

## **“The Media Must Exercise Greater Responsibility in Reporting Information on Lyme Disease”**

When Pope Francis landed at Kennedy Airport during his visit to the U.S. in September, 2015, 12-year-old Julia Bruzzese from Brooklyn, NY, was there to greet him in her wheel chair. She came to get his blessing, hoping that she soon might be cured of her illness and be able to walk again. Though once an active child, she had been sick for the past 4 months and now was unable to walk after losing all feeling in her legs. When a physician from Albany, NY, saw this touching scene on TV, he kindly offered to treat her free of charge at his private practice in Albany. Attempts to have her treated intravenously at home, rather than distant Albany, failed because their health insurance company denied coverage, for the third time. Denial of coverage was based in part on the results of standard diagnostic tests which were negative for Lyme disease, the disease she was believed to have and for which she was to be treated.

The news report of this event (1) raises several questions that were either not addressed or addressed incorrectly. Here are a few that one would hope a competent investigative reporter might have asked to better inform his/her audience, rather than add to the confusion about Lyme disease:

1. What diagnostic tests were done and what were the results obtained?
2. If testing was done by the conventional and FDA/CDC-approved 2-tier test for Lyme disease and the results were negative, upon what was the diagnosis of Lyme disease based? Was it based solely on non-specific symptoms that could be attributed to other medical conditions? The use of another non-validated diagnostic test? Or, was it based on the appearance of an EM rash that is considered to be sufficiently diagnostic for Lyme disease to justify recommended antibiotic therapy that most – if not all—health insurance companies will pay for?
3. We are told that the diagnosis was made by a “specialist”. Was the “specialist” a physician who is board certified in the specialty of infectious diseases, or a general practitioner commonly referred to as a “Lyme literate physician” (LLMD) who mainly sees patients who come to him/her because they believe that they may have Lyme disease and no one else will see them?
4. Most -- if not all -- health insurance companies will cover 2-tier testing for Lyme disease, if the risk of infection is reasonable; however, of note, urban Brooklyn, NY, is not endemic for Lyme disease.
5. Most health insurance companies also will cover recommended treatments for correctly diagnosed Lyme disease; these include the intravenous administration of antibiotics (e.g., ceftriaxone) for patients with certain neurological symptoms. Since such factors would not normally have been grounds for denial of payment, could other factors have been involved in making such a determination? For example, in most cases, health insurance companies will not cover unorthodox therapeutic approaches, i.e., therapeutic approaches with no supporting evidence to indicate that they are beneficial and safe, especially when test results are negative or inconclusive for the diagnosis of Lyme disease. Was coverage denied because the proposed treatment regimen was considered to be of no proven benefit, which appears to have been the case here as stated by the reporter, unjustified in the absence of a valid diagnosis of Lyme disease, or both?

6. Bilateral lower extremity paralysis is extremely rare-- if it occurs at all—in patients with Lyme disease. Since the results of laboratory tests for the diagnosis of Lyme disease were negative, were other possibilities/tests considered to explain such symptoms? If not, wasn't this child denied the opportunity to get the medical treatment she deserved by obsessively focusing on Lyme disease as the one and only viable possibility for her symptoms? Perhaps this is the most tragic outcome of this sad story.
7. We are told that the patient wrote a letter to Governor Cuomo, asking him to try to find a way to compel the health insurance company to pay medical expenses for the treatment of her Lyme disease, in the absence of a positive diagnosis. Under the circumstances described above, is such a request justified? Should a health insurance company be compelled to pay for unproven – and perhaps unsafe—treatment regimens administered to patients who, in the absence of a positive diagnostic test result, may not even have Lyme disease in the first place? It should be noted that in December, 2014, Gov. Cuomo signed a bill that “prohibits the State Office of Professional Conduct, from investigating a licensed physician based solely upon the recommendation or provision of treatment that is not universally accepted by the medical profession” (2). Although the medical profession would not ordinarily object to the use of alternative treatment regimens, as long as there is ample evidence to indicate that they are beneficial and safe, the bill signed by Gov. Cuomo does not include such provisions or safeguards. The net result of such unwise legislation would be to prevent medical review boards from disciplining a physician for malpractice, an outcome that surely would not be in the best interest of safeguarding the public health.

