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FIBROMYALGIA, CHRONIC FATIGUE SYNDROME AND DISABILITY EVALUATION, A Seminar For Disability Attorneys and for Persons with Fibromyalgia or Chronic Fatigue Syndrome who need to understand the process of disability litigation. Dr. Podell is clinical professor in the Department of Family Medicine, UMDNJ-Robert Wood Johnson Medical School. He is a member of the International Myopain Society and of the American Chronic Fatigue Syndrome Association. He practices internal medicine with a special interest in fibromyalgia and chronic fatigue syndrome in Springfield and Somerset New Jersey.

This essay adapts from Dr. Podell's address to the 9th National Conference on Litigating Disability Insurance sponsored by the American Conference Institute, February 23, Miami, Florida. The American Conference Institutes provides educational programs for attorneys who serve both claimants/plaintiffs and insurance companies/defense. Dr. Podell served as the medical expert on Fibromyalgia, Chronic Fatigue Syndrome and related disorders.

1. The syllabus labels fibromyalgia and chronic fatigue syndrome as “subjective disorders”. We are asked to address this question: what is do we mean by “subjective physical disorders” and how do these differ from “non-subjective” physical disorders?

“Subjective physical disorder” is not an actual medical diagnosis or a validated medical term. Nevertheless, it can be useful as a concept for understanding certain issues relevant to disability evaluation.

The term “subjective physical disorder” has been employed to refer to medical conditions for which we have not identified specific findings on physical exam or laboratory tests that can reliably serve as proxy measures of disease severity. This non-specificity increase the reliance we must place on the patient's self-reports of how they feel and function and the evaluation of their credibility through medical records and the opinion of their physicians.

Migraine headache, tension headache, irritable bowel syndrome, irritable bladder syndrome, etc might also be considered as “subjective physical disorders”. However, this essay will focus here on fibromyalgia (FMS) and chronic fatigue syndrome (CFS), because of their prominence for disability claims.

Clinical Differences between Fibromyalgia/Chronic Fatigue Syndrome and “traditional” causes of disability such as angina, emphysema, lumber disc disease, rheumatoid arthritis.

Traditionally, disability insurance carriers have worked more with “non-subjective” physical disorders. That is, condition for which it can be argued that certain physical exam or lab findings might correlate fairly well with illness severity and/or performance limitation.

Thus, if a person claims disability because of severe angina it might be argued that we should see EKG abnormalities suggesting ischemia during the course of an exercise stress test. If severe emphysema, walking fast for 20 minutes should make them huff and puff. Chest x-ray and lung function tests should be abnormal. If a person has a disabling lumbar disc protrusion, we might expect to see the disc protrusion displayed on an MRI. There might be limitation of motion while bending. Certain physical movements should increase pain. If a person were disabled due to rheumatoid arthritis, we might expect to find joint deformity, limited of motion, and, perhaps a high sedimentation rate—suggesting active inflammation.

The world would be simpler if we could apply similar reasoning to every physical illness. However, we cannot.

The American College of Rheumatology Criteria for the diagnosis of fibromyalgia requires one “subjective” along with one objective (actually, semi-objective) element. That is, the patient must complain of chronic wide spread pain affecting all 4 quadrants of the body and also report abnormal pain over at least 11 of 18 predesignated sites (known as tender points), when a standard quantifiable degree of pressure is applied to these sites.

This tender point criteria is objective in the sense that we apply an “objective” degree or pressure, and might also observe wincing or other “objective” signs of pain. However, it is also subjective in the sense that it requires the patient to report that they feel pain. Also tender point counts are not etched in stone. They may vary from day to day. And there is only a weak correlation between the number of tender points that are painful and disease severity and limitations of function. Indeed, the dividing line between fibromyalgia (11+ abnormal tender points) and chronic pain syndrome (10 or fewer tender points)—this dividing line is somewhat arbitrary. Diffuse fibromyalgia like pain with fewer than 11 tender points is called chronic pain syndrome. In principle, some person with chronic pain syndrome could be so limited as to not be able to work, while others, with fibromyalgia, might well be able to carry on with their jobs.

Why have medical specialists defined fibromyalgia using criteria that are in a large part “subjective”?

Fibromyalgia’s defining symptom is wide spread chronic pain. Symptoms, by definition, are and are meant to be “subjective”. They must therefore be based on a patient’s self-report. Thus, the criteria that define the illness requires that we depend on the patient’s self-reports. Unstated, but assumed, is that the validity of these reports depend, to a large degree, on the patient’s credibility. In clinical practice physicians have to make judgment about the truth and accuracy of their patients’ reports. We do this using a combination of the physician’s medical judgment about the illness, the physician’s judgment about the patient’s character, the patient’s prior medical records, and how well the patient’s reports and actual life style match the known characteristics of their illness.

These methods of evaluation all share elements of subjectivity i.e. requiring the patient’s self report, objectivity i.e. medical records, pharmacy prescription, old diaries, etc are objective documents, and partly an exercise of independent medical judgment i.e. are normally expected to

become highly skilled at evaluating the credibility of their patients. Of course, as a rule, physicians tend to believe their patients—unless there is reason not to. A disability insurance company, of course, does not share this obligation. They can and should look critically at whether an individual claimants self reports are in fact true and accurate.

Unfortunately, at present, we often have no standard “ruler”, “thermometer” or “tricolor” that can objectively” measuring disease severity in fibromyalgia or chronic fatigue syndrome.. Such measures might become available in the future e.g. neuroimaging techniques that measure the activity of pain centers in the brain; but for practical real world testing we’re not likely to have these anytime soon. .

