October 3, 2006

BY FACSIMILE AND EMAIL TRANSMISSION

Jo Anne B. Barnhart
Commissioner of Social Security
Social Security Administration
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Via email: regulations@ssa.gov
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Re: Proposed Rules Revising Medical Criteria for Evaluating Immune System Disorders

Dear Commissioner Barnhart:

Set forth below are comments on the Proposed Rules revising the criteria in the Listing of Impairments used by the Social Security Administration (SSA) to evaluate claims involving immune system disorders. The undersigned organizations submitting these comments have extensive expertise in the area of HIV-related treatment and representation of HIV-positive claimants at every stage of the Social Security Administration's disability determination process.[1] Through our many years working in legal and medical programs and multidisciplinary agencies specializing in the needs of people living with HIV, we have learned the common difficulties faced by HIV-positive claimants and the typical responses of disability examiners and adjudicators to claims of disability based on HIV.

I. General Comments

Clearly the Social Security Administration has put a great deal of thought and effort into revising the medical criteria for evaluating immune system disorders. SSA is

[1] We have told organizations and individuals who desire to reference this letter in separate comments that they may refer to our work as the "HIV-Legal Joint Comments."

to be commended for soliciting comments in 2003, before undertaking revision of those criteria, and for carefully considering the comments that it received. We are very pleased to see that important changes to 20 CFR Part 404, Subpart P proposed in the revised criteria reflect concerns that many of us raised during that earlier process. SSA has improved the rules by extensively rewording and reorganizing Sections 14.00 and 114.00. In particular, the expanded discussion of treatment-related topics -- both in general and specifically in the HIV infection context -- is a significant improvement over the current version of the rules. Importantly, the Proposed Rules specifically mention the variability of individuals' responses to treatment, the difficulty of distinguishing side effects of treatment from side effects of infection and the fact that side effects of treatment themselves may result in functional limitations. These changes are important, much needed improvements.

Despite many positive changes in the rules, we believe some additional revisions are needed to remedy problems that we have seen in practice and issues that we anticipate will arise during the years that the revised rules will be in effect. The changes proposed by these comments will more accurately reflect the nature, course and treatment of HIV at this time and in the years ahead. Also, throughout the rules, it is important to include language that makes it clear to those determining claimants' disability that each claimant is entitled to an individualized assessment of his or her situation.

In finalizing the rules, the Social Security Administration should keep in mind the following principles: (1) the rules should accurately and comprehensively reflect the current understanding of HIV disease and treatment; and (2) the rules should include enough general language to accommodate the inevitable changes in understanding and treatment of the disease that will occur during the anticipated eight year life of the rules. Failure to include such general language will result in disabled persons being unfairly denied a finding of disability, because, for example, their medical records do not record the clinical markers written into the listings. HIV disease is still a relatively new disease and the standards for identifying it and its associated conditions, and for treatment, will continue to change. If, over the life of the final rules, the standards for identifying listed conditions change, claimants need to be able to have evidence related to those new standards credited, rather than be required to submit evidence of diagnostic findings which no longer are typically used by the medical profession.

II. Comments on Sections 14.00 (Part A) and 114.00 (Part B) of Appendix 1

A. Sections 14.00(F) & 114.00(F) and 14.08(K) & 114.08(L): The interplay between HIV and mental health should be specifically addressed.

Changes in mental and emotional functioning are often connected to HIV infection. Mental illness may precede HIV infection, as mental illness places people at risk of contracting HIV infection.[2] Mental health issues may accompany HIV infection, as the initial diagnosis of HIV infection can trigger anxiety and depressive disorders. Reservoirs of HIV can accumulate in the brain and cause dementia.[3] Not all current HIV medications effectively cross the blood-brain barrier, and many patients can become resistant to those that do.[4] Additionally, HIV medications can themselves cause mental impairments such as significant memory loss, cognitive deficits, depression, anxiety, paranoia and hypervigilance.[5]

For these and other reasons, mental illness frequently affects people who are living with HIV, and becomes more pronounced as the HIV disease progresses and becomes more severe. Mental health conditions can interfere with self-care, activities of daily living, and adherence to treatment regimens and appointment schedules.[6] Stress, anxiety and depression weaken the immune system and speed disease progression, whether they stem from mental illness, the trauma of the diagnosis, or the rigors of treatment.[7] In evaluating the severity and level of progression of HIV disease in a particular claimant, attention must be paid to signs and limitations that stem from mental and emotional deficits.

