

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

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ROBERT HILTON and LOUIS VASQUEZ, on behalf of
themselves and all others similarly situated,

Plaintiffs,

–against–

LESTER N. WRIGHT, M.D., M.P.H.,
Associate Commissioner/ Chief Medical Officer, for the
New York State Department of Correctional Services;
and the NEW YORK STATE DEPARTMENT OF
CORRECTIONAL SERVICES,

Defendants.
-----X

AFFIRMATION

05 Civ. 1038 (DNH)(DEP)

ALEXANDER A REINERT, an attorney duly admitted to the practice of law in the
State of New York and in this Court, affirms under penalty of perjury as follows:

1. I am an associate with the law firm of Koob & Magoolaghan, attorneys for plaintiffs
Robert Hilton and Louis Vasquez, and as such am fully familiar with the facts and circumstances
of this case. I make this affirmation in support of plaintiffs' Motion for Class Certification
seeking permission to bring this action as the representatives of the class of all prisoners in the
custody of New York State who suffer from Hepatitis C and have been denied medically
prescribed treatment pursuant to Department of Correctional Services policies in violation of
their rights under the Eighth and Fourteenth Amendments to be free from cruel and unusual
punishment.

2. The instant action was commenced by plaintiff Hilton by complaint filed August 17,
2005. Simultaneous with the filing of his complaint, Mr. Hilton moved for a temporary
restraining order seeking to compel defendants to immediately to authorize the combination

antiviral therapy prescribed by his physicians to treat his Hepatitis C. Within days of the filing of Mr. Hilton's application, a Stipulation was executed by the parties, and So Ordered by the court, which provides for the treatment sought by Mr. Hilton. The instant application for class certification is made by Mr. Hilton and Louis Vasquez pursuant to an Amended Complaint filed August 31, 2005.¹ Mr. Vasquez is confined in the Great Meadow Correctional Facility and, like Mr. Hilton, was denied critically necessary treatment for his Hepatitis C as a direct result of defendants' Hepatitis C Protocol, which has no foundation in medical science. See ¶¶ 11-13, infra.

3. Hepatitis C is a blood-borne virus which affects the liver. It is detected through laboratory testing of a person's blood sample. By conservative estimates, there are currently over 9,000 prisoners in New York State correctional facilities who have been diagnosed with Hepatitis C. (Compl. ¶ 131.)

4. Hepatitis C virus attacks and, if not treated, commonly destroys the liver. Liver damage progresses through a series of stages beginning with isolated fibrosis, or scarring, and often culminating in cirrhosis, or pervasive scarring and inflammation. The development of cirrhosis is not only life-threatening in and of itself, but also increases the risk that a patient will develop hepatocellular carcinoma, a type of cancer.

5. The standard clinical treatment of Hepatitis C is a 48-week course of medication combining two antiviral agents, pegylated interferon and ribavirin. The use of such "combination" interferon-ribavirin therapy is now generally considered the standard of care in

¹By letter dated September 2, 2005, plaintiffs have requested that defendants immediately initiate treatment for Mr. Vasquez' Hepatitis C. In the event such treatment is not forthcoming, plaintiffs shall file a motion for a temporary restraining order and preliminary injunction on Mr. Vasquez' behalf.

treating Hepatitis C in patients whose liver deterioration has not reached the stage of decompensated cirrhosis. See National Institutes of Health Consensus Development Conference Statement, “Management of Hepatitis C” [hereinafter “NIH Consensus Statement”], at 14 (2002), available at <http://www.hepprograms.org/drug/hepcconfer.pdf>.² When successful, such combination antiviral therapy can effectively cure sufferers of Hepatitis C, rendering the disease no longer a threat to their health. See NIH Consensus Statement at 15-16. Yet once a patient crosses an identifiable clinical threshold to exhibit “decompensated” cirrhosis, liver function deteriorates beyond repair by antiviral therapy, leaving organ replacement the only treatment capable of restoring a patient to health. See NIH Consensus Statement at 7. Moreover, even in patients who have not developed decompensated cirrhosis, combination antiviral therapy becomes less effective as the liver disease progresses. See NIH Consensus Statement at 20-21.

6. According to figures provided by the New York State Department of Correctional Services (“DOCS”) to the Correctional Association of New York, at least 14% of men and 23% of women entering DOCS custody are infected with Hepatitis C. See The Correctional Association of New York, Conditions of Confinement in 14 New York State Correctional Facilities (“Correctional Association Report”), at 6–7 (June 2005), available at http://www.correctionalassociation.org/PVP/publications/State_of_prisons_02-03.pdf. Men constitute 95% of the New York State prison population, and 64,022 individuals were incarcerated in New York State as of January 2005. Id. at 5–6. Therefore, at least 8,500 men and 700 women infected with Hepatitis C are in DOCS custody.

²The NIH Consensus Statement also indicates that patients who fail to complete a full course of antiviral therapy commonly stand to benefit from the repeat administration of therapy for the full course of treatment. See NIH Consensus Statement at 16-17.

7. Of these approximately 9,200 prisoners infected with Hepatitis C, only 1.4% receive antiviral therapy for Hepatitis C. Id. at 14. However, assuming that the prisoners with Hepatitis C in DOCS custody are similar to other populations infected with Hepatitis C, some 60 to 85% of these prisoners have chronic Hepatitis C and therefore may be candidates for antiviral therapy. See NIH Consensus Statement at 6. Treatment is essential for the 10 to 15% of patients with chronic Hepatitis C who will develop cirrhosis, and should be considered for any patient with chronic Hepatitis C who is at an increased risk of developing cirrhosis. Id. at 6, 19

8. Therefore, while not all of the estimated 9,200 prisoners infected with Hepatitis C are medically appropriate candidates for treatment, it is likely that between 550 and 1100 of them have or will develop chronic Hepatitis C to a degree which merits treatment with antiviral therapy. This class of prisoners, who meet all medical criteria for treatment, will nonetheless be subjected to the same Hepatitis C Protocol that resulted in the denial of treatment to Mr. Hilton and Mr. Vasquez.

Defendants' Hepatitis C Protocol

9. There are two prison-run alcohol and substance abuse treatment programs that are maintained by DOCS: ASAT, which consists of daily classes over a period of six months; and RSAT, which is similar to ASAT but which requires participants to reside in a particular cell-block during the program.

10. Defendants' Hepatitis C protocol requires anyone who has ever admitted to using drugs or alcohol in the past to participate in a prison-run alcohol and substance abuse treatment program before receiving Hepatitis C treatment. See Affirmation of Alexander A. Reinert ¶14

(dated August 17, 2005), attached hereto as Ex. A;³ see also Hepatitis C Primary Care Practice Guideline (March 2003) at p.4 n.11, attached hereto as Ex. B.

11. Significantly, the Hepatitis C protocol has no foundation in medical science. Specifically, as plaintiff Hilton established in the moving papers in support of his Order to Show Cause, there is no medical support for denying treatment for Hepatitis C to a patient who has admitted to drug or alcohol use in the past but who is not contemporaneously participating in a drug treatment program. See Affirmation of Alexander A. Reinert ¶15 (dated August 17, 2005). Informed medical judgment recognizes that even active drug users may be appropriate candidates for Hepatitis C treatment, whether they participate in drug abuse treatment programs or not. Id.

12. Not one of the medical references which purports to support defendants' Hepatitis C Protocol stands for the proposition that completion of a substance abuse program is necessary prior to the initiation of antiviral treatment for Hepatitis C. Instead, each of these references confirms that past substance abuse is never a contraindication to antiviral therapy, and that conditioning receipt of Hepatitis C treatment on contemporaneous substance abuse treatment is only justified, if ever, where a prisoner is actively engaged in substance abuse. See Affirmation of Alexander A. Reinert ¶¶17–21 (dated August 17, 2005).

13. Significantly, DOCS refuses to initiate Hepatitis C treatment unless the patient participates in ASAT or RSAT, even though RSAT and/or ASAT programs are not even offered at many correctional facilities. Moreover, where offered, the programs often have waiting lists for enrollment as participation in the programs is sought after by prisoners attempting to meet

³This affirmation was submitted in support of plaintiff Hilton's application for injunctive relief and is attached hereto for the Court's convenience.

required or recommended programming goals to augment their parole applications.⁴ The programs require full day attendance for a six month period, and preclude the inmates' participation in any other day program or work assignment. RSAT participants must also agree to reside on a particular cell block for the six month period, and therefore forfeit more favorable cell placements such as Honor Block.

14. DOCS and Dr. WRIGHT have applied the ASAT/RSAT requirement, and denied treatment for Hepatitis C to patients until they have participated in or completed the substance abuse counseling programs:

- a. regardless of the stage at which the disease has progressed;
- b. regardless of whether the requirement contravenes the treatment recommendations of DOCS' own treating physicians and specialists;
- c. regardless of how much time has passed since the prisoner last used drugs;
- d. even upon prisoners who have not used drugs for more than a decade;
- e. regardless of whether a prisoner's past use of drugs or alcohol constituted "abuse" under clinical diagnostic criteria such as those enumerated in the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, also known as the DSM-IV;
- f. regardless of whether the ASAT or RSAT programming is actually available in the correctional facility in which the prisoner is confined;
- g. regardless of whether the prisoner had previously completed a substance abuse treatment program, such as Alcoholics Anonymous, Narcotics Anonymous and the like, even if the program completed was offered at and sanctioned by a DOCS' facility;

⁴For example, Mr. Hilton tried to enroll in the program at Altona Correctional Facility but was placed on the waiting list due to popular demand for the program.

h. regardless of whether DOCS actually has space available in its ASAT or RSAT programs to allow the prisoner to fulfill the requirement; and

I. to prisoners who require a second treatment with antiviral therapy, regardless of whether such individuals met the ASAT/RSAT requirement when they were given their first course of treatment with antiviral therapy.