Fortunately, in research rather than “real world” practice settings scientists have made progress using objective means to validate the self-reports for patients with “subjective physical disorders”. The data is especially strong for fibromyalgia, but is also fairly good for chronic fatigue syndrome.

, These research studies “objectively” confirm that typical patients with fibromyalgia actually do perceive the pain they report. They also prove that fibromyalgia patients perceive the pain they report at much lower levels of stimulus than do persons who are healthy. This increased sensitivity or pain augmentation has been given the name “neural sensitization”. Neural sensitization is at its core a physical process, reflective of changes in the structure and function of the pain signaling pathways, primarily within the spinal cord and the brain. (The accompanying article discusses this research in some depth.)

Think of the central nervous system’s pain signaling pathways as the volume knob on a radio. In fibromyalgia the volume is turned up to very high. Thus low level stimuli that causes only minor pain in “normal” persons, causes greater pain in persons among persons with fibromyalgia. The technical name for this amplification is hyperalgesia. Similarly, stimuli that normal individuals do not perceive as painful or distressing, are perceived as pain or paresthesia in the fibromyalgia patient. . The technical term for this is allodynia. Anatomically, neural sensitization may reflect an increase in the size of pain transmitting nerve cells, neurotransmitter alterations, and increased cross connecting synapses among nerve cells that signal pain.

Functional MRI studies provide compelling support for the neural sensitization. Both normal individuals and fibromyalgia patients show changes in the degree of blood flow in certain areas of the brain just at the time that they report feeling pain. However, among fibromyalgia patients these regional blood flow changes occur at much lower levels of stimulus than they do for normals. Similar findings have been documented using other “imaging” tools including SPECT scan and cerebral evoked potentials.

In addition to having a lower initial pain threshold, repeated stimulation causes pain intensity to increase more rapidly in fibromyalgia patients than similar stimulation increases pain in normals. Once the stimulus stops, pain levels decline for both normal persons and those with fibromyalgia. However, pain fades more slowly among those with fibromyalgia. With fibromyalgia, one can cause pain to continue without fading if one continues to apply a very mild level of further stimulus. This same level of mild stimulation does not maintain pain when applied to normals.

Fibromyalgia patients' pain signaling differs from normals in other important ways.. For example, normal persons become temporarily less sensitive to pain shortly after they've exercised. With fibromyalgia we see the opposite. Fibromyalgia patients after exercise are more sensitive to painful stimuli, not less.

The key studies that document neural sensitivity in fibromyalgia were independent of potential confounding factors including co-morbid depression, disability litigation or patient expectations.

There is clear consensus in the fibromyalgia research and clinical community that neural sensitization is a major characteristic of fibromyalgia. There is an up-regulation, augmentation or sensitization of the central nervous system's pain signaling pathways.

These physical changes can be measured in a research setting, but such testing is not yet available for normal clinical evaluation.

Thus, contrary to what we once imagined, the "end organ damage" of fibromyalgia is not primarily in the muscle, joints or in the peripheral nerves. Rather it lies within the pain signaling pathways of the spinal cord and the brain, targets that we don't test with our standard exams.

2. How can we go from our general understanding of FMS and CFS, to apply this understanding to an individual patient?

We know that, as a group, fibromyalgia patients accurately report their pain. However, this does not tell us for sure whether any one specific individual with fibromyalgia is reporting accurately or truthfully.

The number or intensity of tender point abnormalities does not tell us. A person can be very tender on a given day and still be able to work, or not too tender at all and still be disabled. Indeed, the sensitivity of tender points can vary from day to day. Psychological distress is one of many factors that can affect the pain sensitivity of tender points.

Nor aside from tender points, are there any other physical exam findings or laboratory tests whose absence means that fibromyalgia is not present, or that it is mild versus severe. Thus, fibromyalgia patients typically have fairly normal muscle strength, no swelling of joints, normal range of motion, normal peripheral nerve examination, and normal interaction on the kind of "light" mental status examination that would typically be done by internists or neurologists.

However, the opposite is not true. Sub-sets of fibromyalgia patients fairly often have specific physical exam or test abnormalities, that, when present, is evidence that their disease is severe—although not necessarily disabling.

Thus, a subset of patients with fibromyalgia (and chronic fatigue syndrome) have abnormalities of blood pressure and/or heart rate, especially when they remain standing for an extended period. They may have orthostatic hypotension (low blood pressure with standing) and/or postural orthostatic tachycardia syndrome (POTS--heart rate increase with prolonged standing). To the degree that these conditions are substantial and fail to respond to medical

treatment, their presence can support a claim of disability. In contrast, normal orthostatic findings cannot be used as proof that the disease is mild or not disabling.

Another subset of patients with severe fibromyalgia and/or chronic fatigue syndrome report cognitive difficulties—"brain fog"--decreased ability to concentrate and or think quickly, especially with complex or multi-tasked problems. Typically, these persons appear normal on standard office clinical and mental status examination. However, often, but not always, formal neurocognitive testing demonstrates defects consistent with their self-reports. **Formal neurocognitive testing should be done in most cases where cognitive difficulties are a major reason why a person claims they cannot work.**

In some circumstances neurocognitive testing results can underestimate the degree of disability. Thus, patients typically appear for testing on their relatively "good" days, not on their worse days. Many patients "rest up" for several days before the day of testing so they can do their best effort. Plausibly, test scores might be lower on "bad" days, and/or if the "exertion" of testing had to be repeated 5 days a week for several weeks or months—as in a work setting—not just for one or two sessions. On the other hand, a specific test score that is substantially lower than that expected for a person of high intelligence and substantial education, might still fall within the average range, despite the reduction caused by disease. In that case, the lower than expected score would be evidence of a substantial disease effect; but it would remain open for debate over how important that deficit would be with regard to a specific job and level of performance.