The link between HIV infection and mental illness is so strong, moreover, that often primary care providers and infectious disease specialists prescribe compensatory medications such as anti-depressants and anti-anxiety medications to their patients without referring them for psychiatric care or counseling.[8] In such cases, there is no longitudinal history of psychiatric care or assessment, as would be expected in the ordinary claim where the principal disabling impairment is a mental health condition. While such a patient may not have the history of signs and symptoms that document the severity required by SSA's mental health condition listings, these very real and

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[2] *See, e.g.*, Thompson, A., *et al.*, *Psychotropic medications and HIV*, 42 CLIN. INFECT. DIS. 1305-10 (2006); Angelino, A.F., Treisman, G.J., *Management of psychiatric disorders in patients infected with human immunodeficiency virus*, 33 CLIN. INFECT. DIS. 847-56 (2001).
[3] *See, e.g.*, Valcour, V., Paul, R., *HIV infection and dementia in older adults*, 42 CLIN. INFECT. DIS. 1449-54 (2006); Tozzi, V., *et al.*, *Changes in neurocognitive performance in a cohort of patients treated with HAART for 3 years*, 28 J. ACQUIR. IMMUNE DEFIC. SYNDR. 19-27 (2001).
[4] Tozzi, *supra.*
[5] *See, e.g.*, Thompson, *supra*, at 1306-09.
[6] *See, e.g.*, Yun, L.W.H., *et al.*, *Antidepressant treatment improves adherence to antiretroviral therapy among depressed HIV-infected patients*, 38 J. ACQUIR. IMMUNE DEFIC. SYNDR. 432-38 (2005); Angelino, A.F., *supra.*
[7] *See, e.g.*, Ickovics, J.R., *et al.*, *Mortality, CD4 cell count decline, and depressive symptoms among HIV-seropositive women: longitudinal analysis from the HIV Epidemiology Research Study*, 285 JAMA 1466-74 (2001); Tate, D., *et al.*, *The impact of apathy and depression on quality of life in patients infected with HIV*, 17 AIDS PATIENT CARE & STDS 115-20 (2003).
[8] *See, e.g.*, Thompson, *supra*, at 1305.

often severe conditions must be recognized by SSA as a manifestation of HIV infection which contributes to the disabling nature of the disease.

Therefore, we recommend that Sections 14.08(K) and 114.08(L) be modified to recognize specifically that mental health conditions can be a manifestation of HIV infection which, even if they do not rise to the level of severity required by the ordinary mental health condition listings, such as 12.04 (affective disorders including depression) or 12.06 (anxiety disorders), can and should be rightfully considered as repeated manifestations of HIV infection. Also, an additional subsection should be added to Sections 14.00(F) and 114.00(F) to make the points discussed above.

B. Sections 14.00(G) & 114.00(G): More specific discussions of some issues related to treatment are needed.

In the discussion on "variability of your response to treatment" (14.00(G)(2), 114.00(G)(2)), the Proposed Rules note generally various important factors to be considered. Moreover, the Proposed Rules improve upon the existing rules in that they more fully discuss side effects of HIV medication. However, greater discussion of some of those general factors in the specific context of HIV infection should be added to 14.00(G)(5) and 114.00(G)(5). Our experience reveals that the impact on HIV infected persons of treatment failures and the difficulties of adhering to treatment continue to be understood poorly by the Social Security Administration's disability examiners, adjudicators, and even medical consultants. These issues need to be addressed more fully in the Rules, in part to aid adjudicators in fairly and properly handling these issues.

1. Sections 14.00(G)(5) and 114.00(G)(5) should directly address the issue of a claimant's non-responsiveness to HIV treatments.

