| 1 | PROJECT PLAN |
|----|---|
| 2 | Guidelines for the Prevention, Diagnosis, and Treatment of Lyme Disease by the Infectious |
| 3 | Diseases Society of America, the American Academy of Neurology, and the American College |
| 4 | of Rheumatology |
| 5 | |
| 6 | Organizational Sponsorship |
| 7 | American Academy of Neurology (AAN) |
| 8 | American College of Rheumatology (ACR) |
| 9 | Infectious Diseases Society of America (IDSA) |
| 10 | |
| 11 | Other Organizations with Official Representation |
| 12 | American Academy of Family Physicians (AAFP) |
| 13 | American Academy of Pediatrics, Committee on Infectious Diseases (AAP-COID) |
| 14 | American Academy of Pediatrics, Section on Emergency Medicine (AAP-EM) |
| 15 | American College of Physicians (ACP) |
| 16 | Association of Medical Microbiology and Infectious Diseases – Canada (AMMI-CA) |
| 17 | Child Neurology Society (CNS) |
| 18 | Entomological Society of America (ESA) |
| 19 | European Society of Clinical Microbiology and Infectious Diseases (ESCMID) |
| 20 | Pediatric Infectious Diseases Society (PIDS) |

| 1 2 | Guideline Authors | 42 | Conflict of Interest (COI) Review Group |
|--|---|--|---|
| 3 4 5 6 7 8 | Panel Leadership Linda Bockenstedt, MD, Co-Chair, representing ACR Yngve Falck-Ytter, MD, Co-Chair, representing GRADE Paul M. Lantos, MD, Co-Chair, representing IDSA and ACP | 43 44 45 46 47 48 49 | Timothy Beukelman, MD, MSCE (ACR) Stanley C. Deresinski, MD, (IDSA) Liana Fraenkel, MD, MPH (ACR) Gary S. Gronseth, MD (AAN) Cynthia Harden, MD (AAN) Luis Ostrosky-Zeichner, MD (IDSA) |
| 10 11 | Jeffrey A. Rumbaugh, MD <i>Co-Chair, representing</i> AAN | 50 | Organization Staff |
| 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 | Panelists Paul G. Auwaerter, MD, representing IDSA Kelly Baldwin, MD, representing AAN Kiran K. Belani, MD, representing PIDS William R. Bowie, MD, representing AMMI-CA Maria E. Aguero-Rosenfeld, MD John A. Branda, MD David B. Clifford, MD representing AAN Francis J. DiMario Jr., MD representing AAN Francis J. DiMario Jr., MD representing IDSA John J. Halperin, MD representing IDSA John J. Halperin, MD representing IDSA Matthew H. Liang, MD, MPH representing ACR H. Cody Meissner, MD representing AAP-COID Lise E. Nigrovic, MD, MPH representing ACR Amy A. Pruitt, MD representing AAN Jane Glazer Rips, consumer representative Lynda E. Rosenfeld, MD Margot L. Savoy, MD, MPH representing AAFP | 51 52 53 54 55 56 57 58 59 60 61 62 | Thomas S. D. Getchius (AAN) Amy S. Miller (ACR) Jennifer J. Padberg, MPH (IDSA) Medical Librarians Michele Klein Fedyshin, BA, BSN, MSLS, RN Charles B. Wessel, MLS Other Cameron R. Wolfe, MD, Liaison to the IDSA Standards and Practice Guidelines Committee |
| 34 35 36 37 38 39 40 41 | Sunil K. Sood, MD representing IDSA Allen C. Steere, Jr., MD representing ACR Franc Strle, MD, PhD representing ESCMID Robert Sundel, MD representing ACR Jean Tsao, MS, PhD representing ESA Gary Wormser, MD representing IDSA Lawrence S. Zemel, MD representing ACR | | |

Background

Lyme disease is a tickborne bacterial infection caused by several genospecies of *Borrelia burgdorferi* sensu lato. It is the most common vector-borne infectious disease in the temperate northern hemisphere. More than 30,000 annual cases are reported to public health bodies in the United States, but this is thought to be a considerable underestimate of the true disease burden.

Lyme disease causes a variety of acute, subacute, and late clinical manifestations and affects several organ systems, including skin, the nervous system, the heart, and joints. Lyme disease is evaluated and diagnosed clinically, with the added support of laboratory testing when clinically indicated. Patients with Lyme disease, depending on their clinical manifestations, are evaluated by a range of clinicians, including practitioners of internal medicine, pediatrics, family practice, emergency medicine, infectious diseases, neurology, rheumatology, and cardiology.

The clinical complexity of Lyme disease and the breadth of involved specialties necessitate guidelines to advise clinicians on best practices and their evidence basis.

Several Lyme disease guidelines have been produced by different medical societies. These include 1996 and 2007 guidelines from the AAN [1, 2], 2000 and 2006 guidelines [3, 4] and a 2010 review panel report from the IDSA [5], 2004 guidelines from the ESCMID [6], 1997 diagnostic testing guidelines for Lyme disease from the ACP [7] and triennial Lyme disease guidelines from the AAP included in the AAP "Red Book." The current effort will combine the expertise of the aforementioned societies as well as several others to produce a joint, multisociety consensus guideline for the prevention, diagnosis, and treatment of Lyme disease.

Notes on Panel Composition

- 24 Panelists with broad and relevant expertise have been recruited to participate in the
- 25 development of this guideline:
- Rheumatology: Drs. Bockenstedt, Liang, Nocton, Steere, Sundel and Zemel
- Neurology: Drs. Baldwin, Clifford, DiMario, Halperin, Pruitt and Rumbaugh
- Infectious Diseases: Drs. Auwaerter, Belani, Bowie, Ericsson, Krause, Lantos, Meissner,
- 29 Sood, Strle and Wormser
- Cardiology: Dr. Rosenfeld
- Clinical Microbiology: Drs. Aguero-Rosenfeld and Branda
- Family Medicine: Dr. Savoy
- Emergency Medicine: Dr. Nigrovic
- Hospital Medicine / General Internal Medicine: Dr. Lantos
- Pediatrics: Drs. Belani, Krause, Lantos, Meissner, Sood (pediatric infectious diseases),
- Drs. Nocton, Sundel, Zemel (pediatric rheumatology), Dr. DiMario (pediatric neurology),
- and Dr. Nigrovic (pediatric emergency medicine)
- Medical Entomology: Dr. Tsao
- GRADE and Guideline Methodology: Dr. Falck-Ytter
- Consumer representative: Ms. Rips