15. Plaintiffs bring this class action to enjoin defendants from continuing to apply the ASAT/RSAT requirement as a condition of receiving antiviral therapy for Hepatitis C.

STATEMENT OF THE CLASS SOUGHT TO BE CERTIFIED

16. The class sought to be certified comprises plaintiffs and all Hepatitis-C-infected prisoners in DOCS custody who must now or in the future meet defendants' ASAT/RSAT requirement to obtain combination antiviral therapy treatment.

17. The class as defined meets the requirements of Fed. R. Civ. P. 23(a), as well as at least one element of Fed. R. Civ. P. 23(b).

18. Under Rule 23(a),

[o]ne or more members of a class may sue or be sued as representative parties on behalf of all only if (1) the class is so numerous that joinder of all members is impracticable, (2) there are questions of law or fact common to the class, (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class, and (4) the representative parties will fairly and adequately protect the interests of the class.

19. Given the large number of inmates who are infected with the Hepatitis C virus, with at least 500 medically eligible for anti-viral treatment, it would be impracticable to join all members in the suit. Moreover, due to the nature of the illness, and the fluidity of the prison population, class membership will necessarily change as new class members are incarcerated, new cases are diagnosed, individual conditions progress beyond a stage receptive to treatment,

and prisoners are discharged. Therefore the numerosity requirement of Rule 23(a)(1) is satisfied. Further, membership in the class can be easily identified through DOCS' own records. If this is administratively burdensome, a simple questionnaire could be distributed to those prisoners identified as Hepatitis C infected patients.

20. Individual litigation of the issues presented here would further be impracticable due to the dispersion of class members throughout the DOCS facilities, the difficulty for many class members to institute litigation due to their confined status, and the need for prospective injunctive relief to protect future class members.

21. There are questions of law and fact common to the class in that all DOCS prisoners with Hepatitis C are reviewed for medical treatment under the same policy and procedures. Moreover, the standard medical knowledge of the treatment of the disease applies equally to all those infected even though individual patients may be at different stages of the illness. Finally, the class members' right to medical care is an entitlement well established in our constitutional jurisprudence and equally applicable to all proposed class members.

22. Any prisoner with an admitted past history of drug use will be subjected to the same unconstitutional and illegal policy as Mr. Hilton and Mr. Vasquez, both of whom maintain that DOCS' Hepatitis C Protocol violates the Eighth Amendment, the Americans with Disabilities Act, and Section 504 of the Rehabilitation Act. Plaintiffs' claims arise out of the promulgation and enforcement of the relevant section of the DOCS Hepatitis C Primary Care Practice Guideline, and thus the legal grievance of each class member will arise from one single course of action taken by the defendant. Thus the Rule 23(a)(2) requirement of commonality of claims is satisfied.

23. In the instant case, the typicality requirement of Rule 23(a)(3) is met because

plaintiff's claims arise from the same course of events that endanger all members of the class. Any Hepatitis-C-infected prisoner in the custody of DOCS will be subjected to the ASAT/RSAT requirement prior to obtaining treatment, regardless of whether the prisoner has used or abused drugs in the recent past, regardless of whether the prisoner ever has participated in a substance abuse treatment program, regardless of the availability ASAT and RSAT in the facility where the prisoner is incarcerated, and regardless of the recommendations of the prisoner's treating and specialist physicians. Indeed, by treating so many different prisoners the same, defendants themselves have guaranteed that plaintiffs' claims are typical of the class's claims.

24. As plaintiffs contend that treatment should never be conditioned upon an inmate's participation in a substance abuse program, the claims of Mr. Hilton and Mr. Vasquez are typical of the class, regardless of the individual class member's particular history of drug abuse or ability to attend a substance abuse program. It is plaintiffs' position that requiring substance abuse behavior training is an unlawful barrier to the constitutionally required provision of standard medical treatment of a prisoner who has been diagnosed with serious, life-threatening, physical illness.

25. Plaintiffs have no conflict of interest with other potential class members and the denial of treatment will cause them the same injuries as other prisoners who are denied treatment of their Hepatitis C infections. The goal of removing the ASAT/RSAT requirement as a barrier to obtaining treatment is in the interest of all prisoners who are medically eligible for treatment. Those who want to participate in such programs will still be allowed to do so. Thus the first prong of Rule 23(a)(4) is satisfied by Mr. Hilton and Mr. Vasquez acting as the named representatives of the proposed class.

26. The second prong of Rule 23(a)(4) requires a showing that plaintiff's counsel is

“qualified, experienced and able to conduct the litigation.” Plaintiff’s counsel, Koob & Magoolaghan, has over twenty years experience specializing in civil rights litigation, with particular emphasis on the rights of New York State prisoners, and has served as counsel for plaintiff classes in prisoner civil rights actions. See Langley v. Coughlin, 715 F. Supp. 522 (S.D.N.Y. 1989); 709 F. Supp. 482 (S.D.N.Y. 1989), aff’d 888 F.2d 252 (2d Cir. 1989) (decisions denying challenge to class certification, qualified immunity & summary judgment); Powell v. Ward, 487 F. Supp. 917 (1980), aff’d as mod. 643 F.2d 924 (1981), cert. denied, 454 U.S. 832 (1981) (motion on contempt); 540 F. Supp. 515 (S.D.N.Y. 1982) (monitoring of contempt decision); 562 F. Supp. 274 (S.D.N.Y. 1983) (same); sub nom 1993 WL 328837 (S.D.N.Y.), aff’d 22 F.3d 1092 (2d Cir.1994) (same); 1994 WL 673507 (S.D.N.Y.) (final attorney’s fees award), aff’d sub nom, 122 F.3d 1057 (2d Cir. 1995); see also list of representative cases annexed hereto as Exhibit C.

27. The firm also has litigated numerous Eighth Amendment claims for denied medical care, including ongoing challenges to the DOCS Hepatitis C Guideline which is the subject of this lawsuit. While appearing pro bono, counsel have successfully challenged the ASAT/RSAT requirement in the Appellate Division, Second Department. See Domenech v. Goord, 797 N.Y.S.2d 313, 314 (2d Dept. 2005), affirming 766 N.Y.S.2d 287 (Sup. Ct. 2003). Counsel also have appeared as pro bono counsel for a prisoner who has challenged the ASAT/RSAT requirement in federal court, in Morgan v. Koenigsmann, et al., 03 Civ. 3987 (S.D.N.Y.) (KMW) (AJP), and Morgan v. Wright, 04-5651-pr (2d Cir.). Indeed, after Koob & Magoolaghan filed its brief on Mr. Morgan’s behalf in the Second Circuit, Dr. Wright withdrew his appeal rather than file a reply brief or argue the merits of his qualified immunity defense. Finally, counsel have appeared pro bono and secured Hepatitis C treatment for a prisoner who challenged DOCS’

failure to provide a second course of Hepatitis C treatment, in Higgs v. Wright, et al., 04 Civ. 4727 (E.D.N.Y.) (NG) (LB). It is respectfully submitted that counsel's experience with prisoner Hepatitis C cases would be of singular benefit to the class sought to be represented herein.

28. Indeed, Koob & Magoolaghan is one of the few private law firms in the State with a history of prisoners rights litigation. Moreover, counsel have sufficient time and resources to devote to this case, and is free from any conflict which might impede pursuit of the litigation.

29. Class certification here also meets the requirements of Rule 23 (b) under subdivision (2) because plaintiffs challenge the practices and policies employed by defendants in treating prisoners infected with Hepatitis C, and therefore seek injunctive relief that would benefit the class as a whole. The relevant DOCS Hepatitis C Primary Care Practice Guideline rules at issue apply to all prisoners generally, not merely to the named plaintiffs in this action. Furthermore, because the injunctive relief would simply mandate that defendants adequately treat Hepatitis-C-infected prisoners, the management of such relief would not be complicated and judicial economy would be served.

30. In the alternative, the class action is maintainable under Fed. R. Civ. P. 23(b)(1)(B), which permits class actions where "adjudications with respect to individual members of the class . . . would as a practical matter be dispositive of the interests of the other members not parties to the adjudications or substantially impair or impede their ability to protect their interest." Were the court to grant injunctive relief to plaintiffs, the rights of all other similarly situated potential plaintiffs would be profoundly affected because a rule that applied to all prospective class members would have been struck down by the court as a violation of the Eighth Amendment, the ADA, or the Rehabilitation Act. Conversely, were the court to deny plaintiffs' claim, the right of all other prospective plaintiffs to make similar claims would be severely curtailed.

