

## Misappropriated NIH Grants Marginalize Lyme Patients

Six National Institutes of Health (NIH) grants are implicated in misappropriations related to Lyme disease totaling \$11,825,648M. These misappropriations, involving Yale University and the University of Pennsylvania were used to attack Lyme patients, Lyme advocates, organizations and health practitioners who provide care for Lyme patients suffering from on-going and debilitating symptoms.

It was not a lack of oversight or weak procedure that led to the misappropriations. These violations were accomplished by a senior NIH official in concert with a non-governmental organization, the Infectious Diseases Society of America (IDSA) and a grantee who has benefitted from previous NIH grants. The IDSA's financial interests and conflicts of interest (COIs) regarding Lyme and the health and welfare of Lyme patients is well documented.

Taxpayer monies from these grants were used to: <sup>1</sup>

- Discredit Lyme patients, advocacy groups and physicians, and invalidate their experience with the disease;
- Marginalize the Lyme community and advocates from decision-makers that determine access to care and insurance coverage of Lyme;
- Undermine their access to discourse and engagement with scientific and medical communities; and
- Deny their full rights as citizens to engage as stakeholders with government officials on topics of their deep and valid concern.

This research and analysis builds upon decades of documentation and evidence that the CDC, NIH and the IDSA practice and promote institutionalized discrimination against Lyme patients and the Lyme community.

### Yale University Grant Misappropriation

Both Yale University and employee Eugene Shapiro, MD are implicated in misappropriations related to two translational research grants and one patient-oriented research grant. Translational research involves moving knowledge and discovery gained from the basic sciences to its application in clinical and community settings.

Often summarized by the phrases “bench-to-bedside” and “bedside-to-community” research, these grants are: (2) The KL2 : To support newly trained clinicians appointed by an institution for activities related to the development of a successful clinical and translational research career; <sup>2</sup> and (3) UL1 : To support clinical and translational research. <sup>3</sup> The third grant is the K24 Midcareer Investigator Award in Patient-Oriented Research.

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<sup>1</sup> There may be additional federal grants misappropriated for propaganda against the Lyme community and its advocates.

<sup>2</sup> [http://grants.nih.gov/grants/funding/ac\\_search\\_results.htm?text\\_curr=KL2&Search\\_Type=Activity](http://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=KL2&Search_Type=Activity)

<sup>3</sup> [http://grants.nih.gov/grants/funding/ac\\_search\\_results.htm?text\\_curr=UL1&Search\\_Type=Activity](http://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=UL1&Search_Type=Activity)

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In September 2011, the Lancet Infectious Diseases journal published *Antiscience and Ethical Concerns Associated with Advocacy of Lyme Disease*.<sup>4 5</sup> This article is represented as a “Personal View”. The same article titled *Antiscience and Ethical Concerns Associated with Advocacy of Lyme Disease* is found in the US National Library of Medicine and National Institutes of Health (NIH) PubMed central (PMC) database and posted as of July 2, 2015.

The *Antiscience* article makes a series of statements that mischaracterize and discredit the Lyme community, including its practitioners, advocates, suffering and devastated patients and their family members. The article dismisses and trivializes a number of crippling Lyme symptoms and complications. It characterizes Lyme patients as a threat to true Lyme scientists and academics and asserts that unknown, yet powerful, moneyed groups control and dispatch the advocates for nefarious purposes.

Much of what is misstated in the 2011 article reveals the IDSA’s and NIH’s misrepresentation of Lyme science. The CDC’s Lyme policies and programs share this bias. The CDC solely promotes IDSA Lyme Guidelines and claims it is the “best science.” In fact, the IDSA Lyme Guidelines have been removed from the National Guidelines Clearinghouse (NGC) and they have failed to meet the Health and Medicine Divisions (HMD, formerly Institute of Medicine) Standards for Developing Trustworthy Clinical Practice Guidelines<sup>6</sup> or the Grading of Recommendations Assessment, Development and Evaluation (GRADE)<sup>7</sup> Working Group system for grading quality of evidence and strength of recommendations.

The article also misrepresents a competing medical society, the International Lyme and Associated Disease Society (ILADS) as “antiscience and unethical.” The ILADS Lyme Guidelines meet the HMD’s Guidelines for trustworthiness and the evidence-based GRADE standards and are posted on the NGC website.<sup>8</sup> Furthermore, there is no evidence of the authors’ claim that advocates are controlled and dispatched by unknown, powerful and moneyed groups.

