

ABSTRACT

Over the last few decades, the power of patient advocacy groups to affect change in the healthcare system has grown. The internet has made it easier than ever for like-minded individuals to join forces regardless of geography. Patient advocacy serves an important purpose in a strong democratic society; they hold public institutions accountable for their actions, raise awareness for lesser known ailments, and humanize the medical sciences. Recognizing the value of the patient's perspective, many government initiatives have specifically sought out the opinion of patient advocates in developing health policy. One such example is the Federal Framework on Lyme Disease Act (FFLDA). Introduced because of patient concerns that Lyme disease patients were not being properly treated, the FFLDA mandates that the federal government develop a federal framework on Lyme disease that addresses surveillance, guidelines, and best practices. The FFLDA also mandated a conference be held to assist in developing the Framework, which was held in May 2016. In February 2017, the draft Framework was released for public feedback. Controversy surrounding Lyme disease is abundant. Patients, physicians, and researchers disagree about various aspects of the disease, how it manifests, how it should be diagnosed, and how it should be treated. From this gap, numerous diagnostic protocol and treatment regimens have been proposed as more suitable than current guidelines, with varying degrees of evidence supporting their efficacy. The concern is that allowing patient advocates to play such a prominent role in the development of the Framework not only is more costly and slower than expert-driven policy changes, but that it may lead to ineffective or harmful guidelines being implemented. I argue that the role of patient advocates and patient advocacy groups to influence policy making should be limited, particularly in controversial situations or where medical-evidence gaps exist.

I. Introduction

Over the last few decades, the power of patient advocacy groups to affect change in the healthcare system has increased. The internet has made it easier than ever for like-minded individuals to join forces, regardless of geography. Whereas a person with a rare ailment once suffered alone, now patients can find each other with the click of a mouse. Patient advocacy serves an important purpose in a strong democratic society; they hold public institutions accountable for their actions, raise awareness for lesser known ailments, and humanize the medical sciences. Recognizing the value of the patient's perspective, many government initiatives have specifically sought out the opinion of patient advocates in developing health policy. One such example is the *Federal Framework on Lyme Disease Act (FFLDA)*.¹ Throughout the process of assessing the state of health care for Lyme disease in Canada and determining the path forward, patient advocates have played a prominent role. Introduced because of patient concerns that Lyme disease patients were not being properly treated, the *FFLDA* mandates that the federal government develop a federal framework on Lyme disease that addresses surveillance, guidelines, and best practices. The *FFLDA* also mandated a conference be held to assist in developing the Framework, which was held in May 2016. In February 2017, the draft Framework was released for public feedback.

¹ SC 2014, c 37 [FFLDA].

Controversy surrounding Lyme disease is abundant. Patients, physicians, and researchers disagree about various aspects of the disease, how it manifests, how it should be diagnosed, and how it should be treated. From this lacuna, numerous diagnostic protocol and treatment regimens have been proposed as more suitable than current guidelines, with varying degrees of evidentiary support. The concern is that allowing patient advocates to play such a prominent role in the development of the Framework is not only more costly and slower than expert-driven policy changes, but also that it may lead to ineffective or harmful guidelines being implemented. Patient advocates may not contemplate resource allocation in the context of the entire healthcare system. They may not be capable of critically evaluating scientific information, or understanding the need to fund research focused on understanding the disease better rather than funding clinical trials in search of a cure. I argue that the role of patient advocates and patient advocacy groups to influence policy making should be defined and limited, particularly in controversial situations or where medical-evidence gaps exist. Clear guidelines should be established to define the role of patients and patient advocacy groups in health care policy decision-making to manage expectations and streamline the process. Such guidelines will help ensure that the benefits of patient involvement are realized, while protecting the integrity of Canada's health care system.

