# Hepatitis C:

**What is it and How Does it Relate to Social Security Disability Insurance**

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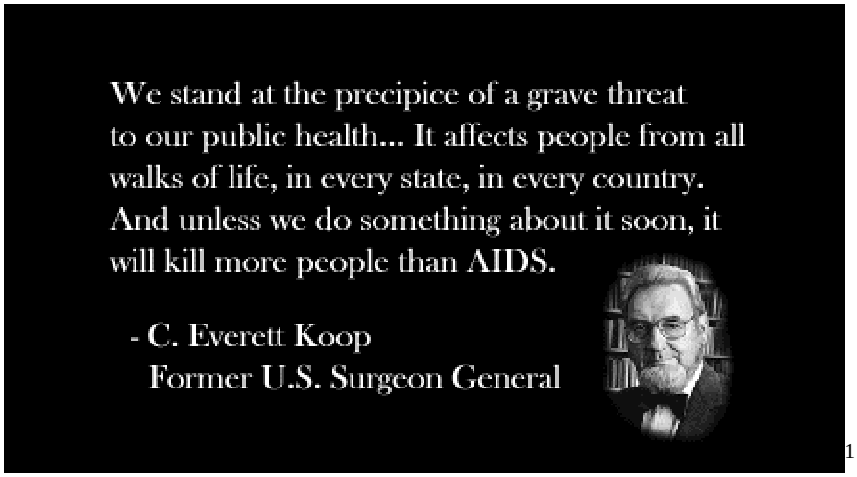
This paper is informational for representatives of SSDI and SSI claimants to help them understand the nature of Hepatitis C, its treatment, and the side effects of said treatments, and to apply this information in the representation of claimants with Hepatitis C at administrative law hearings. This paper is not in any way to be construed as a medical study of Hepatitis C.

Hepatitis C is a threat to people of every nation, color, creed and economic condition. Hepatitis C is a blood borne virus that affects the livers of infected persons causing severe damage resulting in death. Hepatitis C has been called the "silent epidemic" because the majority of people infected are unaware of their infection. Eighty percent of people who have Hepatitis C show no signs or symptoms. Worse still, it can remain asymptomatic for up to ten, twenty and even thirty years before its affects are manifest.



[1]

Hepatitis C is transmitted through the blood; however, the insidious nature of the Hepatitis C virus is that it appears capable of being transmitted indirectly through the common use of razors, tattooing equipment, and most prevalent of all now shared needles. This makes Hepatitis C much more easily transmittable than other viruses such as HIV. Such indirect sources of blood may explain many cases of inter-household related transmission.

"It is suspected that there are, at present, more than 5 million people in the United States that are infected with Hepatitis C, and perhaps as many as 200 million around the world. This makes it one of the greatest public health threats faced in this century, and perhaps one of the greatest threats to be faced in the next century."[2]

Prior to 1990 there were no tests to screen for Hepatitis C and people were at risk for becoming infected through blood transfusions and transplant operations. However,

[1] C.E. Koop, Hepatitis C: An Epidemic for Anyone, *www.epidemic.org.* (1998).
[2] C.E. Koop, Hepatitis C: An Epidemic for Anyone, *www.epidemic.org.* (1998).

since the discovery of new and more scientific testing for the disease the post transfusion infection rate today is negligible.

Hepatitis C is the most common cause of liver cancer in North America. Each year more than ten thousand Americans die from Hepatitis C, and more than 90% of those who have untreated Hepatitis C will carry the virus forever. It takes more than 15 years to develop signs of liver damage, 19 years to suffer permanent liver damage called cirrhosis, and 26 years to develop liver cancer.

**Certain lifestyles increase the risk of infection.**

Intravenous (IV) drug users represent the largest single risk group of Hepatitis C infection. As with HIV, the sharing of contaminated needles and syringes increases the chance of infection dramatically. Some studies indicate infection rates among IV drug users has surpassed 50% and in other studies almost reach 100%.