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Objectives and Scope

The objective of this project is to develop clinical practice guidelines for the prevention, diagnosis, and treatment of Lyme disease, as well as the diagnosis and treatment of other tickborne coinfections potentially transmitted by *Ixodes* species ticks. The guideline will address adults, children, pregnant women, and immunocompromised hosts. Specifically the guideline will cover the following themes:

- Effective measures to prevent tick bites and to prevent Borrelia burgdorferi infection following a tick bite.
- Evidence-based recognition of Lyme disease clinical presentations
- Appropriate selection and interpretation of laboratory diagnostic tests for Lyme disease
- Appropriate choice, duration, and route of antibiotics to treat the various manifestations of Lyme disease
 - Diagnostic and therapeutic approaches to patients with persistent clinical symptoms following antimicrobial therapy
 - Recognition, diagnosis, and treatment of coinfecting pathogens, particularly anaplasmosis and babesiosis
- In contrast to the 2006 IDSA guidelines, this guideline will not provide comprehensive coverage of *Anaplasma phagocytophilum* and *Babesia microti* outside the context of coinfections. Those pathogens will be treated more comprehensively in separate, forthcoming clinical guidelines.

Methodology

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Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology will be used [8]. Population/Patients, Intervention/Treatment, Comparator, and Outcomes (PICO) questions have been developed by the panel and will serve to inform the literature search and guideline recommendations.

Methods of summarizing and rating the quality of evidence and strength of recommendations

For each PICO, outcomes of interest will be identified and rated in terms of importance to decision making (less important, important, and critically important). This guideline will primarily focus on patient-important outcomes, but intermediate outcomes may be used if final health outcomes are unavailable. Where available we will use well-performed existing systematic reviews as the basis of evidence, as recommended by the IOM [9]. If existing systematic reviews are unavailable, not up-to-date, or the outcomes of interest are not reported, we will perform additional analyses where possible from systematic searches of the literature using standard bibliographic resources, PubMed (which includes MEDLINE), EMBASE.com, Cochrane Library, meeting abstracts, conference proceedings, and reference lists of studies. When indicated, we will search for yet unpublished studies by accessing study registries such as clinicaltrials.gov. We will initially focus on evidence from studies with lower risk of bias, such as randomized controlled trials (RCTs). However, if unavailable or methodologically unsatisfactory, or the outcomes of interest are rare, evidence from observational studies will be sought. When estimating baseline risk, rates from control arms of RCTs or well-done cohort studies will be used to inform prevalence rates, incidence or pre-test probabilities.

Studies will be critically appraised for risk of bias or confounding factors using the Cochrane risk of bias tool (for RCTs) or the Newcastle-Ottawa scale for observations studies (or alternate tool if found to be more appropriate). The quality of evidence across studies for each outcome will be rated using the GRADE framework as discussed in detail elsewhere [8]. In short, desirable, as well as undesirable outcomes from the body of evidence pertaining to each PICO will be rated using these 5 criteria: risk of bias, imprecision, indirectness, inconsistency, and publication bias. Criteria for rating up the quality of evidence include large or very large effect and dose-response-gradient.

The rating of the strength of recommendations will follow established GRADE criteria [8]: in addition to the overall quality of evidence, factors such as the balance between benefits and downsides (e.g., harms and inconvenience), patients' values and preferences, and cost-effectiveness will be considered when making recommendations.

Identification of Studies/Management of Studies and Data

The literature search strategy will be developed by medical librarians in consultation with panel members. Searches will be performed in PubMed (which includes MEDLINE (1946–present)), EMBASE.com (1974–present), and the Cochrane Library's (John Wiley & Sons) Cochrane Database of Systematic Reviews (CDSR), Cochrane Central Register of Controlled Trials (CENTRAL), Database of Abstracts of Reviews of Effects (DARE), Health Technology Assessment Database (HTAD), and the NHS Economic Evaluation Database (NHSEED).

References and abstracts will be imported into bibliographic management software (EndNote), duplicates removed, and exported to a literature evaluation database created by the AAN.

Screening, Data Extraction, and Analysis Phases

Author teams will be able to utilize the AAN guideline literature reviewing database once the searches for each question are complete. Results from the literature searches will be loaded into the database, and each title/abstract will be systematically assigned to two separate reviewers. Reviewers will screen each title and abstract within the system and identify whether or not the reference is relevant to the particular clinical question. Results will be collected from the reviewers and an article order report will be compiled. Full manuscripts will then be pulled for each title/abstract deemed relevant, and each will also be reviewed by 2 separate reviewers to make the final determination of which papers to include in the literature base for potential inclusion in the guideline.

Conflict of Interest Disclosure

All members of the guideline panel were required to submit a conflict of interest (COI) disclosure form (appendix 1) and copies of their CVs. A six-person COI review group representative of the three sponsoring organizations was established to review COI forms and CVs for financial and intellectual COI. The six-person COI review group was free from intellectual and financial conflicts. The COI review group determined which members of the guideline panel were deemed to have COI vs. those without relevant COI. The COI review group ensured that the majority of the panel and each co-chair was without potential conflicts (noted in Table 1) and the panel was approved.

| Table 1 is a reflection of what has been reported to the IDSA, AAN, and ACR. In order to |
|---|
| provide thorough transparency, the full disclosure of all relationships, regardless of relevancy |
| to the guideline topic was required. Evaluation of such relationships as potential conflicts of |
| interest was determined by a review process which included assessment by a six person (two |
| people from each lead organization) conflict of interest evaluation group. |
| Population/Patients, Intervention/Treatment, Comparator, and Outcomes (PICO) |
| The following is a list of the clinical questions that will frame and form the foundation of |
| Population/Patients, Intervention/Treatment, Comparator, and Outcomes (PICOs) for the guideline |
| development process. The PICOs will guide the literature searches and, ultimately, the formal |
| recommendations in the final guideline. |
| 1. What are effective measures for preventing <i>Ixodes</i> tick bites (not including repellents)? |
| 2. Which skin and clothing repellents are effective for preventing tick bites and tickborne |
| infections? |
| 3. Should individuals be tested for <i>Ixodes</i> -borne pathogens solely based on the history of a |
| tick-bite? |
| 4. Who should receive antibiotic prophylaxis to prevent Lyme disease after an <i>Ixodes</i> |
| scapularis tick bite? |
| 5. Is antimicrobial prophylaxis indicated to prevent other tickborne diseases? |
| 6. Is antimicrobial prophylaxis indicated after <i>Ixodes pacificus</i> bites? |
| 7. Should the species of a tick be determined after a tick bite? |
| 8. Is antimicrobial prophylaxis indicated after tick bites when the tick species is unknown? |

