks or placebo. The overall SVR12 rate for the sofosbuvir/ribavirin arm was 78%, but again, this broke down to 93% for genotype 2 and 61% for genotype 3. Non-cirrhotic and cirrhotic genotype 2 patients both responded well (92% and 94%, respectively), but genotype 3 non-cirrhotics did much better than cirrhotics (68% and 21%).

Sofosbuvir/ribavirin was generally safe and well-tolerated in all studies. There were few serious adverse events or early treatment discontinuations for this reason.

These results call into question the traditional classification of genotypes 2 and 3 together as "easy-to-treat," mirroring the disparity that recently emerged between HCV subtypes 1a and 1b. Viral variants that were thought to be similar when only interferon was available may be quite different in their response to DAAs.

Gane suggested that genotype 2 and 3 should no be longer be lumped together, as genotype 3 is "behaving as a harder-to-treat virus."

INTERFERON-FREE GENOTYPE 1

The conference featured several reports of all-oral regimens for people with HCV genotype 1.

Mark Sulkowski (*abstract 1417*) reported findings from a Phase 2a proof-of-concept study of sofosbuvir plus Bristol-Myers Squibb's NS5A inhibitor daclatasvir (formerly BMS-790062) for 24 weeks, with or without ribavirin, for patients who did not respond to interferon-based triple therapy containing boceprevir (Victrelis) or telaprevir (Incivek). This open-label trial included 41 participants, most with hard-to-treat HCV genotype 1 and unfavorable IL28B patterns. People with known cirrhosis were excluded, but most had at least moderate fibrosis.

All patients treated with sofosbuvir/daclatasvir and 95% treated with sofosbuvir/daclatasvir/ribavirin achieved SVR12—close to the 100% response rate previously reported for treatment-naïve, non-cirrhotic patients treated for 12 weeks. One person missing from the SVR12 analysis later returned for follow-up, so SVR24 rates were 100% in both arms. This study provides some of the first data on "rescue therapy" after failure of the current standard-of-care.

Gilead has declined to pursue this combination in Phase 3 trials in favor of its own NS5A inhibitor, ledipasvir (formerly GS-5885). Gane (*abstract 14*) presented further data from the ELECTRON trial, confirming that sofosbuvir/ribavirin alone is not adequate for genotype 1. Adding ledipasvir in a triple oral regimen, however, raised the cure rate to 100% for both treatment-naïve patients and prior null responders. Gilead announced in a press release that a co-formulation of sofosbuvir/ledipasvir without ribavirin for eight or 12 weeks led to SVR4 and SVR8 rates of 95% to 100% for treatment-naïve and previously treated patients in the Phase 2 LONESTAR trial, but this is too soon to declare a cure.

A late-breaking poster (*abstract 1423*) presented findings from a Phase 2a trial evaluating a three-drug regimen containing daclatasvir, the protease inhibitor asunaprevir (formerly BMS-650032), and two doses of the non-nucleoside polymerase inhibitor BMS-791325, without ribavirin, for either 12 or 24 weeks. The study enrolled 66 treatment-naïve genotype 1 patients without cirrhosis. Three-quarters had subtype 1a and about two-thirds had unfavorable IL28B patterns.

SVR12 rates ranged from 89% to 94% in an interim intent-to-treat analysis of the three arms that reached this endpoint. SVR24 rates were 94% and 88% for patients treated with 75 mg BMS-791325 for 12 or 24 weeks (the 150 mg arms having not yet reached this point), with all treatment "failures" due to missing data from participants lost to follow-up. The regimen was generally safe and well-tolerated, regardless of BMS-791325 dose or treatment duration, with two serious adverse events and no discontinuations for this reason. Bristol-Myers Squibb indicated that it plans to start a Phase 3 study of daclatasvir, asunaprevir, and BMS-791325 in a fixed-dose co-formulation by the end of the year.

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Finally, Kris Kowdley (*abstract 3*) reported results from the Phase 2 AVIATOR trial, testing a quadruple oral regimen containing three DAAs developed by AbbVie (formerly Abbott)—HCV protease inhibitor ABT450 boosted with ritonavir, NS5A inhibitor ABT-267, and non-nucleoside polymerase inhibitor ABT-333—taken with ribavirin for 12 or 24 weeks. AVIATOR included 438 previously untreated patients and 133 prior null responders without cirrhosis. About 70% of naïve patients and almost all null responders had unfavorable IL28B patterns, and 70% and 60%, respectively, had subtype 1a.