31. The proposed class action is also certifiable under Rule 23(b)(1)(A) which authorizes a class action if “the prosecution of separate actions by . . . individual members of the class would create a risk of . . . inconsistent or varying adjudications with respect to individual members of the class.” Should individual members of the class pursue individual actions seeking injunctive relief, there is a risk of “inconsistent or varying adjudications with respect to individual members of the class.” Id. Here, consistency of the adjudication of the proposed class’s claims is especially important, because it involves the application of a system-wide policy related to medical treatment.

32. Since plaintiffs’ counsel has no conflict of interest and can adequately represent all class members, has already devoted significant resources to identifying and investigating the legal claim, has experience in handling class actions and other complex litigation, is knowledgeable about the applicable law, and is willing and able to devote the necessary resources to the litigation, and is the only applicant for class counsel, plaintiffs’ counsel should be appointed class counsel pursuant to Fed. R. Civ. P. 23(g)(2)(b).

WHEREFORE, affirmant respectfully requests that this Court certify the plaintiff class as all Hepatitis-C-infected prisoners in DOCS custody who must now or in the future meet defendants’ ASAT/RSAT requirement to obtain treatment, and grant plaintiffs such other and further relief as the Court deems just and proper.

Dated: New York, New York
September 2, 2005

s:/Alexander A. Reinert
ALEXANDER A REINERT [Bar No. 512945]

EXHIBIT A

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

-----X
ROBERT HILTON, on behalf of himself and all others
similarly situated,

Plaintiffs,

–against–

LESTER N. WRIGHT, M.D., M.P.H.,
Associate Commissioner/ Chief Medical Officer, for the
New York State Department of Correctional Services;
and the NEW YORK STATE DEPARTMENT OF
CORRECTIONAL SERVICES,

Defendants.
-----X

AFFIRMATION

9:05-CV-1038 (LEK)(GJD)

ALEXANDER A REINERT, an attorney duly admitted to the practice of law in the
State of New York and in this Court, affirms under penalty of perjury as follows:

1. I am an associate with the law firm of KOOB & MAGOOLAGHAN, attorneys for
plaintiff Robert Hilton, and as such am fully familiar with the facts and circumstances of this
case. I make this affirmation in support of plaintiff’s application by for a Temporary Restraining
Order (“TRO”) and Preliminary Injunction directing that defendants effectuate the
recommendations of plaintiff’s treating physicians and immediately initiate antiviral therapy to
treat Mr. Hilton’s Hepatitis C.

2. Mr. Hilton was diagnosed with Hepatitis C as early as 1999. Treatment of chronic
Hepatitis C is generally achieved through combination therapy (a combination of the drugs
interferon and ribavirin). Pegylated interferon, which is a type of interferon administered once
per week, has achieved the highest response rates when combined with ribavirin and is currently
recognized by a consensus of the medical community as the standard treatment for Hepatitis C.

3. The effectiveness of treatment for Hepatitis C is dependent on many factors. Where treatment is delayed, it becomes less effective because chronic Hepatitis C causes increased fibrosis, or scarring of liver tissue, and eventual cirrhosis of the liver. See Declaration of Dr. Brian R. Edlin dated August 16, 2005 (“Edlin Decl.”), at ¶ 13, annexed as Exhibit A. Dr. Edlin is a board-certified internist and infectious diseases specialist who has conducted extensive research on Hepatitis C. Id. ¶¶ 1–5.

4. In addition to making treatment ineffective, progression to cirrhosis or advanced fibrosis exposes patients to an increased risk of developing hepatocellular carcinoma, a cancer of the liver.

5. In light of the foregoing, it is well-accepted within the medical community that Hepatitis C should be treated promptly where medically indicated. This is particularly true because any delay in providing treatment to individuals with chronic Hepatitis C exposes them to an elevated risk of serious physical harm, grave and substantial pain and suffering, and death.

6. Mr. Hilton entered the custody of the New York State Department of Correctional Services (“DOCS”) on August 18, 2004. Immediately prior to his confinement at DOCS’ Downstate Correctional Facility, Mr. Hilton was confined under the custody of the New York City Department of Correction (“NYCDOC”). In May, 2004, while in the custody of NYCDOC, Mr. Hilton tested positive for Hepatitis C, and laboratory test results evidenced that his liver function tests (ALT and AST levels) were elevated. See Exhibit B.

7. Within days of his transfer to Downstate Correctional Facility, DOCS’ medical personnel, who were in possession of the medical records generated at NYCDOC, became aware that Mr. Hilton suffers from Hepatitis C, and that his ALT and AST levels were elevated. See Exhibit C (evidencing the disclosure of Mr. Hilton’s past medical history upon his confinement

to Downstate Correctional Facility).

8. Despite Mr. Hilton's presenting need for the initiation of treatment for his Hepatitis C upon his August, 2004 transfer into DOCS' custody, DOCS scheduled Mr. Hilton to participate in their own Hepatitis screening process, which was not initiated until October, 2004. See Exhibit D (screening documentation generated at the Altona Correctional Facility); Exhibit E (periodic blood test results taken during the screening process, which all similarly evidence his chronic Hepatitis C infection).

9. The screening process initiated by DOCS in October, 2004, which contained both a medical component and a psychological component, was not completed until May, 2005, nine (9) months after Mr. Hilton was transferred into DOCS custody.

10. While the screening process dragged on until May, 2005, Mr. Hilton was referred to a gastroenterologist as early as March 23, 2005 upon the medical finding that Mr. Hilton "meets criteria for [treatment] for HEP C." See Exhibit F. The gastroenterologist substantiated that conclusion on April 22, 2005 when he recommended, consistent with good and accepted medical practice, that DOCS begin treating Mr. Hilton with pegylated interferon and ribavirin. Id. In that recommendation, the gastroenterologist noted that Mr. Hilton had received a liver biopsy in December 1999 which reflected fibrosis and inflammation characterized as Grade 2/Stage 2. Id. As Dr. Edlin notes, fibrosis and inflammation at the level observed on Mr. Hilton's December 1999 biopsy makes treatment "more urgent." Edlin Decl. ¶ 13.

11. Even after Mr. Hilton proceeded through the remainder of the screening process, and obtained clearance for Hepatitis C treatment from the Office of Mental Health, he was not scheduled to commence the critical treatment necessary to address his Hepatitis C. See Exhibit G (evidencing OMH clearance); Exhibit H (evidencing Mr. Hilton's consent for treatment with

antiviral Hepatitis C medication).

12. To date, fifteen (15) months after the NYCDOC tests evidenced a need for treatment, and twelve (12) months after Mr. Hilton was transferred into DOCS custody, Robert Hilton remains without treatment for his Hepatitis C. And, absent judicial intervention, Mr. Hilton will remain without treatment for his Hepatitis C until his release from DOCS custody due to the provisions of DOCS' Hepatitis C Protocol. Significantly, if required to serve the maximum term of his sentence, Mr. Hilton will remain in custody until October 30, 2008.

Defendants' Hepatitis C Protocol

13. There are two prison-run alcohol and substance abuse treatment programs that are maintained by DOCS: ASAT, which consists of daily classes over a period of six months; and RSAT, which is similar to ASAT but which requires participants to reside in a particular cell-block during the program.

14. DOCS Hepatitis C protocol requires anyone who has ever admitted to using drugs or alcohol in the past to participate in a prison-run alcohol and substance abuse treatment program before receiving Hepatitis C treatment. See DOCS Hepatitis C Primary Care Practice Guideline dated March 10, 2003, p.4 at criteria number 11, annexed as Exhibit I; Exhibit J (Memo from Dr. Wright dated March 25, 2003 summarizing the major changes in the revised 2003 guideline)¹.

15. Significantly, the Hepatitis C protocol has no foundation in medical science. Specifically, there is no medical support for denying treatment for Hepatitis C to a patient who has admitted to drug or alcohol use in the past but who is not contemporaneously participating in a drug treatment program. See Edlin Decl. ¶9. Informed medical judgment recognizes that even

¹Upon information and belief, DOCS has subsequently modified its March 10, 2003 guideline, but those modifications are not implicated by the issues presented here.

active drug users may be appropriate candidates for Hepatitis C treatment, whether they participate in drug abuse treatment programs or not. Id. ¶¶9-11.

16. The Hepatitis C Primary Care Practice Guideline purports to be based on the following medical references: Centers for Disease Control and Prevention, Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Disease, 47 MMWR 1 (1998) (available at <http://www.cdc.gov/mmwr/PDF/RR/RR4719.pdf>); Centers for Disease Control, Prevention and Control of Infections with Hepatitis Viruses in Correctional Settings, 52 MMWR 1 (2003) (available at <http://www.cdc.gov/mmwr/PDF/rr/rr5201.pdf>); Chronic Hepatitis C: Current Disease Management, National Institute of Diabetes and Digestive and Kidney Diseases, NIH Pub. No. 99-4230 (May 1999) (available at <http://www.medhelp.org/NIHlib/GF-483.html>); Management of Hepatitis C, National Institutes of Health Consensus Statement (March 24-26, 1997) (available at http://consensus.nih.gov/cons/105/105_intro.htm); and Georg M. Lauer and Bruce D. Walker, Hepatitis C Virus Infection, 345 New Engl. J. Med. 41 (2001), attached hereto at Exhibit K. See Exhibit I, at 8. In addition, as of April 21, 2003, the Hepatitis C Primary Care Practice Guideline also purports to be based on the National Institutes of Health Consensus Development Conference Statement, Management of Hepatitis C (2002) (available at <http://www.hepprograms.org/drug/hepcconfer.pdf>). See Exhibit L (memorandum dated April 21, 2003).

