Jenna Luché-Thayer
Revised September 19, 2016

Global Antibiotic Stewardship Denies Native Americans Lyme Treatment Options

There is valid growing global concern over drug resistant microbes. The 2014 Presidential Executive Order - Combating Antibiotic-Resistant Bacteria frames how the concept of antibiotic stewardship is expected to become comprehensive and farther reaching, it *"requires federal agencies to review existing regulations and propose new regulations…agencies will also be required to define, promulgate and implement stewardship programs in other settings such as…outpatient settings."*

The initial phase of the Antibiotic Stewardship Program (ASP) focuses on hospitals and certain health centers. It is restricted to the use of 'last resort' antibiotics for 'qualifying' pathogens; i.e. drug resistant pathogens. This first phase is being piloted in California and includes the process of preauthorization for such last resort antibiotics. Certain healthcare practitioners are also asked to report on their use of common broad spectrum antibiotics, and to specify what conditions require these antibiotics. This reporting is part of the effort to control use of all antibiotics.

There is also an effort to minimize overall use of common antibiotics. Pediatric antibiotic stewardship has already reduced antibiotic protocols for children regarding a number of common health ailments. [i] Veterinarians and farmers have been asked to reduce and report antibiotic use; audits of antibiotic use may be implemented by third parties. There is a commitment to establishing a national computerized system that will inform and restrict antibiotic use.

This antibiotic stewardship is being piloted and expanded in an incremental manner. One objective of the initiative is the **creation of regulations and laws** that will restrict access and provide strict guidance regarding the use of all antibiotics under all circumstances. The United States (US) government **intends to promote uniform antibiotic regulation and restriction on a global scale.**

The Infectious Diseases Society of America (IDSA) has a central and influential role in shaping the US and global ASP and initiatives. According to the April 2016 announcement for Implementing an Antibiotic Stewardship Program: Guidelines by the Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America [ii] [iii]**,**

Antibiotic stewardship [is] "coordinated interventions designed to improve and measure the appropriate use of [antibiotic] agents by promoting the selection of the optimal [antibiotic] drug regimen including dosing, duration of therapy, and route of administration."

"The benefits of antibiotic stewardship include ***improved patient outcomes****…and optimization of resource utilization across the continuum of care."*

"IDSA and Society for Healthcare Epidemiology of America (SHEA) strongly believe that ASPs are best led by ***infectious disease physicians…"***

The IDSA is also a private medical society with a unique relationship to the US federal Lyme disease policy and programs promoted by the Centers for Disease Control and Prevention (CDC).

The CDC states that the IDSA's Lyme diagnostic and treatment Guidelines represent the "best science" despite their failure to meet the criteria set by the:

- US federal Agency for Healthcare Research and Quality (AHRQ) - the lead Federal agency charged with improving the safety and quality of America's health care system
- National Guideline Clearinghouse (NGC) - the federal website that posts medical Guidelines and provides summaries regarding evidence-based clinical practice Guidelines
- Institute of Medicine (IOM)'s internationally recognized Standards for Developing Trustworthy Clinical Practice Guidelines and the Grading of Recommendations Assessment, Development and Evaluation (GRADE) Working Group system for grading the quality of evidence and strength of recommendations. [iv]

In violation of the US government's federal laws, the CDC has shown continuous preferential treatment for the IDSA, a private medical society. [v] IDSA mischaracterizes Lyme disease as hard-to-catch-and-easy-to-diagnose-and-treat.

IDSA appears to apply its ASP approach according to subjective and financially motivated criteria. For example, there is no language to restrict antibiotic use for patients with acne or cystic fibrosis. The IDSA encourages home infusion services for certain categories of patients, such as patients with urinary tract infections, because such protocols will generate Medicare reimbursements for ID specialists. [vi] [vii] However, the IDSA restricts Lyme treatment to 30 days of antibiotics.