With regard of patients who complain of "brain fog" but do not show deficits on cognitive testing, little research has been done with regard to the potential "mechanisms" involved in causing such symptoms. However, recent research suggests that the mental fatigue that these persons report may relate to the greater effort they require to concentrate. That is, they might do the test as well as others, but have to work much harder to do so. If one pushes on this long enough, increased fatigue and poor concentration might be the result.

Dr. Lange, a neuropsychologist at the New Jersey Medical School and her colleagues have made important contributions. Lange's work is important enough to discuss in some detail (Lange G, Steffner, J, Cook, D et. Al. Objective evidence of cognitive complaints in Chronic Fatigue Syndrome: A BOLD fMRI study of verbal working memory., *NeuroImage* 2005; 26: 513-524):

*In her first studies patients with CFS but no psychological illness showed (on MRI) a significantly larger number of brain abnormalities on T2 weighted images than did persons who had CFS plus psychological illness. These "mentally healthy" CFS patients also showed more MRI abnormalities than did health controls. These "mentally healthy" CFS patients had mostly of small, punctuate, subcortical white matter hyperintensities, found predominantly in the frontal lobes. Lange wrote: **This frontal lobe pathology could explain the more severe cognitive impairment previously reported in this subset of CFS patients. Thus, CFS patients have more anatomical changes in the brain than do healthy controls—independent of whether or not they also have psychological illness.***

Lange et. al. then extended her work to study chronic fatigue syndrome patients using functional MRI, a research imaging system that tracks changes in blood flow in different regions of the brain. Here, Lange all showed that patients with severe chronic fatigue syndrome, when challenged with a mental task, had to recruit many more areas of the brain to fulfill the task than did controls. This was true not only for patients with chronic fatigue syndrome who had abnormalities demonstrated on standard neuropsychological testing, but also on those who neurological test scores were normal.

This confirms that there is something wrong with brain function among chronic fatigue syndrome patients, that current standard neuropsychological tests may be unable to detect. In these patients, they are able to fulfill the initial challenge adequately in the short term, but have to exert substantially greater mental effort to do so. This is consistent with the clinical observation that many CFS patients can think clearly for short periods, but pay the price of increased symptoms and decreased function after prolonged effort.

Lange's paper supports this view:

“Individuals with CFS appear to have to exert greater effort to process auditory information as effectively as demographically similar health adults. Our findings provide objective evidence for the subjective experience of cognitive difficulties in individuals with CFS.”

The Bottom Line: People with CFS might be able to accomplish a short term task fairly well, but they have to work harder to do so. Maintaining that extra effort for many hours at a time, repeated over many days—this might be expected to tend to “wear them out”.

Thus, Lange's findings (and those of others) tends to support the accuracy of self-report for fibromyalgia patients as a group. Similar studies support the accuracy of self-report for groups of patients with fibromyalgia. This gives plausibility to the self-reports of an individual with these conditions who claims to be disabled. But, of course, the credibility of those claims for each individual has to be evaluated for that individual on its own merits.

Conclusion: For many or most persons with fibromyalgia (and chronic fatigue syndrome), there is no physical examination sign or standard laboratory test result that we should expect to distinguish mild versus moderate versus severe disease. Therefore-- except for certain subgroups where cardiovascular or neurocognitive abnormalities are documented-- medical expert and insurance evaluators should not expect (or require) that the presence or absence of any specific “objective” finding reliably distinguish between a disabled and a non-disabled person with FMS/CFS.

One patient/claimant can struggle through her job despite aching muscles and fatigue. Another patient/claimant cannot, and is limited to activity of say, just 3 hours a day. On standard physical exam, standard mental status exam, and standard lab tests,t these two individuals are very likely to look the same. As of 2006, such standard exams lack the ability to tell these two individuals apart—despite their great difference in the their abilities and stamina for sustaining activity.

The non-conclusive nature of physical findings and laboratory tests, places an increased burden on the patient's documented reported history—and its credibility—as the main means currently available for judging the capacity of an individual to sustain work.

3. What reasons do persons with fibromyalgia and/or chronic fatigue syndrome usually give to support their belief that they are unable to work? This question is crucial because, to have face validity, any tool we decide to use to help us judge disability, has, at the very least to address the credibility of the specific claims that the patients are offering.

In an idealized form these are the four most common scenarios described by patients with severe FMS/CFS. In practice, most patients report a mix of three or all four of these scenarios.

Scenario A. “**My pain is bad** even when I do nothing. However, if I am active for, say a half hour, –even if I am sitting-- my pain usually gets worse. I might feel this immediately and it might improve after a rest. I then go back to activity for another short period. However, if I repeatedly push my limits this way, the pain worsens more, accumulating with the total activity of the day. On most days the total amount of time I can do even intermittent activity is very limited, e.g. a total of two to three hours. If I exceed these tight limits my pain usually flares for 24 hours or more. These flare-ups might begin several hours later or the next day (which is common) or even several days later. If I push for several days in a row, then the delayed flare up will be much more severe, and will tend to last longer.”