At AASLD 2012, Kowdley reported SVR12 rates of 99% for treatment-naïves and 93% for null responders treated for 12 weeks. At EASL he added SVR12 findings for arms treated for 24 weeks, and SVR24 data for all arms. Focusing on the 247 patients who received all four drugs for 12 weeks, 96% of treatment-naïve patients and 93% of prior null responders achieved SVR24. The corresponding rates for those treated for 24 weeks were 90% and 95%.

This combination cured more than 90% of patients regardless of prior treatment status, HCV subtype 1a or 1b, or IL28B pattern, though people with cirrhosis were excluded. Treatment was well-tolerated, with only 2% of patients discontinuing treatment due to adverse events and none reporting serious anemia. AbbVie has selected a 12-week regimen of the three DAAs plus ribavirin for further study in Phase 3 trials, and the FDA recently gave the combo a "breakthrough therapy" designation.

CURRENT THERAPY

While many patients and providers eagerly await interferon-free regimens, some people with advanced liver disease need treatment now and cannot wait.

The current standard of care for genotype 1 adds boceprevir or telaprevir to pegylated interferon and ribavirin. First-generation triple therapy works better than interferon/ribavirin alone, but response remains suboptimal for some patients and comes with added side effects.

Hélène Fontaine (*abstract 60*) reported data from the French CUPIC (Compassionate Use of Protease Inhibitors in Cirrhotics) study, in which people with cirrhosis who were not cured with interferon/ribavirin alone were retreated with protease inhibitor triple therapy through an early access program. Among 221 patients followed for at least 60 weeks, SVR12 rates were 41% for people treated with boceprevir and 40% for those receiving telaprevir, but cure rates were better for HCV subtype 1b (51% and 46%) than 1a (31% and 34%). Just over half of patients taking either drug experienced serious adverse events, but discontinuations were more common with telaprevir than boceprevir (21% vs 11%). In addition, 4% of boceprevir recipients and 7% of telaprevir recipients developed infections and 5% in both groups experienced liver decompensation.

Karoline Rutter (*abstract 65*) presented data on use of boceprevir or telaprevir triple therapy in 191 patients in Austria, including 131 with advanced fibrosis or cirrhosis. SVR rates were 47% for people with advanced fibrosis and 28% for those with cirrhosis, compared to 65% for those with absent-to-moderate fibrosis. More than one-quarter experienced serious adverse events, including 18 infections requiring hospitalization and three deaths due to sepsis. The investigators concluded that triple therapy for people with advanced liver disease is “feasible,” but associated with poor outcomes.

Elizabeth Verna (*abstract 23*) reported findings from the CRUSH-C study, which evaluated triple therapy—mostly using telaprevir—in 112 liver transplant recipients with recurrent HCV. Most had moderate-to-severe fibrosis and half had previously been treated post-transplant. Of the 43 patients with at least four weeks of post-treatment follow-up, 65% achieved SVR4, though this rose to 93% for those with extended rapid virological response. However, just 44% of patients with advanced liver disease achieved SVR4, compared to 71% of those without. Here too, adverse events were common. One-fifth experienced serious events requiring hospitalization, 11% discontinued due to adverse events, 4% experienced liver graft rejection, and 4% died from liver-related causes.

Part 2 will appear in the July issue of the *HCV Advocate.*

HEALTHWISE

Hepatitis C and Men

—Lucinda K. Porter, RN

I have written many articles addressing various issues that women with hepatitis C face. When I think about writing an article about men and hepatitis C, I am concerned that the absence of a Y chromosome denies me entrance into forbidden territory. However, it is June, the month that men's clothing is on sale, and when better to talk about men and hepatitis C.

Men account for two-thirds of the chronic hepatitis C virus infections (HCV) in the U.S. Men are more than twice as likely to die from HCV as women are. Approximately 5.4% of U.S. Veterans, particularly from the Vietnam War era, have HCV—triple that of the general U.S. population. The majority of Veterans with HCV are men.

I dedicate this article to all the men I have known who have struggled with HCV. I'll begin with a story about a patient I'll call Fred.

HEPATITIS C AND FATHERHOOD

Fred called me, clearly anxious as he told me that he was afraid that his toddler had been exposed to HCV. Fred had cut his face while shaving, dabbed at the blood with a washcloth, and put the washcloth on the tub to dry. That evening, Fred wandered into the bathroom while his wife was bathing their son. His precious boy was sucking on the washcloth. This was especially upsetting to Fred, since he had acquired HCV perinatally from his mother.