In the NBC report (1), much is said about the unreliability of diagnostic tests for Lyme disease, a statement that is based on ignorance and is not substantiated by the facts. This issue was discussed at great length elsewhere (3); it will not be elaborated upon here. Suffice it to say that there is abundant information to indicate that a seropositive rate of 30% is typical during the very early stages of infection, at the time an EM rash is present, and when serum antibody levels specific for *Borrelia* are low and/or below the minimal level of detection; patients with many weeks or months of infection, are invariably seropositive by 2-tier testing, unless there is a laboratory error or the patient has a humoral immunodeficiency disorder. This is why 2-tier testing for Lyme disease is not recommended in patients with the EM rash; this is the only time during infection when 2-tiered testing is insensitive and not advised (4,5).

Although much was said about flaws in the guidelines proposed by the Infectious Diseases Society of America or IDSA (6), to cast doubt on their value, it should be noted that they are universally accepted and/or recommended by national and international experts on Lyme disease. This includes: the European Federation of Neurological Societies (7); the European Union of Concerted Action on Lyme *Borreliosis* (8); the American Academy of Neurology (9), whose guidelines are almost identical to those of the IDSA; the Canadian Public Health Network (10); and the German Society for Hygiene and Microbiology (11). They also are in agreement with recommendations made by expert panels from at least 10 European countries, i.e., The Czech Republic, Denmark, Finland, France, The Netherlands, Norway, Poland, Slovenia, Sweden, and Switzerland (12). None of these organizations or expert panels – as well as the National Institutes of Health (NIH) or the Centers for Disease Control and Prevention (CDC) – recommend extended antibiotic therapy for the treatment of Lyme disease. It should be noted that the IDSA guidelines, which are posted on the AHRQ Guidelines Clearinghouse (13), are now in the

process of being updated as is required every 5 years. A recent citation review indicates that the IDSA guidelines have been cited in the medical literature 1,119 times; this further attests to their wide-spread acceptance and use within the medical community.

In May of 2008, the IDSA entered into an agreement with Connecticut Attorney General (AG) Richard Blumenthal to voluntarily submit the 2006 Lyme disease guidelines to a special expert review panel to determine if they were based on sound medical and scientific evidence, and whether the guidelines should be modified or revised. To avoid conflict of interest issues, all members of the expert panel were selected through an open application process. An ombudsman was jointly selected by the IDSA and the AG to screen all applicants to ensure that each panel member was without any beneficial or financial interests related to Lyme disease, any financial relationship with an entity that has an interest in Lyme disease, and any conflict of interest; the chairperson as well as all panel members met the required criteria. After multiple meetings, a public hearing, and extensive review of research and other information, the expert panel concluded, in a full report issued in 2010 (14), that the recommendations contained in the 2006 guidelines were medically and scientifically justified on the basis of all available evidence and that no changes in the guidelines were warranted.

There is much misinformation on Lyme disease being disseminated in the media as well as on the internet; much of it has been documented on the American Lyme Disease Foundation (ALDF) website (15). Since such misinformation can adversely impact the public health, it is extremely important to seek information only from reliable sources, e.g., regularly updated websites sponsored by the CDC (16), the NIH (17), and the ALDF (18). In this context, it might be instructive to examine and contrast the credentials of those involved in the preparation of the IDSA guidelines with LLMDs who hold leadership positions in the International Lyme and Associated Diseases Society (ILADS). If one gives precedence to factors such as conducting -- and frequently publishing-- the results of clinical and basic research on Lyme disease (analyzable data), as well as the acquisition of prestigious NIH sponsored grants to support such research, the differences between both groups are painfully obvious, especially if such a comparison excludes opinion papers, letters to the editor, short 1-2 page commentaries, abstracts etc.