Scenario B. **My fatigue and poor stamina** keeps me from working. I feel tired and my stamina is poor even when I do little. However, if I do even light activities for, say, 30 minutes, my fatigue worsens further and my stamina declines. If I keep pushing beyond these limits I become worse still. . If I then rest for 30 minutes or so, I might be able to be active for another 30 minute. But on most days I'm good for only two or three hours a day of activity, even with breaks to rest. If I do more, my fatigue often worsens,. These flare ups might last for 24 hours or more. The flare-up might begin several hours later, or the next day or even several days later. If I push for several days in a row, then the flare up will be much more severe, and will tend to last longer.”

Scenario C. “**My mental concentration is poor.** If I do substantial mental or physical activity my ability to concentrate worsens. The more I do the worse I get. I used to be able to read technical articles and follow what's happening in meetings. Now this is very difficult. I have to reread articles to try to understand them. I cannot pick up and retain facts in meetings. I do okay in normal conversations, but have trouble “finding” words. It's especially hard for me to think quickly, multi-task and doing complicated tasks.

If I push to do cognitive work beyond my limits my mental concentration worsens (as does my pain and fatigue). . If I do too much physical activity, my cognitive abilities suffer.

If push my limits for one day, my concentration (and other symptoms) will be worse later that day or the next. The more intensely, the longer, or the more often I push, the worse and the longer the flare up of symptoms will likely be.

D. Unpredictable Variability in Severity of Symptoms: I am pretty limited even on my relatively “good days”; but, I also have much worse than usual “bad” days when I can do almost nothing at all. These very bad days may occur if I’ve pushed too much on the day before. But, they can also occur unpredictably, even if I watch myself. On these bad days I can usually do little more than get out of bed. No major tasks are feasible.

No expert on fibromyalgia or chronic fatigue syndrome doubts that a significant number of persons with these conditions legitimately experiences one or more of these scenarios. However, that fact with respect to a group, does not by itself tell us whether the claims made by any one individual are, in fact, true and accurate. What tools do we have to help make this judgment with regard to a specific individual?

4. How do physicians evaluate the severity of illness for patients with FMS/CFS when they present in the clinical setting?

In normal clinical practice physicians usually make it a practice to believe what their patients tell them—unless and until they have reason to doubt them.

One reason for doubt might be if the patient’s reports are not consistent with the typical pattern of their disease. For example, it would be very atypical for a patient with FMS or CFS to feel typically 100% well and be highly active for weeks at a time, only to plunge back into severe illness for weeks at a time thereafter. Variation in symptoms from day to day or month to month is typical for severe FMS/CFS, but most of the upswings are still fairly limiting. (Some CFS/FMS patients will refer to periods of being “almost normal”. However, they usually see this in comparison to a very low baseline. Close questioning will usually reveal that their energy reserves are still limited.)

Another reason for doubt might be information from the patient spouse, or other observer claiming that the patient habitually engages in activities that are inconsistent with their self-reports. For example, persons with disabling fatigue and pain due to FMS/ CFS cannot typically play vigorous singles tennis three times a week on a consistent or regular basis. (Such activity might be tolerated once in a while, but would typically flare up their symptoms later that day or the next.)

Another reason that’s highly relevant to the individual’s credibility is the medical judgments of physicians who know the patient well. Physicians who have developed a relationship with a patient will typically develop a medical opinion about their reliability. By and large the judgment of a patient’s credibility made by long-term treating physician has more respect y than does that of a physician who has seen the patient only once, or, if an opinion is based just on a review of the file—not all.

In some charts one can often sense from the physician’s note whether or not the physician has any substantial reservations about the accuracy or truthfulness of the patient’s self-reports. However, in other charts, we cannot tell.

One practical problem is that many physician's notes are often not very detailed. As important, the physicians main focus is most on issues other than quantifying the severity of symptoms or functional impairment. We are often much more interested in making a diagnosis and recommending treatments, than in asking or writing down how long a person can sit in a chair or type on a keyboard.

Thus, a typical physician's visit note might read something like:

Still tired and achy. Ultram helped a little, but had to stop due to nausea nausea. Will send to PT and perhaps try Cymbalta.

This person's illness might be mild, moderate or severe. One cannot tell from this note. If specifically asked to, the physician might have chosen to direct questions in a different way, toward assessing severity and function. However, in real world practice, other priorities take precedence. In an ideal world, physicians might directly quote the language of all their patients' complaints. In practice, our notes are highly selective and condensed. Of course, one would not expect the dermatologist looking at a rash to ask about fatigue.

Despite these limitations, the medical records remain the most important tool we have.

When litigation occurs, these limitations cause a problem for both claimants and defense.

If there is little or no mention of functional limitations in the chart, one cannot necessarily conclude that function was normal or that no limitations were reported. Physicians may regard complaints about reduced function as more a vocational than medical concern. We're normally most concerned about a host of other issues.

Another practical problem is that many physicians don't know enough about the normal pattern of fibromyalgia, such as the post-exertional flare phenomenon. We tend to only see what we look for, and only look for what we know. So, clinical records are often silent, on what, in litigation, may turn out to be very important points.

We also face problems due to the patient's limitations as a communicator—e.g. limitations imposed by the duration of time allowed for a visit, the patient's purpose for certain visits being unrelated to her FMS/CFS complaints.