I reassured Fred that it was incredibly unlikely that his son was at risk. HCV is rarely transmitted via the digestive tract. If his child had open sores, cuts, a bleeding gum from an emerging tooth, then there was a theoretical risk. I referred Fred to his doctor and his child's pediatrician for advice. Fred needed hard-core reassurance, the kind that comes from a blood test. After six months, testing revealed that Fred's son was HCV negative.

Point #1: Although men don't bear children, they become fathers and grandfathers. HCV is rarely passed in families, but the presence of children is an opportunity to review HCV transmission and prevention. Links to more information are provided at the end of this article.

One potential risk that is associated with fatherhood and HCV is during treatment. Since ribavirin may cause fetal damage, men need to be sure that female partners do not get pregnant during and for six months after taking HCV medications. This warning is so important, that hepatitis C treatment carries a Black Box Warning.

Point #2: If pregnancy is a potential issue for your sexual partner(s), be sure that you and your partner use at least two reliable forms of effective contraception during treatment and during the 6-month post-treatment follow-up period.

HEPATITIS C AND SEX

Sexual transmission of HCV is extremely rare among long-term monogamous heterosexual couples. Women may be more likely to acquire HCV sexually from men than vice versa. Disease transmission is riskier when sex involves blood exposure or rupture of skin or membranes. Examples of this are anal sex, fisting, group sex, and sex with a woman during menstruation. Whips, knives, and certain sex toys may cause bleeding. A risky practice that is emerging in our youth is vampire play, which involves biting each other and drawing blood.

The risk of sexual transmission of HCV is increased in the following: men who have sex with men, gay men, sex workers, and people with multiple sex partners. HCV risk is higher in those who have other sexually transmitted infections, particu-

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larly HIV or hepatitis B. People who are co-infected with both HCV and HIV are more likely to transmit HCV; the same may be true for people co-infected with both HCV and hepatitis B virus. HCV risk is higher with a compromised immune system, such as with HIV.

Point #3: Sex is fun; hepatitis C is not. Practice safer sex, and regularly review safer sex information, even if you think you know everything there is to know about minimizing HCV transmission during sex.

HEPATITIS C AND OCCUPATIONAL RISKS

I have a firefighter/paramedic friend who has no known risk factors other than his work. Paul had been a firefighter for a long time, starting before disposable gloves were routinely used. Paul can't even begin to estimate the number of bloody accidents he had responded to, many where he cut himself while aiding a victim.

Any occupation where there is potential blood-to-blood contact carries a risk for hepatitis C transmission. In addition to public safety professions, examples of predominately-male occupations with the potential for blood exposure are military service personnel, healthcare workers, correctional workers, dentists, janitors, and tattoo artists. Barbers who use straight razors or other sharp instruments may have a slight risk. Some sports, particularly boxing, may expose participants to blood.

Paul was treated and no longer has hepatitis C. However, he has been vocal in his community, educating fellow firefighters, police, and paramedics about hepatitis C prevention.

> *"Discussing feelings, symptoms, and side effects are not a sign of weakness; they are information."*

Mike works construction. He contacted me because he regularly nicks himself on the job, and he wants to get rid of HCV. Mike is afraid that he is exposing his co-workers who touch wires and tools that may have residual blood. Although theoretically this could be a risk factor, it is likely low. We talked about some prevention techniques. Mike now carries clean up materials in his toolkit and always has a Band-Aid in his wallet.

Point #4: If you work in an occupation with a risk for blood-to-blood contact, be sure to know what safety precautions are required for your work. Review these regularly, even if you think you know all there is to know about keeping yourself and others safe.

HEPATITIS C AND PSYCHOSOCIAL ISSUES

Steve has HCV and his best friend is a liver specialist I know. The two have talked about Steve's disease over the course of twenty years. Steve is open with this highly regarded hepatologist, but Steve has never talked about his feelings about living with HCV. When I met Steve, I shared that I had HCV. I was the first person he had ever met who had this virus.

At the end of our appointment, I asked Steve if he had any questions. He asked, "Tell me what I can expect when I die from hepatitis C." I was stunned. Steve had no fibrosis and minimal inflammation. He didn't drink alcohol and statistically, he was more likely to die from something other than HCV. However, for many years, he lived his life stoically, assuming that this virus would eventually take his life.