Nevertheless, the US Government is supporting the implementation of the noncompliant IDSA Lyme Guidelines through the ASP. **The noncompliant IDSA Lyme Guidelines have already been quietly adopted by the Indian Health Service (IHS) ASP.**

The native lands are legally independent of the United States of America. However, the US Federal Department of Health and human Services (HHS) is responsible for providing healthcare to the Native American populations. [viii] IHS supports a network of 37 hospitals, 60 health centers, three school health centers, 46 health stations, and 34 Indian health centers to provide services to nearly 1.5 million American Indians and Alaska Natives of 557 federally recognized tribes. [ix]

A 2011 Report to the U.S. Surgeon General Office of the Chief Pharmacist states *"IHS pharmacy is widely known (in the federal sector, private sector and academia) for its innovative pharmacy practice, which includes privileges in disease management…"* [x]

However, it appears that politics are driving IHS antibiotic stewardship approach. IHS pharmacy, once known for its innovative practices, is now following the directives provided in the National Pharmacy Council (NPC) Antibiotic Stewardship Program (ASP) Ambulatory Care Guidelines. [xi]

The NPC ASP Guidelines group different types of infections. They include dental infections, sexually transmitted diseases, skin infections, urinary tract infections, and upper respiratory infections. There are three 'stand-alone' diseases; they are Tuberculosis, Helicobacter pylori and Lyme disease.

All of the diseases - **with the exception of Lyme disease** - have multiple references that informed the understanding of the disease and various treatment options. The section for Lyme disease has one sole reference and that is the substandard and federally noncompliant IDSA Lyme Guidelines.

Additionally, **Lyme is the only vectorborne disease** included under the IHS antibiotic stewardship. There is no mention of the vectorborn West Nile Virus which is not uncommon in a number of Native American areas. There is no mention of the many other tickborne illnesses found in these areas including:

- Babesiosis
- Ehrlichiosis
- Rocky Mountain Spotted Fever
- Southern Tick-Associated Rash Illness
- Tick-Borne Relapsing Fever
- Tularemia
- Anaplasmosis
- Colorado tick fever
- Powassan encephalitis

This striking arrangement may be the result of numerous situations. For example, one of the co-authors of the IDSA/SHEA Antibiotic Stewardship Guidelines has a pivotal and crosscutting role among the key actors promoting the noncompliant Lyme Guidelines. This actor has worked for the CDC, very closely with the IDSA, as a consultant to the IHS while serving as a member of Antimicrobial Resistance Working Group on President's Council of Advisors on Science and Technology and has provided consulting services to the AHRQ on antimicrobial stewardship. [xii]

Altogether, circumstances have combined to place Native Americans who contract Lyme disease and coinfections in harm's way. Those patients who are able to access Lyme diagnostic testing face a 50 percent chance of inaccurate results.[xiii] Inaccurate false negative test results often lead to delayed diagnosis and full systemic complications. A systemic Lyme infection with complications often require more than the one month of antibiotics recommended in the largely opinion-based IDSA Guidelines. Systemic complications may include serious heart, nervous system and immune impairments, organ dysfunction, life-altering damage and death. The continued use of the IDSA Lyme Guidelines by the IHS will generate needless suffering, disability and even death.

According to the IDSA/SHEA Antibiotic Stewardship Guidelines, *"Any antibiotic stewardship intervention must be customized based on local needs, prescriber behaviors, barriers, and resources."*

The promotion of noncompliant medical Guidelines for Lyme treatment of Native Americans shows poor judgment on many different levels. The political optics alone are stunning.

Under HHS leadership, the IHS ignores and excludes federally sanctioned Lyme Guidelines posted on the NGC that conform to criteria of the AHRQ and IOM, fully meet the evidence-based criteria for GRADE and have restored the wellbeing and functional capacities of late stage and chronic Lyme patients.

The federally sanctioned Guidelines were written by the International Lyme and Associated Diseases Society (ILADS) and state, *"Rather than an arbitrary 30-day treatment course, the patient's clinical response should guide duration of therapy… should be made in consultation with the patient and should take into account such factors as the frequency and duration of persistent infection..."* ILADS recognizes that Lyme disease is a complex and serious illness of global epidemic proportion and offers individualized patient-centered treatments.