II. Patient Advocacy Groups

A. The Rise of Patient Advocacy Groups

Patient advocacy groups² are organized non-profit groups that are concerned with medical conditions or potential medical conditions and take actions to help people affected by those conditions and their families.³ Patient advocacy groups often provide services, such as counselling and support groups, they disseminate information via websites and published materials, raise public awareness, and promote research.⁴ These groups generally focus on access to health care services, health inequality, or issues related to specific illnesses and diseases, or some combination of the three. Advocacy, defined as “a catch all word for the set of skills used to create a shift in public opinion and mobilize the necessary resources”⁵ is used to make institutions more reactive to the needs of particular communities or populations.⁶ In health policy, advocacy is necessary to reframe diseases as a social issue rather than a personal problem.⁷

Since the mid-1980s, the ability of patient advocacy groups to participate in the Canadian

² Various terms are used interchangeably in the literature, including patient groups, support groups, consumer groups, and embodied health movements.

³ Susannah L. Rose, “Patient Advocacy Organizations: Institutional Conflicts of Interest, Trust, and Trustworthiness” (2013) 41:3 *JL Med & Ethics* 680 at 680 [Rose].

⁴ *Ibid.*

⁵ Lawrence Wallack et al, *Media advocacy and public health: power for prevention* (Newbury Park, California: Sage Publications, Inc: 1993) at 27.

⁶ *Ibid* at 28.

⁷ *Ibid* at 5.

political system has increased, resulting in a diluting of the traditional approach of evidence-based public health practices.⁸ This rise can be explained by a variety of cultural, economic, and societal factors, including an increasingly educated middle class, tax exemptions for non-profits, increasing awareness of new illnesses, syndromes, diseases, and disorders, and technology that makes it easier to organize individuals.⁹ The success of advocacy groups is reliant on their ability to gain credibility, which they have been able to secure in a number of ways. They have done so primarily by educating themselves, leveraging their power as research subjects, a job only they are capable to fill, and recruiting experts who support their agenda. Advocates have also relied on self-educating. The increasing availability of scholarly articles, clinical trial results and other reputable forms of evidence has made it easier for non-experts to educate themselves. This can make it easier for patients to be taken seriously by experts, but it also increases the likelihood that information will be misinterpreted.¹⁰

The internet and social media have played an important role in the flourishing of patient advocacy groups. Social media has changed the way that individuals and networks interact, share, process, and consume health information, starting in the 1990s with the widespread use of the internet.¹¹ Patients and other interested individuals share medical information, diagnostic information, practical aspects about daily life with the disorder, and potential therapies on blogs, Facebook groups, online chats, and other forums.¹² Social media has also been utilized specifically to create petitions and other campaigns to achieve access to experimental treatments, which is a drastically different approach to the traditional course of drug development and expanded access policies.¹³ Social media and the internet present an opportunity for patients and families to learn from others around the world in similar situations, which can be helpful, particularly to patients suffering from rare diseases disorders, or illnesses. With information being exchanged and shared, it easily becomes vulnerable to misinterpretation and inaccurate reporting, making it difficult to determine what information is accurate.¹⁴

Over the past few decades, many patient advocacy groups have succeeded in achieving their goals. Patient advocacy groups have an inherent credibility as they are perceived as more trustworthy

⁸ Constance A Nathanson, *Disease Prevention as Social Change: The State, Society and Public Health in the United States, France, Great Britain, and Canada* (New York: Russell Sage Foundation, 2007) at 206.

⁹ Ann C. Keller & Laura Packel, "Going for the Cure: Patient Interest Groups and Health Advocacy in the United States" (2014) 39:2 *J Health Pol* 331 at 335 [Keller & Packel]

¹⁰ Steven Epstein. *Impure Science: AIDS, activism, and the Politics of Knowledge* (Berkeley: University of California Press, 1996) at 335-6.

