8 July 2003

Jo Anne B. Barnhart
Commissioner of Social Security
P.O. Box 1770
Baltimore, Maryland 21235-7703
Via email: regulations@ssa.gov
Via telefax: 410-966-2830

Dear Commissioner Barnhart:

Thank you for the opportunity to submit this letter in advance of potential revisions to the rules used to evaluate immune system disorders in individuals seeking disability benefits and insurance payments under Titles II and XVI of the Social Security Act. The undersigned organizations offer our extensive expertise in the area of HIV-related treatment and disability representation to propose medically and legally sound adjustments to sections 14.00 and 114.00 in the Listing of Impairments in Appendix 1 to Subpart P of Part 404 of the regulations ("the listings"). The organizations submitting this letter have worked with thousands of HIV-positive claimants at every stage of the Social Security Administration's disability determination process.[1] Many years working in legal and medical programs and multidisciplinary agencies specializing in the needs of people living with HIV have afforded us extensive knowledge of the common difficulties faced by HIV-positive claimants and the typical responses of disability examiners and adjudicators to claims of disability based on HIV. Since the HIV listings were last revised, HIV disease and its treatment have become increasingly complex. We recognize the legal and medical issues that most often lead to confusion or erroneous determinations regarding people with HIV, and we believe that appropriate modifications of the listings can remedy many of these problems.

In the pages that follow, we suggest that the Social Security Administration make a number of revisions to the listings to more accurately reflect the nature, course and treatment of HIV in the third decade of the epidemic. As medical advances have allowed many people with HIV to live longer lives, some conditions that were disabling ten years ago may be treatable and may no longer inhibit a person's ability to work. At the same time, medication side effects and increasingly common but previously unlisted conditions often present serious new impediments to the functional abilities of many people with HIV. For that reason, as you will see below, we suggest both additions to and deletions from the current listings.[2]

---

[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."

[2]Throughout this letter, we refer primarily to sections 14.00 and 14.08 rather than to the sections of the listings that specifically apply to children with HIV. Despite these shorthand

We request a continuing dialogue with the Social Security Administration as it moves through the process of revisions. We desire response to our input and participation in meetings and discussions with Social Security Administration representatives involved in the review process, prior to and following the anticipated Notice of Proposed Rulemaking. Such an interactive process will help ensure that the complicated area of HIV-related disability law reflects the experiences of the thousands of clients and patients we assist each year.

I. Section 14.00(D) should provide improved and detailed guidance regarding documentation of HIV manifestations, additional discussion of the effects of HIV medications, further explication of the ramifications of mental illness in HIV cases, and direction regarding other aspects of evaluating HIV-positive claimants.

A. Explain that claimants need not provide laboratory evidence to document all manifestations of HIV disease.

Advances in medical diagnostic procedures and progress in understanding clinical manifestations of HIV disease have commonly eliminated the need for laboratory evidence of certain HIV-related conditions. Revisions to the listings should reflect these advances. For example, pneumocystis carinii pneumonia (PCP), previously diagnosed via bronchoscopy, and candida esophagitis, previously diagnosed via endoscopy, are now commonly diagnosed by assessing their clinical manifestations, presumptive criteria, and treatment responses, rather than through laboratory procedures. We suggest that section 14.00(D)(4) be modified to reflect this reality.

B. Provide a more detailed and accurate discussion of the impact of medication on people with HIV.

Discussing the effects of HIV treatment and medication, section 14.00(D)(7) currently recognizes that "[r]esponse to treatment and adverse or beneficial consequences of treatment may vary widely," and advises that "each case must be considered on an individual basis, along with the effects of treatment on the individual's ability to function." These broad statements no longer provide adequate guidance to disability examiners and adjudicators charged with evaluating the functional capacity of people with HIV. In the intervening years, the medical landscape has changed dramatically, creating challenges and problems, as well as opportunities for people with HIV. Although new and effective drug regimens, commonly called "highly active anti-retroviral therapy," or "HAART," have helped to prolong many lives, they have also proved difficult to follow and sometimes independently disabling. Some individuals do not respond to certain combinations of medications, others are hampered in their daily activities by oppressive side effects, and still others are unable to adhere to the restrictive schedules that the

---

citations, please note that we intend our comments to apply to the listings for both adults and children, and we hope that you will consider them with that goal in mind.

medications mandate. As a result, even with medications potentially available, many people with HIV remain unable to engage in substantial gainful activity. As discussed below, we suggest that section 14.00(D)(7) be revised to reflect these complex issues so that SSA's disability adjudicators and the experts upon whom they rely may more accurately determine the functional capacities of people with HIV.

1. Section 14.00(D)(7) should explain that available medications prove ineffective for many individuals with HIV.

First, section 14.00(D) must acknowledge that many individuals may be resistant to medications. Although scientific advances have helped many people with HIV, available medications are not effective for everyone. It is crucial to note that in the treatment arena in particular, people with HIV cannot be regarded monolithically, and that personal responses to medications range widely. As a result, some people do not respond to a certain medication regimen, while others may show an initial positive response followed by a decrease in effectiveness. For some, medication provides only a partial solution to their HIV-related limitations, leaving them in a better condition than if they were untreated, but still unable to work.

Unfortunately, medical knowledge about drug resistance is still in its infancy, and scientists do not yet have enough information to reach definitive conclusions about the long-term efficacy of many medications used to treat HIV. Disturbingly, the incidence of drug resistance has increased in the past few years, both among patients who are receiving medication for the first time and among those who have been in treatment for years.[3] This trend raises the prospect that people currently responding to pharmaceutical treatment will be increasingly susceptible to opportunistic infections and other debilitating conditions in the future.