Sexual contact has been identified as a means of transmitting Hepatitis C. The primary risk factors for infection include: a large number of partners, unprotected sex, simultaneous infection with other sexually transmitted diseases (STDs) and traumatic sexual activity. The rates of infection have been recorded at between 1-18% among homosexually active individuals, 1-10% among heterosexually active individuals, and 1-12% among female prostitutes.

In prison populations the infection rate is reaching epidemic proportions. California, our largest state in the union, reports that infection rates have exceed 80% with certain institutions reporting a nearly 100% rate of infection. [3]

Tattooing in particular causes serious risks even in the presence of good sterilizations. Studies suggest that the ink itself used in tattooing becomes contaminated and thereby transmitting the virus even though the instruments themselves may be sterile. This poses serious consequences for future healthcare professionals because of the popularity of tattoos among today's youth.

Cocaine users have an abnormally high risk of infection since they frequently would share snorting straws, which may have small amounts of blood carrying mucus on them. This behavior combined with the fact that Hepatitis C infections may not become known for ten to twenty years should alarm many middle-aged Americans today who lived life in the fast lane when they were young.

It appears that the debilitating effects of Hepatitis C are more rapid in the elderly. A patient's age at infection has been reported in almost all published studies to have an important impact on the progression of chronic Hepatitis C.

Men, alcoholics, patients with cirrhosis, people over the age of forty, and those affected for 20-40 years are more likely to develop HCV related liver cancer. At least 75% of patients with acute Hepatitis C ultimately develop chronic infection, and most of these patients have accompanying chronic liver disease. Chronic Hepatitis C can cause cirrhosis, liver failure and liver cancer. Liver failure from chronic Hepatitis C is the most

[3] C.E. Koop, Hepatitis C: An Epidemic for Anyone, *www.epidemic.org*. (1998).

common reason for liver transplants in the United States. Hepatitis C is the cause of about half the cases of primary liver cancer in the developed world.

**Hepatitis C is the leading cause of death in HIV patients.**

Co-infection with HCV, Hepatitis C and HIV is common. Co-infection with HVB or HIV has been shown to accelerate the course of chronic Hepatitis C and facilitate the progression of cirrhosis and hepatocellular carcinoma. Approximately 25% of all subjects with HIV are also infected with HCV. Therefore, patients with HCV should be tested both for HVB and HIV markers in the presence of other risk factors.

The estimates of people with HCV could be four times the number of those infected with the AIDS virus. One of the main differences is that HCV does not kill as quickly as AIDS.

Some data now suggest that there is an altered cerebral metabolism in patients with chronic HCV infection which cannot be explained by hepatic encephalopathy or a history of drug abuse. There is a suggestion that there is a biological process underlies the extra hepatic symptoms in chronic HCV infection. People who suffer of HVC also complain of fatigue, lassitude, impaired memory ("Brain fog"), and a perceived inability to function effectively, even in the absence of clinically significant liver disease. It is not known whether social, psychological, or biological factors cause these complaints. **[footnote cite: http://content.nejm.org/cgi/short/349/312]**

**Diagnosis of Hepatitis C.**

Acute Hepatitis C is diagnosed on the basis of symptoms such as jaundice, fatigue, and nausea, along with marked increases in serum ALT.

The most accurate test for Hepatitis C is a liver biopsy.

**Treatment of Hepatitis C.**

The development of effective Hepatitis C vaccines remains a challenge. The development of HCV vaccines have met with little success during the past decade.

> "The therapy for chronic Hepatitis C has evolved steadily since alpha Interferon was first approved for use in this disease more than 10 years ago. At the present time, the optimal regimen appears to be a 24- or 48-week course of the combination of Pegylated alpha Interferon and ribavirin.
>
> "Alpha Interferon is a host protein that is made in response to viral infections and has natural antiviral activity. Recombinant forms of alpha Interferon have been produced, and several formulations (alfa-2a, alfa-2b, consensus Interferon) are available as therapy for Hepatitis C. These standard forms of Interferon, however, are now being replaced by Pegylated Interferons (pegInterferons). PegInterferon is alpha Interferon that has been modified chemically by the addition of a large inert molecule of polyethylene glycol. Pegylation changes the uptake, distribution, and excretion of Interferon,

prolonging its half-life. PegInterferon can be given once weekly and provides a constant level of Interferon in the blood, whereas standard Interferon must be given several times weekly and provides intermittent and fluctuating levels. In addition, pegInterferon is more active than standard Interferon in inhibiting HCV and yields higher sustained response rates with similar side effects. Because of its ease of administration and better efficacy, pegInterferon has been replacing standard Interferon both as monotherapy and as combination therapy for Hepatitis C.