Please note: An important study extended observation on the flare-up phenomenon to include data on the cumulative effects of very modest degrees of exertion. ((Black C and McCully K Time course of exercise induced alterations in daily activity in chronic fatigue syndrome, *Dynamic Medicine* 2005, 4:10)

Six individuals with chronic fatigue syndrome were given a daily walking programs of only 15 to 25 minutes a day with the hope of increasing their daily activity. Activity was measured by an accelometer worn at the waist. Initially these patients were able to increase their daily activity and were able to reach a daily level similar to that of

sedentary controls. However, this increased exertion was also at the price of increasing CFS symptoms. Overall mood, daily fatigue and time spent each day with fatigue all worsened over the course of four weeks as the exercise program progressed.

In order to further examine the idea of a “daily activity limit” a detailed analysis of each subject’s activity each day was performed...a distinct pattern was observed. During the first 4-10 (average of 7) days of exercise, our CFS subjects spent an average, approximately 23 minutes each day exercising. This indicates that the subjects were not only complying with the prescribed exercise, but also were able to reach the daily exercise target...**However, over the final 3 weeks of prescribed exercise, the average time spent each day exercising fell to approximately 8 minutes per day...**In contrast, sedentary control subjects responded to a similar daily walking program by increasing their total daily activity 25-30% for the first week, and were subsequently able to maintain this increase for three additional weeks.

Unlike our initial interpretation that CFS subjects could maintain an activity increased over four weeks, it is now apparent that the CFS subjects were only able to sustain the prescribed increases in activity for 4-10 days. **We believe the reduction in total daily activity levels, primarily from a reduction in time spent exercising, observed during the following 3 weeks were related to greater symptoms of fatigue. These results indicate that the CFS patients in the current study were more likely than controls to develop exercise intolerance.**

5. In a legal setting, how can we judge the validity of the patient’s reports? In particular, what is the validity of the FCE?

Physicians in practice are predisposed to believe in the “good faith” of their patients. In the setting of litigation, a frequent issue becomes when is this assumption valid and when is it not? What tools can we use to evaluate whether what the patient now reports is truthful and accurate?

Because physical exam and lab findings are usually not useful for measuring disease severity, one of the most important sources of relevant evidence is a thorough review of the patient’s medical records, both currently and in the past. Do these “objective” document or contradict the patient’s reported claims? Are these records 1) consistent with the patient’s self report in their disability application? 2) self-consistent within and among different health records? 3) consistent with the pattern of illness typically seen among persons with severe FMS/CFS?

Also from the records one can usually judge whether an adequate work up has been done for other potential causes of illness, and whether the patient has had an adequate course of standard treatment..

In addition to the medical records other “objective” evidence can, in principle, be brought to bear. However, each has its potential weak points along with its strengths, and must be judged

judiciously, and not be misused. For example: Information from the patient's diary; testimony from family members, co-workers, neighbors; videotape surveillance.

5. The special case of the Functional Capacity Evaluation (FCE)

The FCE, as now done, asks a patient to light or moderate activities such as stooping, crawling, squeezing, balancing over a period of several hours. In some cases the testing is repeated on the next day. The examiner then uses the findings over these short periods of time to extrapolate out from this short term data to a judgment about how the subject would fare if similar levels of activity had to be sustained for eight hours a day, forty hours a week, week after week and month after month.

For fibromyalgia and chronic fatigue syndrome is there a scientific or logical basis for making such extrapolations from such short term activity to any conclusion about the ongoing ability to sustain productive work. In brief, the answer has to be a very firm no.

Please recall, the main reasons people with fibromyalgia and chronic fatigue syndrome claim they cannot work is because pushing past their physical limits causes symptoms to flare, typically with a delay of several hours or a day. They can often do a task for several hours, but if they do too much they then pay the price of being worse the next day. This is the delayed post-exertional flare-up phenomenon. This is characteristic of patients with severe FMS/CFS. These patients also report that their worsening with exertion tends to be cumulative. That is, five days of trying to push through causes much more severe and longer flare-ups than does just one day of over-doing. These patients also report that, unpredictably, they have days where they are even much worse, and can barely get out of bed. These are the reasons they claim they can't work.

Does the current FCE of short term activities even seek to address the accuracy of these self-reports. It does not attempt to do so. The current FCE is short term only, makes no effort to ask how the patient felt the next day, and makes no attempt to evaluate function that is in any way comparable to the 40 hours a week required for a job. (In reviewing the raw data in FCE records I sometimes sees notation that the patient complained of feeling worse during or after the session. But almost never do the examiners refer to these complaints in forming their conclusions about what the patient can or cannot do. I have never seen a report where the examiner calls or visits the patient the next day to assess for the expected post-exertional flare-up effects.)

Therefore, the (FCE) as currently used, has no face validity that would justify its algorithms for extrapolating to conclusions about whether a person with FMS/CFS can work. It's like looking for a lost quarter under the bright street lamp despite having dropped it in a less well-lit area half a block away. The FCE, as now set, is a classic example of looking in the wrong place.

To be relevant to the actual claims that claimants make, FCE procedures require modification to specifically assess the severity of symptoms and functional consequences in the hours and days after the testing. Just as important, the FCE needs to develop valid methods of assessing how persons feel and perform after multiple successive days of activity, five days a week and four weeks a month, not just for a few sessions. It would be convenient if one could extrapolate from performance done over several hours, to the ability to sustain performance over days or weeks. However, there is no substantial data that would validate such extrapolations in the case of FMS/CFS. Indeed, most data, and basic logic, argues strongly against it.