The article does make one true statement: “There is no deficiency of either new patients or activists.” As the CDC notes, there are at least 320,000 new cases of Lyme disease annually. Of those 320,000 cases, many are undiagnosed and untreated causing severe disability and even death.

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<sup>4</sup> <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4489928/> - ...is supported in part by grant K24 RR022477 and Clinical and Translational Science Award (CTSA) grants KL2 RR024138 and UL1 RR024139 from the National Center for Research Resources (NCRR; a component of the NIH) and the NIH Roadmap for Medical Research.

[http://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(11\)70034-2/](http://www.thelancet.com/journals/laninf/article/PIIS1473-3099(11)70034-2/)

<sup>5</sup> [http://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(11\)70034-2/abstract](http://www.thelancet.com/journals/laninf/article/PIIS1473-3099(11)70034-2/abstract) authors: Paul G Auwaerter, MD, Johan S Bakken, MD, PhD, Raymond J Dattwyler, MD, J Stephen Dumler, MD, John J Halperin, MD, Edward McSweegan, PhD, Robert B Nadelman, MD, Susan O’Connell, MD, Eugene D Shapiro, MD, Sunil K Sood, MD, Allen C Steere, MD, Arthur Weinstein, MD, Gary P Wormser, MD.

<sup>6</sup> <http://www.nationalacademies.org/hmd/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust/Standards.aspx>

<sup>7</sup> <http://www.gradeworkinggroup.org/>

<sup>8</sup> <http://www.guideline.gov/content.aspx?id=49320&search=lyme+disease+and+ilads+guidelines>

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The goals of the NIH K24 grant are:

- 1) to conduct high quality patient-oriented research to answer important clinical questions and
- 2) to mentor young physicians who conduct patient-oriented research to help them become successful independent investigators. According to the proposal, \$157,391.00 “will allow Dr. Shapiro to continue to spend at least 70% of his time serving as a mentor to young investigators and conducting patient-oriented research.”<sup>9</sup> The responsible NIH/National Center for Advancing Translational Sciences (NCATS) Program Officer is David B. Wilde.<sup>10</sup>

The year the *Antiscience* article was written, Yale received over \$11,400,000 dollars from NIH translational research grants KL2 RR024138 and UL1 RR024139.<sup>11</sup> The responsible NIH/NCATS Program Officer is Carol Merchant.<sup>12</sup>

NIH 2011 - KL2 RR <u>Yale University Clinical and Translational Science Award Program</u>	\$780,586
NIH 2011 - UL1 RR Yale University Clinical and Translational Science Award Program	\$8,043,176
NIH 2011 - UL1 RR <u>Yale University Clinical and Translational Science Award Program</u>	\$2,608,245
NIH 2011 - <u>K24 RR022477</u> patient centered research & mentoring	\$157,391
Total	\$11,589,398

The *Antiscience* article is supported by these three grants and is in direct opposition to the goals of the grant, opposes patient-centered medicine, misrepresents the science it delivers, promotes ideas that create obstacles for Lyme patient care in clinical settings, and undermines patient credibility in all community settings.

### Conflicts of Interest

In 2001, the International Committee of Medical Journal Editors (ICMJE) revised its guidelines on Conflict of Interest (COI) disclosures in manuscripts. “Under the guidelines, authors are responsible for disclosing personal and financial relationships that might bias their work...”<sup>13 14</sup> In theory, Elsevier/ Lancet adheres to this policy. In this case, it appears the Lancet COI policy is only concerned with disclosure rather than how COIs “might bias work”.