17. Not one of the references supplied by defendants provide any medical support for that portion of DOCS' Hepatitis C Protocol that requires completion of a substance abuse program prior to the initiation of treatment for the illness. Instead, each of these references confirms that past substance abuse is never a contraindication to antiviral therapy, and that conditioning receipt

of Hepatitis C treatment on contemporaneous substance abuse treatment is only justified, if ever, where a prisoner is actively engaged in substance abuse.

18. In 1998, for instance, the Centers for Disease Control and Prevention (“CDC”) expressly approved of antiviral therapy for individuals like Mr. Hilton who are at the greatest risk of progressing to cirrhosis and have not actively used intravenous drugs or alcohol for more than six months. See Centers for Disease Control and Prevention, Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Disease, 47 MMWR 1, 14 (1998) (available at <http://www.cdc.gov/mmwr/PDF/RR/RR4719.pdf>). Similarly, in 2003 the CDC addressed the treatment of Hepatitis C in correctional settings and specifically recommended that candidates for antiviral therapy participate concurrently in substance abuse treatment only insofar as they are actively engaged in drug or alcohol abuse. See Centers for Disease Control, Prevention and Control of Infections with Hepatitis Viruses in Correctional Settings, 52 MMWR 1, 25 (2003) (available at <http://www.cdc.gov/mmwr/PDF/rr/rr5201.pdf>).

19. The National Institutes of Health (“NIH”) have been similarly consistent in only recommending substance abuse treatment for those individuals with Hepatitis C who are actively engaged in substance use. The 1997 NIH Consensus Statement referenced by the Guideline sounded a cautionary note only with respect to individuals who have used illicit drugs or alcohol within six months of contemplated antiviral therapy. Management of Hepatitis C, National Institutes of Health Consensus Statement, at 18 (March 24-26, 1997) (available at http://consensus.nih.gov/cons/105/105_intro.htm). The 2002 NIH Consensus Statement is even less supportive of defendants’ policy in that it expressly recommends efforts to increase the availability of antiviral therapy to injecting drug users and further declares that active drug use “in and of itself [should] not be used to exclude such patients from antiviral therapy.” National

Institutes of Health Consensus Development Conference Statement, Management of Hepatitis C, at 19 (2002) (available at <http://www.hepprograms.org/drug/hepcconfer.pdf>).

20. The two remaining medical references relied upon by the Guideline similarly establish, at most, that active, not past, substance abuse may be a contraindication to antiviral therapy in some patients. See Chronic Hepatitis C: Current Disease Management, National Institute of Diabetes and Digestive and Kidney Diseases, NIH Pub. No. 99-4230 (May 1999) (available at <http://www.medhelp.org/NIHlib/GF-483.html>) (describing active substance abuse as a potential contraindication to antiviral therapy); Georg M. Lauer and Bruce D. Walker, Hepatitis C Virus Infection, 345 New Engl. J. Med. 41, 48 (Table 1) (2001), attached at Exhibit K (not listing active or past substance abuse as a contraindication to antiviral therapy).

21. In sum, the medical references which allegedly support the Guideline uniformly indicate that substance abuse programming is not a proper prerequisite to antiviral therapy indicated for individuals who once, but no longer, used drugs. To the contrary, the medical authorities hold that no justification exists for withholding antiviral therapy from candidates, such as Mr. Hilton, whose last drug use predates 1993.

22. Despite the lack of medical support for the Hepatitis C Protocol, defendants have applied the ASAT/RSAT requirement, and denied treatment for Hepatitis C to patients until they have completed the substance abuse program:

- a. regardless of the stage at which the disease has progressed;
- b. regardless of whether the requirement contravenes the treatment recommendations of DOCS' own treating physicians and specialists;
- c. regardless of how much time has passed since the prisoner last used drugs;
- d. even upon prisoners who have not used drugs for more than a decade;

e. regardless of whether a prisoner's past use of drugs or alcohol constituted "abuse" under clinical diagnostic criteria such as those enumerated in the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, also known as the DSM-IV;

f. regardless of whether the ASAT or RSAT programming is actually available in the correctional facility in which the prisoner is confined;

g. regardless of whether the prisoner had previously completed a substance abuse treatment program, such as Alcoholics Anonymous, Narcotics Anonymous and the like, even if the program completed was offered at and sanctioned by a DOCS' facility; and

h. regardless of whether DOCS actually has space available in its ASAT or RSAT programs to allow the prisoner to fulfill the requirement.

23. The application of the Hepatitis C Protocol, and concomitant denial of critical medical treatment, was particularly abhorrent in Mr. Hilton's case because he has not used drugs for more than a decade and had openly admitted to DOCS in 1993 that he used marijuana and sniffed cocaine when he was a teenager. See Affidavit of Robert Hilton ("Hilton Aff.") dated August 10, 2005, at ¶¶ 3–5, 16, attached hereto at Exhibit M.

24. After being informed by medical staff that he was required to participate in a substance abuse treatment program to obtain Hepatitis C treatment, Mr. Hilton immediately attempted to gain entry into a substance abuse program, but was denied same due to the excessively long waiting lists that were in place while at Altona. See Exhibit N. Mr. Hilton's presence on the wait list, and willingness to participate in a substance abuse program to obtain Hepatitis C treatment, was not sufficient to obtain Dr. Wright's approval to initiate antiviral therapy. See id. (stating "Dr. Wright will not approve the medication order until you are actively enrolled in RSAT. I thought the waiting list would be good enough.").

25. Some correctional facilities had more than one thousand (1,000) prisoners on their ASAT/ RSAT waiting lists at or around the time Mr. Hilton applied for entry into the programs. Because of the limited enrollment space, it can take several years before an inmate could become eligible to participate in a substance abuse program. See December 14, 2004 Report by Correctional Association of New York on Clinton Correctional Facility at 4 (available at http://www.correctionalassociation.org/PVP/publications/facility_reports/Clinton12-14-04.pdf).

26. Shortly after Dr. Wright made the decision to deny Mr. Hilton treatment, Mr. Hilton was transferred from the Altona Correctional Facility to the Washington Correctional Facility. Upon his May 16, 2005 transfer Mr. Hilton filed a prison grievance demanding immediate antiviral therapy. The Washington Inmate Grievance Resolution Committee, composed of two prisoners and two staff members, unanimously found that Mr. Hilton's grievance was warranted and that he should be provided with the antiviral therapy, noting that "Grievant should not have to participate in ASAT if not needed in order to receive [sic] treatment for any health related issues." See Exhibit O. The Committee's recommendation, however, was rejected by the facility's superintendent, in reliance upon the Hepatitis C Protocol. See Exhibit P. Thereafter, on July 6, 2005, DOCS Central Office Review Committee upheld the superintendent's decision.

27. On or about July 26, 2005, Mr. Hilton was referred to Washington's ASAT program solely on the basis of information that Mr. Hilton provided to DOCS when he entered DOCS custody in 1993. See Exhibit Q (Guidance and Counseling memo to Mr. Hilton dated July 26, 2005).

28. On or about July 26, 2005, Mr. Hilton nonetheless was denied entry to Washington's ASAT program because he would not be able to complete the six-month ASAT program if he were released on parole on November 2, 2005. See Exhibit R (ASAT Referral form

documenting the denial of Mr. Hilton's application). If Mr. Hilton is not released on parole and serves his maximum sentence, he will not be released until October 30, 2008.

29. Accordingly, first because he was placed on the wait list for RSAT at Altona, and then because of the speculative possibility that he would be paroled three years before his maximum sentence, Mr. Hilton has been denied Hepatitis C treatment because of the unavailability of the substance abuse programs which Dr. Wright has determined are necessary for Mr. Hilton to receive treatment. Dr. Wright has consistently insisted that Mr. Hilton participate in ASAT or RSAT as a condition of receiving the Hepatitis C treatment recommended by the prisons' medical providers. See Exhibit N; see also Exhibit S (Ambulatory Health Record documenting that Mr. Hilton "was not approved by Dr. Wright because he is not enrolled in ASAT").

30. Defendants' refusal to treat Mr. Hilton is contrary to all dictates of a civilized society. Indeed, any further delay in treating Mr. Hilton is unconscionable, as his fibrosis in 1999 had progressed to Stage 2, making treatment "more urgent". Edlin Decl. ¶ 13. Moreover, because successful treatment is less likely as the disease progresses and as a patient ages, id., it is imperative that treatment commence forthwith.

31. For these reasons, plaintiff respectfully requests that this Court schedule a hearing on plaintiff's request for preliminary injunctive relief, and upon such hearing enter an order compelling defendants to immediately initiate Hepatitis C treatment for Mr. Hilton.

