To: DSM-5 Task Force, Somatic Symptom Disorders Work Group

From: _____

Re: Response on the Proposals for Somatic Symptom Disorder and Conversion Disorder

Date: June 12, 2012

The DSM-5 Task Force has thus far failed to address the conceptual and practical problems inherent in DSM-IV somatoform disease constructs. Specifically, its proposals for Somatic Symptom Disorder and Conversion Disorder are actually more flawed than their equivalents in DSM-IV. The criteria for these two diagnoses rely excessively upon purely subjective judgments by clinicians and on the extent of a clinician's awareness of known diseases, and lack the specificity required of valid diagnostic constructs.

To understand just how strongly subjectivity of clinical interpretation can impact diagnostic outcome when using somatoform disorder criteria on a disease with unknown etiology, it is instructive to consider in some detail Johnson et al's "Assessing Somatization Disorder in Chronic Fatigue Syndrome"[1], a study on the reliability of DSM-III-R somatization disorder (SD) criteria and related instruments when applied to patients with chronic fatigue syndrome (CFS). As the DSM-III-R SD diagnostic construct was less subjective and had greater specificity in terms of symptom presentation than the proposed SSD criteria, a careful examination of its flaws, as demonstrated by this study, offers a sobering perspective on real world application of SSD criteria.

CFS is a somatic disease of unestablished etiology; the United States Centers for Disease Control has stated that "Research shows that CFS is not a form of psychiatric illness" and that an essential criterion for its diagnosis is "severe chronic fatigue of 6 months or longer that is not explained by any medical or psychiatric diagnosis". Nevertheless, in spite of such evidence, an opinion persists in the medical community that CFS is in some way a psychosomatic illness, an opinion which can easily influence clinicians in their diagnoses of patients who satisfy CFS criteria. Thus, as Johnson et al noted: "Whether or not symptoms of CFS are considered medically caused will strongly affect the incidence of SD within the CFS population...If the examiner recognizes that the patient's CFS symptoms indicate a physical illness, the diagnosis of SD may not be made. Conversely, if the examiner does not consider CFS a medical illness, the patient's symptom endorsement may lead to the diagnosis of SD."

To begin with, Johnson et al discussed the problems with the DSM-III-R criteria for somatization disorder:

"According to DSM-III-R .. the diagnosis of somatization disorder (SD) requires a person to present with at least 13 symptoms for which no significant organic pathology can be found. The symptoms must have caused the person to take medication, to see a physician, or to have altered her/his lifestyle. The disorder begins before the age of 30 and has a chronic but fluctuating course. However, the diagnosis of SD is extremely problematic in terms of its validity because it involves a series of judgments that can be arbitrary and subjective [...] Specifically, the interviewer must decide if the symptom reported is attributable to an identifiable medical illness. Although such judgments are extremely difficult to make uniformly, the influence of bias introduced by the interviewer's orientation on the prevalence of SD has not been adequately addressed."

They noted the high variation between the estimates of SD prevalence in CFS patient cohorts reported by previous studies and concluded that it was "in itself indicative of the problem in defining SD". They further pointed out that "The difficulty in distinguishing among somatic symptoms that are psychiatric vs. organic in origin can result in overdiagnosis of SD in medical illness, particularly chronic illness", as they had observed in several studies by other authors on somatization in CFS.

Johnson et al took the results of their primary paper instrument, the DIS-III-R somatization section, from CFS, multiple sclerosis and depressed groups plus controls, and interpreted them using four separate criteria sets, each representing "a different approach for judging SD symptoms as psychiatric or physical". Set 1 was an interpretation with a heavy psychiatric bias, consisting of "recording the total number of 48 SD symptoms on the DIS, which were coded as psychiatric" and also scoring as psychiatric all the complaints that are sometimes classified as 'functional somatic', including CFS itself. Set 2 interpreted CDC-defined CFS symptoms as 'organic', not psychiatric.

Additionally, both Sets 1 and 2 were divided into respective "a" and "b" subsets based on whether Escobar's six symptom (for women)/four symptom (for men) cutoff for 'subsyndromal somatization' was used (subgroup "a") or whether the full 13 symptoms was required for 'full' SD diagnosis (subgroup "b"). For Set 3, the most 'pro-biomedical', only potential SD symptoms that existed prior to illness onset (CFS or MS) were scored as psychiatric; everything post-onset that the patient felt were due to their physical disease were scored as physical, not psychiatric. Lastly, Set 4 "used strict DSM-III-R criteria to determine prevalence of SD. Thus, only individuals with onset of CFS before age 30 who had 13 or more SD symptoms" were considered to have SD, and CDC CFS symptoms were again coded as physical in origin.