"Ribavirin is an oral antiviral agent that has activity against a broad range of viruses. By itself, ribavirin has little effect on HCV, but adding it to Interferon increases the sustained response rate by two- to threefold. For these reasons, combination therapy is now recommended for Hepatitis C, and Interferon monotherapy is applied only when there are specific reasons not to use ribavirin. **[cite footnote: Chronic Hepatitis C: Current Disease Treatment]**

Recently a leading Gastroenterologist has suggested the increasing the current medication doses for Hepatitis C because no new therapies are likely to be developed in as long as a decade.

"Right now we are all doing studies but the results from those studies won't be available for awhile yet," eminent liver expert Carroll B. Leevy told a *Medical Herald*-sponsored Hepatitis C. forum.

We have 750,000 Americans with HIV and four million with Hepatitis C," he said. "Clearly more money and effort is spent on HIV than Hepatitis C.

We spend less than 10 percent on Hepatitis C [research] compared to what we spend on HIV."

"Liver-related deaths will tremendously increase to we are left in a situations where we are not going to have any therapies until 2010." – Carroll B. Leevy, M.D.[4]

The centers for disease control suggest there are four million Americans with Hepatitis C. The experts say this is only the tip of the iceberg. Also, it is much more common in minority populations. 3.2% of African-Americans in the country are infected with Hepatitis C as compared to 1.5% of the majority of Americans. It is twice as common in minority populations as compared to majority populations.

The poor tolerability and efficacy of treatments has driven research to find safer and more effective medicines. The recent development of Pegylated Interferon combined with Ribivarin increased the sustained viral responses to 55%; even higher doses give better responses. The most frequent side effects experienced during Interferon A and B, and Pegylated Interferon treatment are flu-like syndromes, fever, fatigue and injection-site reactions. The primary objective for the treatment of Hepatitis C virus and related chronic Hepatitis C is to eradicate infection and prevent the progression of the disease to cirrhosis and thereby preventing complications associated with end-stage liver disease.

Hepatitis C has been treated with Interferon A and B along with a combination treatment with Ribivarin. Recently there has been new Interferon preparations such as Pegylated IFNs (PEG-IFNs), have been introduced in the practice.

[4] L. Edkins, Hepatitis C Dosage Hike Is the Remedy, *The Medical Herald, Volume 16, No. 1,* (2004).

Recent results from major studies of combined Pegylated Interferons and Ribivarin have shown great increases in the efficacy of treatment. HCV infection was eradicated in some cases up to 54% of patients treated with PEG-IFN□-2b with similar results with PEG-IFN□-2a treatment. Interferon is a substance that has been synthesized to match one of the naturally occurring substances in the body. These are proteins produced by special cells that are made when the body recognizes a foreign substance entering it. It acts as part of the protein mechanism against infection and is stimulated by a viral attack such as the flu virus. It appears that Interferon is actually the substance that seems to be the major factor in the flu-like symptoms and fatigue associated with Hepatitis C.

There have been studies that show that fatigue and psychological disturbance occur frequently in chronic diseases. The fatigue experienced by patients with HCV infection is more severe and intransigent and responds poorly to relieving factors.

Also, patients with HCV infections are more depressed and have greater feelings of anger and hostility compared with patients with non-liver chronic diseases.