In 2008 Senator Richard Blumenthal, then Connecticut’s Attorney General announced that his:

*“antitrust investigation has uncovered serious flaws in the Infectious Diseases Society of America’s (IDSA) process for writing its 2006 Lyme disease guidelines and the IDSA has agreed to reassess them with the assistance of an outside arbiter. The IDSA guidelines have sweeping and significant impacts on Lyme disease medical care. They are commonly applied by insurance companies in restricting coverage for long-term*

<sup>9</sup> <http://grantome.com/grant/NIH/K24-RR022477-10>

<sup>10</sup> Wilde, David NCATS Employee, [david.wilde@nih.gov](mailto:david.wilde@nih.gov) - 301-435-0799

<sup>11</sup> <http://grantome.com/>

<sup>12</sup> Merchant, Carol NCATS Employee, [carol.merchant@nih.gov](mailto:carol.merchant@nih.gov) - 301-435-0605

<sup>13</sup> <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3152484/>

<sup>14</sup> <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3152484/#R5>

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*antibiotic treatment or other medical care and also strongly influence physician treatment decisions. Insurance companies have denied coverage for long-term antibiotic treatment relying on these guidelines as justification. The guidelines are also widely cited for conclusions that chronic Lyme disease is nonexistent.”*<sup>15</sup>

Eight of the articles' authors served on the panel for the 2006 IDSA Lyme disease guidelines. The COIs detailed under *Antiscience and Ethical Concerns Associated with Advocacy of Lyme Disease* remain as bold, comprehensive and self-serving as those detailed in the 2008 investigation. It should be noted that one of the articles' co-authors is Gary P Wormser, MD. Dr. Wormser is an editor for this Lancet journal as well as a member of the IDSA. This appears to be an undisclosed COI.<sup>16</sup>

### Role of NIH and multiple authors

The *Antiscience* article appears to have multiple “principle authors.” According to federal policy on KL2 grants, the grant recipient is the author ultimately responsible for the paper. The article states that “Shapiro is supported by grant K24...and grants KL2 and UL1...” According to his grant [proposal](#) “During the period of the currently-funded K-24 award, Dr. Shapiro has published papers that have had an impact on public health policy.” Therefore, the Lancet version of the article gives the impression that Shapiro is the main author.

However, the [PMC version](#) of the article states that Paul G. Auwaerter, MD is the principal author. As noted, eight of the articles' authors served on the panel for the 2006 IDSA Lyme disease guidelines. They include Shapiro, IDSA's current Vice President Auwaerter and IDSA's current President Johan S. Bakken. President Bakken “participated in the construction of the paper and reviewed the final draft.”

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<sup>15</sup> <http://www.ct.gov/AG/cwp/view.asp?a=2795&q=414284>

<sup>16</sup> <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4489928/> see Conflicts of Interest: Paul G Auwaerter has served as a consultant for Oxford Diagnostics and has participated in expert testimony in two medico-legal suits about possible Lyme disease. He has equity interest in Johnson & Johnson, no products of which are referred to in this article. Raymond J Dattwyler is part owner of and has stock in Biopeptides Corporation, no product of which is referred to in this article, has received payment for providing expert testimony in malpractice cases and holds patents on vaccine and diagnostic technology with SUNY at Stony Brook Biopeptides. J Stephen Dumler has received support for travel to meetings from DiaSorin and has license of US patent 5,955,359 to Focus Diagnostics; none of these declarations are directly related to the contents of this article. John J Halperin has served as an expert witness in several medico-legal cases concerning Lyme disease and has equity in Abbott, Bristol-Myers Squibb, Johnson & Johnson, and Merck; no products from these companies are referred to in this article. Edward McSweeney was a former program officer for Lyme disease at the US NIH. Robert B Nadelman has served as an expert witness in malpractice litigation involving Lyme disease. Eugene D Shapiro is a board member of the American Lyme Disease Foundation, for which no compensation is received. He has reviewed Lyme disability claims and medical records for the Metropolitan Life Insurance Company and has provided medico-legal testimony. Gary P Wormser is a board member of the American Lyme Disease Foundation for which no compensation is received, has served as an expert witness in malpractice cases involving Lyme disease, has research grants from the NIH/Immunetics, BioRad, DiaSorin, and BioMerieux to study diagnostic tests for Lyme disease, none of which is mentioned in the manuscript, and has equity in Abbott, a company not known to have any approved product for Lyme disease. Bakken, Dattwyler, Dumler, Halperin, Robert B Nadelman, Eugene D Shapiro, Allen C Steere and Gary P Wormser have served on the panel for the 2006 IDSA Lyme disease guidelines. Bakken, Susan O'Connell, Sunil K Sood, Steere and Arthur Weinstein declare that they have no conflicts of interest.