Because our experience reveals that the issue of drug resistance is often poorly understood by SSA's disability examiners, adjudicators, and even medical consultants, section 14.00(D) should address the subject in additional detail. Specifically, section 14.00(D)(7) should discuss three issues related to drug resistance. First, the provision should explicitly state that the mere fact that an individual does not respond to HAART does not indicate that he or she is not disabled or is not credible. Medical professionals generally agree that HIV therapies must be individualized to be effective. Nonetheless, SSI and SSDI claimants and their representatives frequently encounter medical "experts" who testify that an individual would be capable of working if only he or she were willing to adapt his or her lifestyle to the demands of medications. 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, are not supported by recent medical data on HIV treatment, and therefore cannot be controlling in a disability determination case.

---

[3] *See*, *e.g.*, Little, S.J., Holte S., Routy J-P, et al., *Antiretroviral drug resistance among subjects recently infected with HIV*, 347 N. ENGL. J. MED. 385-94 (2002).

Second, because response and resistance to medication vary from individual to individual, the regulations should also explain that an individual's initial positive response to treatment does not necessarily indicate a current or future ability to work. Indeed, many individuals experience drug resistance that allows them to achieve only limited success with medication. While "[m]aximizing viral suppression with a regimen that is well tolerated is a reasonable goal for patients with limited viral resistance," it is not always an option. Instead, "[a]chieving partial viral suppression with a goal of maintaining CD4+ T-lymphocyte counts and preventing opportunistic complications is a more realistic goal in many patients with highly resistant virus."[4]

Third, the regulations should note that there are only a limited number of available medication combinations, and that certain individuals may have fewer treatment options than others. 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 one fewer option for relief in the future. With fewer available treatment options, the person is statistically more likely to become susceptible to illness and disabling conditions or, if the individual is already disabled, he or she is less likely to recover in the near future. For instance, if a claimant has not suffered one of the opportunistic infections listed in sections 14.08(A) through (L) or the recurrent infections in section 14.08(M), but experiences certain symptoms suggested in section 14.08(N) and has exhibited resistance to all available medication, he or she may be highly susceptible to disabling illness. This claimant's hope of successful treatment for symptoms is diminished. While disability determinations may not necessarily turn on the statistical chances of future injury, the regulations should account for this complicating factor for people with HIV.

2. Section 14.00(D)(7) should explain that people with HIV may experience disabling side effects from medical treatment.

Section 14.00(D)(7) should also be amended to include a more detailed discussion of the potentially disabling side effects of HIV medications. The regulation currently states that "[m]edical treatment must be considered . . . in terms of any side effects of treatment that may further impair the individual." Again, this broad mandate is vaguely helpful, but does not provide adequate guidance to SSA's decision makers, who may be unfamiliar with the unique and sometimes overwhelming side effects associated with HAART. We suggest that section 14.00(D) provide a more detailed description of the types of side effects that may complicate the treatment of individuals with HIV, as well as a discussion of how side effects should be considered in determining whether an individual with HIV meets or equals a listed condition. The adverse effects of medications are particularly noteworthy for people with HIV, because in many cases the combination of side effects can be disabling on their own. These side effects

---

[4] A. Collier, *Treatment of Patients with Drug Resistant Virus*, Session 23, 9TH CONFERENCE ON RETROVIRUSES AND OPPORTUNISTIC INFECTIONS, February 27, 2002.

often persist even as powerful drugs succeed in reducing the level of HIV in the patient's blood, resulting in tests that show low or undetectable viral loads.[5] Additionally, it is often unclear whether a particular condition is caused by HIV-related immune suppression or by the medication taken to treat immune suppression. Moreover, in many cases, side effects impinge upon both quality of life and functional capacity, yet are unavoidable, since those who respond to medications generally must take them to survive.[6]

Accordingly, we suggest two specific modifications to section 14.00(D)(7). First, the regulation should clarify that the side effects of HIV medications can be independently disabling. Patients who are taking HAART may experience persistent nausea, vomiting, severe diarrhea, malaise and fatigue, joint and muscle pain, or insomnia.[7] Certain protease inhibitors can lead to metabolic changes associated with heart disease.[8] Efavirenz has been linked with an increased incidence of severe psychiatric illness, including suicidal depression, agitation, aggression, and hallucinations.[9] Indinavir (Crixivan) can cause hemolytic anemia and liver damage in small numbers of patients, although its most common side effect is kidney stones, which can lead to

---

[5]Thus, claimants may be disabled under section 14.00(D) even if laboratory blood tests indicate that their viral loads are low or undetectable. Furthermore, viral load measures only the amount of HIV in a person's blood and does not reveal virus which may reside in "reservoirs" in the lymph nodes, organs, etc., where replication apparently does not stop even when the viral load reading is undetectable. In July 2000, Nature Medicine documented research findings from the National Institute of Allergy and Infectious Diseases and the University of Washington indicating that viral load rebounds to high levels when HAART ceases. In April 2001, the same journal reported that HIV replicates in the thymus before reentering the blood stream. Thus, an individual's laboratory results may indicate a very low or undetectable viral load while the virus continues to replicate or mutate in the body. Section 14.00(D) should therefore reflect that a low or undetectable viral load is not a reliable indicator that the individual is healthy or functionally capable of work.

[6]In his study of the longevity of the efficacy of HAART, Bernard Hirshel notes that "the fear of side effects has increased. In a transversal study within the Swiss Cohort, the prevalence of clinical side effects was 47 percent." Bernard Hirshel, Antiviral Therapy 2002, 6th INT. CONG. HIV. DRUG THERAPY (2002) ;6: Abstract No. KL3, the Gardiner-Caldwell Group, Ltd. <http://www.aegis.com/conferences/hiv6/k18.html>.

[7]Christiane Schieferstein, *Management of HIV Side Effects*, *in* HIV MEDICINE (Hoffman & Kamps, eds., Flying Publisher 2003) <www.hivmedicine.com/textbook/haart/nw1.htm>.

[8] *New Research Confirms Role of Heart Disease as a Treatment By-Product*, 18 AIDS ALERT, February 7, 2003 <http://www.aegis.com/news/ads/2003/ad030265.html>.