The CDC's preferential promotion of the noncompliant outdated IDSA Lyme Guidelines has continued without interference from other branches of the US government. Indeed, the US government has provided the IDSA an additional global platform - Antibiotic Stewardship – to further institutionalize discrimination against Lyme patients and to arbitrarily restrict their access to evidence-based, patient-centered treatment options.

Under HHS leadership, the IHS are utilizing their pharmacists to implement this discriminatory practice. To date, there has been unchecked implementation of these noncompliant Guidelines through the IHS.

Furthermore, 44 states have legislation in place that can make use of pharmacists to act as both primary health care providers and to restrict Lyme treatment options. In many of these cases, pharmacists have the authority to prescribe but not the authority or skills to provide the clinical diagnosis recommended for Lyme and coinfections. [xiv]

Given the unchecked impunity of the CDC with regards to Lyme and the IDSA, it is reasonable to assume the federal government will allow the antibiotic stewardship initiative to:

- fast track codification of the noncompliant largely opinion-based IDSA Lyme Guidelines into law
- utilize the national pharmacy network to **restrict access** to clinical diagnosis of Lyme and sanctioned treatments.

Should this occur, the arbitrary denial of federally sanctioned Lyme treatment options will become a lawfully entrenched practice of discrimination against a vulnerable group.

The arbitrary withholding of IOM sanctioned treatment options for Lyme, chronic Lyme/TBD is both cruel and degrading, violates basic patient rights and often results in unnecessary debilitation, disability and pain. Furthermore, it is a **violation of Lyme patients'** human rights.

The Indian Health Service ASP is currently violating a number of human rights articulated in the Universal Declaration of Human Rights, including:

Article 5 *"No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment"*

Article 27 *"Everyone has the right … to share in scientific advancement and its benefits."* [xv]

Across the globe, persons living with Lyme/TBDs and their healthcare providers have experienced firsthand how the CDC's commitment to one private medical society's Lyme Guidelines is resulting in increasing and unacceptable levels of undiagnosed illness, chronic and untreated illness, disability and death from Lyme and coinfections.

To date, the global antibiotic stewardship initiative's objective to ensure *"The benefits of antibiotic stewardship to improve patient outcomes"* excludes those persons living with Lyme, chronic Lyme and tickborne diseases.

Jenna Luché-Thayer
Founder, Global Network on Institutional Discrimination ™
Holding institutions accountable for political and scientific solutions

Jenna Luché-Thayer is a political strategist and advocate working across the globe to help institutions remedy entrenched practices of discrimination that interfere with their higher purpose.

Currently, Luché-Thayer is assisting institutions and communities to:

- Overcome more than 30 years of discriminatory practices against those living with Lyme, chronic Lyme and tickborne diseases (TBD) and
- Build a humane and rights based patient-centered response to the Lyme disease epidemic.

Luché-Thayer has written numerous analytical documents that are on Congressional and Senate record and have been submitted as expert testimony to governments in numerous countries. Her analyses and documentation related to the lack of adherence to the Affordable Care Act

(ACA) and violations of civil rights and patient rights for those with Lyme disease are currently under review by the US Department of Health and Human Services (HHS). She is spearheading a global initiative that documents these concerns for review by those in the United Nations responsible for the protection of human rights.

Her Lyme disease analyses have prompted an invitation to participate in the Intergovernmental Panel on Climate Change (IPCC) Working Group on Impacts, Adaption and Vulnerability. She acts as a spokesperson, advisor and subject matter expert as requested.

Luché-Thayer's expertise includes government transparency and 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 65 sponsored 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.

Endnotes

[i] http://www.healio.com/pediatrics/pediatric-id/news/online/%7Bee3c39d1-6f0f-4ed1-8d3c-5576efe2bd6f%7D/alternative-asp-model-significantly-reduces-pediatric-antibiotic-use

[ii] http://www.idsociety.org/Antimicrobial-Agents/#Antimicrobial Stewardship

[iii] Support for these Guidelines was provided by the Infectious Diseases Society of America (IDSA) and the Society for Healthcare Epidemiology of America (SHEA).