32. Mr. Hilton is not proceeding via a Notice of Motion because the illness from which he suffers, Hepatitis C, is a progressive disease that requires the initiation of critical medical care without further delay, which result cannot be achieved pursuant to the briefing and hearing schedule prescribed by Local Civil Rule 7.1. Because of the importance of minimizing any

additional delay in the initiation of treatment for Mr. Hilton's Hepatitis C, it is respectfully requested that a hearing on plaintiff's requested emergency relief be held as soon as is practicable, and no later than Friday, August 26, 2005. Attached hereto as Exhibit T is plaintiff's Proposed Temporary Restraining Order. Attached hereto as Exhibit U is plaintiff's Proposed Preliminary Injunction.

33. On August 15, 2005, I contacted Roger Kinsey, in the Albany office of the New York State Office of Attorney General, and informed him of plaintiff's intention to seek the emergency relief requested herein. I spoke with Mr. Kinsey again today and he instructed me that service of papers should be accomplished by emailing the relevant papers to Mr. Kinsey, and sending via overnight mail hard copies to the New York State Department of Correctional Services' central office.

WHEREFORE, affirmant respectfully requests that this Court schedule a hearing on plaintiff's request for preliminary injunctive relief as soon as is practicable, and upon such hearing enter an order compelling defendants to immediately initiate Hepatitis C treatment for Mr. Hilton, and grant Mr. Hilton such other and further relief as the Court deems just and proper.

Dated: New York, New York
August 17, 2005

s:/Alexander A. Reinert
ALEXANDER A REINERT [Bar No. 512945]

EXHIBIT B

New York State
Department of Correctional Services
Division of Health Services

Hepatitis C Primary Care Practice Guideline

Updated by: John Howard, MD., Peter Piliro, MD., Linda Klopf, RN., Karen Wameling, Pharm.D., Frank Lancelotti, MD

INTRODUCTION:

This practice guideline represents an approach to the current management of hepatitis C disease that is consistent with community standards of care and is appropriate in our corrections settings. It should be noted that the treatment plans recommended in this document are not necessarily all inclusive. This guideline represents the current state of knowledge regarding treatment agents for the management of hepatitis C. However, this field of science is evolving very rapidly. New information and treatment agents will result in changes in therapeutic options. As such, the committee will periodically review and revise this document to ensure that this guideline remains current. The current update incorporates the latest recommendations from the National Institute of Health Consensus Conference held in June 2002.

Acute Hepatitis C: The average incubation period for acute hepatitis C is 6 to 7 weeks but may range from 2 to 26 weeks. Persons with acute disease are typically asymptomatic or have a mild clinical illness with a self-limiting course up to 6 months. Fulminant hepatic failure in acute disease is rare.

Chronic Hepatitis C: Chronic hepatitis C develops in approximately 70% of HCV-infected persons, and approximately 20% of these individuals will eventually develop cirrhosis over a period of 20 to 30 years. Overall, approximately 5% will develop hepatitis C over this time period. The progression to chronic liver disease is usually insidious, advancing without symptoms or physical signs in the majority of patients during the first two decades after infection. HIV infected inmates may have an accelerated course. Frequently, chronic hepatitis is not recognized until symptoms appear with the development of advanced liver disease. Patients with chronic hepatitis C are at higher risk for morbidity and mortality if they develop either acute hepatitis A or B.

SCREENING:

Inmates that are at high risk for hepatitis C are those with a history of HIV infection, IVDU, intranasal cocaine use, STDs, blood transfusions before 7/92, hemodialysis, infusion of clotting factor before 1987, tattoos or body piercing with unsterile equipment, solid organ transplants, or unexplained elevated LFTs or symptoms of hepatitis. These inmates should be screened for Hepatitis C. Currently universal screening for hepatitis C antibody is not indicated.

DIAGNOSIS:

EIA (enzyme immunoassay) blood testing is done on those inmates at risk to detect the presence of antibodies to hepatitis C. In patients with risk factors and any elevated LFTs, a confirmatory test is not necessary. For patients without an identified risk factor or normal LFTs, a qualitative HCV RNA and a confirmatory RIBA (Recombinant Immunoblot Assay) should be done to verify the diagnosis. In immunocompromised patients where the Hepatitis C antibody is negative, but Hepatitis C is strongly suspected, a qualitative Hepatitis C PCR should be obtained.

REPORTING:

Persons who have hepatitis C disease must be reported to the county health department using the procedure outlined in Health Services Policy 8.01. The Regional Infection Control Nurse shall be notified. An entry shall be made on the FHS Problem List for hepatitis C lab test (antibody) positive (code 0702). If LFTs are persistently elevated or clinical symptoms develop, an entry should be made for hepatitis C disease (code 0701).

The following problem list codes should be utilized if the inmate starts therapy for disease:

- 0703 - Hep C Rx. Initiated
- 0704 - Hep C Rx. Discontinued, Other
- 0705 - Hep C Rx. Discontinued, Medical
- 0706 - Hep C Rx. Completed
- 0709 - Hep C Rx. Refused

EVALUATING HEPATITIS C:

LFTs: Should be tested at 8-12 weeks after diagnosis. Those with normal values should be monitored every 6-12 months. Those with elevated LFTs should be monitored every 8-12 weeks. Those patients with an elevated ALT should be considered for specialist referral and treatment. During this monitoring period, if the inmate is being considered for treatment, they should receive ASAT programming promptly. If standard ASAT/RSAT programs are not available in a particular facility, a workbook program may be utilized through inmate programs (a request should be made through the facility Deputy Superintendent of Programs).

CRITERIA FOR TREATMENT: Anti-HCV therapy should be considered in accordance with the following criteria. Completing the Hepatitis C Consult Request E-Form (copy attached) will assist the clinician in evaluating the inmate for possible treatment. Clinicians should order the "Hepatitis C Treatment Assessment Panel" to obtain the required lab studies to complete the E-Form. This form is used for biopsy consults, or to obtain treatment approval from Dr. Wright. You may add comments to the end of form.

~~There are three ways to access the Hepatitis C Consult Request E-Form.~~

Go to 4.1 screen and type in the command field EF "HEP C CON"

Go to 4.4 screen and type in "find HEP C CON 999HLTCKO, enter "S" next to E-Form

Go to 4.4 screen and scroll down to 'HEP C CON'. Enter "S" next to E-Form

1. Confirmed serologic diagnosis of Hep C (EIA with or without qualitative HCV RNA and documented viremia by quantitative HCV RNA).
2. Absence of chronic hepatitis B (negative hepatitis B surface-antigen or hepatitis B viral load [PCR]).
3. Elevated ALT.
4. Adequate liver synthetic function (albumin, prothrombin time, bilirubin) and grade A Child-Pugh Classification Score (see attached work sheet: Child-Pugh Classification of Severity of Liver Disease). The Child Pugh Classification Score is a method to determine the severity of liver disease based on laboratory and clinical parameters. Patients with a grade A score are able to be treated, where as grade B and C scores indicate decompensated liver disease and are a contraindication to treatment.
5. Inmates should receive the following baseline evaluations prior to initiating HCV treatment as side effects of treatment need to be differentiated from pre-existing conditions. This should be done prior to referral to a specialist or biopsy.

Obtain HCV Treatment Assessment Panel which includes:

- Serum aminotransferase levels (ALT), albumin, bilirubin, prothrombin time, and creatinine
- CBC with differential and platelet count
- Prottime and Partial Thromboplastin time (PT, PTT)
- Thyroid function studies (TSH)
- HBsAg and HBcAb unless Hepatitis B surface antibody positive

Additional Requirements:

- Physician evaluation and clearance
 - Psychiatrist evaluation and clearance (if indicated)
 - HIV or ID specialist evaluation and clearance (if indicated)
 - Quantitative HCV RNA PCR
 - HCV genotype
6. Pregnancy is a contraindication to treatment. Female inmates of childbearing potential should have a negative pregnancy test 14 days before initiating therapy and every 30 days until completion of treatment.
 7. WBC > 3,000 cells/cubic ml, ANC (Absolute Neutrophil count > 1000), platelets > 50,000/cubic ml and hemoglobin > or = 10 grams in the absence of cardiac disease, (12 grams if cardiac disease present).

- ~~8. Absence of uncontrolled thyroid disease.~~
9. Absence of autoimmune disease or history of solid organ transplantation.
10. No history of major depression or other major psychiatric illness unless cleared by a psychologist or psychiatrist to receive anti-HCV treatment.
11. No evidence of active substance abuse (drug and/or alcohol) during the past 6 months (check urine toxicology screen if drug use is suspected). Those who have a substance use history must successfully complete or be enrolled in an ASAT/RSAT program.
12. Age greater or equal to 18 years.
13. Anticipated incarceration adequate to complete evaluation and treatment; 9 months of genotype 2 and 3, 15 months for genotype 1 or 4, from the time of referral (this includes the 12 month treatment course.). Inmates who will not predictably complete a course of treatment should receive a baseline evaluation and be referred for medical follow-up and treatment upon release.
14. All inmates diagnosed with Hepatitis C should be strongly encouraged to receive HIV testing.
15. A highly motivated patient. The lengthy duration and significant potential side effects of anti-HCV treatment should be explained to the inmate to assess anticipated compliance with therapy. The inmate will sign an informed consent detailing the above. Refusal to sign the consent form will be taken as refusal of treatment and a refusal form will be activated.
16. Medical Hold: Hepatitis C patients will remain on Facility Medical Hold if:
 - The patient is undergoing an initial work up for treatment consideration under the auspices of a specialist.
 - Care is being provided by a primary MD and there are scheduled appointments.