[9]*Efavirenz Effects Worse than Reported, Study Says*, AIDS ALERT, January 24, 2003 <http://www.aegis.com/news/ads/2003/ad030159.html>.

kidney failure if not diagnosed and treated.[10] Both protease inhibitors and nucleoside reverse transcriptase inhibitors (NTRIs) are thought to be toxic to mitochondria, causing side effects such as peripheral neuropathy, myopathy, cardiomyopathy, myositis, lactic acidosis, hepatic steatosis, lipodistrophy, pancreatitis and anemia.[11] Even as new medications offer new hope for some people with HIV, corresponding new side effects create new impairments. For example, Fuzeon, a recently approved injectable fusion inhibitor which has generated a fair amount of publicity this year, can result in very painful injection sites and can potentially cause further physical effects, including fever, nausea, vomiting, low blood pressure, paralysis, rigors, severe rash, and breathing trouble.[12] Even people with HIV who show few or no symptoms of the underlying virus may be disabled as a result of medications, and Section 14.00(D) should reflect this fact.

Second, the regulation should clarify that conditions such as those listed above should not be discounted or disregarded simply because a medical provider cannot determine whether they are symptoms of HIV or effects of medication. Because the side effects of HAART may be very similar to the symptoms of the underlying illness, the medical evidence may not specifically delineate the cause or source of the complaints. At the same time, the claimant may not know (or care) whether the chronic diarrhea, fatigue, nausea, vomiting, or memory loss that he or she experiences are symptoms or medication side effects. Unfortunately, because the cause of the conditions may be indeterminate, medical experts, disability examiners and adjudicators often simply conclude that a claimant's symptoms are medication "side effects," such that the Step 3 assessment as part of the sequential evaluation of the disability determination process is cursory and incomplete. As a result, during the Step 4 and Step 5 analysis, the disability examiners and adjudicators then assume that a claimant has a higher level of residual functional capacity, because the claimant's complaints have been minimized as medication side effects. Section 14.00(D) should correct these errors by explaining that symptoms and medication side effects are often indistinguishable in the context of HIV, and that all such manifestations – whatever the cause – should be fully considered during the Step 3 analysis.

---

[10] *Indinavir (Crixivan), Simple FactSheet*, AIDS TREATMENT DATA NETWORK (Last updated April 23, 2002) <http://www.atdn.org/simple/indi.html>.

[11] *Mitochondrial Damage from HIV Drugs*, *Simple FactSheet*, AIDS TREATMENT DATA NETWORK (Last updated August 22, 2003) <http://www.atdn.org/simple/mito.html>; National Cancer Institute, *Study Sheds Light on Cause of an AIDS Treatment Side Effect* <http://www.cancer.gov/newscenter/HIVmitochondrion>, citing Mukhopadhyay A., Wei B., Zullo S.J., Wood L.V., Weiner H., 2002, *In vitro evidence of inhibition of mitochondrial protease processing by HIV-1 protease inhibitors in yeast; a possible contribution to lipodystrophy syndrome,* 1 MITOCHONDRIAN 511-518 (2002).

[12]U.S. Department of Health and Human Services, AIDSINFO DRUGS DATABASE, (last updated April 29, 2003) <http://www.aidsinfo.nih.gov/document/data/Drug_lib/NonTechnical/DRUG_Non_Tech_0306.html>.

Finally, section 14.00(D)(8) should be similarly revised to recognize the common impact of medication side effects on claimants' functional abilities. The conclusion of section 14.00(D)(8), which currently discusses the assessment of an individual's ability to complete tasks timely, should explicitly recommend that the side effects of HAART be taken into account in this evaluation. As noted above, medications such as Efavirenz, for instance, can cause side effects including memory loss, difficulties processing information, paranoia, hallucinations (which affect sleep and/or cause insomnia), nightmares, and "hangover"-like symptoms. Because the effects of medication may impair a claimant's ability to complete tasks in a timely manner, section 14.00(D)(8) should advise SSA's disability examiners and adjudicators to consider the impact of such side effects when assessing a claimant's functional capacity.

3. Section 14.00(D)(7) should explain that people with HIV commonly have difficulty adhering to restrictive HAART regimens, and that claimants should not be penalized for adherence difficulties.

Even people who respond to HAART and do not experience disabling side effects have difficulty adhering to a strict and sometimes overwhelming regimen of medications. Medical providers often expect people with HIV to take dozens of 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. A regimen of thirty or more pills per day is difficult to maintain, even with pill boxes, timers and other compliance devices. Moreover, considering the often debilitating side effects of the medications, some individuals may have understandable difficulty taking all their medications all the time. For obvious reasons, perfect adherence is often particularly difficult for people who experience mental illness. Unfortunately, patients are often punished severely by their own bodies for the most minor transgressions; even brief interruptions in treatment may lead to virus mutation and resistance.[13]

These adherence problems haunt all people with HIV who have access to medication, including HIV-positive children. 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. These difficulties merit understanding as medical complications. When considering a child's inability to adhere to medication, SSA's disability examiners and adjudicators should not simply conclude that the child or his/her parent

---

[13]For a review of literature regarding adherence, *see* 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). The article notes that "the more we learn about adherence, the more clear it becomes that an individualized and flexible approach is essential." *See also* Golin, C.E., et al., *A Prospective Study of Predictors of Adherence to Combination Antiretroviral Medication*, 17 J. GEN. INT. MED. 756 (2002).

is not credible due to "poor compliance," nor should medical experts, disability examiners or adjudicators assume that the child has a higher residual functional capacity than medical records indicate. These complications merit serious consideration when assessing whether an HIV-positive child claimant meets a listing.[14]

Section 14.00(D) should address these issues by including a discussion of the difficulty of adherence to HIV medications, particularly in children and people with mental illness. The regulation should indicate that the failure of a particular medication or a claimant's admitted lack of adherence should neither reflect on the claimant's credibility nor indicate that his or her functional capacity is artificially low. Because adherence to HAART is particularly difficult, and because individuals who have not adhered may no longer have the option of resuming treatment, claimants should not be penalized for their failure to adhere to complicated medication regimens.