[iv] IOM is now the Health and Medicine Divisions (HMD)

[v] Lyme organizations and government officials in many countries know: key CDC Directors responsible for Lyme disease are members of IDSA and there are no non-IDSA members among the Directors responsible for CDC's Lyme policy and programs; IDSA collaborates closely with big Pharma and members of IDSA hold key positions at medical journals, research institutions and institutions of higher learning; IDSA has a long and documented history of conflicts of interest (COI) regarding Lyme - IDSA COIs include patients on Lyme test kits, accepting payments from Lyme vaccine manufacturers and acting as expert witnesses for health insurance companies to deny coverage for federally sanctioned patient-centered Lyme treatment options. For example, the 2008 Connecticut antitrust suit against IDSA describes the Ad Hoc International Lyme Disease Group. The Ad Hoc group was formed in 2005 and included government employees from CDC, NIH and IDSA. According to an overview of the suit written by science writer Kris Newby and Lorraine Johnson of LymeDisease.org: *"The ad-hoc group convened during government-funded, closed-door meetings and had members who were researchers with significant commercial interests in Lyme disease tests and vaccines. It excluded the public and researchers whose views were not aligned with those of the IDSA. The group essentially set national*

*Lyme disease policy and controlled the national research agenda in Lyme disease without public oversight or transparency. Subsequently, a large percentage of government grants were awarded to the [IDSA] group's members."*Overview of LymeGate Findings, Prepared by Kris Newby and Lorraine Johnson.

[vi] http://www.idsociety.org/IDSA_Statement_on_Reintroduction_of_Home_Infusion_Legislation/

[vii] It should be noted that Alan Tice, MD and IDSA fellow, founded the first professional association for home infusion services known as Outpatient Intravenous Infusion Therapy Association (OPIVITA).

[viii] This relationship has been in place since the 1960s Transfer Act that authorized the transfer of maintenance and operation of hospital and health facilities for Indians to the Public Health Service "Page 3763 TITLE 42—THE PUBLIC HEALTH AND WELFARE § 2002 -CHAPTER 22—INDIAN HOSPITALS AND HEALTH FACILITIES: SUBCHAPTER I—MAINTENANCE AND OPERATION § 2001. Hospitals and health facilities transferred to Public Health Service; restriction on closing hospitals (a) All functions, responsibilities, authorities, and duties of the Department of the Interior, the Bureau of Indian Affairs, Secretary of the Interior, and the Commissioner of Indian Affairs relating to the maintenance and operation of hospital and health facilities for Indians, and the conservation of the health of Indians, are transferred to, and shall be administered by, the Surgeon General of the United States Public Health Service, under the supervision and direction of the Secretary of Health and Human Services."

[ix] In 1996, a memorandum from the IHS Director established IHS pharmacists as primary care providers (PCPs) and allows for privileges to include prescriptive authority.

[x] The *Improving Patient and Health System Outcomes through Advanced Pharmacy Practice* - A Report to the U.S. Surgeon General 2011, Office of the Chief Pharmacist, makes a solid case for maximizing the expertise and scope of pharmacists to improve access to care and reduced health care costs - Under Appendix A: National Clinical Pharmacy Specialist (NCPS) Program, see Issue Indian Health services references.

[xi]https://www.ihs.gov/nptc/includes/themes/newihstheme/display_objects/documents/resources/IHSAntibioticStewardshipProgramAMBCARE.pdf

[xii] The AHRQ is required to document the advancement of antibiotic stewardship efforts in fiscal year 2017 as directed by the 2016 Appropriations Bill.

[xiii] http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2078675/

[xiv] The *Improving Patient and Health System Outcomes through Advanced Pharmacy Practice* - A Report to the U.S. Surgeon General 2011, Office of the Chief Pharmacist

[xv] http://www.ohchr.org/EN/UDHR/Documents/UDHR_Translations/eng.pdf