Their results were extremely revealing. No patients were diagnosed with SD by Set 3, whereas nearly 100% of CFS patients received an SD diagnosis in Subset 1a - however, this dropped to 52% in set 1b. More interestingly, despite the scoring of CDC CFS criteria as physical in Set 2, there was a >70% SD diagnosis rate in Subset 2a, but only 12% in Subset 2b. The difference in the subsets shows the huge change resulting from reduced specificity of SD criteria. Also of interest is that only one CFS patient was diagnosed with SD by Set 4 criteria, i.e. strict DSM-III-R SD criteria combined with exceptions for CDC CFS criteria.

In other words, the study predicts that a clinician who recognized CFS as a legitimate somatic disease by the CDC definition and stuck to the DSM-III-R criteria for SD would have found only a single one of the 42 CFS patients' results consistent with an SD diagnosis, whereas a clinician who used less specific SD criteria, even while recognizing the CDC CFS symptoms as physical, would have found 10% to more than 70% to have SD (depending on the number of symptoms he used as a cutoff). It should be noted that the authors repeated Set 4 with DSM-IV SD criteria without significantly different results.

Johnson et al concluded that "the homogeneity of a patient population is critical when trying to evaluate a controversial syndrome such as CFS. The present study used the most homogeneous group of CFS patients of any study to date. Even with this reduced variability, prevalence rates of SD ranged from 0 to 98% depending on whether CFS symptoms were coded as being due to a physical illness or not [...] Thus, the judgments made regarding whether a symptom is coded as physical or psychiatric dramatically affect prevalence rates of SD in CFS".

They noted the relatively high rate of somatization diagnoses in this study in Set 2 and in other studies using similar criteria, explaining that "These relatively high rates of SD, even after removing CDC criteria CFS symptoms from the equation, indicate that CFS subjects report many non-CFS symptoms that are then coded as psychiatric by the individual collecting the information".

Those 'non-CFS symptoms' found with high prevalence in this study included dizziness (76% of CFS subjects), shortness of breath and tachycardia (55%), nausea, and 'loss of feeling'. Significantly, these symptoms are frequently reported by both CFS and myalgic encephalomyelitis (ME) patients, and in fact were incorporated into older ME definitions, the later Canadian Consensus ME/CFS definition, and the recently published International Consensus definition of ME [2,3]. Both CFS and ME patients have frequently been found to have associated dysautonomias - including Neurally Mediated hypotension and POTS - which themselves would explain complaints of dizziness, tachycardia, and shortness of breath. Tachycardia is also a feature of deconditioned or metabolically-

challenged bodies under physical strain, as is likely to be the case for people with a chronic physical illness. As for loss of feeling and nausea, various forms of neuropathy, parathesia, and gastrointestinal dysfunction are also commonly associated with ME and CFS. Thus, without taking the clinical experience of biomedical specialists in CFS and ME into consideration, the average clinician relying upon somatoform disease criteria or similar psychiatric instruments would be prone to misdiagnosing CFS and ME patients with SD. This could potentially be the case with any disease with which the diagnosing clinician is relatively unfamiliar.

The results for CFS in this study demonstrate the excessively subjective nature of an archetypal somatoform disorder diagnosis, and its vulnerability to clinician bias. This study's results for MS patients also underlined the importance of a higher symptom number cutoff, and therefore higher specificity; MS patients received an SD diagnosis at least 15% of the time in subsets 1a and 2a (which reduced the cutoff from 13 to either 6 or 4) but were undiagnosed in all other sets.

Unfortunately, rather than truly address the fundamental problems with the DSM-III-R SD criteria revealed by Johnson et al and other studies, the DSM-IV added a far less specific, far more subjective diagnosis called Undifferentiated Somatoform Disorder (USD). And now, the DSM-5 Task Force proposes to replace both of these diagnoses with a new construct, Somatic Symptoms Disorder (SSD), which is even less specific than USD and which is utterly dependent on subjective clinical interpretation.

Flawed as they may themselves be, the DSM-IV criteria for somatization disorder did at least have greater operational specificity than both the USD and SSD criteria, by virtue of their requirements for a certain pattern and number of symptoms. Unfortunately the DSM-IV SD and USD criteria both allow the clinician to determine, without any guidance, whether a given symptom is explicable by a known general medical condition. That's a problem because it makes the huge assumption that each doctor has, or has access to, ultimate knowledge of every known disease. The DSM-IV SD and USD criteria also allows for a somatization disorder diagnosis whenever the patient's response to symptoms is deemed 'excessive' or 'unwarranted'. There is no operationalization for this criterion, no burden of proof on the clinician - his/her subjective opinion, as superficial as it may be, at any given time, is considered to be enough.