Inmates are releasable from medical hold and may be transferred within the CATCHMENT AREA if:

Patient is under the care of gastroenterology services, treatment has been initiated and condition is stable (approximately 4 weeks pst tx).

Those inmates whose care is being provided by a primary MD and have no appointments scheduled can be transferred anywhere.

SPECIAL TREATMENT ISSUES:

1. HIV infection complicates Hepatitis C treatment. Therefore, clearance is required by an HIV or ID Specialist before initiating therapy. Current CD4 & VL must be included on the e-form as they will be evaluated as part of the treatment approval process.
2. Interferon-alpha does have efficacy for treatment of chronic hepatitis C infection complicated by mixed essential cryoglobulinemia. Treatment should be considered in consultation with a specialist.

3. Treatment with interferon-alpha in persons with hepatitis C and chronic active hepatitis B viral coinfections is contraindicated since the response to therapy is unpredictable and difficult to safely monitor.
4. Many experts currently recommend a pre-treatment liver biopsy. Anti-HCV treatment is relatively contraindicated for persons with compensated cirrhosis, since response to treatment is poor. (Treatment is contraindicated for persons with decompensated cirrhosis, since treatment often exacerbates disease resulting in severe life threatening sequelae.) Specialty evaluation and liver biopsy to confirm the diagnosis of hepatitis, exclude other causes of liver disease, grade the severity of injury, and assess the degree of fibrosis should occur for all patients who are type 1 or 4 or HIV coinfecting. Liver biopsy will not be mandated for genotype 2 or 3, but should be done if clinically indicated.

TREATMENT ISSUES:

1. Treatment for Hepatitis C almost universally results in side effects. The treating physician should ensure that the inmate is aware of all potential side effects prior to prescribing therapy. An influenza-like reaction usually occurs within 6-8 hours of initial treatment with interferon alpha. This acute reaction normally abates with subsequent treatments and can be partially abated by premedication with antipyretics. Side effects of chronic irritability, fatigue, myalgia, headaches, rage, confusion, and neuropsychiatric disorders can occur. Severe incapacitating depression can develop. Bone marrow suppression including anemia, leukopenia and thrombocytopenia are serious side effects of interferon that should be anticipated and monitored closely. Thyroiditis, hyperthyroidism and hypothyroidism have been reported in 2.5-20% of persons treated with interferon and may not be reversible upon cessation of drug therapy. Inmates with side effects to interferon should have their dosage reduced or therapy discontinued depending on the severity of the side effects. Very serious sequelae of interferon treatment occur in 2% of patients and may include cardiac decompensation, renal failure, pneumonitis, severe bone marrow suppression and suicide.

Ribavirin has several toxicities. Anemia occurs in approximately 10% of patients usually in the first two - four weeks of treatment. This may result in deterioration of cardiac function and/or exacerbation of symptoms of coronary disease. Monitoring of CBC's should occur at weeks 2 and 4 and, if anemia develops, dose adjustment or discontinuation of ribavirin, (see package insert) or use of alfa epoietin should occur. Ribavirin is contraindicated in women who are pregnant.

Significant teratogenic and/or embryocidal potential have been demonstrated for ribavirin in all animal species studied. Women of childbearing potential and men must use effective contraception during treatment and during the 24 weeks post-treatment follow-up period. Finally, ribavirin in combination with interferon-alpha may exacerbate previously noted interferon toxicities.

2. The recommended treatment regimen for the HCV treatment naive patient is pegylated interferon-alpha combined with ribavirin for 24 - 48 weeks. (see Table 1 and package inserts). For patients in whom ribavirin is contraindicated, monotherapy with pegylated interferon-alpha subcutaneously is acceptable. (See table II) The duration of therapy depends on HCV genotype and initial response to therapy (See algorithm Figure 1). Predictors of a positive response to therapy for hepatitis C include:
 - Age < 45
 - Short duration of disease
 - Low hepatic iron stores
 - Absence of cirrhosis
 - Presence of minimal fibrosis
 - Genotype 2 or 3
 - Female gender
 - HCV viral load < 2 million copies per ml

3. Inmates should receive at minimum the following evaluations during treatment for HCV:
 - Evaluations for adverse drug reactions should be done before each injection, (by nurses) for the first two weeks of treatment and then at least biweekly thereafter. This should be done by the nurse administering the injection and be recorded on the Adverse Drug Reaction Screen form (see attached). Physician evaluations should be done monthly.
 - Specialty evaluations as clinically indicated.
 - Psychiatry evaluations when clinically indicated.
 - CBC with differential count, platelets, LFTs BUN, and creatinine at 2nd and 4th weeks of treatment and monthly thereafter. These should be recorded on the HCV Treatment Review Form (see attachment).

4. An uncommon, but clinically pertinent side effect of anti-HCV treatment is worsening of hepatitis. New elevations in ALT levels during treatment for hepatitis C may signify progression to liver failure and are an indication for urgent specialty consultation for consideration of cessation of therapy. Therapy may need to be temporarily held pending consultation.

5. The length of anti-HCV treatment depends on the patient's HCV genotype and week 12 response to therapy. After 12 weeks of treatment, a quantitative HCV RNA PCR should be obtained. A favorable response is indicated by an undetectable HCV RNA PCR or at least a 2- \log_{10} (110-fold) reduction in HCV RNA (eg: initial HCV RNA is 2,000,000 copies and at week 12 it is less than or equal to 20,000 copies).

If the patient has an undetectable HCV RNA and (a) is genotype 1 or 4, treatment should continue for a total of 48 weeks, or (b) is genotype 2 or 3, treatment should continue for a total of 24 weeks. If the patient is genotype 1 and is not undetectable, but has had at least a 2- \log_{10} reduction in viral load, then continue treatment and obtain a quantitative HCV RNA at week 24. If the week 24 HCV RNA is undetectable, then complete a total of 48 weeks of treatment. If the week 24 HCV RNA is still detectable, but the ALT is now normal, then complete a total of 48 weeks of treatment. Finally, if the week 24 HCV RNA is still detectable and the ALT is still elevated, treatment should be stopped.

If the patient does not have a favorable response (as defined above), then the decision to continue treatment is based on whether or not the ALT has normalized: (a) if the ALT is normal, then consider completing therapy (decision should be made in consultation with the specialist), or (b) if the ALT is elevated, then discontinue therapy.

For patients with genotype 2 or 3 who complete 24 weeks of therapy, a quantitative HCV RNA PCR should be obtained 24 weeks later to assess whether the patient has had a sustained virologic response. For patients with genotype 1 or 4 who complete 48 weeks of therapy, a quantitative HCV RNA PCR should be obtained 24 weeks later to assess whether the patient has had a sustained virologic response.

Figure 1 provides a summary of these recommendations.

6. Serial liver biopsies following a baseline study are not routinely indicated except in those who fail treatment or do not initiate treatment where consideration should be given to repeat biopsy every 3 to 5 years to re-stage disease progression.
7. Retreatment of non-responders is rarely indicated. Retreatment of responders who have relapsed will be evaluated on a case by case basis. For patients who failed to respond or relapsed after interferon plus ribovirin therapy or pegylated interferon plus ribovirin, there is currently no approved therapy for retreatment. The e-form "Hep C Consult Request" should be fully completed so that an evaluation may be made.

8. The completed E-form, "Hepatitis C Consult Request Form" will be sent to the Deputy Commissioner for Health Services for review/approval before medications may be ordered from Central Pharmacy.
9. If treatment is approved, medications can be ordered/reordered by using the E-Form "HEP C MED" which is addressed to Central Pharmacy (copy attached).
10. Special circumstances should be addressed directly with the Chief Medical Officer.

OTHER CONSIDERATIONS:

1. All patients determined to have chronic hepatitis C should be screened for hepatitis A and B using HAV IgG, HbsAb, HbcAbIgG and HbsAG. When clinically indicated, hepatitis B and/or A vaccine should be administered (if Hepatitis A and/or B serologies indicate no prior infection).
2. For patients with cirrhosis, a liver ultrasound and serum alpha-fetoprotein should be obtained every six months to assess for hepatocellular cancer. Liver transplantation may need to be considered in end stage cirrhosis.

References

Centers for Disease Control and Prevention Recommendations for prevention and control of hepatitis C virus (HVC) infection and HCV-related chronic disease. MMWR 1998;47 (RR-19):1-39.

Management of hepatitis C. NIH Consensus Statement 1997; March 24-26;15(3):1-41.

Federal Bureau of Prisons Treatment Guidelines for Viral Hepatitis; September 1, 1997; (2-28).

Chronic Hepatitis C: Current Disease Management, NIH Publication No. 99-4230, June 1999.