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Under Contributors, Ed McSweegan “prepared the first draft, worked on subsequent drafts, and helped with the literature search” Ed McSweegan was an employee with the National Institutes of Health (NIH) when this article was supported by three NIH grants.<sup>17 18</sup>

*According to [federal statute \[41 use 504. SEC. 5.\] \(1\) ...purpose of the relationship is the transfer of money... to the...other recipient in order to accomplish a public purpose of support or stimulation authorized by Federal ' statute...rather than acquisition for the direct benefit or use of the Federal Government; and \(2\) no substantial involvement is anticipated between the executive agency...and the...other recipient during performance of the contemplated activity.](#)<sup>19</sup>*

NIH employee McSweegan has an irregular role of ‘substantial involvement’ that is exceptional for a federal grant. He had an essential and clearly stated role in the development of the ‘*Antiscience* article.’ In this case, the grantee does not appear to have an independent voice. The grantee appears to provide a “direct benefit” to the NIH.

It appears that the NIH and the IDSA had full ownership of this process and colluded in using patient-oriented research and translational research grant monies to produce an article to marginalize Lyme patients and the Lyme community.

### **Article doesn’t conform to policy regarding public access**

The article does not conform to the NIH or Elsevier policy regarding public access. The NIH Public Access Policy requires peer-reviewed, accepted manuscripts to be deposited ...at the time of acceptance for publication.<sup>20</sup> Grant activity code KL2 requires disclosure when the ‘paper that directly results from the funding award’.<sup>21</sup> According to federal law, the Clinical and Translational Science Award for institutions must be cited in [the] resulting publications.<sup>22</sup> Lancet is published by Elsevier. Elsevier policy is “to deposit PubMed Central (PMC) author manuscripts on behalf of Elsevier authors reporting NIH funded research ...12 months after final publication.”<sup>23</sup>

There was a three year public access delay for this article.

### **University of Pennsylvania Grant**

The University of Pennsylvania and NIH employee Edward McSweegan are implicated in misappropriations of grants to support articles that attempt to discredit the views and actions of Lyme patients and activists regarding the LYMERix vaccine that was withdrawn from the market after a series of lawsuits related to adverse events.

In 2007, McSweegan sent Correspondence to the Editor of Cambridge Journal Epidemiology & Infection regarding *The Lyme Vaccine: A Cautionary Tale* by LE

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<sup>17</sup> <https://www.linkedin.com/in/edwardmcsweegan?>

<sup>18</sup> <https://ned.nih.gov/search/ViewDetails.aspx?NIHID=0010041510>

<sup>19</sup> <https://www.gpo.gov/fdsys/pkg/STATUTE-92/pdf/STATUTE-92-Pg3.pdf>

<sup>20</sup> <http://www.nihms.nih.gov/db/sub.cgi?page=faq>

<sup>21</sup> <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-091.html>

<sup>22</sup> <http://ycci.yale.edu/news/newsletter/winter2012/>

<sup>23</sup> [http://oad.simmons.edu/oadwiki/Publisher\\_policies\\_on\\_NIH-funded\\_authors](http://oad.simmons.edu/oadwiki/Publisher_policies_on_NIH-funded_authors)

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Nigrovic and KM Thompson.<sup>24</sup> His correspondence indicates that the article did not go far enough to discredit the views and actions of Lyme “Activists and self-described ‘Lyme victims’ [who] had devoted years of effort to raising an obscure tick-borne nuisance in Old Lyme, Connecticut to a national reportable disease...”

According to the FOIA documentation cited in the [2012 Congressional Testimony LYME DISEASE: A COMPREHENSIVE APPROACH TO AN EVOLVING THREAT](#), NIH employee McSweegan asked in 2007, “*Anyone know of any academic sociologists or historians interested in doing a paper on the politics of Lyme disease? Maybe Robert Aronowitz at UPenn?*”<sup>25</sup>

Coincidentally, in 2008 NIH/National Library of Medicine (NLM) grant was awarded to Aronowitz. Prior to this grant, Aronowitz received six NIH grants. This grant’s stated purpose was to “contribute to the intellectual foundations of more effective disease prevention policies and practices” and “suggest greater inclusiveness in policy making by individuals and groups with a legitimate stake in the outcomes of prevention policies”.<sup>26</sup> The 2008 grant was followed by two additional grants that shared the same objectives.<sup>27</sup> During 2008 and 2009 the NIH Program Officer was Hua-Chuan Sim. The 2010 Program Officer was Alan Vanbiervliet.<sup>28</sup>