The Rules should specifically state that the mere fact that an individual does not medically respond to highly active antiretroviral therapy ("HAART") does not indicate that he or she is not disabled or is not credible. SSI and SSDI claimants and their representatives continue to encounter medical "experts" who seemingly assume that for every individual with HIV infection a treatment can be prescribed that will, if adhered to, enable the individual to work. When reaching conclusions about claimants' functional limitations, these consultants assume that the claimants are capable of responding positively to treatment through a mix of adherence, lifestyle alteration and sheer willpower. Such conclusions, however, fail to recognize that prescribed treatments are not effective or suitable for every HIV infected person. Although the general section on response to treatment acknowledges the need to

consider individual variability, this problem in the HIV context is persistent enough to warrant specific reference in Sections 14.00(G)(5) and 114.00(G)(5).

In addition, the Rules should note the increasing fragility of persons who do not respond to prescribed treatment and the impact on them of reduced treatment options. If an individual fails to respond to a particular combination of medications, either because he or she is naturally resistant, because the virus mutates in the body or for some other reason, that individual has fewer options for relief in the future. With fewer available treatment options, the person is more susceptible to complications, illness and disabling conditions. With this increased susceptibility to opportunistic infection and other medical complications come additional mental health implications, as stress, fear, depression and anxiety compound the claimant's physical fragility. In many such cases, physicians instruct their patients to reduce their exposure to infection by limiting their contact with other people, stress and adverse weather conditions. A claimant with few treatment options is likely to have created a very structured environment to reduce his or her risk of infection and illness. Whether the claimant avoids subsequent infection at the expense of his or her relationships, mobility, freedom and mental health is itself a manifestation of HIV disease and the direct result of the damage to his or her immune system caused by HIV. The discussion in sections 14.00(G)(5) and 114.00(G)(5) should specifically require that the fragile and tenuous position of a claimant with HIV be taken into account. We recommend that an additional subsection be added to each of those sections, reading "i. Whether you have exhausted most or all treatment alternatives."

2. Sections 14.00(G)(5) and 114.00(G)(5) should directly address the difficulty of adhering to treatment regimen.

For many people with HIV disease, their prescribed treatment regimens are very complicated and difficult to follow. They may be required to take numerous pills each day at several different times of the day and night, to keep certain medications refrigerated, to take some on an empty stomach and to take others with food. The requirements of HAART can be dizzying, difficult to follow, and potentially embarrassing. In addition, the often-debilitating side effects of the medications -- e.g., diarrhea, nausea, vomiting, neuropathy, fatigue -- make it difficult for some individuals to take each of their prescribed medications at every prescribed time.[9] Unfortunately, patients are often punished severely by their own bodies for the most minor

[9] *See, e.g.*, Trotta, M.P., *et al.*, *Treatment-related factors and highly active antiretroviral therapy adherence*, 31 J. ACQUIR. IMMUNE DEFIC. SYNDR. S128-31 (2002); Stone, V.E., *Strategies for optimizing adherence to highly active antiretroviral therapy: lessons learned from research and clinical practice*, 33 CLIN. INFECT. DIS. 865-72 (2001).

transgressions; even brief interruptions in treatment may lead to virus mutation and resistance.

Many people living with HIV experience these adherence problems, but, for obvious reasons, perfect adherence is especially difficult for some populations. In particular, people who experience mental illness have difficulties adhering to their treatment regimen because of their mental health conditions. Persons who are homeless or who lack Medicaid or other insurance coverage are also likely to have great difficulty accessing their medications and adhering exactly to prescribed treatment. In addition, HIV-positive children are particularly subject to adherence problems. For children, the bad taste of the medications, the repetition of the regimen, the appearance of being different at school, and an inherent lack of maturity and full understanding of the need for the medications all affect a medical provider's and a parent's ability to maintain compliance in an HIV-positive child.[10]

At present, some claimants are penalized by adjudicators for their inability to adhere to a strict and sometimes overwhelming regimen of medications. Therefore, Sections 14.00(G)(5) and 114.00(G)(5) of the Rules need to directly address this issue. Those sections should include a discussion of the difficulty of adhering to HIV treatment regimen and directly acknowledge that there are many valid reasons why individuals with HIV disease do not perfectly adhere to their prescribed treatment regimen, such as the individual's mental illness or young age; logistical difficulties (e.g., lack of access to refrigeration) precluding exact compliance; debilitating side effects from the medication; and inability to afford the prescribed treatment. The Rules also should state that a claimant's admitted lack of adherence to HAART should neither reflect on the claimant's credibility nor indicate that his or her functional capacity is artificially low. The individual's reasons for non-perfect adherence need to be taken into account, and we are concerned that the subsections of 14.00(G) do not provide sufficient guidance to adjudicators. Because adherence to HAART is particularly difficult, and because individuals who have not adhered may no longer have the option of resuming a particular treatment, claimants should not be penalized for their failure to adhere to complicated medication regimens.

