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## Jane Marke

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The Tick Borne Disease Working Group has put out its report, and IDSA is upset...They criticize the group and outline their complaints: They do not want further research into treatment with antibiotics, urge use of surveillance criteria for diagnosis, while at the same time admitting the failure of current tests.

They propose to replace these with their own: CDC is developing next-generation testing. It's time for this agency to get out of the business of patenting tests and treatments which it can then mandate. Many companies are working on next-gen, but their tests will never make market when they compete with CDC/FDA/IDSA working on their own and making policy.

Main Points:

- 1) The Report: CDC criteria for epidemiology reporting not be used for clinical diagnosis. IDSA: they SHOULD be used and clinical diagnosis must be based on LABORATORY testing. (read: Elisa, patent owned by CDC principals)
- 2) The Report: There is a need for further research on the best antibiotic approach: IDSA: There is no need for research on antibiotic treatment since "There is clear, widely accepted scientific evidence indicating that a 10-28 day course of antibiotics, depending on the stage, will kill Lyme disease bacterium in humans in all but the rarest of cases."
- 3) IDSA: The letter states: "Lyme disease causes well-characterized presentations". This is contrary to everything we know about Lyme. Most of you reading this know this well. The host/coinfections/immune status all determine the presentation.
- 4) IDSA: "The current FDA-approved serologic test works best for patients who have been infected for at least two to four weeks.....". "In patients who are just infected, the diagnosis is best made if the characteristic rash...." That's true, inasmuch as tests are not positive in the first weeks after infection, ever. But only a small percent get the rash. If we rely on a rash plus testing, we'll miss over 60% of early cases.
- 5) IDSA: On where research is needed: "As serologic tests may remain positive for decades after successful treatment of Lyme disease, development of a test that provides supportive evidence that a patient has been...cured of infection would be of great benefit". REALLY!. They want research funds directed to a test to prove that patients with symptoms after a 12-21 day course of antibiotics who are still sick have been cured. This has to be the most inappropriate way to spend our tax dollars. Proving sick patients are well. But no research on treatment. (since they don't believe there are patients who are unwell despite current recommendations.)
- 6) Quote: "The CDC is also developing next-generation direct diagnostic test....to improve on current serological tests". So here they admit that current serological tests are insufficient, and propose we wait for the new ones they are developing and will hold the patent for. Like the C6 Elisa. CDC/FDA/NIH/IDSA should not be in the business of patenting tests they then have the power to turn into policy. This is work scientists working in academia and privately should be able to bring to market without competing with government agencies. We need to remove the profit the funding agencies receive by reversing Bahr-Dole.