NIH 2010- G13 LM	History of Health Risks in American Society and Medicine	
	Aronowitz, Robert Alan / University of Pennsylvania	\$78,750
NIH 2009- G13 LM	History of Health Risks in American Society and Medicine	\$78,750
NIH 2008- G13 LM	History of Health Risks in American Society and Medicine	\$78,750
	Total	\$236,250

The June 2012 Milbank Quarterly article [The Rise and Fall of the Lyme Disease Vaccines: A Cautionary Tale for Risk Interventions in American Medicine and Public Health](#), by Aronowitz is derived from the grants-funded book *History of Health Risks in American Society and Medicine*.<sup>29</sup> Both the book and the article were funded by the same NIH grants.

However, the *Lyme vaccine* article diverges significantly from the purpose of the grant. The portion of the grant monies used to research and publish the *Lyme vaccine* article did not “contribute to the intellectual foundations of more effective disease prevention policies and practices” and “suggest greater inclusiveness in policy making by individuals and groups with a legitimate stake in the outcomes of prevention policies”.

<sup>24</sup> <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2870557/>

<sup>25</sup> <https://www.hsdl.org/?view&did=729437> (Pg.46) 4. EDWARD MCSWEEGAN, NIH, SUGGESTS THAT ROBERT ARONOWITZ OF UPENN WRITE AN ARTICLE ON THE POLITICS OF LYME DISEASE

<sup>26</sup> [https://projectreporter.nih.gov/project\\_info\\_description.cfm?projectnumber=1G13LM009587-01A1](https://projectreporter.nih.gov/project_info_description.cfm?projectnumber=1G13LM009587-01A1)  
<https://www.nlm.nih.gov/ep/Awards2008.html#Gra>

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3460208/> This article was funded in part from grant 1G13 LM009587-01A1 from the National Library of Medicine, NIH, and DHHS for History research.

<sup>27</sup> <http://grantome.com/grant/NIH/G13-LM009587-02>

<sup>28</sup> 2008 and 2009 Program Officer Sim, Hua-Chuan, NLM Employee - [hua-chuan.sim@nih.gov](mailto:hua-chuan.sim@nih.gov) 301-594-4882, 2010 Program Officer Vanbiervliet, Alan, NLM Employee - [alan.vanbiervliet@nih.gov](mailto:alan.vanbiervliet@nih.gov) 301-594-1297

<sup>29</sup> <http://www.ncbi.nlm.nih.gov/pubmed/22709388> Grant 1G13 LM009587-01A1 from the National Library of Medicine, NIH, and DHHS

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Instead, Aronowitz defines Lyme advocates as not having academically rigorous scientific opinions as opposed to the scientific method and academic rigor that informs “Lyme experts”. His statement that “advocates and experts have often lived in entirely different universes” misrepresents the fact many advocates are well-informed and well-regarded in their home communities. It ignores the fact that many advocates are scientists and medical professionals.

The author misstates that “the inclusion of patients...and other stakeholders in the planning and execution of clinical trials and policymaking” is not a central concern to the Lyme community. Thereby indicating that the Lyme community is uninterested in engaging with government officials and the medical and science communities at the local, state and federal levels. He suggests that the inclusion of Lyme stakeholders would not increase “fairness, accurate research sampling, different perspectives, and so forth.”

Aronowitz makes the following recommendations in the paper:

- (1) Stop the conversation between the “experts” and the advocates
- (2) Forgo engagement of the advocates as stakeholders and members of the public
- (3) Exclude their patient-centered views
- (4) Ignore their voiced concerns or proposed solutions.

These stunning recommendations run counter to US federal and state policies and standards for best practices regarding patient-centered medicine and open government.

### Compliance Irregularities

Neither the *Antiscience* article nor the *Lyme vaccine* article conforms to the grants’ objectives. Neither meet basic performance standards and both are opposed to Lyme patient-centered medicine. In addition, NIH senior official McSweegan had a role of substantial involvement that is unusual for federal grants. In the case of both articles, the grantees appear to provide a direct benefit to the NIH bias regarding the misrepresentation of Lyme science and Lyme patients.