Is there any objective scientific evidence that would justify an extrapolation from the short term FCE to a conclusion about ability to sustain continuing performance?

Implicit in the use of FCE for FMS/CFS is an unproved (and probably false) assumption that the claimant's performance during one or two several hours sessions of activity, can be extrapolated out to predict how they will fare if similar activities are repeated, say eight hours a day, on a regular basis over days, weeks and months. However, there is not valid evidence to support this assumption. Indeed, for FMS and CFS, there has been almost no attempts to even try to test the "extrapolation assumption.

To assess whether there was any science behind applying the FCE to FMS/CFS I searched the medical literature data base of the National Library of Medicine. This data base contains essentially all English Language medical publications since 1966, and also a large number of foreign language publications. **Based on the National Library of Medicine's data base there are no published controlled studies at all that support the validity of any currently standard FCE protocol for predicting or extrapolating the disability status of persons with FMS or CFS.**

On November 7, 2005 I submitted the keywords: *functional capacity evaluation and fibromyalgia*. This search yielded only one single reference. (Valkeinen, et al,. Changes in knee extension and flexion force, EMG and functional capacity during strength training in older females with fibromyalgia and healthy controls. Rheumatology . 2004 Feb;43(2):225-8.)

Valkeinen's study did not address the validity of the FCE, and was not relevant to our issue. Rather it showed that 13 elderly females with fibromyalgia could be trained to improve muscle strength and walking speed.

A search using the keywords *functional capacity evaluation and chronic fatigue syndrome* disclosed five articles. None of these articles provided any evidence to

support the validity of the FCE for patients with CFS. Indeed, their conclusions tend to point to the contrary.

Article #1: Ross, et. al. (Arch Intern Med. 2004 May 24;164(10):1098-107.) reviewed the literature on how to measure, monitor and treat disability in patients with chronic fatigue syndrome (CFS). The conclusion states:

For questions of disability and employment in CFS, the limitations inherent in the current literature are extensive. Methodologically rigorous, longitudinal, and interventional studies are needed to determine baseline characteristics that are associated with the inability to work and interventions that are effective in restoring the ability to work in the CFS population. Simple and consistent evaluations of functional capacity in patients with CFS are needed.

Article #2: Nijs J De Meirleir K Wolfs S, Duquet W.(Clin Rehabil. 2004 Mar;18(2):139-48.)

CONCLUSIONS: These results suggest a moderate association between exercise capacity and activity limitations/participation restrictions in patients with CFS. **The observed correlations lack strength to predict activity limitations/participation restriction based on exercise capacity parameters.** Disability evaluation in CFS should therefore encompass both exercise capacity testing and measurements at the activity/participation dimension

Article #3: Barrows, D (Am J Occup Ther. 1995 Apr;49(4):327-37.):

Abstract: Chronic Fatigue Immune Dysfunction Syndrome (CFIDS) is estimated to affect 2 to 5 million people in the United States. Despite its high incidence, persons with CFIDS have been neglected by the medical community mainly because there is no singular confirming diagnostic test or proven effective treatment. The CFIDS population is incorrectly stereotyped as upper-middle-class, white, female hypochondriacs; consequently, symptoms often are belittled or ignored. **In reality, CFIDS is a severe medical condition that affects women, men, and children of any race and often causes long-term or total disability. The results of a modified functional capacity evaluation developed by the author and completed on 86 persons with CFIDS between 1988 and 1990 confirm that this population has severe physical and cognitive disabilities that affect their professional, familial, and social lives. The results of these evaluations are used to present a profile of persons with CFIDS that can serve as a basis for understanding this population and for guiding intervention.**

Please note, this study documented disability in a group of patients with CFS, using their own FCE protocol. They did not assess or attempt to validate any of the standardly used FCE protocols. Nor did they attempt to validate their own protocol against actual work-place measurements of the ability to work.

Article #4: Morriss, R et. Al. Psychosom Res. 1998 Nov;45(5):411-7.)

The Chalder fatigue scale is widely used to measure physical and mental fatigue in chronic fatigue syndrome patients, but the constructs of the scale have not been examined in this patient sample. We examined the constructs of the 14-item fatigue scale in a sample of 136 chronic fatigue syndrome patients through principal components analysis, followed by correlations with measures of subjective and objective cognitive performance, physiological measures of strength and functional work capacity, depression, anxiety, and subjective sleep difficulties. There were four factors of fatigue explaining 67% of the total variance. Factor 1 was correlated with subjective everyday cognitive difficulties, concentration difficulties, and a deficit in paired associate learning. Factor 2 was correlated with difficulties in maintaining sleep. Factor 3 was inversely correlated with grip strength, peak VO₂, peak heart rate, and peak functional work capacity. Factor 4 was correlated with interview and self-rated measures of depression. The results support the validity of mental and physical fatigue subscales and the dropping of the "loss of interest" item in the 11-item version of the fatigue scale

This study did not address any of the standard FCE protocols or attempt to validate their use for extrapolating from any test to predict the actual ability to work.

The fifth study was a clinical trial for treating chronic fatigue syndrome with an antiviral medicine. It did not evaluate any FCE protocols.

Therefore, so far as can be determined from the published medical literature there are no published studies that attempt to validate any of the currently used FCE protocols with regard to their validity for predicting disability among persons with FMS or CFS.

Validating current FCE protocols' use for other medical conditions is beyond the scope of this essay. However, the available literature certainly shows a degree of controversy and skepticism with regard to the ability to extrapolate work status from the FCE—even in conditions which have been relatively well researched such as low back pain.