9. Should ticks that have been removed from patients be tested for pathogens?

| 147 | 10. What is the preferred initial antibiotic therapy for acute localized Lyme disease? |
|-----|--|
| 148 | 11. Is parenteral therapy superior to oral therapy for acute localized Lyme disease? |
| 149 | 12. How long should early localized Lyme disease be treated? |
| 150 | 13. What is the preferred antibiotic regimen to dually treat cellulitis and acute localized Lyme |
| 151 | disease? |
| 152 | 14. What agents and therapies are not recommended for Lyme disease? |
| 153 | 15. What is the appropriate antibiotic management for acute neurological manifestations of |
| 154 | Lyme disease, such as meningitis, cranial neuropathy, or radiculoneuropathy? |
| 155 | 16. Under what circumstances will CSF examination alter the treatment of patients with cranial |
| 156 | neuropathy, meningitis, or encephalomyelitis, or radiculoneuropathy due to Lyme disease? |
| 157 | 17. Should patients with Lyme disease and papilledema be treated with techniques to reduce |
| 158 | intracranial pressure? |
| 159 | 18. Should patients with Lyme disease and facial nerve palsy receive corticosteroids in addition |
| 160 | to antimicrobial therapy? |
| 161 | 19. Should patients with Lyme disease-related parenchymal involvement of the brain or spinal |
| 162 | cord be treated with oral or parenteral antibiotics? |
| 163 | 20. Should patients with Lyme disease who experience encephalopathy (i.e. delirium) be |
| 164 | treated as if they have Lyme meningitis or Lyme disease of the parenchymal central nervous |
| 165 | system? |
| 166 | 21. For which neurological presentations should the diagnosis of Lyme disease be considered? |
| 167 | 22. Which patients with atrioventricular nodal block or myopericarditis due to Lyme disease |
| 168 | require hospitalization? |

| 169 | 23. Which patients with Lyme carditis require a pacemaker? |
|-----|---|
| 170 | 24. What is the preferred antibiotic choice, route, and duration for outpatients with Lyme |
| 171 | carditis? |
| 172 | 25. Should all patients with early Lyme disease receive an electrocardiogram to screen for Lyme |
| 173 | carditis? |
| 174 | 26. Should patients with Lyme carditis receive steroids? |
| 175 | 27. Should patients with Lyme carditis be treated with aspirin? |
| 176 | 28. What is the utility of erythrocyte sedimentation rate, C-reactive protein, and other |
| 177 | measures of systemic inflammation to aid in the diagnosis of Lyme carditis? |
| 178 | 29. Should patients admitted to the hospital and treated with IV antibiotics for Lyme carditis be |
| 179 | switched to oral antibiotics at hospital discharge? |
| 180 | 30. Should patients being evaluated for acute myocarditis or chronic cardiomyopathy of |
| 181 | unknown cause be tested for Lyme disease? |
| 182 | 31. What are the preferred antibiotics and route of administration for Lyme arthritis? |
| 183 | 32. What is the optimal duration of oral antibiotics for the initial treatment of Lyme arthritis? |
| 184 | 33. What is the optimal duration of IV antibiotic therapy for Lyme arthritis? |
| 185 | 34. Should a second course of antibiotics be considered for a patient in whom Lyme arthritis |
| 186 | does not resolve completely? |
| 187 | 35. What is the preferred second course of antibiotic treatment for patients in whom Lyme |
| 188 | arthritis has not completely resolved? |
| 189 | 36. Are intra-articular steroids, in conjunction with antibiotics, safe and effective for the |
| 190 | treatment of Lyme arthritis? |

| 191 | 37. Should synovial fluid aspiration be performed for outpatients with suspected Lyme |
|-----|--|
| 192 | arthritis? |
| 193 | 38. How should antibiotic-refractory Lyme arthritis be treated? |
| 194 | 39. Should patients with the following clinical presentations be tested for Lyme disease? |
| 195 | a. muscle weakness/myositis |
| 196 | b. uveitis |
| 197 | c. small joint arthritis |
| 198 | d. fibromyalgia-like syndromes |
| 199 | e. tendinitis/bursitis |
| 200 | 40. Should patients with persistent symptoms following standard treatment of Lyme disease |
| 201 | receive additional antibiotics? |
| 202 | 41. Does the duration, route, or antibiotic used for initial treatment of Lyme disease influence |
| 203 | the likelihood of persistent symptoms following treatment? |
| 204 | 42. What clinical syndromes are attributable to prolonged, or chronic, infection with <i>B</i> . |
| 205 | burgdorferi? |
| 206 | 43. Are chronic, nonspecific symptoms associated with B. burgdorferi infection in patients who |
| 207 | lack objective clinical signs? |
| 208 | 44. Are prolonged symptoms following treatment for Lyme disease more common in patients |
| 209 | who are simultaneously infected with multiple tickborne pathogens? |
| 210 | 45. Should patients with prolonged, nonspecific symptoms be tested for tickborne pathogens |
| 211 | (other than Borrelia burgdorferi)? |

| 212 | 46. What are the preferred antibiotics, route of administration, and treatment duration for HG/ |
|-----|--|
| 213 | (human granulocytic anaplasmosis)? |
| 214 | 47. Is antibiotic choice or duration different for HGA / Lyme disease co-infection than for HGA |
| 215 | alone? |
| 216 | 48. Which diagnostic tests should be used for the diagnosis of HGA? |
| 217 | 49. What is the preferred test for acute symptomatic babesiosis? |
| 218 | 50. What is the preferred test to confirm parasite eradication following treatment? |
| 219 | 51. Should symptomatic patients who are seropositive for babesiosis be treated if they have |
| 220 | negative blood smears or PCR? |
| 221 | 52. Should asymptomatic patients with a positive diagnostic test for babesiosis receive |
| 222 | treatment? |
| 223 | 53. What are the preferred treatment regimens for babesiosis? |
| 224 | 54. Is antibiotic choice or duration different for babesiosis / Lyme disease co-infection than for |
| 225 | babesiosis alone? |
| 226 | 55. Is exchange transfusion indicated for severe babesiosis? If so, what criteria should be used |
| 227 | for initial or repeat exchange transfusion, and should full or partial exchange be used? |
| 228 | 56. Does the percent parasitemia influence therapeutic choice for babesiosis? |
| 229 | 57. What is the appropriate treatment duration, monitoring, and follow up of |
| 230 | immunocompromised patients with severe babesiosis? |
| 231 | 58. Under what circumstances do patients with persistent parasitemia require re-treatment for |
| 232 | babesiosis? |
| 233 | 59. Should patients with Lyme disease be evaluated for Bartonella infection? |