4. Section 14.00(D)(7) should explain that claimants should not be penalized for their participation in structured treatment interruptions (STI) or "drug holidays."

Finally, along with the discussion of resistance, side effects and adherence, section 14.00(D)(7) should explain that a standard course of treatment for HIV may include "structured treatment interruptions" and "drug holidays" during which a doctor advises a patient to temporarily cease taking medications. Structured treatment interruption (STI)[15] and "drug holidays" may help alleviate the severity of side effects and assist the assessment of the effectiveness of certain medications and the resistance of the body's immune system: "This approach may be useful in

---

[14]Proper consideration of children with HIV/AIDS may require expert testimony and/or review of the medical evidence by a pediatric AIDS specialist. This, however, may not be feasible, due to the small number of such specialists in the United States.

[15]Slovick, *Planned drug interruption: Can the Immune System 'Re-learn' How to Fight HIV?*, 9 POSITIVE LIVING 12-13, 50 (March 2000). At the 7th Conference on Retroviruses and Opportunistic Infections, which took place in San Francisco, California from January 30 - February 2, 2000, a number of medical abstracts were presented, documenting studies in which anti-retroviral medications were halted. In some instances, the subjects' immune systems "shut off" when not exposed to the virus in large amounts. Allowing the viral load to climb before re-starting the anti-retroviral medications "brought back" the immune systems' ability to attack the virus, resulting in "an increase in the amount and effectiveness of [the] immune response to HIV." Additionally, a March/April 2002 article has summarized a number of the studies from the 2001 Retrovirus Conference (and from other conferences) to note that STI's still can be a viable treatment option for those persons who have been exposed to virtually all HAART medications, who have developed "multi-drug resistance," and who have virtually no treatment options remaining. *See* S. Berger, *Structured Treatment Interruption and Immune Reconstitution*, 13 POSITIVELY AWARE (2002).

acute primary HIV infection after HAART therapy, where the patient may already have the immune capability to respond to exogenous antigens, and in the chronic HIV setting after some degree of immune reconstitution with HAART. STI may also be useful in patients with multidrug-resistant HIV, where stopping therapy may allow emergence of wild-type virus and permit use of recycled antiretroviral drugs to suppress virus replication."[16] Because of the complicated risks involved, not every HIV-positive claimant will be able to take advantage of an STI or "drug holiday"; in this area as well, treatment must be tailored to the unique responses of the individual claimant. Section 14.00, however, should explain that STI's and "drug holidays" are valid treatment options.

Claimants and their representatives consistently confront ill-informed disability examiners, adjudicators and medical experts who misconstrue doctor-approved STI's or "drug holidays" as noncompliance. STI's and "drug holidays" may be valid and useful methods of treatment of people with HIV. Therefore, the fact that an individual stops taking medication pursuant to his/her doctor's recommendation cannot constitute either evidence of non-compliance or evidence to challenge the claimant's credibility.

C. The significant interplay between HIV and mental illness warrants a complete discussion of mental health issues in section 14.00(D).

Mental illness and mental limitations routinely exacerbate the risk of HIV infection and progression of HIV disease in numerous ways. On the infection front, certain mental illnesses may contribute to the risk of infection as, for instance, a bipolar individual may, when manic, feel invincible and may engage in high-risk sexual practices. HIV diagnosis commonly triggers aspects of or full-blown anxiety and depressive disorders. After infection has occurred, mental illness commonly contributes to physical progression of HIV disease, as any number of mental health conditions may interfere with the ability to care for oneself in general and often specifically interfere with the ability to adhere to medication regimens. Stress, anxiety, and depression strongly influence the physical health of people with HIV, causing the immune system to weaken and speeding disease progression.[17] These issues are further complicated by

---

[16]Mitsuyasu, "Immune Reconstitution With Antiretrovirals, Immunotherapy, and After Structured Treatment Interruption," 7th Conference on Retroviruses and Opportunistic Infections, January 31, 2000, at 3. *See also* Hirschel, B., "Strategic Treatment Interruptions: Where Are We?," 9th Conference on Retroviruses and Opportunistic Infections, Session 21, February 26, 2002.

[17]*See*, *e.g.*, Angelino, A.F., Treisman G.J., *Management of Psychiatric Disorders in Patients Infected with Human Inmunodeficiency Virus*, 33 CLIN. INFECT. DIS. 847-56 (2001); Ichkovis, 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 1466-1474 (2001); Tate, D., et al., *The Impact of Apathy and Depression on Quality of Life in Patients Infected with HIV*, 17 AIDS PATIENT CARE AND STDS 115-120 (2003).

the fact that the virus itself actually causes mental impairments or dementia in a certain number of people it infects.

Meanwhile, it is the experience of the drafters of these comments that mental illness is frequently under-diagnosed and under-treated in disability claimants. For that reason, we strongly suggest that the confluence of mental illness and HIV disease is so prominent as to merit a specific directive that full development of the record include inquiry into mental health and the ramifications of mental disorders for HIV-related disability claims.

D. Section 14.00(D) should specifically state that only HIV/AIDS specialists can competently assess HIV-related medical issues.

The complicated nature of HIV disease and treatments necessitates that physicians who perform consultative examinations, review HIV/AIDS claimant files, or testify as experts during hearings should be HIV/AIDS specialists. Medicaid programs already reflect the need for specialization in HIV assessment and treatment,[18] as do recent structural provisions governing health maintenance organizations that serve people living with HIV.[19]

Given the rapid and complicated developments in the HIV medical field, we cannot reasonably expect that general practitioners or medical personnel who are not HIV/AIDS specialists will yield "expert" opinions. Section 14.00 should therefore mandate that only infectious disease specialists or HIV/AIDS specialists are qualified to render expert opinions in adult or child HIV/AIDS disability determinations. Both the HIV Medicine Association and the American Academy of HIV Medicine consider medical providers to be "HIV experienced" or "HIV specialists" only if the providers have, among other things, (1) provided continuous and direct medical care to at least twenty patients with HIV over the past two years and (2) completed at least thirty hours of HIV-related continuing medical education over the past two years. We strongly suggest that the modified listings adopt this two-part standard as the minimum criteria for any medical expert who participates in the disability determination process when the claimant alleges that he or she has an HIV-related disability.