¹¹ Tim K. Mackey & Virginia J. Schoenfield, "Going "Social" to Access Experimental and Potentially Life-saving Treatment: An Assessment of the Policy and Online Patient Advocacy Environment for Expanded Access" (2016) 14:17 *BMC Medicine* [Mackey & Schoenfield]; Musa Mayer, "Patient Advocacy in Research: Merely an Afterthought?" (2011) 4:2 *Patient* 69 at 69 [Mayer].

¹² J.G. Hall, "The Role of Patient Advocacy/Parent Support Groups" (2013) 103:12 *South African Medical Journal* 1020 at 1020. [Hall].

¹³ Mackey & Schoenfield, *supra* note 11.

¹⁴ Gayle A. Sulik, Carrie Cameron & Robert M. Chamberlain. "The Future of the Cancer Prevention workforce: Why Health Literacy, Advocacy, and Stakeholder Collaborations Matter" (2012) 27: Suppl 2, *Journal of Cancer Education* S165 at S167.

than corporations or other public agencies with obvious biases to cut costs.¹⁵ As a result, they are increasingly consulted by healthcare agencies, research institutions, medical societies and the drug industry.¹⁶ Perhaps the most influential case study documenting the power of patient advocacy groups is HIV/AIDS advocacy. In the 1980s, HIV/AIDS activists successfully campaigned for more research and more attention to the condition, but the concentration of the efforts was randomized controlled trials. Well-organized activists attacked various aspects of standard randomized controlled trials, arguing that certain requirements, such as the exclusion of patients who take other medication unrelated to the study, were unnecessarily restrictive.¹⁷ Eventually joined by sympathetic clinicians, activists succeeded in persuading researchers that prerequisites for randomized controlled trials could be relaxed without sacrificing scientific integrity. Many patients also refused to participate in research where there was a possibility they might receive a placebo instead of an active agent, arguing that it was inhumane to knowingly withhold potential treatment. Ultimately, activists were successful in changing clinical trial practices, and convinced scientists and researchers to view them as valuable contributors.¹⁸

B. The Role of Patient Advocacy Groups

Patient advocacy groups serve a variety of functions. Their actions impact the public, health policy, and the lives of patients. Advocacy organizations promote diverse public interests separate from government and corporate interests and raise awareness about illnesses and diseases that may not otherwise be discussed.¹⁹ They seek change through activism, lobbying to different government agencies to insert the patient perspective into a field typically dominated by health care professionals.²⁰ Patient advocacy groups are capable of affecting health policy in many ways; in this paper, I focus on two broad categories: research and information dissemination.

When it comes to research, advocacy groups have typically been involved in three areas: funding, design, and ethics. Advocacy groups can play a large role in the allocation of research funds. Proponents of funding advocacy contend that advocacy involvement in research funding allocation will result in a research budget more consistent with public preferences and interests, better informed government officials and scientists, and will benefit patients and their families. Their involvement will

¹⁵ Rose *supra* note 3 at 680; Lofgren, *supra* note 6 at 228.

¹⁶ Cinzia Colombo et al, "Patient Organizations' Funding from Pharmaceutical Companies: Is Disclosure Clear, Complete and Accessible to the Public? An Italian Survey" (2012) 7:5 PLoS ONE at 1; Hall, *supra* note 12 at 1020.

¹⁷ Mayer, *supra* note 11 at 69; Keller & Packel, *supra* note 9 at 333; Dresser, Rebecca. *When Science Offers Salvation: Patient Advocacy and Research Ethics* (New York: Oxford University Press, 2001) at 24 [Dresser].

¹⁸ *Ibid* at 24-5; Margo Michaels & Deborah Collyar "Research Advocacy in Traditional Research Settings: Questions of Influence and Legitimacy in Jo Anne L Earp, Elizabeth A. French & Melissa B. Gilkey, eds, *Patient Advocacy for Health Care Quality: Strategies for Achieving Patient-centered Care* (Mississauga: Jones and Bartless Publishers, 2008) at 446.