With regard to compliance with statutes, the *Antiscience* article had exceptional delays regarding public access and related transparency. The apparent COI involving Wormser serving as both the Lancet editor and article author was not disclosed. Accountability for the *Antiscience* articles’ content is weak and linked to unusual authorship practices. Possible reasons for the *Antiscience* article’s lack of credible content include the number and nature of both individual and institutional COIs among the contributing authors.

More than 15 years of documentation detail IDSA members’ COIs and related misrepresentation of Lyme science. These records are the baseline from which the misappropriation actions show an escalation of malfeasance on the part of the IDSA. Their participation in this misappropriation, waste and other irregularities raise questions as to whether the remaining monies have been used according to their grant agreements.

Furthermore, the redirection of the misappropriated grant monies is chilling. These tax dollars were redirected to create articles that marginalize the Lyme community, further the professional and financial interests of the IDSA and reinforce the misrepresentation of science in CDC Lyme policy and programs.

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The entire impact of these two articles is unknown. It has been verified that the products of these misappropriations have carried forward as citations that contaminate other research efforts.<sup>30</sup> In addition, the *Antiscience* article continues to disseminate via citations and quotes in other articles. For example, on March 30, 2016 Prolonged Antibiotic Treatment Gave No Relief for Lasting Lyme Symptoms, by A. Chen referencing a Lyme study also quoted the 2011 *Antiscience* article. It stated that Lyme advocacy organizations were creating "a parallel universe of pseudoscientific practitioners, research, publications and meetings." This March 2016 article was in turn disseminated to 889 media platforms.

Decades of [exhaustive documentation](#) show how Lyme patients are mistreated by the medical establishment. These include formal testimonials at the state and federal level, other widely read [publications](#), and accounts vetted and shared through [television](#) and [radio](#) media.<sup>31 32 33</sup> These two articles have probably contributed to the number of events whereby health professionals' behave in a [dismissive](#), [bullying](#), scornful and [unprofessional](#) manner towards Lyme patients.<sup>34 35 36</sup>

It is quite possible these two articles have reduced the numbers of Lyme stakeholder opportunities to engage in any number of state and federal meetings, including those on Lyme policy discussions and public health outreach. They may have also encouraged the discrediting of Lyme advocates' contributions in any these settings.

### Recommendations from the Office of the Inspector General

The following recommendations are excerpted from two 2015 Office of the Inspector General reports. These recommendations apply to the findings of this report.

*"The DHHS is the largest grant-making organization and third-largest contracting agency in the federal government, with \$402 billion and \$21 billion awarded,*

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- <sup>30</sup> <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3460208/citedby/> and [http://www.ncbi.nlm.nih.gov/pubmed?linkname=pubmed\\_pubmed\\_citedin&from\\_uid=21867956](http://www.ncbi.nlm.nih.gov/pubmed?linkname=pubmed_pubmed_citedin&from_uid=21867956)
1. Immunization with a *Borrelia burgdorferi* BB0172-derived peptide protects mice against Lyme disease. Small CM1, Ajithdoss DK1, Rodrigues Hoffmann A1, Mwangi W1, Esteve-Gassent MD1. PLoS One. 2014 Feb 5;9(2):e88245. doi: 10.1371/journal.pone.0088245. eCollection 2014.
  2. New-onset panic, depression with suicidal thoughts, and somatic symptoms in a patient with a history of Lyme disease. 1.Garakani A, Mitton AG. Case Rep Psychiatry. 2015;2015:457947. doi: 10.1155/2015/457947.
  3. Bill C-442: Shining the limelight on the Lyme-like? Laupland KB, Valiquette L. Can J Infect Dis Med Microbiol. 2014 Sep;25(5):239-40.
  4. Lyme and associated tick-borne diseases: global challenges in the context of a public health threat. Perronne C. Front Cell Infect Microbiol. 2014 Jun 3;4:74. doi: 10.3389/fcimb.2014.00074. eCollection 2014.
  5. Lyme arthritis in Southern Norway--an endemic area for Lyme borreliosis. Haugeberg G, Hansen IJ, Skarpaas T, Noraas S, Kjelland V. BMC Infect Dis. 2014 Apr 5;14:185. doi: 10.1186/1471-2334-14-185.
  6. Bullying *Borrelia*: when the culture of science is under attack. Auwaerter PG, Melia MT. Trans Am Clin Climatol Assoc. 2012;123:79-89; discussion 89-90.
- <sup>31</sup> <http://sufferingthesilence.com/about-the-book/#sthash.GG8KVvmN.ZtqIrqHP.dpbs>
- <sup>32</sup> <http://www.drphil.com/slideshows/slideshow/6835/?id=6835&showID=1826>
- <sup>33</sup> <http://www.peoplespharmacy.com/2015/06/11/show-996-mystery-and-lyme-disease-misdiagnosis/>
- <sup>34</sup> [http://www.twistoflymebook.com/A\\_Twist\\_of\\_Lyme/About\\_the\\_Author.html](http://www.twistoflymebook.com/A_Twist_of_Lyme/About_the_Author.html)
- <sup>35</sup> <http://www.lymenet.de/literatur/tuttle/bullying%20of%20Lyme%20patients.pdf>
- <sup>36</sup> <https://lis.virginia.gov/cgi-bin/legp604.exe?131+sum+HB1933>