II. The listed conditions in sections 14.08 and 114.08 should be maintained with certain modifications.

---

[18]See, for example, New York's "special needs plans" that must be accessible to all HIV-positive patients, based upon their requirements for expert care.

[19]The California Health Care Association considers HIV/AIDS a medical specialty, and California's governor signed legislation in 2000 requiring that standing health maintenance organization referrals for HIV/AIDS patients must be directed to HIV/AIDS specialists.

A. "Stand-alone" listings remain an important component of the HIV disability assessment process.

The "stand-alone" diagnoses of opportunistic infections set forth in sections 14.08(A) through (L) compose an important part of the listings. Despite progress in HIV medication regimes since the listings were promulgated in 1993, diagnosis with one of the conditions currently listed in sections 14.08(A) through (L) unfortunately continues to demonstrate that an individual has a severely compromised immune system and, typically, profound functional limitations. For that reason, the Social Security Administration must maintain "stand-alone" listings. Some "stand-alone" diagnoses have become less prevalent since the listings were devised, but when they do occur, they remain disabling. Furthermore, as discussed above, as resistance to medications has increased in the last several years, growing numbers of individuals have become susceptible to "stand-alone" conditions.[20] The opportunistic infections currently listed are disabling events and are sensible indicators of the inability to work.

Furthermore, the mere fact that an individual has survived or will survive an opportunistic infection does not indicate that the individual is not disabled. As noted above, survival of opportunistic infections requires a medical regimen that typically involves high-toxicity drugs that are difficult to tolerate, with severe side effects that commonly prevent sustained work. Because of continuing uncertainty regarding the long-term effectiveness of medications, the fact that a given individual currently experiences a serious listed condition indicates that the individual is--and may remain--disabled.

B. The descriptions of the conditions currently listed in section 14.08 should be modified to account for the variety of disabling impairments experienced by people with HIV.

While many of the listings in sections 14.08(A) through (L) remain as useful today as they were in 1993, we suggest several modifications that take into account changes in the course and treatment of HIV-related illness. The suggestions listed below reflect the course of the disease, the entirety of the effects of new medical treatments available to those living with HIV/AIDS, and new research and medical knowledge regarding quality-of-life issues for people who may be living longer lives.

1. Section 14.08(C)(1)

---

[20]For a discussion of the increasing incidence of drug resistance, *see* Little, S.J., Holte S., Routy J-P, et al., *Antiretroviral drug resistance among subjects recently infected with HIV*, 347 N. ENGL. J. MED. 385-94 (2002).

Section 14.08(C)(1) describes the listing for disability in protozoan or helminthic infections. The listing includes cryptosporidiosis, isosporiasis, or microsporidiosis, with diarrhea lasting for one month or longer. The one-month requirement in this section is extreme and unrealistic; most people who suffer such a long bout are dead by the end of a month. For that reason, the listing should be revised to require that the claimant's diarrhea last two weeks at the most.

2. Section 14.08(D)

Section 14.08(D) currently includes only five viral infections that, on their own, are disabling. We suggest adding Varicella Zoster virus as a "stand-alone" opportunistic infection in this section. This virus causes very painful skin lesions along the nerve tracts, and pain may persist even after visible symptoms disappear. Especially for people with a weakened immune response, the virus is recurrent and very painful, and therefore quite disabling.

3. Section 14.08(D)(5)

Section 14.08(D)(5) currently states 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. While such a cross-reference is valuable, it does not fairly reflect the complicated medical realities faced by people who are infected with both HIV and Hepatitis C ("HCV") or Hepatitis B ("HBV"). While co-infection with HIV and hepatitis may not have been a major concern for persons with HIV or AIDS in 1993, "liver disease caused by Hepatitis C is now the second leading cause of death of HIV patients."[21] Moreover, HCV progresses "about twice as fast" in people with HIV.[22] And because people with HIV are often ineligible for liver transplants, end-stage liver disease is a common cause of death. Simultaneous treatment of both HIV and hepatitis is critical for people who experience co-infection, but "both diseases require long courses of punishing drugs that can work against one another, while the HIV drugs can be toxic to the liver that the Hepatitis C drugs are trying to protect."[23] Such complications are common to HIV-positive people with either HCV or HBV.[24]

---

[21] *HIV Patients Face a New Epidemic*, THE BOSTON GLOBE, September 19, 2000, at D1. See also *Hepatitis C Poses New Threat to Many With AIDS*, NEW YORK TIMES, May 1, 2001, at F7. See generally 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. 831-7 (2002).

[22] Id.

[23] Id.

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 merely cross-referencing the listing for hepatitis does not adequately reflect the extent of functional impairment of a person with both HIV and hepatitis. 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. Section 14.08(D)(5) should reflect the fact that co-infection complicates treatment of both conditions.

4. Section 14.08(E)(3)

Section 14.08(E)(3) details various types of lymphoma which can cause disability in people with HIV. Central Nervous System (CNS) lymphoma, a very severe lymphoma of the brain which is difficult to treat, should be added to the listing.

5. Section 14.08(F)

Section 14.08(F) describes "stand-alone" conditions "of the skin or mucous membranes . . . with extensive fungating or ulcerating lesions not responding to treatment (e.g., dermatological conditions such as eczema or psoriasis, vulvovaginal or other mucosal candida, condyloma caused by human papillomavirus, genital ulcerative disease)." The requirement that lesions be "extensive fungating or ulcerating" is too limiting and should be revised to include rash, itching, and burning as symptoms to consider in evaluating the condition. All of these symptoms can cause severe insomnia and are disabling on their own.