As an SSA advocate, it's irrelevant how your client contracted Hepatitis C. It's only important to clearly show the ALJ that your client is suffering from the side effects of the disease. "Alpha Interferon has multiple neuropsychiatric effects. Prolonged therapy can cause marked irritability, anxiety, personality changes, depression, and even suicide or acute psychosis. Patients particularly susceptible to these side effects are those with preexisting serious psychiatric conditions and patients with neurological disease."[5]

[5] A.S. Gershon, M. Margulies, R.M. Gorczynski, E.J. Heathcote, Chronic Hepatitis C: Current Disease Management, *Journal of Viral Hepatitis, Volume 7, Issue 6*, (2000), pg. 397.

There are also studies that suggest people who suffer HCV infection have increased impairments in health related quality of life issues. These findings are independent of severe liver disease. There are numerous findings of people suffering from fatigue and depression in chronic HCV infection and this may account for the reduction in their quality of life. Also there is evidence of neurocognitive impairment in HCV infection. In recent studies in post mortem brain tissue raises the possibility that HCV infection of the central nervous system may be related to the reported neuropsychological symptoms and cognitive impairment.

"Most doctors who see and treat patients with chronic Hepatitis C (CHC) will be all too aware of the frequency with which patients complain of non-specific symptoms that they attribute to their infection. Fatigue, malaise, musculoskeletal and right upper abdominal discomfort feature alongside complaints of reduced cognitive function and mental clouding (`brain fog') [1-5].

"Clinically significant depression, even before treatment with -Interferon, is widely reported [6-8]. Anxieties regarding diagnosis, prognosis and treatment are commonplace in our clinics, despite patients being increasingly well informed, frequently through the Internet. There is often a history of previous or ongoing substance abuse and patients may have associated emotional problems or personality traits. When the well-established psychological sequelae of chronic disease [9] and stigmatization [10] are also factored in, it is unsurprising that studies of health-related quality of life (HRQL) consistently report reduced well-being in patients with CHC compared to population norms [11-14]. Given the complex nature of many of the above interrelated factors, which themselves are unrelated to hepatic necroinflammation or to fibrosis, it is not unexpected that studies of HRQL in CHC find no association with the stage of liver disease or the serum alanine aminotransferase level. Despite this, there is good evidence that patients'

perceptions of well-being improve after successful anti-viral therapy, suggesting that the determinants of impaired HRQL are, at least in part, related to the disease process itself [14,15]. Although there is now a substantial literature reporting impaired HRQL in CHC, the determinants of impaired HRQL and the aetiology of the extrahepatic symptoms have received far less attention. In this issue of the Journal, Fontana and colleagues have addressed the question of whether psychiatric symptoms may contribute to the impaired HRQL in CHC patients [16].[6]

People with histories of substance abuse and intravenous drug use or alcohol dependence seem to have a poorer quality of life situation than those that do not suggesting that the medical process itself may exacerbate anxiety symptoms in some individuals.

> Of note, a history of intravenous drug use or alcohol dependence was not associated with emotional distress. Patients who returned to the clinic had significantly higher emotional distress than new patients (patients who expected to die from CHC had the highest BSI scores), suggesting that the medical process itself may exacerbate anxiety symptoms in some individuals.[7]

The prevalence of psychiatric symptoms among HCV patients is twice that one would expect. Cognitive impairment has been recognized; also impairments of attention, concentration, and working memory were identified. All these were independent of depression. This raises the intriguing possibility that HVC may also affect the central nervous system.

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[6] D.M. Forton, S.D. Taylor-Robinson, H.C. Thomas, Reduced Quality of Life in Hepatitis C – Is It All In the Head?, *Journal of Hepatology, Volume 36(3),* (2002), pgs.435-438.
[7] D.M. Forton, S.D. Taylor-Robinson, H.C. Thomas, Reduced Quality of Life in Hepatitis C – Is It All In the Head?, *Journal of Hepatology, Volume 36(3),* (2002), pgs.435-438.