The proposed SSD criteria remove whatever specificity might be said to exist in the DSM-IV somatization disorder criteria, lower the necessary number of symptoms to just one (as in the USD criteria), and concentrate on the worst aspect of the DSM-IV SD and USD criteria - the (previously optional) 'excessive complaint' criterion - expand it, and makes it even more subjective, and therefore even more likely to be misapplied. Further, the SSD criteria contain no specification - however optional - that symptoms must be medically unexplained, which allows SSD to be applied as a 'bolt-on' diagnosis to any disease or condition.

Mayou et al wrote of the somatoform disorders: "Abolish the somatoform disorder category. The somatoform disorder term, concept, and category have failed psychiatrists, nonpsychiatric physicians, and patients. There seems to be little reason to retain them." [4]

Mayou et al criticized the existing somatization disorder definition in part because it relies on "counting the number of 'unexplained' somatic symptoms and so lacks even face validity as a psychiatric disorder". But the DSM-5 SSD Work Group's 'solution' is to simply remove the stricture of counting 'unexplained' symptoms within a specified distribution and instead have the entire diagnosis depend on the clinician's subjective assessment of whether patient has been worrying too much about a given symptom, and whether that symptom warrants so much concern or interest to begin with.

In other words the Work Group is replacing what was at best a fairly arbitrary scoring and

'counting' of possibly psychogenic symptoms with something even worse; all a clinician will have to do now is perceive a single symptom as the excessive focus of a patient's concern or time in order to give them a psychiatric diagnosis. That lowers the threshold of symptoms identified as potentially psychiatric in origin from 13 (DSM-III-R) to as little as 1 required for diagnosis. As noted by Johnson et al, lowering that threshold can lead to dramatic overdiagnosis of patients with somatoform disorder diagnoses. How would SSD criteria have fared in that study? One can predict that both SSD and USD criteria would have performed abysmally in the CFS patients groups, and that while the USD criteria may have overdiagnosed the MS patient group, the SSD criteria would have done so at a much higher rate.

Psychiatry does not have the tools to insure that a practitioner can accurately determine the relative weight of contributing factors - somatic or psychiatric - to a patient's symptoms or overall condition. Yet the diagnostic framework of the proposed SSD diagnosis is built on the assumption that such tools exist. As they do not, SSD must be regarded as an untenable diagnostic entity.

There are similar basic flaws in the suggested DSM-5 criteria for Conversion Disorder. Like other diagnoses that have been grouped in the somatoform disorders category, conversion disorder is based on a speculative mechanism that is the product of conjecture and outmoded psychiatric theories, and it is nonscientific because it does not allow for the development of falsifiable hypotheses. Nevertheless, it has appeared in one form or another in all DSM editions to this point; its criteria in DSM-IV-TR are as follows:

"A. One or more symptoms or deficits affecting voluntary motor or sensory function that suggest a neurological or other general medical condition.

B. Psychological factors are judged to be associated with the symptom or deficit because the initiation or exacerbation of the symptom or deficit is preceded by conflicts or other stressors.

C. The symptom or deficit is not intentionally produced or feigned (as in Factitious Disorder or Malingering).

D. The symptom or deficit cannot, after appropriate investigation, be fully explained by a general medical condition, or by the direct effects of a substance, or as a culturally sanctioned behavior or experience.

E. The symptom or deficit causes clinically significant distress or impairment in social, occupational, or other important areas of functioning or warrants medical evaluation.

F. The symptom or deficit is not limited to pain or sexual dysfunction, does not occur exclusively during the course of Somatization Disorder, and is not better accounted for by another mental disorder." [5]

If the mechanism of conversion disorder is based on speculative hypothesis with no empirical validation, how can conversion disorder ever be said to better account for symptoms that are not fully explained by a 'general medical condition'? How can it be a preferred explanation to any unknown or equally hypothetical medical condition?

Thus, the diagnosis of conversion disorder is of dubious clinical validity to begin with. But again, instead of addressing this problem, the SSD Work Group has only made this diagnosis less specific by removing Criteria B and C from the DSM-IV version. This results in criteria that are so non-specific that not only do they technically qualify as a subset of Somatic Symptom Disorder - it is not immediately clear how the two could be distinguished, and on what basis Criterion C would lead one to prefer a conversion disorder diagnosis over SSD, since SSD may also apply to "a symptom affecting voluntary motor or sensory function" - but they also no longer contain any requirement of evidence of psychopathology.