III. Comments on Sections 14.08 (Part A) and 114.08 (Part B) of Appendix 1

The Proposed Rules properly recognize that an individual does not have to satisfy the specific listings set forth in Sections 14.08 and 114.08 to be found to suffer an impairment that is severe enough for him or her to be disabled for purposes of Title II and Title XVI. For example, Sections 14.00(G) and 114.00(G) state that a person may

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[10] *See, e.g.*, Pavia, A. T., *Primary care of infants and children with HIV*, HIV InSite Knowledge Base Chapter, July 2001, accessible at http://hivinsite.ucsf.edu/InSite?page=kb-03-01-14# S6.1.7X.

be disabled due to the effects of treatment -- including the interactive and cumulative effects of treatments -- without meeting the "stand-alone" listings and that the effects of treatment must be considered on an individual basis. As another example, 14.08(K) clearly states that repeated manifestations of HIV infection that are not listed in 14.08(A)-(J)[11] can be the basis for a disability finding, as can repeated manifestations of conditions that are listed in 14.08(A)-(J) but lack the required findings of those listings.

Even though evaluation of an individual situation cannot be limited to consideration of the disabling impairments specified in Sections 14.08 and 114.08, those "stand-alone" diagnoses of opportunistic infections are an important part of the rules. Diagnosis with a condition listed in those sections demonstrates that an individual has a severely compromised immune system and serves as a useful and sensible indicator of the inability to work. Therefore, the specific listings of impairments facilitate determinations of disability where an individual does meet one of the "stand-alone" listings. To more accurately reflect the current medical understanding of the disabling impairments experienced by people living with HIV and to allow for changes in that understanding over the next several years, some additional language should be added to Sections 14.08 and 114.08.[12]

A. The "stand-alone" listings should include general language anticipating changed understanding over the life of the rules.

As recognition that medical knowledge regarding the effects of HIV disease and HIV treatments will change over the anticipated eight year life of the rules, we recommend that the following language be added as a final subcategory for listings 14.08(A) through (F) and 114.08(A) through (F): "an infection or condition that is systemic or disseminated."

B. The descriptions of some conditions currently listed in Sections 14.08 and 114.08 should be modified to better account for the variety of disabling impairments experienced by people living with HIV.

1. Sections 14.08(D) and 114.08(D): Viral infections

[11] Section 114.08(L) makes the same point with reference to 114.08(A)-(K).

[12] Based on current medical knowledge, additional conditions beyond those set forth in these comments could appropriately be added to Sections 14.08 and 114.08. We have included only a few specific conditions, which we consider most significant at present. Sections 14.08(K) and 114.08(L) importantly recognize that other conditions not specified in the listings may serve as a basis for a finding of disability.

Sections 14.08(D) and 114.08(D) both currently state that a person with HIV meets a Step 3 listing if he or she meets the criteria for hepatitis set out in Section 5.05. We recognize that SSA has decided to remove all reference listings in the Proposed Rules. However, when removing the reference listing to Section 5.05, the Proposed Rules should have retained a reference to hepatitis. The current references to hepatitis in the HIV listings do not adequately address the complicated medical realities faced by people who are infected with both HIV and Hepatitis C ("HCV") or Hepatitis B ("HBV").