¹⁹ Sheila M. Rothman, "Health Advocacy Organizations and Evidence-Based Medicine" (2011) 305:24 *Journal of the American Medical Association* 2569 at 2569 ; Rose, *supra* note 3 at 680.

²⁰ *Ibid*; Melissa B. Gilkey, Jo Anne L. Earp & Elizabeth A. French "What is Patient Advocacy" in Jo Anne L Earp, Elizabeth A. French & Melissa B Gilkey, eds, *Patient Advocacy for Health Care Quality: Strategies for Achieving Patient-centered Care* (Mississauga: Jones and Bartless Publishers, 2008) 21.

help to reallocate funding more consistent with public preferences, because scientific curiosity and professional reasons, which typically guide research funding allocation often deviate from public preferences. Funding advocacy helps to bring the human costs of disease and illness to the forefront of the decision-making process. Furthermore, funding advocacy can help raise public awareness, which can also lead to higher rates of local funding and charitable giving.²¹

However, the power of patient advocacy groups lobbying for research funds can have undesirable consequences. It can result in research funding allocation that exacerbates social inequalities rather than alleviating them. It can result in funding poor-quality studies where advocates are powerful, while neglecting more impactful studies with less powerful advocates. Many interests are at stake when research funding allocation decisions are made, and when patient advocates sit at the table they do not do so equally across all diseases and illnesses. Groups with powerful connections or more “presentable” diseases may have an advantage accessing funds.²² This was the case with HIV/AIDS advocates, who were incredibly powerful and educated. Comparatively, advocates for rarer, less prevalent diseases may not benefit from that same knowledge and skill base.²³ This is problematic because more effective advocates may not represent the health issues that should be prioritized, based on objective criteria such as social burdens of disease and the potential for scientific funding. If advocacy groups continue to influence funding decisions, it is possible that funding could end up focusing on conditions that affect influential groups or individuals rather than conditions that affect other populations equally.²⁴ In doing so, quality of the proposed studies may become subordinate to the influence of the groups, resulting in funding poorly designed studies that contribute little to health and medical sciences. To counter this, policies should be put in place to ensure that interest groups have fair representation in research decision making.²⁵

In terms of research design, advocacy groups can both add to and detract from research quality and impact. Involving patient advocates can help to encourage collaboration among researchers and refocus to more practical, meaningful goals as opposed to preferring research that will be most influential for their career.²⁶ When researchers consult participants of studies to see what their concerns are and what matters to them, this increases enrollment, community support, and cooperation of participants.²⁷ Advocates have a unique understanding of the impact of illness and disease on patients and families, which can help determine what research proposals should deserve funding. This personal knowledge of the impact of disease can counteract the “professional myopia” that results when scientists stray too far from the humanistic goals of medical research.²⁸ Advocates can also have a negative impact on research design and progress. Advocates tend to focus on research solely with the hopes of finding a cure. Critics of the involvement of patient advocates in research design and funding

²¹ *Ibid* at 96.

²² *Ibid* at 97.

²³ *Ibid* at 156.

²⁴ *Ibid* at 98.

²⁵ *Ibid* at 156.

²⁶ Mayer, *supra* note 11 at 70.

²⁷ Dresser, *supra* note 17 at 30-32.

²⁸ *Ibid* at 154.

note that this may deter progress as research focusing on basic scientific principles may be undervalued compared to research, even poorly designed research, that may provide a new treatment.²⁹ Advocacy groups can also unwittingly impede research progress by advocating for research studies that are too narrow, focusing on specific treatments rather than basic science that is critical to clinical progress. In doing so, they can promote unproven interventions, prolonging, or in some cases even precluding research to determine the effectiveness of such interventions.³⁰