On October 28, 2015, a PubMed search (19) was done to determine the numbers of publications on Lyme disease authored by each individual listed in Tables 1 and 2. Search terms included the author's name and Lyme disease (e.g., Smith JB and Lyme disease). The URL for each individual search is provided so that the reader can easily assess the nature and quality of the reference citations retrieved by the search. The search revealed that IDSA guidelines panel members had a total of 1,174 publications on Lyme disease of which the vast majority were research publications with analyzable data (Table 1). By contrast, those holding positions of leadership in ILADS had a total of only 109 publications on Lyme disease; only 15 (14%) could be considered to be research publications with analyzable data. Based on these findings, one is compelled to ask: "Who are the experts on Lyme disease?" and, when it comes to getting reliable information about Lyme disease, "Whose opinion should one value the most?"

### References

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14. <http://cid.oxfordjournals.org/content/51/1/1.long>
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16. <http://www.cdc.gov/lyme/index.html>
17. <http://www.niaid.nih.gov/topics/lymeDisease/Pages/lymeDisease.aspx>
18. [www.aldf.com](http://www.aldf.com)
19. <http://www.ncbi.nlm.nih.gov/pubmed?tool=cdl&otool=cdlotool>

Table 1

Number of Publications on Lyme Disease for Panel Members who Prepared the IDSA Guidelines

IDSA Guidelines Author	Total Number of Publications on Lyme Disease (URL for Search)
Wormser, GP	199 ( <a href="http://www.ncbi.nlm.nih.gov/pubmed/?term=Wormser+GP+and+Lyme+disease">http://www.ncbi.nlm.nih.gov/pubmed/?term=Wormser+GP+and+Lyme+disease</a> )
Dattwyler, RJ	66 ( <a href="http://www.ncbi.nlm.nih.gov/pubmed/?term=Dattwyler+RJ+and+Lyme+disease">http://www.ncbi.nlm.nih.gov/pubmed/?term=Dattwyler+RJ+and+Lyme+disease</a> )
Shapiro, ED	45 ( <a href="http://www.ncbi.nlm.nih.gov/pubmed/?term=Shapiro+ED+and+Lyme+disease">http://www.ncbi.nlm.nih.gov/pubmed/?term=Shapiro+ED+and+Lyme+disease</a> )
Halperin JJ	76 ( <a href="http://www.ncbi.nlm.nih.gov/pubmed/?term=Halperin+and+Lyme+disease">http://www.ncbi.nlm.nih.gov/pubmed/?term=Halperin+and+Lyme+disease</a> )
Steere, AC	234 ( <a href="http://www.ncbi.nlm.nih.gov/pubmed/?term=Steere+AC+and+Lyme+disease">http://www.ncbi.nlm.nih.gov/pubmed/?term=Steere+AC+and+Lyme+disease</a> )
Klempner, MS	32 ( <a href="http://www.ncbi.nlm.nih.gov/pubmed/?term=Klempner+MS+and+Lyme+disease">http://www.ncbi.nlm.nih.gov/pubmed/?term=Klempner+MS+and+Lyme+disease</a> )
Krause, PJ	33 ( <a href="http://www.ncbi.nlm.nih.gov/pubmed/?term=Krause+PJ+and+Lyme+disease">http://www.ncbi.nlm.nih.gov/pubmed/?term=Krause+PJ+and+Lyme+disease</a> )
Bakken, JS	11 ( <a href="http://www.ncbi.nlm.nih.gov/pubmed/?term=Bakken+JS+and+Lyme+disease">http://www.ncbi.nlm.nih.gov/pubmed/?term=Bakken+JS+and+Lyme+disease</a> )
Strle, F	118 ( <a href="http://www.ncbi.nlm.nih.gov/pubmed/?term=Strle+F+and+Lyme+disease">http://www.ncbi.nlm.nih.gov/pubmed/?term=Strle+F+and+Lyme+disease</a> )
Stanek, G	98 ( <a href="http://www.ncbi.nlm.nih.gov/pubmed/?term=Stanek+G+and+Lyme+disease">http://www.ncbi.nlm.nih.gov/pubmed/?term=Stanek+G+and+Lyme+disease</a> )
Bockenstedt, L	37 ( <a href="http://www.ncbi.nlm.nih.gov/pubmed/?term=Bockenstedt+L+and+Lyme+disease">http://www.ncbi.nlm.nih.gov/pubmed/?term=Bockenstedt+L+and+Lyme+disease</a> )
Fish, D	92 ( <a href="http://www.ncbi.nlm.nih.gov/pubmed/?term=Fish+D+and+Lyme+disease">http://www.ncbi.nlm.nih.gov/pubmed/?term=Fish+D+and+Lyme+disease</a> )
Dumler, JS	43 ( <a href="http://www.ncbi.nlm.nih.gov/pubmed/?term=Dumler+JS+and+Lyme+disease">http://www.ncbi.nlm.nih.gov/pubmed/?term=Dumler+JS+and+Lyme+disease</a> )
Nadelman, RB	90 ( <a href="http://www.ncbi.nlm.nih.gov/pubmed/?term=Nadelman+RB+and+Lyme+disease">http://www.ncbi.nlm.nih.gov/pubmed/?term=Nadelman+RB+and+Lyme+disease</a> )
(Totals)	1,174