6. Section 14.08(G)(1)

Section 14.08(G)(1) explains that a person with HIV meets a listing if he or she experiences anemia as described under the criteria in section 7.02. Since 1993, Erythropoietine (Procrit) has become available for treatment, such that the listing should be revised to state that anemia is a "stand-alone" listing if "refractory to treatment," meaning that if erythropoietine is ineffective, the condition can be quite severe and is therefore disabling.

7. Section 14.08(G)(3)

---

[24]Peters, M., "Pathogenesis of Chronic Hepatitis B," 9th Conference on Retroviruses and Opportunistic Infections, Session 18, February 26, 2002.

Section 14.08(G)(3) states that granulocytopenia, as described under the criteria in section 7.15, is a "stand-alone" disabling condition. In 1993, there was no treatment for granulocytopenia. Now GCSF or GMCSF is available for treatment. For that reason, claimants should only qualify as disabled if treatment for granulocytopenia proves ineffective or if they qualify under another subsection of the regulations.

8. Section 14.08(H)(2)

Section 14.08(H)(2) regarding neurological manifestations of HIV infection, including peripheral neuropathy, should acknowledge that the debilitating pain often accompanying these manifestations can be disabling in and of itself. Whether a claimant can effectively ambulate is too strict a standard.

9. Section 14.08(I)

Section 14.08(I) currently explains that HIV wasting syndrome may be disabling if accompanied by either chronic diarrhea or chronic weakness and fever. Wasting can be disabling even in the absence of those manifestations when it is accompanied by constitutional symptoms such as weakness, lack of muscle strength, fatigue, malaise, or inability to lift. The listing should be modified accordingly. Additionally, to the extent that a person with wasting syndrome suffers from chronic diarrhea, the requirement in section 14.08(I) that the individual have two or more loose stools each day for more than a month is far 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. Finally, the listings should note that body mass index (BMI) and body cell mass (BCM) can be relied upon as a more accurate indication of the severity of wasting in a given individual.[25]

10. Section 14.08(J)

Section 14.08(J) explains that diarrhea can be a disabling condition if it lasts for more than one month and requires intravenous hydration, intravenous alimentation or tube feeding. This section should be modified to 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. Such claimants experience chronic diarrhea in an extremely debilitating manner, even if their physicians have not recommended intravenous treatment. Moreover, because intravenous hydration may exacerbate diarrhea, it typically is not advised as a means to remedy diarrhea.

---

[25] *See* Nemechek P.M., Polsky B., and Gottlieb M.S., *Treatment guidelines for HIV-associated wasting*, 75 MAYO CLIN. PROC. 386-94 (2000).

C. Section 14.08 should be modified to add three new stand-alone listed conditions.

While the stand-alone conditions currently listed in section 14.08(A) through (L) catalogue the majority of physical ailments that can independently disable people with HIV, the current list fails to mention two disabling conditions that frequently affect people with HIV. For that reason, we suggest that section 14.08 be modified to add the following stand-alone listings:

1. CD4+ counts below 100 cells/mm^3

Section 14.00(D) currently includes a discussion of the predictive value of gauging CD4+ cell counts, which can often serve as a measure of an individual's immune system health. As a general matter, untreated HIV infection causes the depletion of CD4+ cells, leading over time to clinical complications and increased immune suppression. According to the Centers for Disease Control and Prevention's official classification, a person with HIV has AIDS if his/her CD4+ count falls below 200 cells/mm^3.[26] As an individual's CD4+ count drops below 200 cells/mm^3, his or her susceptibility to illness increases dramatically. When an individual has as few as 100 T-cells per cubic millimeter, he or she typically exhibits an extreme susceptibility to opportunistic infections and disabling illness. Additionally, when one's T-cell count drops to such a low level, he or she is more likely to have trouble tolerating medication and therefore is less likely to recover his/her functional capacity in a short period of time. CD4+ counts below 100 cells/mm^3 commonly coincide with one or more of the "stand-alone" disabling opportunistic infections listed in section 14.08(A) through (L). Those individuals whose CD4+ counts are dangerously low but who have not yet experienced an opportunistic infection are highly susceptible to such infections and other pervasive manifestations of HIV disease. Because people with HIV whose CD4+ counts are lower than 100 cells/mm^3 commonly experience graver physical conditions and exhibit lower functional capacities than individuals with stronger immune responses, section 14.08 should state that people with such low CD4+ counts automatically meet a listing.

2. Chronic or acute pancreatitis

Pancreatitis is a potentially disabling--and sometimes fatal--condition that can be caused by either HIV or certain HIV medications. Most commonly, pancreatitis in people with HIV is caused by the medication didanosine (ddI) or other nucleoside reverse transcriptase inhibitors.[27] The condition may cause severe abdominal pain, nausea, vomiting, fever, chills, and shortness of

---

[26]United States Department of Health and Human Services, *1993 Revised Classification System for HIV Infection and Expanded Surveillance Case Definition for AIDS Among Adolescents and Adults*, 41(17) MORBIDITY MORTALITY WEEKLY REPORT (1992).

[27]John G. Bartlett & Joel E. Gallant, *Medical Management of HIV Infection* 204 (2003).

breath, and can result in admission to a hospital's intensive care unit for two to three weeks at a time. When an individual experiences acute pancreatitis, he or she may experience profound weight loss and long-term food intolerance. These manifestations may continually recur when the cause of the pancreatitis persists or when lasting damage has been done to the pancreas. In such cases of chronic pancreatitis, the affected individual may suffer numerous painful and debilitating relapses. Unfortunately, there is no cure for the condition.

Because pancreatitis is frequently associated with HIV infection and nucleoside reverse transcriptase inhibitors, we suggest that section 14.08 specifically indicate that a person with HIV is disabled if he or she either (1) meets or equals the listing 5.08 for digestive disorders, or (2) requires hospitalization for pancreatitis three or more times in a one-year period.

D. Section 14.08(N), which discusses repeated manifestations of HIV-related conditions, should be amended to more specifically discuss certain disabling manifestations of HIV.