Perhaps more influential than their role in research design is the power of patient advocacy groups to disseminate information. This issue is two-fold. The first issue to consider is where advocates receive their information and how they interpret it, and the second issue is how patient advocacy groups take that information and communicate it to their group members and the public. The common thread through the transfer of information between scientists, advocates, and the public is the role of the media and the disastrous effects of inaccurate reporting. Advocates receive and collect much of their information from the media; if media reports fully captured the nuances of scientific and medical journal articles, this could represent a revolutionary empowerment of advocates and the public, leveling the playing field between professionals and non-professionals.³¹ Unfortunately this is not typically the case. There are many examples of the harms that have occurred following an inaccurate news story regarding a possible treatment or medical breakthrough.³² Inaccurate reporting, often the result of pressure on journalists and scientists to exaggerate research results, can generate interest in treatments or interventions with little evidence supporting their effectiveness, or may similarly discourage patients from seeking treatment or services with demonstrable effectiveness by inappropriately skewing the risks. Such media coverage can also cause patients and the public to support policies and research funding allocations not based in evidence.³³ This short-sighted reporting style, favoured for its economic and career boosting effects by both scientists and journalists, can have dire long-term consequences: it erodes public trust in both medical and media institutions.³⁴ On top of this, patient advocacy groups tend to further exaggerate the benefits or risks of research results reported by the media in their reporting to their group members. Patients trust these organizations to act on their behalf and to provide accurate information, and patient advocacy groups are regarded as a trusted news source.³⁵

Advocacy groups influence patients' understandings of various aspects of the illness or disease they concern themselves with, and help them make decisions about health care and participation in

²⁹ *Ibid* at 154-5.

³⁰ *Ibid* at 10.

³¹ *Ibid* at 131.

³² See e.g. *ibid* at 132-3 (for examples of the consequences from inaccurate news reporting).

³³ Roberto Grilli, "Media Have Key Role in Shaping Use of Health Services" (1999) 319:7212 *British Medical Journal* 786; See generally Dresser, *supra* note 17 at 134-139 (different effects of journalists and scientists on media misinformation).

³⁴ *Ibid* at 141.

³⁵ National Health Council "Key Survey Findings" (1997), as cited in Dresser, *supra* note 17 at 148 (US survey found that 93 % of respondents said advocacy groups were among the most believable sources of health information, receiving the same credibility rating as physicians).

research studies.³⁶ It is clear that there are still many unknowns associated with including patients in the policy making process. While the benefits are significant enough to warrant continue involvement of patients, the possible drawbacks warrant further study into how to best mitigate or eliminate some of the above-mentioned challenges, so that the benefits of patient advocacy can be realized and utilized.

III. Lyme Disease and Patient Advocacy

A. Background

Lyme disease provides a contemporary case study of the impact of patient advocacy on health policy and law, both locally in Canada and internationally. The history of Lyme disease is steeped in advocacy. It was first discovered in Old Lyme, Connecticut in 1975 after concerned mothers “pressed it into medical consciousness” by advocating on behalf of their children.³⁷

Lyme disease is now the most common vector-borne disease in North America, and has been the source of ongoing controversy.³⁸ There is extensive disagreement regarding many aspects of the disease, including diagnosis, treatment, symptoms, and nomenclature, that has created a large amount of confusion among patients and the public. Numerous patient advocacy groups have formed in Canada, most notably the Canadian Lyme Disease Foundation (CanLyme), a registered non-profit charitable organization that focuses primarily on awareness, research, literature review, and advocacy.³⁹ Numerous other national and regional support and advocacy groups exist, with varying levels of advocacy efforts.⁴⁰ The rest of this paper will examine the impact of Lyme disease patient advocacy groups in influencing the policy change.

B. Legislative Response

In response to constituent concern, Member of Parliament Elizabeth May introduced Bill C-442, *An Act Respecting a Federal Framework on Lyme Disease*.⁴¹ In 2014, the *FFDLA* received royal assent and became law. Section 3 of the *FFDLA* requires the federal government to develop a comprehensive

³⁶ Dresser, *supra* note 17 at 131.