The Proposed Rules recognize generally that the interactive and cumulative effects of treatment for both HIV and hepatitis must be evaluated when an individual suffers from both. (Section 14.00(G)(1)(f).) However, the complicated interplay between HIV and hepatitis warrant greater recognition in the listings. Although simultaneous treatment of both HIV and hepatitis is critical for people who experience co-infection, the two treatment regimens can work against one another. Drugs used to treat HIV can undercut the benefits sought through treatment for HCV because the HIV drugs are toxic to the liver.[13] And HCV-related liver disease has been found to accelerate among people infected with HIV.[14] Similar complications occur in HIV-positive people with HBV.[15]

In short, people who are infected with both HIV and hepatitis are more prone to illness, more difficult to treat, and less able to function than people who are only infected with a hepatitis virus. This compounding effect means that it is not sufficient to allow such persons to be separately evaluated under the listing for hepatitis as well as the listing for HIV. The liver listings themselves do not contemplate overall suppression of the immune system, the necessity of taking medications that damage the liver or the other complications of HIV/AIDS. Nor is it sufficient to allow for consideration of the interactive and cumulative effects of treatment and to reference "hepatitis" in Section 14.08(K). To adequately reflect the extent of functional impairment of a person with both HIV and hepatitis, Sections 14.08(D) and 114.08(D) should reference hepatitis, where co-infection with both HIV and HCV or HCB complicates treatment of both conditions.

2. Section 14.08(H): HIV wasting syndrome

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13 *See, e.g.*, Braitstein, P., *et al.*, *Special considerations in the initiation and management of antiretroviral therapy in individuals coinfected with HIV and hepatitis C*, 18 AIDS 2221-34 (2004).

14 *See, e.g.*, Braitstein, *supra*; Sherman, K.E., *et al.*, *Hepatitis C virus prevalence among patients infected with human immunodeficiency virus: a cross-sectional analysis of the US Adult AIDS Clinical Trials Group*, 34 CLIN. INFECT. DIS. 831-37 (2002).

15 *See, e.g.*, Khalili, M., *Coinfection with hepatitis viruses and HIV*, HIV InSite Knowledge Base Chapter, March 2006, accessible at http://hivinsite.ucsf.edu/InSite?page=kb-05-03-04.

Section 14.08(H)'s listing of HIV wasting syndrome should be revised to reflect more current medical knowledge about this condition. As currently written, this listing is too restrictive in its documentation requirements.[16] The listing should note that body mass index (BMI) and body cell mass (BCM) can be relied upon as accurate indicators of the severity of wasting in a given individual.[17] The requirements with regard to diarrhea are too restrictive: a person with HIV who experiences wasting is typically functionally unable to work if he or she experiences diarrhea for two weeks and experiences protein deficiency. Although a documented fever is a useful clinical indicator of wasting syndrome, it should not be necessary that the claimant have many temperature readings throughout a month or longer period. Moreover, wasting can be disabling even in the absence of the listed manifestations when it is accompanied by constitutional symptoms such as weakness, lack of muscle strength, fatigue, malaise, or inability to lift. As an alternative to evidence of diarrhea or fever, the listing should specify that it can be satisfied by documentation of other objective evidence of significant involuntary weight loss. To do so, wording comparable to that used in Section 14.00(F) regarding documentation of HIV infection could be added: "OR Documented by other generally acceptable methods consistent with the prevailing state of medical knowledge or clinical practice."

3. Sections 14.08(I) and 114.08(I): Diarrhea

Sections 14.08(I) and 114.08(I) (unchanged from their predecessor sections in the current rules, adopted in 1993) need to be modified to reflect current medical views regarding diarrhea and its treatment. These sections now should include those HIV/AIDS claimants who suffer from diarrhea, lasting over one month, with multiple loose stools per day and/or bowel incontinence, despite modifications in HAART therapy and antidiarrheals. Many patients with disabling diarrhea do not require hydration and therefore are not treated with intravenous hydration. "Tube feeding" also is not a useful indicator of diarrhea; it is rarely used now to treat diarrhea and, in fact, diarrhea has been identified as a complication associated with tube feeding.[18] Thus, diarrhea can rise to the level of being disabling without the objective findings in the current listing being met. The listing should be changed to allow documentation by other objective evidence, such as reports of a rectal exam, stool culture, or fecal

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16 *See, e.g.*, Mangili, A., *et al.*, *Nutrition and HIV infection: review of weight loss and wasting in the era of highly active antiretroviral therapy from the Nutrition for Healthy Living cohort*, 42 CLIN. INFECT. DIS. 836-42 (2006) (noting problems with using defining criteria of weight loss plus diarrhea or fever).