Table 2

Numbers of Publications on Lyme Disease for ILADS Board Members or Officers

ILADS Officers or Board Members	Total Number of Publications on Lyme Disease (search URL)	Publications with Analyzable Data
Cameron, DJ	14 ( <a href="http://www.ncbi.nlm.nih.gov/pubmed/?term=Cameron+DJ+and+Lyme+disease">http://www.ncbi.nlm.nih.gov/pubmed/?term=Cameron+DJ+and+Lyme+disease</a> )	1
Shor, SM	0 ( <a href="http://www.ncbi.nlm.nih.gov/pubmed/?term=Shor+SM+and+Lyme+disease">http://www.ncbi.nlm.nih.gov/pubmed/?term=Shor+SM+and+Lyme+disease</a> )	0
Moorecraft, T	1 ( <a href="http://www.ncbi.nlm.nih.gov/pubmed/?term=Moorcraft+T+and+Lyme+disease">http://www.ncbi.nlm.nih.gov/pubmed/?term=Moorcraft+T+and+Lyme+disease</a> )	1
Shea, LJ III	0 ( <a href="http://www.ncbi.nlm.nih.gov/pubmed/?term=Sheas+LJ+and+Lyme+disease">http://www.ncbi.nlm.nih.gov/pubmed/?term=Sheas+LJ+and+Lyme+disease</a> )	0
Green, C	4 ( <a href="http://www.ncbi.nlm.nih.gov/pubmed/?term=Green+C+and+Lyme+disease">http://www.ncbi.nlm.nih.gov/pubmed/?term=Green+C+and+Lyme+disease</a> )	3
Liegner, KB	11 ( <a href="http://www.ncbi.nlm.nih.gov/pubmed/?term=Liegner+KB+and+Lyme+disease">http://www.ncbi.nlm.nih.gov/pubmed/?term=Liegner+KB+and+Lyme+disease</a> )	2
Maloney, EL	7 ( <a href="http://www.ncbi.nlm.nih.gov/pubmed/?term=Maloney+EL+and+Lyme+disease">http://www.ncbi.nlm.nih.gov/pubmed/?term=Maloney+EL+and+Lyme+disease</a> )	1
Schwartzbach, A	2 ( <a href="http://www.ncbi.nlm.nih.gov/pubmed/?term=Schwarzbach+A+and+Lyme+disease">http://www.ncbi.nlm.nih.gov/pubmed/?term=Schwarzbach+A+and+Lyme+disease</a> )	1
Stricker, RB	70 ( <a href="http://www.ncbi.nlm.nih.gov/pubmed/?term=Stricker+RB+and+Lyme+disease">http://www.ncbi.nlm.nih.gov/pubmed/?term=Stricker+RB+and+Lyme+disease</a> )	6
Totals	109	15 (14% of total)