**THE NEED TO EDUCATE**

Ten times more people suffer from Hepatitis C than from AIDS, and yet 100% more money is spent on research for HIV than HCV, why is that? African-Americans have a two times higher rate of infection with HCV than the general population for whatever reason. What do these things tell us? **They simply tell us this, the squeaky wheel gets the grease.**

The overall population of people with HIV are well-funded, well-educated, well-healed, well-informed, and they are politically motivated. The majority of the people who are carrying the HCV infection are not even aware that they are infected. Therefore the funding is sorely lacking in the research to find a cure for Hepatitis C as opposed to the research funded the cure of HIV when compared to populations of the infected persons.

What can be done to change this? We must educate the population as a whole as to the outbreak effects, ravages and results of Hepatitis C. We must educate the general population as well as the politicians so that appropriate pressure can be placed on the government to fund further research.

Two hundred million people worldwide are infected with HCV. The disease takes ten to twenty years to become noticed. Five million Americans are presently infected with HCV. Over ten thousand people die each year from HVC in the United States. What do these numbers mean? They mean that in the future we will see an

enormous rise in the cases of acute Hepatitis C with the inevitable consequences, cirrhosis of the liver, liver disease, liver transplantation and renal failure and death.

The time is now to educate the populations, educate the medical community and educate the government in funding faculties in order to increase the amount of revenue going into the research for Hepatitis C and its cure. We are least a decade away from any new treatment. The time to act is now.

Twenty-five percent of all HIV infected persons are infected with HCV virus. The majority of deaths of people suffering from HIV die of HCV.

**TREATMENT**

Despite encouraging and positive results of present treatment, several other clinical problems remain. The most significant being that a large number of patients receiving both PEG-IFN□-2a and PEG-IFN□-2b and Ribivarin need to discontinue treatment due to the occurrence of adverse events associated with the therapy. In fact up to 42% of patients treated with PEG-IFN□-2b required dose reductions due to adverse effects and 13% stopped treatment all together for safety reasons. The observed rate of flu-like symptoms were 63%, of inflammation at the injections site 43%, adverse abdominal symptoms 26% and psychiatric disturbances 13%. Therefore, it is concluded that although there has been some success with Pegylated Interferons treatment, it requires longer treatment at higher doses. As a result of the increased risk of side effects from the longer treatment and higher doses, patients are less likely to follow through with the prescribed treatment. When considering that the long-term goal is the eradication of

infection and prevention of progression of the disease, the number of people who either reduce treatment or stop treatment is significant.

> Interferon and ribavirin combination therapy for chronic Hepatitis C produces a number of well-described side effects that are dominated by fatigue, influenza-like symptoms, hematologic abnormalities, and neuropsychiatric symptoms. Combination therapy with Pegylated Interferons (pegInterferon alfa-2a and alfa-2b) yields an adverse event profile similar to standard Interferon, although the frequency of certain adverse events may vary by preparation. Premature withdrawal from therapy due to adverse events was required in 10% to 14% of participants in registration trials of these agents.[8]

**All subjects who are treated with Pegylated Interferons and Ribivarin experience at least one adverse side effect.**

> The most frequent adverse events reported after administration of peg -Interferon were an influenza-like syndrome (46%), injection site reaction (58%), headache (46%), and fatigue/malaise (23%).[9]

> "Peg-Interferon alfa-2b and Interferon alfa-2b cause or aggravate fatal or life-threatening neuropsychiatric, autoimmune, ischemic, and infectious disorders."[10]

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[8]M.W. Fried, Side Effects of Therapy of Hepatitis C and Their Management, *Journal of Hepatology, Volume 16(5 Suppl 1),* (2002), pgs. S237-44.

[9] J. Henkel, Hepatitis C: New Treatment Helps Some, But Cure Remains Elusive, *U.S. Food and Drug Administration,* (1999).

[10] J. Henkel, Hepatitis C: New Treatment Helps Some, But Cure Remains Elusive, *U.S. Food and Drug Administration,* (1999).

