Public Comment on the IDSA's
2019 Draft Guidelines for the Prevention, Diagnosis and Treatment of Lyme Disease

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A. Comments on "Prolonged symptoms following treatment of Lyme disease"

I. Regarding considerations relating to lines 1490-1492:
"The question remains whether patients with these highly heterogeneous symptoms but no alternative diagnosis should be treated as if they had Lyme disease… No higher quality studies have addressed this question."

1. The guideline's first consideration on this central issue is that current testing reveals no abnormalities with this patient group, with the implication that this should lead providers to doubt the existence of CLD. Reasoning here is clinically inadequate, and therefore unsafe.

First, unless we embrace an irrational level of faith in medicine's current diagnostic capabilities, failure of current testing methods will not support the conclusion that disease is not present. In the context of new and poorly understood diseases, scientific considerations should lead us to expect a failure of current testing methods.

Second, there is considerable professional debate about new forms of testing that may or may not reveal CLD. The guideline does not have to accept any particular conclusion from research on testing methods for CLD. However, if the guideline wants to take a position on the testing debate it must do so directly, with rigorous support for its conclusions. In the absence of that support, objectivity, and safety, demand that the guideline must directly acknowledge professional debate, and professional uncertainty, about the adequacy of current testing methods for CLD.

2. The guideline's second consideration on the existence of CLD is that studies suggest "prolonged antimicrobial therapy is not helpful". The guideline does present evidence for this therapeutic conclusion, though many researchers, physicians, and patients would insist that the guideline fails to consider the whole range of research on the issue. What's important regarding lines 1490-1492 is that this second consideration is intended to address the challenge of scientific uncertainty about the reality of CLD. Specifically, the guideline clearly suggests that the failure of prolonged antimicrobial therapy should lead providers to conclude that LD is not present – but the guideline fails to provide any evidence or reasoning to support that suggestion.

Even if it's true that prolonged antimicrobial therapy is not helpful (and the guideline does not seem to resolve that question), this will not support a recommendation to reject the presence of Lyme disease. In contexts where we consider the possibility of new and poorly understood diseases, failure of current therapies will never imply that disease is not present. On the contrary, it will strengthen concerns about the inadequacy of current scientific understanding.

3. The guideline should be commended for acknowledging the state of scientific uncertainty about CLD. In response to that uncertainty, however, without stating a clear position, the guideline provides two "considerations" that are clearly intended to convince providers that Lyme disease is not present in CLD patients. Neither consideration supports that conclusion.

The possibility of disease – not the actuality of disease – is the driving force behind the practice of medicine. For this reason, in every case where the question of disease remains unanswered, physicians in practice recognize an imperative to err on the side of clinical caution. The standard of care demands that practice guidelines must respect that same imperative. Every recommendation (including those regarding treatment and those regarding disease conception) must be directly stated, and directly supported by evidence. When the question of the presence of disease remains unanswered by science (as the guideline suggests it does with CLD), recommendations that encourage providers to reject the possibility of disease must be supported to the highest standards of scientific rigor.

It is unfitting, and unsafe, for an organization like IDSA to implement a practice guideline that encourages providers to reject the possibility of disease on the basis of vague, unsupported considerations.

II. Regarding lines 1499-1502:
"Research needs: Although many patients diagnosed with chronic Lyme disease have other diagnosable and potentially treatable disorders, many

have 'medically unexplained symptoms' – poorly understood symptom complexes that lack a unifying medical diagnosis. Studies to better understand this disorder or group of disorders, and the development of effective treatment strategies would be highly beneficial."

1. At this point the guideline has acknowledged scientific uncertainty about the existence of CLD, and though it has not directly stated that providers should reject it as a disease entity, the guideline has offered two vague, unsupported considerations that encourage providers to do so. With this in mind, we come to final recommendations about research. Again, the guideline fails to state a position here clearly, but it directs providers to accept that CLD patients do not suffer from LD – that they suffer either from alternative, diagnosable diseases or from 'medically unexplained symptoms' (MUS). This very substantive conclusion about the disease entity CLD does not belong in the section on research recommendations. The existence of CLD is a matter of central importance to this guideline, both on the basis of patient safety and on the basis of the public's general relationship with the medical profession. For this reason, the guideline's position on CLD cannot be implied. The IDSA's view on this issue must be clearly stated in a way that invites rigorous consideration of its scientific support.

2. The guideline presents considerable evidence to support the conclusion that many CLD patients suffer from unrecognized diseases other than Lyme. While that material is valuable and important for patient care, once again, the reasoning that leads from there to the conclusion that CLD is not a cohesive or serious disease entity remains entirely unclear.

On this point, it's helpful to note some parallels. Systemic lupus is called "the great imitator" because it is so often mistaken for other diseases. Neither clinicians nor researchers have suggested or implied that this should lead us to question the cohesion or seriousness of SLE as a disease entity. Similarly, at this time the NIH is committed to biological research on ME/CFS, and one of the studies it supports (led by Avindra Nath of NINDS) aims to show that many ME/CFS patients actually suffer from other diseases. Neither study leaders nor the NIH approach this research with the sensibility that high rates of misdiagnosis will support the conclusion that ME/CFS is not a genuine or serious disease entity.

It seems likely that many patients diagnosed with ME/CFS, and with CLD, are actually suffering from other diseases, but that reality in no way implies that either condition lacks cohesion, or seriousness, as a disease entity. If the guideline means to suggest that it does, this unusual reasoning would require support with considerable scientific evidence.