| 234 | 60. Should patients with suspected Lyme disease also be tested for spotted fever group |
|-----|---|
| 235 | rickettsial diseases (e.g., Rocky Mountain spotted fever)? |
| 236 | 61. When should co-infection (Anaplasma, other Erhlichia, Babesia, Borrelia miyamotoi, |
| 237 | Powassan virus, or other) be suspected in an individual with Lyme disease? |
| 238 | 62. Should individuals be tested for Lyme disease if they lack plausible exposure in an endemic |
| 239 | region? |
| 240 | 63. What is the preferred antibiotic treatment regimen for borrelial lymphocytoma? |
| 241 | 64. What is the preferred antibiotic treatment regimen for acrodermatitis chronicum |
| 242 | atrophicans? |
| 243 | 65. What is the preferred treatment regimen for STARI (the southern tick associated rash |
| 244 | illness)? |
| 245 | 66. Which tests can aid in the diagnosis of erythema migrans? Which is the diagnostic strategy |
| 246 | of choice, and when should alternatives be considered? |
| 247 | 67. Which tests can aid in the diagnosis of early neuroborreliosis with central-nervous system |
| 248 | involvement? What is the diagnostic strategy of choice, and when should alternatives be |
| 249 | considered? |
| 250 | 68. Which tests can aid in the diagnosis of early neuroborreliosis without central-nervous |
| 251 | system involvement? What is the diagnostic strategy of choice, and when should |
| 252 | alternatives be considered? |
| 253 | 69. Which tests can aid in the diagnosis of late neuroborreliosis? What is the diagnostic |
| 254 | strategy of choice, and when should alternatives be considered? |

| 255 | 70. Which tests can aid in the diagnosis of Lyme carditis? What is the diagnostic strategy of |
|-----|---|
| 256 | choice, and when should alternatives be considered? |
| 257 | 71. What is the appropriate diagnostic strategy for patients with acute, nonspecific febrile |
| 258 | illnesses in whom Lyme disease is suspected? |
| 259 | 72. Which tests can aid in the diagnosis of Lyme arthritis? What is the diagnostic strategy of |
| 260 | choice, and when should alternatives be considered? |
| 261 | 73. Which tests can aid in the diagnosis of acrodermatitis chronica atrophicans? What is the |
| 262 | diagnostic strategy of choice, and when should alternatives be considered? |
| 263 | 74. Which tests can aid in the diagnosis of borrelial lymphocytoma? What is the diagnostic |
| 264 | strategy of choice, and when should alternatives be considered? |
| 265 | 75. Are non-standard or unvalidated tests for Lyme disease (including urine testing, CD57, |
| 266 | lymphocyte transformation tests, unconventional culture techniques, and non-standardized |
| 267 | serologic tests) acceptable for the diagnosis of Lyme disease? |
| 268 | 76. Are there serodiagnostic testing strategies that could substitute for standard 2-tiered |
| 269 | serologic testing? |
| 270 | 77. Should the results of a <i>B. burgdorferi</i> ELISA be reported independently of the overall 2-tier |
| 271 | test result? |
| 272 | 78. Should the presence, absence, or intensity of individual bands be routinely listed in a <i>B</i> . |
| 273 | burgdorferi Western blot test report? |
| 274 | 79. If a first tier ELISA is performed and is negative, is it ever indicated to perform second tier |
| 275 | Western immunoblots? |

276 80. Under what circumstances is a positive serologic test for Lyme disease insufficient to justify
277 treatment for Lyme disease? (In other words, what is the positive predictive value of a Lyme
278 test) Should asymptomatic patients be treated solely based on a positive test for Lyme
279 disease?
280 81. Under what circumstances should a patient be treated for Lyme disease despite a negative

serologic test? (In other words, what is the negative predictive value of a Lyme test)

Table 1. Disclosures of Relationships

| Author | Primary employer | Intellectual Property | Advisory/ Consult | Speakers | Stocks | Expert Testimony | Other | Research Grants/Contracts | Organizational Benefit | Activities W/Other Orgs | Family |
|------------------|--|--------------------------|--|----------|----------------|---|-------|--|---------------------------|--|--|
| Aguero-Rosenfeld | New York University School of Medicine | NR | NR | NR | NR | Legal testimony/consulta tion - Lyme | NR | NR | | NR | NR |
| Auwaerter | Johns Hopkins University School of Medicine | NR | Unrelated - FDA Unrelated - Genentech Unrelated -Cerexa Unrelated - Medscape, Content Provider/ID Advisory; Unrelated -Johns Hopkins POC-IT ABX Guide - editor/content | | Unrelated -JNJ | On rare occasions (3 in last ten years), related to expert opinion regarding lyme disease | | Cerexa – NXL-102; Fisher Center for Environmental ID – Lyme Studies | | Medscape – Advisory Board; FDA – Advisory Board | Spouse – Venture Capital (Biologics, Cardioloogy, nothing ID- related) |
| Baldwin | Geisinger Medical Center | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| Belani | Children's Hospitals and Clinics of Minnesota | NR | NR | NR | NR | NR | NR | NIH RO1(PI at Duke University) - PFN RO1Multicenter study to understand the epidemiology diagnosis and treatment of Pediatric Invasive fungal infections; Internal Research Grant Program at Children's Hospitals and Clinics of Minnesota-Procalcitonin for early detection of septic arthritis (Coinvestigator) | | NR | NR |
| Bockenstedt | Yale University, | NR | NR | NR | NR | NR | NR | NIH/NIAID: R01AI085798: Real-Time Imaging of Vector-Borne Lyme Borreliosis Pathogenesis & Persistence N01AI50031: Innate Immune Pathways in Elderly & Immunosuppressed Populations R33AI100191-03: A New Cytokine-Based Immunoassay for the Diagnosis of Lyme Borreliosis R44AI096598-01: Diagnostic Assays for Early Lyme Borreliosis Using In-Vivo Expressed Antigens 1R43 AI096628-01: A Lyme | NR | NR | NR |

| Author | Primary employer | Intellectual Property | Advisory/ Consult | Speakers | Stocks | Expert Testimony | Other | Research Grants/Contracts | Organizational Benefit | Activities W/Other Orgs | Family |
|--------|-----------------------------------|--|----------------------|----------|--------|---------------------|-------|---|---------------------------|--|--------|
| | | | | | | | | Disease Vaccine Using Newly Identified In Vivo Expressed Antigens R21 AI109486-01A1: Development of Novel Therapeutics for Babesia Microti Infection R44 AI085725-01: A Serologic Assay to Measure Successful Lyme Borreliosis Antibiotic Therapy NIH/NIAMS: P30AR046032: The Entheseal Response to Borrelia burgdorferi in Murine Lyme Borreliosis | | | |
| Branda | Massachusetts General Hospital | • Partners Healthcare, I am a co-inventor on an application for a patent to protect intellectual property. The application is entitled "Compositions and Methods for the Detection of Bacterial Infections Associated with Lyme Disease." Our group is seeking patent protection for an idea for a point- of-care testing device that could be used in the diagnosis of Lyme disease and other tick-borne infections. The patent application was filed on our behalf by Partners Healthcare, which is the parent | NR | NR | NR | NR | NR | Alere, IncMassachusetts General Hospital (MGH); Diagnosis and Pathogenesis of Early Lyme Disease bioMerieux, Inc - | NR | Journal of Clinical Microbiology - Editorial Board | NR |