## PSYCHOLOGICAL, EMOTIONAL AND/OR MENTAL ADVERSE EFFECTS OF TREATMENT

Side effects occur in all patients who take Interferon and Pegylated Interferon treatments. The major side effects being fatigue, muscle aches, head aches, nausea, vomiting, skin irritations and the injection site, low grade fever, weight loss, irritability and depression. Also, in a combination treatment which is the most recommended at the present time with Ribivarin. Ribivarin also causes side effects, and the combination treatment is generally less well tolerated than Interferon monotherapy. The most common side effects with Ribivarin are anemia, fatigue and irritability, itching, skin rash, nasal stuffiness, sinusitis, and cough. Fatigue may be considered one of the neuropsychiatric side effects of Interferon alpha and Ribivarin treatment.

Neuropsychiatric side effects can be the most troublesome and unpredictable, but their mechanisms are poorly understood. Interferon is not thought to readily cross the blood-brain barrier. These effects include fatigue, asthenia, drowsiness, lack of initiative, irritability, confusion, and apathy; behavioral, mood, and cognitive changes are a relatively frequent dose-limiting toxicity. Severe depression may occur and suicidal ideation is well described. This can be more marked in patients with a history of depression, but suicide has been reported in patients without a previous psychiatric history.[11]One of the cruel factors or ironic factors of treatment for Hepatitis C is an increase in emotional upset that the treatment can bring to the patient. Recent studies have indicated that patients who had no significant progressed or

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[11] G. Dusheiko, Side Effects of Interferon Alpha in Viral Hepatitis, *www.hepnet.com/nih/dusheiko.html.* (2002).

decompensated liver disease, and no grade of liver damage, had high rates of depression and anxiety. Depression was higher in older patients than in younger patients. Also of significance, patients who were advised not to undergo Interferon treatment had higher rates of depression and anxiety. The problem is that there is no vaccine to prevent Hepatitis C. The only reasonable treatment is Pegylated Interferons with Ribivarin. This can help approximately 80% of those diagnosed with the disease. However, many patients stopped treatment because of increases in depression and anxiety.

"We are looking at a very common side effect, and we need to devote more time and research money to study these side effects, like depression, because if we don't treat the side effects, we won't succeed with treating the disease," he says. [12]

In another study for the Portland VA Medical Center it was found that the majority of patients that treated with Interferon therapy developed at least some depressive symptoms and 33 % of those patients met the criteria of major depression during Interferon treatment.

> "Many people who have Hepatitis C have depression, and their depression becomes so uncomfortable they often stop treatment on their own without seeing a physician, or their doctor will stop the Interferon," says Dr. Peter Hauser, associate director of the Northwest Hepatitis C Resource Center at the Portland VA Medical Center. "But if they don't stay on the medicine, they don't have the chance to be treated."[13]

[12] J. Billingsley, Interferon Causes Major Depression For Hepatitis C Patients: Depression Is Common and Should Be Treated, Study Says, *HealthScout News Reporter*.
[13] J. Billingsley, Interferon Causes Major Depression For Hepatitis C Patients: Depression Is Common and Should Be Treated, Study Says, *HealthScout News Reporter*.

One interesting aspect of depression is that it appears to be lesser in African-Americans than it is in the rest of the population as a whole. African-Americans are also much more resistant to the treatment of Interferon therapy. There may be some connection to their lack of response to Interferon and the lower incidence of depression.

> Hauser says that African-Americans, who have a much higher prevalence of Hepatitis C than do whites, have a very poor response to Interferon therapy and there could be a connection between their lack of response to Interferon and the low incidence of depression.[14]

A much more serious side effect is suicidal behavior (suicidal thoughts, suicide attempts and completed suicides). Such behavior is rare, but it still exists in a few people who are receiving Interferon treatments.

Even the manufacturers are aware of the dangerous side effects of Interferon, as the following warning suggests.

**WARNING**

> **Alpha Interferons, including INTRON® A, cause or aggravate fatal or life-threatening neuropsychiatric, autoimmune, ischemic, and infectious disorders. Patients should be monitored closely with periodic clinical and laboratory evaluations. Patients with persistently severe or worsening signs**

[14] J. Billingsley, Interferon Causes Major Depression For Hepatitis C Patients: Depression Is Common and Should Be Treated, Study Says, *HealthScout News Reporter*.