The tendency to "grin and bear it" is frustrating to me as a nurse. During HCV treatment, patients, particularly men, would not report a side effect until it became intolerable. Brian, a patient with a rash, called me, wondering if he should come in to the clinic or wait for his next regular appointment. I knew Brian well enough to know that if he was calling, he should be seen immediately. When he took off his shirt, he revealed an angry brilliant rash covering his torso. It was the worst rash I had seen up to that point, and apparently, my facial expression was not a "poker-face." Brian said my reaction was an affirmation that he made the right decision to come to the clinic, and he said,

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"I thought you were going to tell me to 'buck up Buttercup.'"

Men are less likely to talk about their feelings than women are. They may ignore or keep complaints to themselves. Some men don't have experience with putting words to feelings, and even if they can identify a feeling, they may not know how to explain it. This seems to occur most frequently when men are depressed.

Men's experience of depression may differ from that of women. The chief complaint among men with depression is fatigue or other physical symptoms, such as sleeping problems, sexual dysfunction, stomachache or backache. Men are more likely to have trouble concentrating and making decisions. They may feel stressed and irritable, and act angry and hostile when depressed. They may worry more and use alcohol or drugs to cope.

Suicidal thoughts clearly indicate depression. Women are more likely to attempt suicide, but men are more likely to succeed. Thoughts of hurting yourself or others are serious problems requiring immediate medical help.

Don't be afraid to seek medical help for depression; it is a treatable condition. Millions of men battle depression. Those who have publicly talked about their own struggles with depression are Buzz Aldrin, Johnny Carson, Terry Bradshaw, Louis C.K., Jon Bon Jovi, and Jon Hamm, to name a few. Depression is not a character defect—it is a medical problem.

Point #5: Discussing feelings, symptoms, and side effects are not a sign of weakness; they are information. There are no bad data. Always report thoughts of hurting yourself or others. Seek medical advice for depression.

SPECIAL POPULATIONS: HEMOPHILIA, INCARCERATION AND VIOLENCE

There is an increased risk of hepatitis C in special populations that are predominately male. This includes those with hemophilia, a rare bleeding disorder in which the blood doesn't clot normally. The most common form is inherited, passed from mother to son. Every year, about 1 in 5,000 males is born with hemophilia. Anyone who received clotting factors before 1987 or a blood transfusion prior to 1992 needs to be tested for hepatitis C.

More men than women are in prisons and jails. The Centers for Disease Control and Prevention estimates that 12%–35% of prison inmates are chronically infected with HCV, compared to 1%–1.5% in the uninstitutionalized US population.

Men are more likely to be exposed to violence, and thus blood. There is not much research about violence and risk for hepatitis C, but common sense suggests it needs to be examined.

Point #6: Know your risk factors. Even if you do not have hepatitis C risk factors, if you wonder if you have a history of exposure based on blood-to-blood contact, it is reasonable to request an HCV test.

Men's health is beginning to make headlines. Health activists are raising awareness about men's risk of prostate cancer and other medical issues. Let's add hepatitis C to the list.

Lucinda K. Porter, RN, author of *Free from Hepatitis C* is a long-time contributor to the HCV Advocate. Her blog is http://lucindaporterrn.com

Resources

- *A Guide to HIV/HCV Coinfection*
- *Bleeding Disorders and Hepatitis C*
- *Environmental Stability of HCV*
- *Gay Men and Hepatitis C Poster*
- *HCV and Tattoos*
- *Hepatitis C Transmission and Prevention: Personal Care Settings*
- *Occupational Exposure to Hepatitis C*
- *Planned Parenthood*
- *Sexual Transmission of Hepatitis C*
- *Sexual Transmission of Hepatitis C FAQs*
- *Transmission and Prevention of HCV: An Overview*

DISABILITY & BENEFITS

Affordable Care Act in 2014

—Jacques Chambers, CLU

Since being enacted in March, 2010, the Affordable Care Act (sometimes called ObamaCare) has already initiated some changes in healthcare delivery, permitting children to stay on parents' coverage until age 26, covering preventive care at 100%, and prohibiting lifetime limits on benefits, just to name a few.

Effective January 1, 2014, however, the law is going to completely overhaul how health insurance is provided. The implementation of this law will cause the greatest changes in health insurance since the inception of Medicare in 1965. One of the most important changes is that every legal resident will be able to purchase health insurance regardless of their medical condition or health history. Just as important, premium rates can no longer be based on an insured person's health history.