| Author | Primary employer | Intellectual Property | Advisory/ Consult | Speakers | Stocks | Expert Testimony | Other | Research Grants/Contracts | Organizational Benefit | Activities W/Other Orgs | Family |
|----------|--|--|---|----------|--------|--|-------|--|---------------------------|-------------------------|-----------------------|
| | | company of Massachusetts General Hospital, my employer. A patent has not yet been issued and no money has been paid either directly to me or to my institution in relation to this patent application. • Unrelated – AdvanDx, Provided consultation about current assays and development of | | | | | | | | | |
| Bowie | University of British Columbia | future assays. NR | NR | NR | NR | On behald of AMMI – Canada - Canadian Senate Subcommittee reviewing Bill C- 442, An Act respecting a National Lyme Disease Strategy | NR | Canadian Institute of Health Research - Active Surveillance of Adverse Events Following Immunization Among Healthcare Workers Immunized with the Influenza Vaccine GSK-Sentinel surveillance for influenza requiring hospital admission in Canadian adults Pfizer Canada-Sentinel surveillance for pneumococcal disease among hospitalized Canadian adults CIHR – Ecosystem approach to antibiotic stewardship - Closed | NR | NR | NR |
| Clifford | Washington University in St. Louis | NR | Unrelated - Biogen – DSMB Unrelated - Takeda/Millennium-Adjudication Committee, FDA Unrelated - Amgen-Adjudication Committee, FDA Unrelated - Amgen – adjudication panel Unrelated - Pfizer – | | NR | NR | NR | NIH-NIAIA-AIDS Clinical Trials Unit NIH-NIMH, NINDS Charter Study; NIH-NINDS-NeuroNEXT Clinical Trial Network NIH-NIA-Dominantly INherited Alzheimer Study; Alzheimer's Association- Dominantly inherited Alzheimer Study; NIH-NINR-R01 for HIV in | NR | NR | Spouse – J&J Stock |

| Author | Primary employer | Intellectual Property | Advisory/ Consult | Speakers | Stocks | Expert Testimony | Other | Research Grants/Contracts | Organizational Benefit | Activities W/Other Orgs | Family |
|-------------|---|--------------------------|--|----------|---|---------------------|-------|--|---------------------------|---|--------|
| | | | DSMB Unrelated - Genentech — Adjudication member Unrelated - Genzyme - DSMB Unrelated — GSK, PML Adjudication Committee Unrelated — Merck, DSMB member Unrelated — Inhibikas, Consultant Unrelated - BMS, PML Adjudication committee | | | | | adolescents , elders and frailty | | | |
| DiMario | CT Children's Medical Center, Hartford , CT | NR | NR | NR | NR | NR | NR | Novartis - A three-arm, randomized, double-blind, placebo-controlled study of the efficacy and safety of two troughranges of everolimus as adjunctive therapy in patients with tuberous sclerosis complex (TSC) who have refractory partial-onset seizures. | NR | NR | NR |
| Ericsson | University of Texas Medical School at Houston | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| Falck-Ytter | VA Medical Center, Cleveland; University Hospitals of Cleveland | NR | NR | NR | NR | NR | NR | Cleveland Research and Education Foundation: Telaprevir vs. Boceprevir - a pragmatic RCT | NR | NR | NR |
| Halperin | Atlantic Health System | NR | NR | NR | Unrelated - Abbott Labs Unrelated - Abbvie Unrelated - Merck Unrelated - J&J | Legal-Lyme | NR | CDC-Atlantic Health-Serum Samples of MS pts from Lyme Endemic areas | NR | Neurology (journal)- Editorial Board Member | NR |
| Krause | Yale School of Public Health | NR | NR | NR | NR | NR | NR | Gordon and Llura Gund Foundation: Human Tick- borne Diseases Research NIH - Immunetics, Inc. grants (Andrew Levin, PI) - (NHLBI) Title: Screening and Confirmatory Test for Human Babesia - Closed NIH Immunetics, Inc. grants- (NHLBI) Title: Babesia Antigen Detection Assay for Blood | NR | NR | NR |

| Author | Primary employer | Intellectual Property | Advisory/ Consult | Speakers | Stocks | Expert Testimony | Other | Research Grants/Contracts | Organizational Benefit | Activities W/Other Orgs | Family |
|----------|--|--------------------------|----------------------|----------|---|---------------------|-------|---|---------------------------|---|-----------------------|
| | | | | | | | | Screening - Closed NIH/NIAID R43AI096598: Diagnostic Assays for Early Lyme Borreliosis Using In-Vivo Expressed Antigens NIH/NIAID R33-AI100191: A New Cytokine-Based Immunoassay for the Diagnosis of Lyme Disease NIH/NIAID R43AI085725: A serologic assay to measure successful Lyme borreliosis antibiotic therapy NIH/NIAID R21 AI09486-01A1: Development of novel therapeutics for Babesia microti infection | | | |
| Lantos | Duke University Health System Duke University School of Medicine | NR | NR | NR | NR | NR | NR | Mentored Clinician-Scientist Career Development Award: NIH / NCATS award number KL2TR001115 | NR | NR | NR |
| Liang | Brigham and Women's Hospital Boston VA | NR | NR | NR | Unrelated - Sequenom Unrelated - J&J | NR | NR | Arthritis Foundation-Brigham and Women's Hospital; NIH-NIH-Brigham and Women's Hospital Veterans Affairs-Boston VA Healthcare | NR | FDA Advisory Panel; Research Grant Council of Hong Kong-Reviewer Lupus Clinical Trials Consortium- Board member | Spouse – Stock J&J |
| Meissner | Tufts Medical Center-Tufts School of Medicine | NR | NR | NR | NR | NR | NR | NR | NR | AAP – COID Consultant; CDC Workgroups; NIH DSMB's | NR |
| Nigrovic | Boston Children's Hospital Division of Emergency Medicine | NR | NR | NR | NR | NR | NR | NICHD: Fluid therapy and cerebral injury in pediatric diabetic ketoacidosis U01HD06417-01 [Kuppermann/Glaser] Site PI Goal: To study fluid therapy and risk of cerebral injury for children in diabetic ketoacidosi PPQI Foundation Cost effective management of minor blunt head trauma Novel diagnostics for Lyme disease Boston Children's Hospital Pilot Research Grant | NR | Decision editor- Annals of Emergency Medicine | NR |