**or symptoms of these conditions should be withdrawn from therapy. In many but not all cases these disorders resolve after stopping INTRON A therapy.**[15]

## FATIGUE

The next and perhaps most ironic of all side effects of treatment of Interferons and Pegylated Interferons in combination treatments with Ribivarin is the side effect of fatigue.

As we have addressed earlier, fatigue is a major component of people suffering with Hepatitis C. The fatigue is akin to **exhaustion**, not just being tired. Unfortunately it is also a side effect of Interferon treatment along with flu-like symptoms.

## FLU-LIKE SYMPTOMS AND FATIGUE

Studies have shown that treatment with combination Pegylated Interferon with Ribivarin are similar to Interferon alpha treatment side effects.

The following shows a chart indicating the common side effects of Interferon alpha experiments and Pegylated Interferon treatments.

[15] http://www.introna.com/introna/indications/hepatitis_c/index.jsp

## Most Common Adverse Events in a Recent Large Trial of Patients Treated With Interferon Alfa 2b (3 MU=15 ug) (percentage)

| Preferred Term | IFN a-2b 15ug |
|---|---|
| | |
| Headache | 82 |
| Fatigue | 67 |
| Fever | 45 |
| Rigors | 44 |
| Myalgia | 55 |
| Pain | 44 |
| Arthralgia | 44 |
| Back pain | 36 |
| Abdominal pain | 39 |
| Nausea | 35 |
| Insomnia | 30 |
| Pharyngitis | 31 |
| Nervousness | 28 |
| Infection upper | 33 |
| Diarrhea | 24 |
| Pain limb | 25 |

| | |
|---|---|
| Depression | 25 |
| Anorexia | 17 |
| Granulocytopenia | 25 |
| Erythema | 15.3 |
| Dizziness | 24 |
| Cough | 17 |
| Dyspepsia | 18 |
| Anxiety | 18 |
| Thrombocytopenia | 16 |
| Sinusitis | 22 |
| Influenza like | 11 |
| Leukopenia | 12 |
| Pain neck | 12 |
| Pain skeletal | 14 |
| Alopecia | 25 |
| Paraesthesia | 9 |
| Pruritus | 13 |
| Rash | 14 |
| Chest pain | 14 |
| Hot flushes | 7.2 |

| | |
|---|---|
| Emotional lability | 11 |
| Rhinitis | 15 |
| Increased sweating | 11 |
| Vomiting | 10 |
| Resp tract congestion | 14 |
| Dysmenorrhea | 9.4 |
| Thyroid testabnormal | 4 |
| Conjunctivitis | 8.1 |
| Constipation | 5 |
| Thinking abnormal | 12 |
| Hypertriglyceridemia | 6 |
| Tinnitus | 4 |
| Pain eye | 5.5 |
| Earache | 6 |

Extremely rare side effects can have a cardiovascular aspect to them.

Both benign and severe cardiac manifestations have been reported. Cardiac arrhythmias, including supraventricular tachycardia but also sudden death and

ventricular arrhythmias, have been reported. There are single case reports of dilated cardiomyopathy. Hypotension has been reported in large trials. [16]

The consequences of Interferon and Pegylated Interferon treatments are an enhancement of the neuropsychiatric side effects; an increase in flu-like symptoms; and an increase in extreme fatigue.

**CONCLUSION**

How does this all fit in with social security disability? The cases on point with Social Security and Hepatitis C are not well understood. There is not much legal history on which we can rely to understand the relationship of Hepatitis C with Social Security Disability.

When a case is before an ALJ, he must assess all the evidence, in particular medical evidence related to the claimants alleged disability. Unfortunately, in most cases the ALJ will not have a sufficient understanding of the affects Hepatitis C. Most likely, the ALJ also will not have a sufficient understanding of the Hepatitis C treatment and its side effects. As discussed infra, these side effects include but are not limited to flu-like symptoms, extreme fatigue, malais, and depression.