This change in the method of obtaining health insurance is going to be of the greatest benefit to persons with no insurance, those having individual coverage, and those receiving their coverage from an employer with less than 50 employees. Coverage under these new plans will take effect on January 1, 2014, but enrollment in the plans begins on October 1, 2013. In the next few months you will be seeing much more about it as a major informational campaign is rolled out. Special efforts will be made to encourage healthy young persons to enroll since their participation is vital to the financial stability of the program, yet they are a group that may be reluctant to enroll.

PATIENT'S BILL OF RIGHTS

Under the law, a new "Patient's Bill of Rights" summarizes the goals of giving the American people the stability and flexibility they need to make informed choices about their health. The new healthcare law puts consumers back in charge of their health care.

The Patient's Bill of Rights:

- Provides Coverage to Americans with Pre-existing Conditions: You will be eligible for health coverage regardless of your medical condition or health history.
- Protects Your Choice of Doctors: Choose the primary care doctor you want from your plan's network.
- Keeps Young Adults Covered: If you are under age 26, you may be eligible to be covered under your parent's health plan.
- Ends Lifetime Limits on Coverage: Lifetime limits on most benefits are banned for all new health insurance plans.
- Ends Arbitrary Withdrawals of Insurance Coverage: Insurers can no longer cancel your coverage just because you made an honest mistake.
- Reviews Premium Increases: Insurance companies must now publicly justify any unreasonable rate hikes.
- Helps You Get the Most from Your Premium Dollars: Your premium dollars must be spent primarily on health care – not administrative costs with limits on how much of your premiums can be used for administrative costs.
- Restricts Annual Dollar Limits on Coverage: Annual limits on your health benefits will be phased out by 2014.
- Removes Insurance Company Barriers to Emergency Services: You can seek emergency care at a hospital outside of your health plan's network.

COVERAGE MANDATE

Effective January 1, 2014, all legal residents of the U.S. must

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have health insurance. It may be individually purchased directly from insurance companies or through one of the health insurance exchanges being set up in each state.

Employers with 50 or more employees will face tax penalties if they don't offer health insurance to all full-time employees. Employers with less than 50 employees are not required to offer health insurance to their employees, however, if they do, they may take advantage of the healthcare exchanges.

One reason for requiring everyone to be covered is to provide an incentive that will prevent healthy, younger persons from not applying until they need it. In insurance terms, this is the "spread of risk"; the more the spread includes healthy, young people who don't usually require a lot of medical care, the more reasonable premium rates will be for all.

PURCHASING COVERAGE

The simplest way for persons to purchase health insurance coverage is to use their state's exchange. This marketing tool will allow insurance companies to offer coverage, but, as elaborated on in this column in February, they must offer no more than four standardized plans. All plans must provide an easy-to-understand explanation of coverage called a Summary of Benefits and Coverage (SBC).

The exchanges will be on line. Personal assistance will be available through counselors by telephone, and some states are opening brick and mortar stores with trained counselors. The resources at the end of this article can direct you to your state's exchange website.

Under the exchanges, the only factors that can affect an individual's rates are the person's age, their geographical location, and the plan selected. Gender and health history cannot be considered. The law also provides for a surcharge for smokers, however, the implementation of that provision may not be the same in all states.

PENALTIES FOR NOT PURCHASING HEALTH INSURANCE

As an incentive for all to purchase health insurance, tax penalties will be assessed on persons who do not purchase health insurance. The penalty starts in 2014 as 1% of family income with a minimum dollar amount. It rises until the penalty is 2.5% of family income in 2016, with increases that track inflation in the following years.

The only persons not penalized for not purchasing health insurance are: undocumented residents, incarcerated persons, Native American Indians, families whose income is so low they are not required to file income tax returns, and persons whose religion conflicts with the concept of receiving such benefits.

PREMIUM COSTS

It is widely believed that the premiums for health insurance will rise substantially initially, primarily due to the broader coverage required by the law and because medical costs continue to rise. There are provisions in the law that are aimed at controlling the rise in costs, but it may be some time before the results of those provisions are seen in the marketplace.

However, there will be generous subsidies for persons buying coverage through the state health exchanges. The subsidies are available to those individuals who are not otherwise eligible for other public programs such as Medicare, Medicaid, Children's Health Insurance Program or military coverage. Also, persons covered under employer plans are not eligible for the subsidies unless the employer plan covers less than 60% of medical charges or the employee portion of the premiums is over 9.5% of the employee's income.