| Author | Primary employer | Intellectual Property | Advisory/ Consult | Speakers | Stocks | Expert Testimony | Other | Research Grants/Contracts | Organizational Benefit | Activities W/Other Orgs | Family |
|-----------|--|--------------------------|----------------------|----------|--|---------------------|--|--|---------------------------|---|--------|
| | | | | | | | | Harvard Catalyst Novel Serologic diagnostics for Lyme disease | | | |
| Nocton | Medical College of Wisconsin | NR | NR | NR | NR | NR | NR | Abbvie Laboratories A Longterm multicenter longitudinal post-marketing observational registry of Humira (adalimumab) in children with active juvenile idiopathic arthritis (STRIVE REGISTRY); Bristol-Meyers-Squibb- An Observational Registry of Abatacept in Patients with Juvenile Idiopathic Arthritis NIH Gene Expression in Pediatric Arthritis Foundation Childhood Arthritis Foundation Childhood Arthritis and Rheumatology Research Alliance Registry Arthritis Foundation, Learning Networks, ACR, AHRQ, and Centered for Education and Research on Therapeutics - Pediatric Rheumatology Care and Outcome Improvement Network NIH - Macrophage Activation Syndrome in Systemic Juvenile Idiopathic Arthritis | NR | NR | NR |
| Pruitt | University of Penn | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| Rips | Consumer Rep, Omaha, NE | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| Rosenfeld | Yale University School of Medicine | NR | NR | NR | Abbott Unrelated - GE | NR | Unrela ted - Boston Scienti fic, Fellow ship Suppo rt Unrela ted - Medtr onic Fellow ship Suppo | Boehringer Ingelheim Pharmaceuticals, Inc – GLORIA-AF | NR | Heart Rhythm Society - Member, Patients and Caregivers Subcommittee, Education Committee; Connecticut American College of Cardiology- Council Member | NR |

| Author | Primary employer | Intellectual Property | Advisory/ Consult | Speakers | Stocks | Expert Testimony | Other | Research Grants/Contracts | Organizational Benefit | Activities W/Other Orgs | Family |
|----------|---|--------------------------|---|----------|--------|---------------------|---|--|---------------------------|---|--------|
| | | | | | | | rt • Unrela ted - St. Jude Fellow ship Suppo rt | | | | |
| Rumbaugh | Self Employed | NR | NR | NR | NR | NR | NR | Center for AIDS Research: Neuropathogenesis of Cryptococcal Meningitis Biogen Idec: Stratify-2, DECIDE Hoffman-La Roche LTD: OPERA Sun Pharma: Baclofen ER Capsules (GRS) in Subjects With Spasticity Due to Multiple Sclerosis Genzyme: CARE MS | NR | NR | NR |
| Savoy | Christiana Care Health System | NR | Unrelated - Highmark Health Equity Physician Advisory Council: provide advice regarding Highmark's current activities around health equity (e.g., upcoming outreach efforts or events) AAFP: Adolescent Immunization Project Advisor | NR | NR | NR | AAFP: Honoraria for attending Commissio n meeting and teaching at annual assembly | NR | NR | Delaware Academy of Family Physicians, Editor of DelFamDoc journal; AAFP: Commission member. | NR |
| Sood | North Shore LIJ Health System | NR | NR | NR | NR | NR | NR | NIH - DMID/Collaborative Antiviral Study Group/Herpes simplex prenatal diagnosis, CMX001 in neonatal herpes, Oral valganciclovir in CMV, Ganciclovir in premature infants | NR | NR | NR |
| Steere | Mass General Hospital Harvard Medical School | NR | Unrelated – Baxter Bioscience Unrelated – Institute of Systems Biology Immunetics | NR | NR | NR | NR | NIH/NIAID: Autoimmunity to ECGF in Lyme; ACR: Identification of HLA-DR – presented pertides in synovial tissue; Mathers foundation – Identification of autoantigenic epilopes English Ronter Mitchell Foundation: Studies of Lyme disease | NR | NR | NR |

| Author | Primary employer | Intellectual Property | Advisory/ Consult | Speakers | Stocks | Expert Testimony | Other | Research Grants/Contracts | Organizational Benefit | Activities W/Other Orgs | Family |
|---------|--|--------------------------|------------------------------------|----------|--------------------|---|---|--|---------------------------|--|--------|
| | | | | | | | | Dunsworth –Fitzgerald Foundation: Studies of rheumatoid arthritis | | | |
| Strle | University Medical Center Ljubljana, Slovenia | NR | NR | NR | NR | NR | NR | Slovenian Research Agency (ARRS): UMC Ljubljana/Diseases and causative agents of tick-borne infections (P3-0296); Slovenian Research Agency (ARRS): UMC Ljubljana/Duration of antimicrobial treatment of erythema migrans (J3-3636); Slovenian Research Agency (ARRS): Medical Faculty Ljubljana/Classical and modern approaches to etiology determination of gastroenteritis (J3-4252); Slovenian Research Agency (ARRS): UMC Ljubljana/Proteomic and aptamer-based approaches for study of host-pathogen interaction in staphylococcal and clostridial infections (J3-5500) | NR | NR | NR |
| Sundel | Boston Children's Hospital | | NR | NR | NR | Unrelated - Conway, Homer & Chin-Caplan, P.C. – Vaccine Injury | Unrelated - UpToDate – Content Editor | NIAMS-RFA-AR-12-006 - Empowering Physicians with Evidence-Based Decision Support for Pediatric Rheumatologic Diagnoses | NR | NR | NR |
| Tsao | Michigan State University | NR | NR | NR | NR | NR | Michigan Lyme Disease Association Contributio n to research program | National Science Foundation: Michigan State University/Dept of Fisheries & Wildlife/Collaborative Research: Testing Alternative Hypotheses for Gradients in Lyme disease in the Eastern U.S.: Climate, Host National Science Foundation: Michigan State University/Dept of Fisheries & Wildlife/Hybridization and heritability of host-seeking behavior of nyphal Ixodes scapularis ticks, the vector of Lyme disease | NR | Ticks and Tickborne Diseases: Associate Editor | NR |
| Wormser | New York Medical | NR | Baxter – DSMB, | NR | Unrelated - Abbott | Legal firms- | NR | CDC: | NR | Am Lyme Disease | NR |