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*respectively, in FY 2014...Across the Department, vulnerabilities have been identified in HHS grants, demonstrating the need for purposeful and consistent federal oversight.*

*The Department needs to take more aggressive action to identify poorly performing grantees and those at risk of mispending federal dollars...or prevent them from continuing to receive grant funds...*

*The Department and OIG should continue to provide training on identifying and pursuing misconduct in grants and contracts.*

*Grant and contract officers should more actively coordinate with and refer potential fraud to OIG for investigation...Moreover, the Department needs to implement a program to actively pursue fraud under the Program Fraud Civil Remedies Act (PFCRA). ”<sup>37 38</sup>*

### Specific Recommendations

1. Initiate immediate oversight and stringent review of all current Lyme grants to all of IDSA’s institutional affiliations by impartial parties. Lax enforcement of grant rules and policies, explicit engagement or tacit support for the content of these articles have disqualified the NIH and CDC from this role.
2. Require deep institutional analysis by an independent party regarding how IDSA financial interests have shaped: (1) NIH resources allocations regarding Lyme and co-infections research; and (2) CDC Lyme policies and programs.
3. Investigate all individual and institutional actors implicated in these misappropriations. NIH awards should be suspended until the investigation is completed. Pending the conclusion of the investigations, implicated federal employees should be barred from any form of management of monies, representational roles for their agencies, publications release and decision-making roles on all and any policies, programs and research related to Lyme and co-infections.
4. Initiate immediate, comprehensive and formal countermeasures to the institutionalized practice of discrimination against Lyme patients and the Lyme community.
  - Develop and extend a formal federal policy and statutes that confer “special considerations,” protections, and resources to Lyme patients.
  - These special considerations should be developed with Lyme stakeholders - Lyme patients, advocates, organizations, health care professionals and scientists who serve the Lyme community. These stakeholders should be identified and nominated by the Lyme community.
  - These special considerations should be extended and made accessible to Lyme patients throughout the nation.
  - All recipients of government contracts, grants and cooperative agreements must make provisions for Lyme patients that conform to these special considerations.

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<sup>37</sup> <http://oig.hhs.gov/reports-and-publications/top-challenges/2015/challenge04.asp>

<sup>38</sup> OIG Report, [U.S. Department of Health and Human Services Met Many Requirements of the Improper Payments Information Act of 2002 But Did Not Fully Comply for Fiscal Year 2014](#), May 2015

## **Misappropriated NIH Grants Marginalize Lyme Patients**

May 2016, authored by Jenna Luche-Thayer

Jenna Luché-Thayer's expertise includes government transparency, accountability, and the integration of marginalized groups. Luché-Thayer is informed by three decades of professional policy and grassroots experience in 40 countries. She has extensive experience in congressional relations, testimony and legislation. She has worked with governments, the United Nations, nonprofits and the corporate world and has over sponsored 65 publications. Luché-Thayer received the International Woman's Day Award for Exemplary Dedication and Contributions to Improving the Political and Legal Status of Women (US government) and built the Highest Ranking Technical Area in Accomplishment, Innovation & Comparative Advantage for United Nations Capital Development Fund.

With support from the Patient Centered Care Advocacy Group.