A diagnosis that is based on absence of evidence rather than positive signs will capture any case that is not readily explained by standard medical workups or by well-known disease processes. Clearly, then, the proposed DSM-5 conversion disorder is little more than a dustbin diagnosis for unexplained neurological symptoms. Is it accurate or ethical for such a dustbin category, which is designed NOT to be specific to psychiatric etiologies, to be defined as psychiatric? One of the rationales given on the DSM-5 site for removing criterion B is that the latter "confounds clinical description with a proposed but unproven etiology". But having a DSM diagnosis by definition implies psychiatric, or at least non-somatic, etiology, and therefore patients who have purely somatic neurological problems could be easily mislabeled by these criteria with what is viewed as predominantly psychiatric illness. This in turn could lead to many harmful ramifications for the patient, including a premature end to investigation into the true cause for their symptoms, inappropriate treatment recommendations, and termination of health benefits.

The major weakness of all somatoform disorder definitions has been the attribution of medically unexplained symptoms to psychiatric factors by default, without any burden or means of proof, which is inherently unscientific. The proposed change to the new criteria for conversion disorder removes even the slightest necessity of evidence for psychiatric morbidity, leaving an entirely negative psychiatric definition. How can the absence of a known biomedical pathology be taken as positive evidence of psychopathology, especially when the mechanism for conversion is itself purely hypothetical?

The fact remains that no one has provided sufficient empirical evidence that any 'conversion' or 'somatization' mechanism even exists. A re-examination of the basic validity and specificity of these somatoform disorder diagnostic constructs is therefore long overdue. Reducing the specificity of these somatoform disorder criteria is the last thing the DSM-5 task force should be doing; either these diagnoses and their precedents should be abandoned altogether until there is sufficient scientific evidence to support such constructs or, at least, the DSM-IV criteria for somatization disorder should be conserved in the DSM-5 while a far more thorough, independent appraisal of the validity and utility of the proposed CD, SSD constructs, as well as of the extant USD construct, takes place.

It is important to consider that the implementation of these new criteria for both SSD and conversion disorder could significantly hinder new disease discovery, or proper surveillance and diagnosis of emerging disease or rare diseases. The SSD criteria are so vague that they could capture any medically unknown disease of sufficient severity; the new conversion disorder criteria could do the same for such diseases with neurological symptoms. Similarly, cases of any disease that is not well understood, not well known to most clinicians, or difficult to diagnose could potentially wind up in either of these dustbin categories, and their labeling as 'somatoform' would discourage further investigation in such cases. Thus the decreased specificity of the proposed SSD and conversion disorder criteria will inevitably lead to overdiagnosis and misdiagnosis that could have far reaching effects.

I find it troubling that the larger community of non-psychiatrist clinicians and researchers have not had a tangible role in the development of the DSM's diagnoses. Such input would be especially relevant for somatoform disease, in which psychiatric and physical illness are hypothesized to overlap. A collaboration with biomedically-oriented clinicians and researchers would no doubt offer broader perspectives on the confusing and contentious issue of somatoform disorders and the design of any proposed diagnoses.

I therefore suggest the DSM-5 task force seek a much broader consensus on the issue of somatoform disorder diagnoses, and abandon plans for adding any diagnosis that has highly questionable clinical validity and/or is based on unvalidated hypotheses. The newly proposed criteria for both SSD and conversion disorder should be abandoned for these reasons.

The magnitude of damage that can be done to patients through inappropriate psychiatric

diagnoses, psychiatric overdiagnosis, and the resulting biomedical underdiagnosis cannot be overstated. Simply put, people's lives and relationships have been made much more difficult or even destroyed, and their much-needed health benefits/disability pay cut or stopped entirely, due to misdiagnosis with somatoform disorders. In the continued application of these diagnoses and their further development, I urge the DSM-5 Task Force to consider that the precept "Do No Harm" may be violated as much by inherently flawed diagnostic entities as it may be by flawed practitioners.

References

1: Johnson SK, DeLuca J, and Natelson BH. "Assessing Somatization Disorder in Chronic Fatigue Syndrome". *Psychosomatic Medicine 1996; 58:50-57*

2: Carruthers et al "Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: Clinical Working Case Definition, Diagnostic and Treatment Protocols" *J Chronic Fatigue Syndrome 2003, 11(1): 7-115*

http://name-us.org/DefintionsPages/DefinitionsArticles/ConsensusDocumentFull.pdf

3: Carruthers et al "Myalgic Encephalomyelitis: International Consensus Criteria" *J Intern Med 2011; 270(4): 327–338*

4: Mayou R et al. "Somatization Disorders: Time for a New Approach in DSM-5" *Am J Psychiatry 2005; 162: 847-855*

5: Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition - Text Revision, Washington, DC, American Psychiatric Association, 2000.