| Author | Primary employer | Intellectual Property | Advisory/ Consult | Speakers | Stocks | Expert Testimony | Other | Research Grants/Contracts | Organizational Benefit | Activities W/Other Orgs | Family |
|--------|---|--------------------------|--|----------|--------|---|-------|--|---------------------------|--|--------|
| | College | | Advised on clinical trials; • Legal firms— Lyme | | | Lyme; • Missouri Board of Registration for the Healing Arts-Lyme | | Subjective Symptoms after Treatment of Lyme Disease Gene Expression Biomarkers for Diagnosis of Lyme Disease Contracts to provide sera on various types of lyme cases NIH: The Health Burden of a Recently Discovered Borrelia Spirochete Metabolic Biomarkers and biosignatures for improved diagnosis of Lyme disease. Screening and confirmatory test for human babesia Immunetics, Inc: Various studies on the 06 Lyme test on diagnostics for babesiosis; BioMerieux Diagnostic test for Lyme disease BioRad Diagnostic test for Lyme disease (more than 2 yrs ago) DiaSorin, Inc Diagnostic test for Lyme disease (more than 2 yrs ago) Rarecyte Inc., Diagnostic test for Lyme disease Institute for Systems Biology Biomarkers for outcome in | | Foundation— Board; CID – Ed Board VBZD – Ed Board Ticks & Tick Borne Dis – Ed Board | |
| Zemel | Connecticut Children's Medical Center | NR | Unrelated – Novartis Promotional Speakers Bureau | NR | NR | NR | NR | Lyme disease NR | NR | NR | NR |

Abbreviations: NR-None reported

Infectious Diseases Society of America Disclosure of Interests Form for Clinical Practice Guideline Panel Members

Instructions: Please carefully read, complete, sign, date and submit this form. *Please note that this form and the data herein can be saved to your computer for future use/updating.*

All guideline panel chairs and members should act in the best interest of IDSA, AANI and ACRh, its membership, and the public. Decisions should not be influenced by personal financial interests or by other extraneous considerations. Each guideline panel member has a high duty and obligation to disclose any potential conflict of interest and to abstain from any decision where a conflict of interest exists. A potential conflict of interest exists if a guideline panel member has a financial or other beneficial interest that might bias his or her decisions or actions concerning matters before the Panel. In the interest of full disclosure, any relationship with a pharmaceutical, biotechnology, medical device, or health related company or venture should be disclosed.

Acknowledgement of this policy and disclosure filing will be done by each panel member prior to the initiation of the guideline development process and annually thereafter until publication of the guideline. In between this filing, it is the responsibility of each individual to disclose in writing any new potential conflicts of interest. Copies of all filings will be kept at the IDSA headquarters office and will be listed in summary format in the Acknowledgements section of the published work (per *Clinical Infectious Diseases* policy). Please consider your activities and financial relationships/investments that are *current*, *future and for the preceding two years* when responding. Attach additional pages if necessary.

| 1. | NAME | 2. | DATE | | 3. | IDSA ACTIVITY BEING CONSIDERED FOR (e.g., guideline panel on X) |
|-----|---|--------|--------------------|-------------------------------|--------|---|
| | <u>_</u> | | | | | <u> </u> |
| | | | | | | |
| 4. | PRIMARY EMPLOYMENT (and other salaried positions): If | self-e | employed, but form | ally paid through a corporati | ion oı | r other entity, indicate "self-employed" under Employer. |
| Emp | ployer | | | Position | | |
| | | | | | | |
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If you have NO relationships, investments, activities, etc., to report please go directly to the last page.

FOR INTERESTS ≤ 10,000

| 5. FINANCIAL R | ELATIONSHIPS/INCOME | (For Interests ≤ \$10,000) | | |
|----------------------------------|---|---|---|--|
| Company/ Organization Name | Does this company have a product (drug, device, etc) related to the topic? | Is this relationship Current or Past? | Check all that apply and include description where appropriate | Paid to You/Your Institution? |
| | | | Advisory/Consultant Role - What was the nature of your Advisory/Consultant Role (select): Click to Select Describe: | Paid directly to me Paid to my institution |
| | | ☐ Current – currently engaged with company; | Promotional (non-CME) Speakers Bureau - What was the nature of your Promotional (non-CME) Speakers Bureau Role: Describe: | Paid directly to me Paid to my institution |
| _ | Yes (provide | ➤ If current, are you willing to divest | ☐ Stocks/Bonds | Paid directly to me Paid to my institution |
| | drug/device name): | yourself of this relationship until after | Honoraria (describe): | Paid directly to me Paid to my institution |
| | □No | the guideline is published? Yes; No Past - no longer engaged with company | Expert Testimony (describe): | Paid directly to me Paid to my institution |
| | | | Ownership Interests (describe): | Paid directly to me Paid to my institution |
| | | | ☐ Intellectual Property (e.g., Patent, copyright, license (planned, pending or issued)) (describe): | Paid directly to me Paid to my institution |
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| | | | Advisory/Consultant Role - What was the nature of your Advisory/Consultant Role (select): Click to Select Describe: | Paid directly to me Paid to my institution |
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| 5. FINANCIAL R | ELATIONSHIPS/INCOME | (For Interests <u><</u> \$10,000) | | |
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| Company/ Organization Name | Does this company have a product (drug, device, etc) related to the topic? | Is this relationship Current or Past? | Check all that apply and include description where appropriate | Paid to You/Your Institution? |
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| 5. FINANCIAL R | ELATIONSHIPS/INCOME | (For Interests <u><</u> \$10,000) | | | | | | | | | | | | |
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FOR INTERESTS \$10,001 - \$25,000

| 6. FINANCIAL R | ELATIONSHIPS/INCOME | (For Interests \$10,001 - \$25 | 5,000) | |
|----------------------------------|--|--|--|---|
| Company/ Organization Name | Does this company have a product (drug, device, etc) related to the topic? | Is this relationship Current or Past? | Check all that apply and include description where appropriate | Paid to You/Your Institution? |
| | ☐ Yes (provide drug/device name): ——— | □ Current – currently engaged with company; ➤ If current, are you willing to divest yourself of this relationship until after the guideline is published? □ Yes; □ No □ Past - no longer engaged with company | ☐ Advisory/Consultant Role - What was the nature of your Advisory/Consultant Role (select): Click to Select Describe: ☐ Promotional (non-CME) Speakers Bureau - What was the nature of your Promotional (non-CME) Speakers Bureau Role: Describe: ☐ Stocks/Bonds ☐ Honoraria (describe): ☐ Expert Testimony (describe): ☐ Ownership Interests (describe): ☐ Intellectual Property (e.g., Patent, copyright, license (planned, pending or issued)) (describe): ☐ Other Remuneration (describe): | Paid directly to me Paid to my institution Paid directly to me |
| | ☐ Yes (provide drug/device name): ☐ No | ☐ Current – currently engaged with company; > If current, are you willing to divest yourself of this relationship until after the guideline is published? ☐ Yes; ☐ No ☐ Past - no longer engaged with company | | Paid to my institution Paid directly to me Paid directly to me Paid to my institution Paid directly to me |