Section 14.00(D)(6) currently states:

> The criteria in 14.08 do not describe the full spectrum of diseases or conditions manifested by individuals with HIV infection. As in any case, consideration must be given to whether an individual's impairment(s) meets or equals in severity any other listing in appendix 1 of subpart P (e.g., a neoplasmic disorder listed in 13.00ff). Although 14.08 includes cross-references to other listings for the more common manifestations of HIV infection, other listings may apply.

Section 14.08(N) reiterates this basic point, indicating that HIV-positive claimants may be disabled by repeated manifestations of HIV-related conditions. Despite the existence of these provisions, SSA decision makers often conclude that a particular claimant does not meet or equal section 14.08(N) because the manifestations, symptoms, or signs that the claimant experiences do not rise to the level of another "stand-alone" listing. The text of section 14.08(N) therefore should be expanded to describe some of the additional manifestations that, when recurrent or in combination with others, impair the functional capacity of a person with HIV. To that end, we suggest that section 14.08(N) refer to the following conditions:

1. Lipid disorders

Lipid disorders, including lipodystrophy or lipoatrophy, are serious conditions that often result from HIV and HIV therapies. For some individuals, lipid effects cause psychological trauma, which subsequently affects their ability to continue working. Additionally, people who experience lipid disorders may be susceptible to elevated blood fat levels and cardiovascular disease, as well as diabetes because of altered glucose metabolism.

2. Diabetes Mellitus

Because they affect the body's ability to store glucose, protease inhibitors often cause diabetes mellitus. Researchers from Washington University in St. Louis reported in the *Journal of Biological Chemistry* that human fat cells absorb less glucose after exposure to protease inhibitors, which also results in lipodystrophy. This type of diabetic complication may not rise to the level of the diabetes listing, but may contribute to disability.[28]

3. Symptomatic Hyperlactatemia (or lactic acidosis)

Lactic acidosis, a condition that results in elevated lactate levels, abdominal cramps and liver abnormalities, was one of the first recognized metabolic complications of anti-retroviral medications. In February 2002, it was reported at the 9th Conference on Retroviruses and Opportunistic Infection that the risk for Symptomatic Hyperlactatemia more than doubles with each nucleoside reverse transcriptase inhibitor (NRTI) that is added to an individual's medication regimen. Lactic acidosis is life-threatening, and chronic or severe acidosis carries a high probability of death. The condition may cause organ dysfunction, activity intolerance, the development of fatty liver, and bone disease. Considering the severity of the condition and the added complication of immune suppression, we suggest including lactic acidosis in section 14.08(N).

4. Metabolic abnormalities

Section 14.08(N) should mention the disabling potential of metabolic abnormalities resulting from a temporary or permanent loss of blood supply to the bones. Osteomalcia, or bone wasting, causes spontaneous fractures and horrific pain, and can be disabling. Similarly, avascular necrosis (AVN) resulting in bone erosion and collapse can cause disabling pain. Although the cause of these bone conditions is unknown, it appears that HAART may play a role. Although a metabolic condition is not necessarily disabling, when recurrent, any of these bone conditions can seriously affect functional capacity.

5. Infarction and cardiac problems

For several years, medical literature has documented the fact that HAART medications can cause infarction. Research by the Centers for Disease Control and Prevention has shown that patients

---

[28]For a discussion of incidence and treatment of diabetes mellitus in people with HIV, *see* Dube, M.P., *Disorders of Glucose Metabolism in Patients Infected with Human Immunodeficiency Virus*, 31 CLIN. INFECT. DIS. 1467-75 (2000).

on HAART have five times the usual risk of heart attacks, as well as increased risk of hyperglycemia, hyperlipidemia and even hypertension. Additionally, research has established that HIV-positive individuals with lipodystrophy have significantly greater risk of cardiovascular disease than HIV patients without lipodystrophy.[29] While HAART-related heart conditions may not always rise to the level of the cardiac listings, evidence of medication-induced infarction or impaired cardiac capacity must be considered as a manifestation of HIV/AIDS.[30]

6. Other common disabling manifestations of HIV

Section 14.08(N) currently lists a number of symptoms and signs of HIV-related illness that may be disabling, including fatigue, fever, malaise, weight loss, pain, and night sweats. We suggest that the list of potentially disabling repeated symptoms be expanded to include nausea, vomiting, memory loss, concentration problems, cognitive processing difficulties, headaches and insomnia. People with HIV commonly suffer from these conditions, and severe or repeated manifestations are potentially disabling.

In conclusion, we appreciate the opportunity to submit the fruits of our collective expertise at this early juncture in the Social Security Administration's review process for the HIV listings. We look forward to a productive continuing discussion as the process moves forward. To facilitate that discussion, we ask that, on behalf of the undersigned, you contact Hayley Gorenberg, AIDS Project Director, Lambda Legal, 120 Wall Street, Suite 1500, New York, New York, 10005, telephone (212) 809-8585, email hgorenberg@lambdalegal.org.

Sincerely yours,

---

[29] This medical study was reported by Reuters Health Information Services, <www.reutershealth.com>, with details published in the January 1, 2001 issue of 32 CLINICAL INFECTIOUS DISEASES 130-139 (2001).

[30] For general information on this issue, *see* Barbaro et al., *Incidence of Dilated Cardiomyopathy and Detection of HIV in Myocardial Cells of HIV-Positive Patients*, 339 NEW ENG. J. MED 1093-9 (1998); Holmberg, S., *et al.*, "Protease Inhibitor Drug Use and Myocardial Infarctions in Ambulatory HIV-infected Persons," 9th Conference on Retroviruses and Opportunistic Infection, February 28, 2002; Haney, *Study Says AIDS Drugs May Increase Heart Attack Risk*, ASSOCIATED PRESS, February 28, 2002; *Will HIV or HAART affect the heart?*, 8 POSITIVE LIVING 43 (1999).