³⁷ John J. Halperin, “Prolonged Lyme Disease Treatment: Enough is Enough” (2008) 70 *Neurology* 986 at 986. [Halperin].

³⁸ T.F. Hatchette, I. Davis & B.L. Johnston “Lyme Disease: Clinical Diagnosis and Treatment” (2014) 40:11 *Canada Communicable Disease Report* 194 at 196.

³⁹ Canadian Lyme Disease Foundation, “About”, online: <<https://canlyme.com/about/>>.

⁴⁰ See e.g. Lyme Action Group, online: <<http://lymeactiongroup.blogspot.ca/>>; Lyme Disease Network, online:

<<http://www.lymenet.org/SupportGroups/Canada/>>; Lyme Ontario: About Us, online:

<<http://lymeontario.com/about/about-us/>>; Ontario Lyme Alliance, online:

<<http://www.ontariolymealliance.ca/aboutus.html>>; Lyme Disease Association of Alberta: What We Do, online:

<<http://www.albertalyme.org/about-ldaa/what-we-do>>.

⁴¹ Canada, 2nd Sess, 41st Parl, 2013 (assented to 16 December 2014).

framework on Lyme disease addressing prevention, education, surveillance, and treatment.⁴² The framework's goal is to improve current diagnostic and treatment protocols to decrease the physical, psychological and financial burdens on patients with Lyme disease. After the *FFLDA* became law, the public was encouraged to provide feedback on the Federal Framework's goals. The Public Health Agency of Canada ("PHAC") held a consultation period from June 1, 2015 to June 30, 2015 to allow stakeholders and Canadians to submit feedback on the three themes of the Conference: national medical surveillance, guidelines, and education and awareness.⁴³ CanLyme expressed discontent for not being consulted in the creation of the consultation questions, stating that,

Without any consultation with the most important stakeholders, PHAC sent this survey out to physicians, nurses, naturopaths, and patient groups...[i]t directs those respondents to the survey to answer pre-designed questions, offers very limited ability for input, and is more about seeking data about who responds, and how they like what the government has done so far. It provides no room for the debate of the quality of the data PHAC has gathered and disseminated using our tax dollars.⁴⁴

PHAC has stated that a summary of the consultation period will be posted on their website, but as of January 31st 2017 there is no online summary report available.

Additionally, in June 2015 a one-day "Best Brains Exchange" ("BBE") workshop was held by the Canadian Institute of Health Research and PHAC in Ottawa. Attendees included physicians, clinicians, researchers, and policy makers. The goal of the workshop was to "highlight existing and relevant research evidence on the topic; identify where gaps in evidence lie; bring together both decision maker and researcher expertise on the issue; and, candidly discuss the applicability of the research."⁴⁵ The BBE allowed over 35 stakeholders from different jurisdictions and disciplines to share perspectives on the diagnosis of Lyme disease. The objective of the BBE was to determine how effective current diagnostic tests are in detecting Lyme disease at various stages (early, late, and post-treatment), and what novel methods are promising for improving diagnosis.⁴⁶ During the BBE, presenters and participants recognized the current challenges with diagnosing Lyme disease. Areas for further research were identified, including innovation from other fields, such as oncology, exploring biodiversity of ticks and the *B. burgdoferi* bacteria, the need for better information exchange between academics and clinicians, and transitioning from passive surveillance to active surveillance.⁴⁷

As mandated by the *FFLDA*, the Federal Framework on Lyme Disease Conference was held on May 15-17, 2016 in Ottawa. The aim of the conference was to assist in the development of a framework

⁴² *Supra* note 1.

⁴³ Public Health Agency of Canada, "Consultation on the Federal Framework on Lyme Disease" (28 July 2015) online: <http://www.phac-aspc.gc.ca/about_apropos/engagement-participation/lyme-consultation-eng.php>.