| 6. FINANCIAL R | ELATIONSHIPS/INCOME | (For Interests \$10,001 - \$25 | 5,000) | |
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| Company/ Organization Name | Does this company have a product (drug, device, etc) related to the topic? | Is this relationship Current or Past? | Check all that apply and include description where appropriate | Paid to You/Your Institution? |
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| 6. FINANCIAL RELATIONSHIPS/INCOME (For Interests \$10,001 - \$25,000) | | | | | | |
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| Company/ Organization Name | Does this company have a product (drug, device, etc) related to the topic? | Is this relationship Current or Past? | Check all that apply and include description where appropriate | Paid to You/Your Institution? | | |
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FOR INTERESTS ≥ 25,001

| 7. FINANCIAL RELATIONSHIPS/INCOME (For Interests ≥ \$25,001) | | | | |
|--|--|---|---|--|
| Company/ Organization Name | Does this company have a product (drug, device, etc) related to the topic? | Is this relationship Current or Past? | Check all that apply and include description where appropriate | Paid to You/Your Institution? |
| | ☐ Yes (provide drug/device name): ——— ☐ No | ☐ Current – currently engaged with company; ➤ If current, are you willing to divest yourself of this relationship until after the guideline is published? ☐ Yes; ☐ No ☐ Past - no longer engaged with company | Advisory/Consultant Role - What was the nature of your Advisory/Consultant Role (select): Click to Select Describe: | Paid directly to me Paid to my institution |
| | | | Promotional (non-CME) Speakers Bureau - What was the nature of your Promotional (non-CME) Speakers Bureau Role: Describe: | Paid directly to me Paid to my institution |
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| | | | Honoraria (describe): | Paid directly to me Paid to my institution |
| | | | Expert Testimony (describe): | Paid directly to me Paid to my institution |
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| 7. FINANCIAL RELATIONSHIPS/INCOME (For Interests > \$25,001) | | | | |
|--|--|--|--|---|
| Company/ Organization Name | Does this company have a product (drug, device, etc) related to the topic? | Is this relationship Current or Past? | Check all that apply and include description where appropriate | Paid to You/Your Institution? |
| | ☐ Yes (provide drug/device name): ——— ☐ No | ☐ Current – currently engaged with company; > If current, are you willing to divest yourself of this relationship until after the guideline is published? ☐ Yes; ☐ No ☐ Past - no longer engaged with company | ☐ Advisory/Consultant Role - What was the nature of your Advisory/Consultant Role (select): Click to Select Describe: ☐ Promotional (non-CME) Speakers Bureau - What was the nature of your Promotional (non-CME) Speakers Bureau Role: Describe: ☐ Stocks/Bonds ☐ Honoraria (describe): ☐ Expert Testimony (describe): ☐ Ownership Interests (describe): ☐ Intellectual Property (e.g., Patent, copyright, license (planned, pending or issued)) (describe): ☐ Other Remuneration (describe): | Paid directly to me Paid to my institution Paid directly to me Paid directly to me Paid directly to me Paid to my institution Paid directly to me Paid directly to me Paid directly to me |
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| 7. FINANCIAL RELATIONSHIPS/INCOME (For Interests ≥ \$25,001) | | | | |
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| Company/ Organization Name | Does this company have a product (drug, device, etc) related to the topic? | Is this relationship Current or Past? | Check all that apply and include description where appropriate | Paid to You/Your Institution? |
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| I HAVE NO INTERESTS TO DISCLOSE | | | | |
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| | | | | |
| I certify that I have read IDSA's Conflict-of-Interest Policy and have disclosed ALL declarable relationships as defined therein, if any. | | | | |
| E-Signature | Date | | | |

Deliberate failure to comply with this disclosure requirement may result in a disqualification from this and future participation in IDSA-sponsored activities.

REFERENCES

1

- 2 1. Halperin JJ, Shapiro ED, Logigian E, et al. Practice parameter: treatment of nervous system Lyme
- disease (an evidence-based review): report of the Quality Standards Subcommittee of the American
- 4 Academy of Neurology. Neurology **2007**; 69:91-102.
- 5 2. Halperin JJ, Logigian EL, Finkel MF, Pearl RA. Practice parameters for the diagnosis of patients
- 6 with nervous system Lyme borreliosis (Lyme disease). Quality Standards Subcommittee of the American
- 7 Academy of Neurology. Neurology **1996**; 46:619-27.
- 8 3. Wormser GP, Dattwyler RJ, Shapiro ED, et al. The clinical assessment, treatment, and prevention
- 9 of lyme disease, human granulocytic anaplasmosis, and babesiosis: clinical practice guidelines by the
- 10 Infectious Diseases Society of America. Clin Infect Dis 2006; 43:1089-134.
- 11 4. Wormser GP, Nadelman RB, Dattwyler RJ, et al. Practice guidelines for the treatment of Lyme
- disease. The Infectious Diseases Society of America. Clinical infectious diseases : an official publication of
- the Infectious Diseases Society of America **2000**; 31 Suppl 1:1-14.
- 14 5. Lantos PM, Charini WA, Medoff G, et al. Final report of the Lyme disease review panel of the
- 15 Infectious Diseases Society of America. Clinical infectious diseases : an official publication of the
- 16 Infectious Diseases Society of America **2010**; 51:1-5.
- 17 6. Brouqui P, Bacellar F, Baranton G, et al. Guidelines for the diagnosis of tick-borne bacterial
- diseases in Europe. Clinical microbiology and infection: the official publication of the European Society
- of Clinical Microbiology and Infectious Diseases **2004**; 10:1108-32.
- No authors listed. Guidelines for laboratory evaluation in the diagnosis of Lyme disease.
- 21 American College of Physicians. Annals of internal medicine 1997; 127:1106-8.
- 22 8. Guyatt GH, Oxman AD, Vist GE, et al. GRADE: an emerging consensus on rating quality of
- evidence and strength of recommendations. BMJ **2008**; 336:924-6.
- 24 9. Committee on Standards for Developing Trustworthy Clinical Practice Guidelines. Clinical
- 25 Practice Guidelines We Can Trust. Washington, DC: Institute of Medicine, National Academies Press,
- 26 **2011**.