For example see Pranksy and Dempsey from the Liberty Mutual Research Institute for Safety, Center for Disability Research (J Occup Rehabil. 2004 Sep;14(3):217-29.):

*Physicians, employers, insurers, and benefits adjudicators often rely upon functional capacity evaluations (FCEs) to determine musculoskeletal capacity to perform physical work, often with legal or occupational consequences. **Despite their widespread application for several decades, a number of scientific, legal, and practical concerns persist. FCEs are based upon a theoretical model of comparing job demands to worker capabilities. Validity of FCE results is optimal with accurate job simulation and detailed, intensive assessments of specific work activities. When test criteria are unrelated to job performance, or subjective evaluation criteria are employed, the validity of results is questionable. Reliability within a subject over time may be adequate to support the use of serial FCE data collection to measure progress in worker rehabilitation. Evaluation of sincerity of effort, ability to perform complex or variable***

jobs, and prediction of injury based upon FCE data is problematic. More research, especially studies linking FCE results to occupational outcomes, is needed to better define the appropriate role for these evaluations in clinical and administrative settings.

Innes and Stroker, in their internet essay on the Validity of work-related assessments concluded:

As with reliability, **most work-related assessments have limited evidence of validity.** A number had insufficient evidence on which to base an assessment of the level of validity. **Of those that had adequate evidence, validity ranged from poor to good.** Work-related assessments with adequate evidence of moderate to good validity included some attachments of the BTE Work Simulator, DOT-RFC, EPIC Lift Capacity, ERGOS Work Simulator, MESA/System 2000, PWPE, Singer/New Concepts VES, Smith PCE, Spinal Function Sort, Valpar CWS and WorkAbility Mk III. Other instruments had contributory evidence that began to establish moderate to good validity. These included AME, ARCON, Cal-FCP, Isernhagen FCE, Lido WorkSET, PILE, WEST Standard Evaluation and the Work Box.

There was, however, no instrument that demonstrated moderate to good validity in all areas. Very few work-related assessments were able to demonstrate adequate validity in more than one area, or with more than one study, even when contributory evidence was included. **This highlights the need for further research to be conducted in this area.** Test developers, clinicians and academics are strongly encouraged to continue investigating the validity of work-related assessments.

The acceptance of work-related assessments on the basis of their longevity in the marketplace and clinic should not be assumed to equate with adequate validity...

Should we design an FCE protocol that actually observes patients for any 8 hours a day, for a full 5 day week.? In some ways that might make sense, if such a protocol could then be validated to demonstrate validity with respect to long term ability to work. However, based on our knowledge of FMS and CFS, this degree of vigorous testing would be expected to seriously exacerbate illness in a subset of patients, creating a hazard that would not be acceptable ethically (not to mention the potential legal implications).

If the FCE is to be used at all, it must be redesigned to specifically address the four common scenarios reported by claimants, including the post-exertional flare up problem, cognitive/concentration complaints, and the fact that an FCE takes place over one or two days, while work is ongoing. Current FCE protocols for CFS/FMS lack any validated bases for extrapolating from the ability of a subject to function during an observation period of several hours to predict their ability to maintain themselves in a work setting on an ongoing basis. Until such validation research is performed and published, current FCE, protocols lack even face or construct validity application to FMS and/or CFS. Current evidence does not support its use.

6. Chronic Fatigue Syndrome. How do we diagnose it?

As of 1994, an expert panel report convened by the Center for Disease Control provided these opinions:

The chronic fatigue syndrome is a clinically defined condition characterized by severe disabling fatigue and a combination of symptoms that prominently features self-reported impairments in concentration and short-term memory, sleep disturbances, and musculoskeletal pain

*Diagnosis of the chronic fatigue syndrome can be made only after alternate medical and psychiatric causes of chronic fatiguing illness have been excluded. **No pathognomonic signs or diagnostic tests for this condition have been validated in scientific studies**; moreover, no definitive treatments exist for the chronic fatigue syndrome.*

*Recent longitudinal studies suggest that some persons affected by the chronic fatigue syndrome improve with time but that **most remain functionally impaired for several years***

Now, fast forward to early 2006. Progress has been made in validating this condition. Chronic Fatigue Syndrome is accepted as a real and physical ailment, although its cause and its mechanism are not well understood.

Physicians who specialize in chronic fatigue syndrome, are generally in agreement on these as medical facts:

1. CFS is a real and a primarily physical illness. In principle, CFS is distinguishable from psychological and other physical illnesses.

2. Misclassification can occur i.e. where fatigue caused by psychological problems is incorrectly attributed to CFS ; where fatigue due to CFS is incorrectly attributed to psychological illness. A sophisticated medical judgment may be required to judge the relative importance of physical versus psychological factors.

Non-specialist physicians typically accept the above conclusions. However, some remain skeptical.

What Medical Work Up is Required before diagnosing chronic fatigue syndrome (CFS)?

CFS (like FMS) is partly a diagnosis of exclusion. That is, often (but not always), other conditions that produce similar symptoms have to be ruled out in order to diagnose FMS or CFS.

The Center for Disease Control Criteria for CFS were designed to identify patients for research studies. These criteria exclude persons from research studies on CFS if they have also had schizophrenia, melancholic depression, untreated hypothyroidism, morbid obesity and certain other conditions. Such persons could, in principle, suffer from CFS but they are not put into research

studies of CFS, since the co-occurrence of these other conditions, makes it difficult to determine which disease is contributing how much to their symptoms.