Magnolia Contreras
Director of Public Policy
AIDS Action Committee of Massachusetts, Inc.
294 Washington Street, 5th Floor
Boston, MA 02108

David C. Harvey
Executive Director
AIDS Alliance for Children, Youth & Families
1600 K Street, NW, #200
Washington, DC 20006

Ronda B. Goldfein, Esq.
Executive Director
AIDS Law Project of Pennsylvania
1211 Chestnut Street, Suite 600
Philadelphia, PA 19103

Tanya Reeves, Esq.
Client Services Director
AIDS Legal Referral Panel
1663 Mission Street, Suite 500
San Francisco, CA 94605

Brandon M. Macsata
Executive Director/CEO
American Congress of Community Support & Employment Services (ACCSES)
1875 Eye Street, NW, 12th Floor
Washington, DC 20006-5409

Lola J. Thrower
HIV Services Team Leader
Arkansas Department of Health
4815 W. Markham, Slot 33
Little Rock, AR 72205-3867

Kelley Stewart
Community Liaison
Health Promotion and Disease Prevention
Ryan White Title I Office
Baltimore City Health Department
210 Guilford Avenue
Baltimore, MD 21202

Frank Dean, CEO
Executive Director
BASIC NWFL, Inc.
PO Box 805
Panama City, FL 32402

Daliah Heller
Executive Director
CitiWide Harm Reduction
260 East 143rd Street
Bronx, NY 10451

Christopher J. Bowes
Executive Director
Center for Disability Advocacy Rights ("CeDAR")
841 Broadway, Suite 605
New York, NY 10003

Sheila Hall, Esq., HIV/AIDS Law Project Director
Gail E. Silverstein, Staff Attorney/Clinical Supervisor
East Bay Community Law Center
HIV/AIDS Legal Unit
3130 Shattuck Avenue
Berkeley, CA 94705

Dr. Gene Copello
Executive Director
Florida AIDS Action
P.O. Box 16705
Tampa, FL 33687-6705

Ronald Johnson
Associate Executive Director
Gay Men's Health Crisis
119 West 24th Street
New York, NY 10011

Greater Upstate Law Project, Inc.
80 St. Paul Street, Suite 660
Rochester, NY 14604

Julie Justicz
Director of Advocacy
Health & Disability Advocates
205 W. Monroe, 3rd Floor
Chicago, IL 60606

Leslie F. Kline Capelle
Public Benefits Staff Attorney
HIV & AIDS Legal Services Alliance, Inc. (HALSA)
3550 Wilshire Blvd., Suite 750
Los Angeles, CA 90010

Errol A. Chin-Loy
Senior Vice President
Housing Works Inc., Housing Works AIDS Adult Day Health Care Programs
Housing Works Legal and Advocacy Departments
320 West 13th Street
New York, NY 10014

Toby Newman, LMSW-ACP
Clinical Social Worker
Jewish Family Service
4131 South Braeswood Boulevard
Houston, TX 77025

Saneese Stephen, MPAS, RPA-C
Senior Management Consultant/Physician Assistant
HIV Services
Kings County Hospital Center
451 Clarkson Ave., "H-3"
Brooklyn, NY 11427

Hayley Gorenberg
AIDS Project Director
Lambda Legal Defense and Education Fund
120 Wall Street, Suite 1500
New York, NY 10005

Sally Friedman
Senior Staff Attorney
Legal Action Center
153 Waverly Place
New York, NY 10014

Cathy Bowman, Esq.
HIV/AIDS Coordinator
Legal Support Unit
Legal Services for New York City (LSNY)
350 Broadway, 6th Floor
New York, NY 10013

Barbara Samuels, Esq.
Social Security/SSI Coordinator
Author, *Social Security Disability Claims: Practice & Procedure, 2d Ed.* (West Group); *New York Elder Law Handbook* - Social Security, Social Security Disability and SSI chapters (Practising Law Institute)
Legal Services for New York City (LSNY)
350 Broadway, 6th Floor
New York, NY 10013

Jon M. Baris, Esq.
Legal Services of Eastern Missouri, Inc.
4232 Forest Park
St. Louis, MO 63108

Jeremy Rosen, Esq.
National Law Center on Homelessness & Poverty
1411 K Street, NW, Suite 1400
Washington, D.C. 20005

National Organization of Social Security Claimants' Representatives (NOSSCR)
Government Affairs Office
1101 Vermont Ave., NW, Suite 1001
Washington, DC 20005

Richard Hahn - PLWA
Co-Chair, Steering Committee
Ryan White HIV CARE Network of NENY
272 Broadway
Albany, NY 12204

Cynthia Schneider, Esq.
HIV Project Director
South Brooklyn Legal Services
105 Court Street
Brooklyn, NY 11201

Cheryl Hage-Perez
Executive Director
Support Ministries
31 Sixth Street
Waterford, NY 12188

William E. Arnold
Executive Director
TII CANN-Title II Community AIDS National Network
1775 T Street, NW

Washington, DC 20009

Karen Stuart, Paralegal/Coordinator
Eric Moore, Paralegal
HIV/AIDS Law Project
Volunteer Lawyers Program
305 South 2nd Avenue
Phoenix, AZ 85003

Whitman-Walker Clinic
1701 14th St., NW
Washington, DC 20009

Valorie Mackey Adrio, MA, LMFT
Licensed Marital and Family Therapist
4579 Laclede Avenue, #276
Saint Louis, MO 63108

Howard Aaron Aronow, MD
Co-Investigator
National Neurological AIDS Bank
11645 Wilshire Boulevard, Suite 770
Los Angeles, CA 90025

Paul Hampton Crockett
HIV+ Attorney/Advocate
Author, *HIV Law* (Random House)
The Crockett Law Firm
1737 SW 12 Street
Miami, FL 33135

Howard L. Graham
Attorney at Law
535 Dock St., #107
Tacoma, WA 98402

Thomas P. McCormack
Public Benefits Policy Consultant
Author, *AIDS Benefits Handbook* (Yale Press, 1990)
611 G Street, SW
Washington, DC 20024

Sarah B. Patterson
Attorney at Law
1610 SE 32 Avenue
Portland, OR 97214