⁴⁴ Canadian Lyme Disease Foundation, "The Federal Government of Canada NOT Acting in Good Faith so Far on Bill C-442", (6 June 2015) online: <<https://canlyme.com/2015/06/06/the-federal-government-of-canada-not-acting-in-good-faith-so-far-on-bill-c-442/>>.

⁴⁵ Canadian Institutes of Health Research "Best Brains Exchange Report – Lyme Disease Diagnostics" (31 March 2016) online: <<http://www.cihr-irsc.gc.ca/e/49713.html>>.

⁴⁶ *Ibid.*

⁴⁷ *Ibid.*

to prevent and reduce Lyme disease-related health risks, focusing on medical surveillance for tracking, guidelines and best practices, and standardized educational materials.⁴⁸ The Government of Canada released a Summary Report of the Conference, indicating that 62% of the in person and online participants self-identified as patients, caregivers, or patient groups.⁴⁹ Jim Wilson, president of CanLyme, described this as a “well balanced” conference.⁵⁰ I respectfully disagree, and instead argue that patient and patient advocate perspectives eclipsed those of the other attendees. Key messages identified in the Conference Summary include the lack of awareness of Lyme disease within the medical community, the prevalence of misdiagnosis, discontent with patients seeing multiple specialists, prevalence of patients seeking treatment outside of Canada, and the inadequacy of diagnosing, reporting, and awareness of Lyme disease. Key messages from patients related to Guidelines and Best Practices include the need for interim solutions for improved diagnostics while science catches up, and protection for physicians who treat outside the existing treatment guidelines, among other things.⁵¹

In February 2017, the draft Federal Framework was made available to the public for review and comments.⁵² The draft is vague, but given the current state of knowledge on Lyme disease, making specific promises or suggestions is not feasible. The draft framework identifies broad projects to be undertaken, such as conducting a costs analysis of the direct and indirect costs of Lyme disease in Canada, and implementing new data collection methods. Most of the actions focus on expanding current programs or initiatives or supporting research endeavors. A petition on Change.org has already been initiated asking the government to reject the draft Framework, proposing that “[t]he draft framework is a violation of Public Health’s [sic] mandate, Bill 442 and possibly the Canadian Charter of Rights and Freedoms (s.7).”⁵³ As of February 17, 2017, the petition has been signed by over 20,000 supporters. Can Lyme has also spoken out against the draft Framework, arguing that the draft fails to meet the mandate of the *FFLDA* and calling for the draft to be “set aside and rewritten with the patients and their experts.”⁵⁴

⁴⁸ Government of Canada, “Conference to Develop a Federal Framework on Lyme Disease May 15-17, 2016: Conference Summary Report” (October 20, 2016) online: <http://healthy Canadians.gc.ca/publications/diseases-conditions-maladies-affections/summary-report-lyme-2016-conference-rapport-sommaire/index-eng.php?_ga=1.86750232.1497520611.1485190863> [Conference Report].

⁴⁹ *Ibid* (the remainder was 6% provincial government, 5% academic/research, 7% federal government, 13% medical professional/association, 7% other).

⁵⁰ Canadian Lyme Disease Foundation, “Draft of report to parliament regarding Bill 442 now online and open to public input” (7 February 2017) online: <<https://canlyme.com/2017/02/07/draft-of-report-to-parliament-regarding-bill-442-now-online-and-open-to-public-input/>> [“Draft of report”].

⁵¹ Conference Summary, *supra* note 48.

⁵² Government of Canada, “Consultation on the draft Federal Framework on Lyme disease” (17 February 2017) online: <<https://www.canada.ca/en/public-health/programs/consultation-draft-federal-framework-lyme-disease.html>>.

⁵³ “Ticking Lyme Bomb in Canada. YOU are at RISK. Sign now!” Change.org online: <https://www.change.org/p/minister-philpott-ticking-lyme-bomb-in-canada-fix-canada-s-lyme-action-plan-now?source_location=topic_page> (assuming that Public Health refers to the Public Health Agency of Canada, also that Bill 442 refers to former Bill c-442, now the *FFLDA*) [“Ticking Lyme Bomb”].