However, other diseases are fully compatible with the diagnosis of CFS, and do not exclude persons from participation in research studies on CFS. Thus, one can have depression, anxiety, rheumatoid arthritis, etc. at the same time as CFS and/or FMS. When there are several co-occurring conditions, the physician must judge how much each co-occurring condition contributes to a specific individual's disability.

In theory, a person with mild CFS and severe depression could be disabled primarily due to their depression. In that case properly treating their depression would still leave them still somewhat tired due to CFS, but able to work. Another individual might have severe CFS plus mild, moderate or severe depression. If CFS is severe, then treating their depression is likely to improve mood, but is not likely to much improve their physical stamina/CFS.

One way to distinguish the effects of CFS vs. depression is to look at the patient's response to physical exertion. Persons with CFS/FMS typically become worse after physical exertion. In contrast, persons with depression as their main problem do not usually feel worse after physical exertion. Indeed many people with depression tend to feel better with exercise.

The 1994 CDC Criteria specifically allows the diagnosis of CFS in the presence of each of the following conditions:

1. Any condition defined primarily by symptoms that cannot be confirmed by diagnostic laboratory tests, including fibromyalgia, anxiety disorders, somatoform disorders, nonpsychotic or nonmelancholic depression, neurasthenia, and multiple chemical sensitivity disorder. (Please note: The DSM-IV definition of somatoform disorder forbids making the diagnosis of somatoform disorder if there is a concurrent physical ailment that can account for the patient's symptoms e.g. fibromyalgia or chronic fatigue syndrome.)
2. Any condition under specific treatment sufficient to alleviate all symptoms related to that condition, and for which the adequacy of treatment has been documented. Such conditions include hypothyroidism for which the adequacy of replacement hormone has been verified by normal thyroid-stimulating hormone levels or asthma in which the adequacy of treatment has been determined by pulmonary function and other testing.
3. Any condition, such as Lyme disease or syphilis, that was treated with definitive therapy before development of chronic symptomatic sequelae.

4) Any isolated and unexplained physical examination finding, or laboratory or imaging test abnormality that is insufficient to strongly suggest the existence of an exclusionary condition. Such conditions include an elevated antinuclear antibody titer that is inadequate to strongly support a diagnosis of a discrete connective tissue disorder without other laboratory or

When there are multiple conditions present, one important task for the medical expert is to judge how much each condition contributes to the patient's limitations, and the degree to which treatment for a co-occurring illness is likely to improve the patient's pain, stamina or other limitations.

7. What is appropriate medical treatment for FMS and CFS?

FMS: Currently, there are no FDA approved drug treatments for FMS. However, more than a half dozen medicines have at least one double blind study showing some benefit. However, less than half the patients in these studies benefit from any given medicine. Intolerance due to side effects are very common. For persons with severe FMS, while the degree of improvement is occasionally impressive, most often the degree of improvement is fairly modest.

An appropriately slowly graded exercise program is helpful in fibromyalgia; doing no exercise at all may, over time, make things worse. However, for persons with severe disease, the amount of exercise tolerated is often very limited.. Pushing past their limits, may make patients worse. Exercise often must be started at very low levels, and advanced very slowly. The degree of improvement with even a well-programmed regimen is typically fairly modest. Even an appropriate exercise program would usually not bring a disabled patient to the point where he or she can return to work.

Cognitive Behavioral Therapy (CBT) a kind of short term, practical reality based counseling tends to be helpful. Many persons with any severe chronic illness, including CFS and FMS, tend to fall into a negative style of thinking. This may exacerbate both physical and emotional issues. However, the benefit from CBT, while often worth having, is also usually fairly modest.

If depression or anxiety become a problem, these should be treated. Often the primary care physician can do that quite well. In other cases, referral to psychiatrist or psychologist should be considered.

For Chronic Fatigue Syndrome, we have less research on treatment than we do for fibromyalgia. There are no FDA approved treatments. Indeed, there are no medicines on the market with any good double blind studies suggesting benefit for this disease. Very low level exercise and CBT are probably useful, but, for persons with severe disease, the degree of improvement with these methods is typically fairly small.

8. What should we make of the frequently used phrase: The medical records fail to show any objective evidence that the patient is unable to perform the duties of his or her job? This phrase is another example of “looking in the wrong place”.

This discussion is analogous to and partly repeats the issues discussed in sections, # 1-4 above. However, because this phrase or a close variant is used so often, it should be addressed directly.

When a physician or case worker states that “there is no objective evidence” one wants to infer that the writer believes that one should be able to find “objective evidence” if the patient were disabled. It implies that there is some finding on physical exam or lab test that should be present when one is disabled and absent when one is not. The problem with this inference is that it is medically false. The reasons for this conclusion has already been discussed. Hence, this use of the “no objective evidence” phrase is, at its core, misleading.

Consider this case. We line up two 33 year old women with CFS and Fibromyalgia. One is completely unable to work because of markedly reduced physical stamina. The other is tired and achy but able to get through a 40 hour work week. How should these two differ on physical exam, or lab tests?

All experts on FMS and CFS would agree, that there is no finding observable on an office physical examination or laboratory test that should reliably distinguish between the two

persons. Their standard examination should look just the same. To suggest that there should be physical exam or lab findings that distinguish between these two—a kind of “Do you still beat your wife” question-- misunderstands the nature of FMS and CFS. Of course, this brings us back to the patient’s reported history, it’s consistency and credibility, as the fundamental issue.

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