3. It is highly problematic that the IDSA advocates management of CLD patients who do not suffer from other diseases under the rubric of 'medically unexplained symptoms' (MUS). First, the guideline has provided no evidence to support the assertion that providers must choose between alternative diseases and MUS – because up to this point it has provided only vague considerations to support the repeated implication that CLD is not a cohesive or serious disease entity.

Second, at the very end of the guideline's consideration of CLD, it broaches the topic of MUS with an approach of deliberate ambiguity. The term 'MUS' will suggest to patients that for those who don't suffer from other diseases the guideline advises providers to remain open to the possibility the CLD is indeed a disease. In reality, however, the term 'MUS' serves to inform providers that in the absence of other diagnoses, CLD patients should be managed as psychosomatic, with the hope that research in psychiatry will improve the general success of care for psychosomatic conditions.

On an issue of such immense clinical and public importance, it is worrisome to see the IDSA opting for this calculated misrepresentation of its recommendations. If the organization means to inform the medical community of a considered opinion that CLD is a psychosomatic condition, it has a scientific obligation to state that clearly and unequivocally for the record. More than that, if the IDSA means to direct providers to diagnose CLD patients as psychosomatic, the organization has an ethical obligation to explain that in the guideline in a way that will be unambiguous for the patient community. Without truthfulness of this kind, the IDSA encourages violation of the right to informed consent to care for patients with CLD.

Third and most importantly, it should be concerning to every medical professional who reads the draft guideline that the IDSA's final recommendations propose rejection of the possibility of disease without offering careful, judiciously cautious evidence for that position. No question arises in medicine that's more pressing or more serious than the question of the presence of disease. At the level of individual patient care, and at the level of professional guidelines, it is a question that must always be addressed with rigor and scientific objectivity – because these are the best tools available for relieving suffering and avoiding harm. The guideline proceeds as if the question of the presence of disease in patients with CLD is somehow less pressing or less serious than it is other settings where diagnostic uncertainty arises. The IDSA has apparently imagined that medicine's defining question can be addressed in this guideline with two cryptic final sentences that remain wholly unsupported.

4. Finally, it is surprising and concerning that the IDSA's recommendations for research on CLD do not mention that reputable, peer-reviewed biological research on the condition is substantial, and clearly growing. If the organization feels it has a scientific basis for discouraging research of this kind, it has an

obligation to state that position directly, and to support the claim in a rigorous way. In the absence of such support, the basic duty of medical beneficence demands that the guideline must acknowledge biological research on CLD, and encourage it as a potential route to relief from suffering and protection from harm.

Summary of I and II:

A. The guideline recognizes scientific uncertainty about the existence of what the public knows as "chronic Lyme disease" (CLD), but its considerations about this issue lack the forms of caution that characterize a reasonable standard for care in cases of diagnostic uncertainty.

B. The guideline's most definitive statements about the presence of disease in CLD patients are presented with deliberate ambiguity in its recommendations for research. These statements encourage psychosomatic diagnosis for CLD patients, though they fail to support that directive, and fail to note the importance of caution in every case where providers make the leap from diagnostic uncertainty to exclusion of disease.

B. General Comments on Entire Draft

I. The guideline fails to specify how, or why, its recommendations differ from new coding for Lyme disease as it will be implemented with ICD-11.

This is both a practical and theoretical problem. Practically speaking, providers will be unclear about how to align these recommendations with the ICD's new coding. This guideline offers a general picture of Lyme disease – and particularly, chronic Lyme disease – that's different from what we will see in the ICD. The guideline should explicitly address and support that disparity.

II. The guideline advances an attitude of hubris about management of patients with CLD, because it fails to acknowledge the very serious risks that arise when poorly understood conditions are attributed to psychological causes in error.

History speaks loudly and clearly on this issue. Multiple sclerosis, Parkinson's disease, endometriosis, peptic ulcer, HIV/AIDS: all of these diseases were initially construed by the profession as psychosomatic in error, and for every one of these diseases that error lead to suffering and harm on a scale that's painful

even to contemplate. That fact does not establish that the IDSA is making an error of this kind with CLD, but it certainly does indicate that humility is a clinical necessity.

Even if the guideline provided evidence to support its implicit conclusion that CLD is psychosomatic – and, to be very clear, the guideline provides no evidence at all in support of that implicit claim – it would remain problematic for the guideline to fail to note the history of this kind of error, and the profound importance of taking steps to avoid it. There is no room for scientific dispute about medicine's distaste for uncertainty or its inclination to attribute what it does not understand to patient psychology – and there is no room for scientific dispute about the magnitude of human suffering that has resulted from this form of overconfidence. In every case where the profession considers new and poorly understood conditions, it must be centrally mindful to avoid these kinds of harms.

On this point, ME/CFS is a cautionary tale, one that should be directly acknowledged at some point in the guideline. There is unanimous consensus among US governmental health organizations that although ME/CFS has been managed as a psychosomatic condition for decades, that approach has been a mistake, one that's stunted the biological research that will ultimately lead to relief and protection from harm for tens of millions of patients. Medical organizations, it's important to note, felt utterly convinced over the last three decades that it was wise to guide providers to psychosomatic diagnosis and management of ME/CFS – and they were mistaken. Professional acknowledgement of this error by the NAM, the NIH, and the AHRQ indicates that a new level of caution is in order with all guidelines on contested conditions. If the IDSA is unconvinced of the need for this kind of caution on the basis of patient safety (and that would be reprehensible), the organization should be convinced of it on political and financial grounds – and as a matter of history's retrospective opinion on the IDSA during the time of uncertainty about chronic Lyme disease.