17 *See, e.g.*, Mangili, A., *supra*; Nemechek, P.M., *et al.*, *Treatment guidelines for HIV-associated wasting*, 75 MAYO CLIN. PROC. 386-94 (2000).

18 *See, e.g.*, Finucane, T.E., *et al.*, *Tube feeding in patients with advanced dementia: a review of the evidence*, 282 JAMA 1365-70 (1999); Bliss, D.Z., *et al.*, *Acquisition of Clostridium difficile and Clostridium difficile-associated diarrhea in hospitalized patients receiving tube feeding*, 129 ANNALS INTER. MED. 1012-19 (1998).

occult blood test. As with wasting syndrome, general language should be added, comparable to that used in Section 14.00(F) regarding documentation of HIV infection: "OR Documented by other generally acceptable methods consistent with the prevailing state of medical knowledge or clinical practice."

C. Chronic pancreatitis should be added as a "stand-alone" listing in Sections 14.08 and 114.08.

Although pancreatitis is now referenced in 14.00(G)(5)(a) (as a side effect of antiretroviral drugs) and in 14.08(K), the Proposed Rules fail to acknowledge the seriousness of residual chronic pancreatitis among people with HIV disease. Chronic or relapsing pancreatitis among people with HIV disease severely impairs those individuals' abilities to function.[19] Serious, life-threatening pancreatitis can develop as a side-effect of medications used to treat HIV disease.[20] The condition may cause severe abdominal pain, nausea, vomiting, fever, chills, and shortness of breath, and can result in admission to a hospital's intensive care unit for two to three weeks at a time.[21] Also, it may result in profound weight loss and long-term food intolerance. These manifestations may recur continually when the cause of the pancreatitis persists or when lasting damage has been done to the pancreas. The affected individual may suffer numerous painful and debilitating relapses. Unfortunately, there is no cure for the condition. Because the presence of pancreatitis can be an important marker of HIV-related drug toxicities that could also limit life-saving treatment options or complications of HIV-related opportunistic infections, we recommend that Sections 14.08 and 114.08 include chronic pancreatitis as a "stand-alone" listing, satisfied by evidence of one or more episodes of pancreatitis from which clinical recovery is incomplete after six months and is accompanied with disabling symptoms (such as, but not limited to, abdominal pain, diarrhea, significant weight loss, nausea, anorexia, and glucose intolerance requiring frequent monitoring or treatment).

D. Sections 14.08(K) and 114.08(L) should be revised to anticipate changes in medical understanding and treatment of HIV disease.

Of course, over the anticipated eight year life of the new rules, changes in the understanding of HIV disease and its treatment will inevitably result in the recognition of new manifestations of the disease and its treatment that should be considered in

[19] *See, e.g.*, Dragovic, G., *et al.*, *Incidence of acute pancreatitis and nucleoside reverse transcriptase inhibitors usage*, 16 INT'L J. OF STD & AIDS 427-29 (2005); Gan, I., *et al.*, *Pancreatitis in HIV infection: predictors of severity*, 98 AM. J. GASTROENTEROL. 1278-83 (2003).
[20] *See, e.g.*, *id.*
[21] *See, e.g.*, Dragovic, *supra.*

determining disability. To take that into account and to reflect the non-exhaustive listing of manifestations in Sections 14.08(K) and 114.08(L), the following general language should be added to those sections: "Special consideration should be given to other conditions, signs and symptoms deemed by the primary care provider as contributing to substantial functional limitations."[22]

If you have any questions or wish for clarification regarding any of the above comments, please contact, on behalf of the undersigned, Bebe J. Anderson, HIV Project Director, Lambda Legal, 120 Wall Street, Suite 1500, New York, New York, 10005, telephone (212) 809-8585, email banderson@lambdalegal.org.

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[22] In addition, as discussed above, Sections 14.08(K) and 114.08(L) should be modified to specifically recognize that mental health deficits can be a manifestation of HIV infection that should be considered as repeated manifestations of HIV infection.

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