Lauer GM, Walker BD. Hepatitis C Virus Infection. New England J Med 2001;345:41-52

Centers for Disease Control and Prevention Recommendations for Prevention and Control of Infections with Hepatitis Viruses in Correctional Settings. MMWR 2003;52 (RR-1).

EXHIBIT C

KOOB & MAGOOLAGHAN

Notable Case List

PRISONERS' RIGHTS CASES

A. Reported Cases of Interest

Tortorici v. Goord, 216 F.R.D. 256 (S.D.N.Y. 2003) (decision holding quality assurance documents discoverable). This civil rights action was commenced on behalf of the mother, father, brothers, sister and Estate of Ralph Tortorici after Ralph tragically committed suicide at the age of 31. The case settled for \$800,000.00 plus attorneys' fees in the amount of \$375,000.00, upon substantial evidence regarding the systemic deficiencies in the delivery of mental health treatment to inmates who suffer serious psychiatric illnesses, and upon the shocking revelation that Ralph Tortorici was all but abandoned by the mental health practitioners responsible for his treatment and care.

Jackson v. Johnson, 118 F. Supp. 2d 278 (N.D.N.Y. 2000), aff'd in part, appeal dismissed in part, 2001 WL 735902 (2nd Cir. 2001). This case was a civil rights action on behalf of a 14 year old who, while confined in a medium security youth facility owned and operated by the New York State Division for Youth, was subjected to two violent and unlawful assaults by Youth Division Aides that left him with permanent brain damage and quadriplegia. The case settled on the eve of trial for \$9,750,000, the largest award in a civil rights action in the history of the Northern District of New York. See N.Y.L.J., 2/26/02, p.1 (announcing the settlement). One result of the case was a new policy initiated by State Attorney General Eliot L. Spitzer, who ordered the 521 lawyers in his office to terminate their use of race-based mortality tables in assessing damages for plaintiffs who sue the State (see NYLJ, 4/21/99, p.1) (announcing the change in policy at the Attorney General's office). The case also resulted in the implementation of a new Physical Restraint Technique throughout the Division for Youth to assure that another youth would not suffer similar injuries.

Smith v. Goord, 222 F.R.D. 238 (N.D.N.Y. 2004) (decision granting plaintiff discovery of personnel files, and training and job performance documents). This civil rights action was commenced on behalf of a former inmate who suffers from a serious psychiatric illness but was nevertheless housed in solitary confinement under horrific and inhumane conditions, and warehoused without treatment in "mental health" observation cells, under equally appalling conditions. After the District Court granted plaintiff's motion seeking access to very valuable discovery materials the case settled for \$115,000.00 plus attorneys' fees.

Baker v. Coughlin, et al., 77 F.3d 12 (2nd Cir. 1996) (decision finds N.Y. Corr. L. § 24 a bar to state negligence claims). This was a civil rights action for the death of 18 year old prisoner at a boot camp correctional facility who was subjected to excessive force and the denial of emergency medical treatment. The case settled for \$1,000,000 in damages to the deceased's mother for

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wrongful death and payment of \$300,000 in attorneys fees. Included in the settlement was an agreement for a meeting between the deceased's mother, the Commissioner of the Department of Correctional Services and a Governor's representative to discuss the problematic use of excessive force in State boot camps. The case resulted in a new training initiative by the Department of Corrections.

Brown v. Coughlin, 758 F. Supp. 876 (S.D.N.Y. 1991) (denial of summary judgment motion), later reported at 869 F. Supp. 196 (S.D.N.Y. 1994). This case was brought for the deliberate indifference of municipal defendants to a prisoner's need for adequate medical treatment for a simple fracture of the leg, which resulted in a below-the-knee amputation. The case was settled for \$600,000.

D'Angelo v. New York City Health and Hospitals Corp., 929 F. Supp. 129 (S.D.N.Y. 1996) (denial of summary judgment). This civil rights action arose from the August 1982 death of Sonia Yglesias, who at the age of 33 and while in the custody of the City of New York, died approximately 24 hours after her admission to the secure psychiatric unit at Elmhurst Hospital. The action, brought twelve years after her death on the theory that the claims did not accrue and/or were tolled because of a coverup masterminded by the city relating to the cause of death, included claims for loss of the parent-child relationship. The case settled for \$750,000 inclusive of attorneys' fees.

Langley v. Coughlin, 715 F. Supp. 522 (S.D.N.Y. 1989); 709 F. Supp. 482 (S.D.N.Y. 1989), aff'd 888 F.2d 252 (2d Cir. 1989) (decisions denying challenge to class certification, qualified immunity & summary judgment). This was a class action challenge to punitive segregation and the inadequate mental health treatment given mentally ill prisoners. The case settled with an injunction and damage fund of \$350,000 for all class members who had been confined in solitary confinement during the relevant period, with additional damages to those prisoners denied mental health care. The case resulted in payment in excess of \$900,000 in attorneys fees and \$100,000 in costs, primarily for expert witness testimony, awarded as requested. The case led to new protocols for the delivery of mental health services and new protections for prisoners confined to solitary throughout the New York State Department of Correctional Services.

Powell v. Ward, 487 F. Supp. 917 (1980), aff'd as mod. 643 F.2d 924 (1981), cert. den'd, 454 U.S. 832 (1981) (motion on contempt); 540 F. Supp. 515 (S.D.N.Y. 1982) (monitoring of contempt decision); 562 F. Supp. 274 (S.D.N.Y. 1983) (same); *sub nom* 1993 WL 328837 (S.D.N.Y.), aff'd 22 F.3d 1092 (2d Cir.1994) (same); 1994 WL 673507 (S.D.N.Y.) (final attorney's fees award), aff'd *sub nom*, 122 F.3d 1057 (2d Cir. 1995). This class action sought contempt and a permanent injunction for violations of due process in prison disciplinary proceedings. A settlement fund was established in the amount of \$125,000 in lieu of civil contempt fines. Over \$1 million dollars was paid in attorney's fees in the case, which proceeded

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over the course of two decades and changed the entire system of disciplinary hearings throughout the New York State Department of Correctional Services and developed the law on civil contempt. Before it concluded, well over 100 Court orders were entered.

Kagan v. State of New York, 221 A.D.2d 7, 646 N.Y.S.2d 336 (2nd Dept. 1996). This case was commenced after claimant, an inmate at the Bedford Hills Correctional Facility, lost her hearing in one ear because of the prison's negligent provision of medical care. After trial, a judge in the Court of Claims awarded \$304,000 to our client. See \$304,000 Negligence Award Won by Inmate Rendered Deaf, NYLJ, 8/3/92, p.1. The award was affirmed on appeal.

McCormick v. Gray, 1993 WL 437788 (S.D.N.Y.) This case was a challenge to the State's attempt to prevent a husband and wife from residing together after both were released from prison. After our law firm successfully challenged the policy, the District Court awarded attorneys' fees in full.

B. Unreported Decisions & Settlements

Almodovar v. Andrews, 00CV0599 (W.D.N.Y.) This civil rights action was commenced after Sarah Almodovar was brutally assaulted by correction officers because she cooperated in an investigation conducted by the Inspector General's office into sexual harassment by guards at the Albion Correctional Facility. After months of pre-trial discovery, the case settled for \$135,000.00.

Rosado v. Graceffo, 99-Civ.-551 (W.D.N.Y.) This civil rights action was commenced on behalf of an inmate who was denied medical treatment for a painful and disfiguring dermatological condition which grotesquely scarred his face and body, thus subjecting him to continuous ridicule during his period of incarceration. After appropriate treatment was obtained, a settlement was reached in the amount of \$139,241, including attorney's fees of \$49,241.

Battiste v. Artuz, et al., 99 Civ. 0503 (RWS) (S.D.N.Y.). This civil rights action arose from the State's failure to provide a prisoner with adequate psychiatric care for his serious mental illness. As a result, the prisoner committed suicide. The case was settled for \$350,000 inclusive of attorneys' fees.

Gray v. The State of New York, Claim No. 75070-A (N.Y. Ct. Claims). This case was brought in the Court of Claims after a prisoner died because of delayed treatment and diagnosis of colon cancer. The Court of Claims judge awarded \$505,000 in 1993 after trial.

Davidson, et al. v. Artuz, et al., 98 Civ 6019 (JSM) (S.D.N.Y.). This civil rights action arose from the death of a 29-year-old prisoner who, while serving lengthy consecutive sentences,

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suffered from an asthma attack and died as a result of defendants' refusal to respond to the vociferous pleas for help from the prisoner population. The case, which included claims for loss of companionship for decedent's mother and three children, settled for \$900,000 inclusive of attorneys fees.

Morales v. Curley, 93 Civ. 4734 (RPP) (S.D.N.Y.). This case was brought for the wrongful death of a psychiatrically ill prisoner who had been placed in a seclusion cell within a mental health unit without proper medical treatment or review for a two day period and subsequently died from dehydration while in transit to a psychiatric hospital. The case settled at trial for \$950,000 to the parents and payment of \$100,000 in attorneys' fees. A complaint filed by counsel post-settlement regarding the licensure of the responsible psychologist resulted in the imposition of disciplinary action.