A glitch has developed over the final issue noted above, "those employees whose portion of the premiums is over 9.5% of the employee's income." One court has ruled that it only applies to the employee's premium, not that of his or her dependent's coverage. Since that is the largest portion of the premium, if upheld, it almost defeats the purpose of the provision. This

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issue will hopefully be resolved by the October 1 Open Enrollment period.

The subsidies will be large enough to limit the insurance premiums of a family to a sliding scale percentage of their family income, ranging between 2% and 9.5% for persons whose income is between 100% and 400% of the Federal Poverty Level.

Using the newly published Federal Poverty Guidelines for 2013, 100% of the Federal Poverty Level in the contiguous 48 states is $11,490 for an individual and $23,550 for a family of four. 400% of the Federal Poverty Level is $45,960 for an individual and $94,200 for a family of four. These amounts are higher in Alaska and Hawaii. For a complete table of the Federal Poverty Level released 04-01-2013, go to: *https://www.federalregister.gov/articles/2013/01/24/2013-01422/annual-update-of-the-hhs-poverty-guidelines#t-1*.

Families with incomes below the Federal Poverty level will be eligible for Medicaid. In those states not expanding their Medicaid coverage to accommodate these persons, individuals will not be penalized for not purchasing health insurance.

Families with incomes over 400% of the Federal Poverty Level, which is only about 9% of the uninsured population, may still use the exchanges to purchase health insurance but they will not be eligible for any premium subsidy.

More Information

There are many websites with information about the new law. As with anything on the internet, care should be taken to make sure you are getting accurate and current information.

Two of the most informative and reputable sites are:

- **Henry J. Kaiser Family Foundation** (*http://kff.org/health-reform/*) provides information on the law state by state, and the site is constantly updated as regulations and changes occur.
- **HealthCare.gov** (*www.healthcare.gov*) is an official website managed by the U.S. Department of Health & Human Services.

Drug News

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topline interim results are listed in the table on page 1 (sofosbuvir (SOF), ledipasvir (LED), ribavirin (RBV)).

Note: The combination of the drugs listed above are in Phase 3 studies. Recently, Gilead submitted clinical trial data from their Phase 3 studies to the FDA for marketing approval of SOF/PEG/RBV combination therapy for the treatment of HCV genotypes 1,3,4,5 and 6, and SOF/RBV (without interferon) therapy for the treatment of HCV genotype 2 and 3. Gilead's interferon-free clinical trial (SOF/LED with and without RBV) for HCV genotype 1 patients is currently in phase 3 clinical trials.

JANSSEN

The three drug combination of Simeprevir/PEG/RBV is under FDA review for the treatment of HCV genotype 1. On May 1, 2013 Janssen announced that the combination had been granted Priority Review by the FDA. Priority Review is granted when a drug offers a major advancement in care or if it provides a treatment option when there is no adequate treatment available. The addition of simeprevir (once-a-day dosing) to pegylated interferon and ribavirin increased overall cure rates, reported to have fewer side effects than the current standard of care of PEG/RBV plus telaprevir or boceprevir and the majority of people in the simeprevir groups were able to complete therapy at week 24. Another bonus is that simeprevir is only taken once-a-day (QD) which is definitely an improvement of taking the current HCV protease inhibitors that require multiple pills every 7 to 9 hours.

JENNEREX

The FDA has granted orphan drug designation for Jennerex's oncolytic immunotherapy PexaVec for the treatment of hepatocellular carcinoma (HCC/liver cancer). The drug is currently in a Phase 2 study for the treatment of liver tumors. The orphan drug status is granted to investigational drugs that will provide better treatment options than currently approved medications or for a serious condition that needs more effective treatment, but there is a relatively small patient population. The orphan drug status allows companies market exclusivity for 7 years. This will help the company recoup some of the expenses involved in drug development.

For more on the latest in the HCV Drug Pipeline see *"The Next Wave: Janssen/Tibotec and Gilead File for FDA Approval," by Alan Franciscus, Editor-in-Chief, HCV Advocate, May 2013.*

Also, be sure to check out the *HCV Advocate News & Pipeline Blog* for the latest news about and access to current clinical trials.

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The HCV Advocate offers information about various forms of intervention in order to serve our community. By providing information about any form of medication, treatment, therapy or diet we are neither promoting nor recommending use, but simply offering information in the belief that the best decision is an educated one.

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