The SSA practitioner also cannot assume the Commissioner's medical expert is fully aware of the significance of the side effects of treatment for Hepatitis C. Therefore, it is incumbent upon the claimant's representative to educate the ALJ and, if need be, the

[16] G. Dusheiko, Side Effects of Interferon Alpha in Viral Hepatitis, *www.hepnet.com/nih/dusheiko.html.* (2002).

medical expert as to the significant effects of treatment and the consequences of those effects on a claimant.

An ALJ must give controlling weight to a treating physician's opinion on a claimant's medical condition unless the opinion is not well supported by medical findings or is inconsistent with other record evidence. **[cite: need the case cite]** An ALJ may consider the claimant's testimony less credible if the medical evidence does not support the symptoms to the extent alleged. It is essential that the ALJ address each of the Avery Factors at hearing in order to make a decision based upon sufficient and substantial evidence.

This is a conundrum with Social Security and Hepatitis C cases. One of the most significant side effects or results of Hepatitis C is extreme fatigue. Extreme fatigue is a subjective complaint that cannot be tested. However this does not mean that it does not exist. When one considers that prior to 1989 there was no test for Hepatitis C certainly there were persons suffering from the disease yet there were no objective tests could tell the finder of fact that it existed, but it certainly did exist.

Therefore it is incumbent on the claimant's representative to educate the ALJ and if need be the medical expert to the significance to both the disease of Hepatitis C and the treatment of hepatitis and its disabling factors and the disabling factors of the side effects of treatment.

It is the responsibility of the claimant's representative to educate the ALJ and the medical examiner as to the unique nature of Hepatitis C and its treatment. When one

understands that treatment with the Interferons and the Pegylated Interferons is to prevent the ultimate end result which is cirrhosis of the liver, liver cancer, liver transplantation, end-stage liver disease and ultimately death. It is stunning to learn that a significant number of patients will choose to discontinue treatment despite the catastrophic outcome rather than suffer the side effects of treatment. What this means is that patients realize they will eventually die if they don't treat their Hepatitis C with the Pegylated Interferon combination therapy. Yet they consider the side effects so severe, that they choose death rather than treatment. This choice, I submit, does not indicate slight side effects.

You can have the flu not for a couple of days but for a couple of weeks. Mental clouding, ("brain fog"), depression and suicide.

A number of studies have also investigated the effects of illegal drug use but neither chronic use of cocaine nor heroine has been found to increase cerebral choline-containing compounds. Therefore it is unlikely that a history of IV drug use underlies the MR abnormalities in the HCV group.

Since the onset of clinically apparent liver disease typically occurs between 10 and 20 years after HCV infection, we are now seeing the effects of long-standing infection — namely, end-stage liver disease, cirrhosis, liver cancer, and death.

Therefore one must consider the quality of life during treatment and the risk involved with side effects when and during treatment and whether the risk of the side effects outweighs the long-term goal of treatment.

(MIGHT WANT TO MOVE FOLLOWING PARAGRAPH TO EARLIER IN THE PAPER)

Contaminated blood product, dirty needles and instruments, and injection drug use are the main parenteral routes of transmission. Cultural practices, such as acupuncture, tattoo, body piercing and scarring, also play a role.[17]

Hepatitis C is a blood borne virus 10 times more prevalent than the HIV virus. There is an approximated estimated 5 million Americans suffering from Hepatitis C, 80% of which do not know they have the disease. Worldwide it is mind boggling there are 200 million persons infected with Hepatitis C. It is known as the silent epidemic because there is a ten to twenty year time period before its ravages become known. I call it the "Pamela Anderson effect" because people suffering from Hepatitis C look great, but are basically dying inside, unaware of the seriousness of their condition.

Hepatitis C is the major cause of liver transplants in this country. If untreated the disease will claim more people than there are available transplants.

The most recent treatment is Pegylated Interferons which are synthetics that can stay in the body longer and are easier to treat. However the side effects of Pegylated Interferons are similar to if not the same as Interferon therapy.

The number of HCV patient eligible for current treatments and the rate of completion of those treatments were much lower in clinical practice than in clinical trials.

[17] http://content.nejm.org/cgi/content/short/349/3/312