Ortiz v. Stancari, 94 Civ. 1685 (DAB) (S.D.N.Y.). In this case, we represented a prisoner who was sodomized and raped by another prisoner known to officials at Westchester County Jail for his violent propensities. The case settled for a total of \$295,000.

Rosario v. Coughlin, 91 Civ. 1664 (KMW) (S.D.N.Y.). This civil rights action was brought on behalf of six prisoner paraplegics for instances of denied or delayed medical care. The case settled prior to expert discovery, prior to any pre-trial order, and without the expense of defending any dispositive motions by defendant, for total damages of \$1,000,000 and \$200,000 in attorneys' fees.

EMPLOYMENT DISCRIMINATION CASES

Petrovits v. New York City Transit Authority, 2003 WL 22349676 (S.D.N.Y.) (denying the defendant's motion for judgment notwithstanding the verdict); 2004 WL 42258 (granting attorneys' fees). This sex discrimination case was tried over six days, and resulted in a jury finding that Joan Petrovits was denied a promotion due to her sex. The jury awarded Ms. Petrovits \$150,000.00 in compensatory damages, and Magistrate Judge Eaton thereafter entered an Order compelling the defendants to promote her, awarding back pay, and awarding attorneys' fees to Koob & Magoolaghan and our trial co-counsel, the New York University Civil Rights Clinic.

Pfeiffer v. Lewis County, 308 F. Supp. 2d 88 (N.D.N.Y. 2004) (denying defendants' motion for summary judgment). This case was litigated on behalf of the only woman ever employed in the Lewis County Sheriff's Department in a supervisory position after she was demoted from her position as Dispatch Supervisor and denied equal terms and conditions of employment due to her sex. After we defeated the County's motion for summary judgment the case settled very favorably for an undisclosed amount.

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Hernandez, et al. v. Cite, et al., 03 Civ. 8822 (S.D.N.Y.); Anzures, et al. v. Park Avenue Café, et al., 04 Civ. 2993 (S.D.N.Y.); Baizan et al v. Cite Restaurant et al., 04 Civ. 10134 (S.D.N.Y.): These civil rights lawsuits were commenced on behalf of 23 restaurant workers who alleged that they were underpaid in violation of federal and state wage and hour laws, and, in some cases, discriminated against due to their race while working at two fashionable Manhattan restaurants, Cité and Park Avenue Café, managed by Smith & Wollensky Restaurant Group. Represented by the Urban Justice Center, the CUNY Law School Immigrant Rights Clinic, and Koob & Magoolaghan, the workers settled their claims in exchange for financial compensation and changes in workplace policies and procedures.

Karibian v. Columbia University, 812 F. Supp. 413 (S.D.N.Y. 1993), rev'd 14 F.3d 773 (2nd Cir. 1994), cert denied 512 U.S. 1213, 114 S. CT. 2693. This lawsuit was brought under Title VII against university and supervisors for sexual harassment. The District Court held that a discrimination plaintiff who submits to her employer's demands for sexual favors can never recover in a sexual harassment suit. The Second Circuit reversed, noting that such a rule would have the effect of rewarding the most successful harassers, and in doing so announced a new, liberal theory of liability in instances where harassment is by supervisors. The decision resulted in amendments to the EEOC guidelines in such cases. See NYLJ, 2/26/94 p.1 ("The Second Circuit Court of Appeals yesterday announced a new liberal theory of employer liability for a supervisor's sexual harassment of an employee. . . [e]mployers are liable for abusive work environment if the supervisor 'uses his actual or apparent authority to further the harassment' . . . complainants in such circumstances need not show an employer's failure to respond to a complaint or no reasonable avenue for complaints"). After a jury verdict of \$450,000, the District Court granted judgment n.o.v. to defendants.

Romei v. Shell Oil Company, 1991 WL 692884 (Sup. Ct. N.Y. Cty.) (decision on summary judgement motion). In this disability discrimination case, we represented an employee who alleged that Shell Oil discriminated against him based upon the belief that the plaintiff had AIDS. In 1994 a jury awarded plaintiff compensatory and punitive damages in the amount of \$121,000.

Goordineer v. Greenville Board of Fire Commissioners, 234 A.D2d 371, 651 N.Y.S.2d 92 (2d Dept. 1996), leave to appeal denied, 89 N.Y.2d 812, 657 N.Y.S.2d 405 (1997) (finding plaintiff's complaint timely because of "continuing nature" of discrimination), after remand, 277 A.D.2d 314, 716 N.Y.S.2d 685 (2d Dept. 2000) leave to appeal dismissed, 96 N.Y.2d 792, 725 N.Y.S.2d 642 (2001) (successfully defending challenges NYS Division of Human Rights' decision finding plaintiff, a decorated volunteer fire fighter, had been discriminated against on the basis of her sex in her application for work as a full time paid fire fighter). The case was resolved by a confidential settlement.

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Burke v. Lord & Taylor (S.D.N.Y.). This civil rights action challenged plaintiff's termination on the ground that defendant had discriminated against him because he had AIDS. After the Court denied defendants' motion for summary judgment, a confidential settlement was reached.

Woodley v. Macy's, (S.D.N.Y.). This case involved a Macy's employee who annually played Santa Clause, but who was denied re-employment after he disclosed that he was taking AZT. A confidential settlement was negotiated in 1995 by the Hon. Mario Cuomo, who was appointed to mediate the case by the U.S. Bankruptcy Court. See A Bittersweet Visit By an Ailing Santa: An AIDS Patient Dusts Off His Costume, and His Lawsuit, New York Times, 12/16/94, p. B1.

DISABILITY RIGHTS CASES

Locher v. UNUM Life Insurance Company of America, 389 F.3d 288 (2d Cir., 2004) (clarifying standard to be applied by the District Courts in determining whether to consider evidence outside the administrative record). This ERISA litigation was commenced on behalf of a legal secretary who was compelled to resign her position after developing Chronic Fatigue Syndrome. More than a decade after she was first diagnosed, and after prevailing at trial before the Hon. Laura Swain, Ms. Locher was finally awarded benefits. Locher v. UNUM Life Insurance Co. of America, 126 F. Supp. 2d 769 (S.D.N.Y. 2001). Because of the importance of the case to the rights of the disabled, the Second Circuit decision was reported on the front page of the New York Law Journal on November 16, 2004, and in follow-up articles on ERISA litigation as well. See Rights of Disability Insurance Claimants Boosted With Decision, N.Y.L.J., 2/15/2005, p4. Ms. Locher was awarded back benefits with interest and Koob & Magoolahgan was awarded attorneys fees of \$268,000.

Sansevera v. DuPont , 859 F. Supp. 106 (S.D.N.Y., 1994). In this ERISA action on behalf of an individual with chronic fatigue syndrome, the Court awarded back benefits, interest and attorneys' fees to our client. See Benefits' Denial For Disability Held Arbitrary, N.Y.L.J., 8/8/94, p.1.

Mermelstein v. NYU Medical Center, 89 Civ. 4003 (MLJ) (S.D.N.Y.). This action for discrimination on the basis of disability, commenced on behalf of a psychiatric resident, was settled pursuant to a confidential stipulation.

OTHER CIVIL RIGHTS CASES

The Mount Kisco Worker's Project v. The Village/Town of Mount Kisco, 96 Civ. 8335 (BDP) (S.D.N.Y.). This class action was brought on behalf of the day laborers of Mount Kisco who successfully challenged the Village's mandatory hiring site for day laborers, the midnight housing raids conducted on Latino homes, and the summary eviction of Latinos from the public

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park as violative of their rights under the First Amendment and the Due Process and Equal Protection clauses of the U.S. Constitution. Years later, plaintiffs successfully prevailed on a motion to hold the defendants in contempt of the Consent Decree entered in the case.

Melchor v. The Village/Town of Mount Kisco, 97 Civ. 0010 (BDP) (S.D.N.Y.). This civil rights action was brought on behalf of eleven Latinos who were summarily ejected from their home during an illegal housing raid, not allowed to re-enter for a period of seven hours, and subjected to criminal prosecution. The criminal charges against our clients were either withdrawn or dismissed, and in the civil rights action, damages were awarded to each plaintiff in the amount of \$20,000.

Stern v. Resnick, 99 Civ. 10053 (CM) (S.D.N.Y.). In this case, a preliminary injunction was granted against a landlord who, at the request and support of the Village of Mount Kisco, sought to evict the owner of a Chinese restaurant who had altered her menu to attract a Latino clientele. The case resulted in a confidential settlement.

Ramos v. New York City, 05 Civ. 637 (S.D.N.Y.). This civil rights action was commenced after seventeen (17) year old Jose Ramos was handcuffed and arrested by a security officer at the New York City public high school he attended because of the officer's unlawful and discriminatory animus against Mr. Ramos. Not long after the litigation was commenced, the courage of this young man was rewarded when the city agreed to compensate him in the amount of \$12,500 for the harm suffered as the result of the officer's actions.

Hammonds v. Schweiker, 535 F. Supp. 276 (S.D.N.Y. 1982); 652 F. Supp. 491 (S.D.N.Y. 1987). In this case, we successfully sought social security survivor's benefits for an "illegitimate" child. See U.S., Teenager In 10-Year Battle Over Child Benefits, NYLJ, 2/3/97, p.1.