⁵⁴ “Draft of report”, *supra* note 50.

C. Implications

Lyme disease patients and patient advocacy groups have been involved at almost every step of the policy process. While their activities in general are not troubling, there are a few reasons for concern. First, many Lyme disease advocates hold beliefs about Lyme disease with either no scientific support, or supported by flawed science. Comparisons have been drawn between Lyme disease advocates and other anti-science movements such as anti-vaxxers.⁵⁵ Some of the controversial views held by advocates include the following: Lyme disease requires being treated by months or years of antibiotics⁵⁶, Lyme disease can be transmitted sexually or in-utero⁵⁷, and the concept that Lyme disease can present as a chronic disease.⁵⁸

Additionally, many of the changes sought by patients show a clear disregard for the broader implications for the Canadian healthcare system. For example, patients advocated for the need to amend the *Health Care Act* to reimburse past and future out-of-pocket expenses incurred by patients not covered by provincial health insurance, without acknowledging the consequences of providing coverage for treatment or therapies not deemed useful or safe by evidence. Patients advocated for automatic testing of spouses of patients with Lyme disease, due to their beliefs that Lyme disease can be transmitted through bodily fluids, without consideration for the privacy implications of such a policy, or the impracticality of such a practice.⁵⁹ Patients also advocated for lifting restrictions on prescribing antibiotics, based on their belief that long-term antibiotics are necessary for treatment and management of chronic Lyme disease. Currently, there are recommendations regarding the appropriate course of antibiotics for the treatment of Lyme disease, however this does not prevent physicians from using their clinical judgement to treat outside those limits, provided they are doing so in the best interest of their patients.⁶⁰ Patients seem to be operating on the understanding that physicians will be prosecuted or punished for treating outside these guidelines, however it has been made clear that physicians are encouraged to use their judgement within reason.⁶¹ This suggestion fails to consider the implications of lifting such restrictions, such as antibiotic resistance or potential abuse by physicians.

⁵⁵ See Paul G. Auwaerter et al, "Antiscience and Ethical Concerns Associated with Advocacy of Lyme Disease" (2011) 11:9 *Lancet Infectious Disease* 713 at 720 [Auwaerter].

⁵⁶ See e.g. Halperin, *supra* note 37.

⁵⁷ See e.g., Raphael B. Stricker & L. Johnson, "Lyme Disease: The Promise of Big Data, Companion Diagnostics and Precision Medicine" (2016) 9 *Infection and Drug Resistance* 215 citing Raphael B. Stricker & Marianne J. Middelveen, "Sexual Transmission of Lyme Disease: Challenging the Tickborne Disease Paradigm" (2015) 13, *Expert Review of Anti-Infective Therapy* 1306 (both articles allude to the possibility of Lyme disease being sexually transmitted, however studies cited are either animal studies, or only find evidence of bacteria in vaginal and semen secretions, not that it can be transmitted via those secretions); See also "Ticking Lyme Bomb", *supra* note 57.

⁵⁸ Auwaerter, *supra* note 55 at 68-70.

⁵⁹ Conference Report, *supra* note 48.

⁶⁰ Government of Canada, "For Health Professionals: Lyme Disease" (02 August 2016) online: <<https://www.canada.ca/en/public-health/services/diseases/lyme-disease/health-professionals-lyme-disease.html#a3>> (treatment guidelines are listed, however it is specified that "[t]he regimens may need to be adjusted depending on a patient's age, allergies, medical history...").

⁶¹ See e.g. Conference Report, *supra* note 48.

While policy changes sought by patients were not reflected in the draft Framework they have already demonstrated the willingness and capability to continue to fight. If patient advocates are successful in changing the language or substance of the Framework, there are many implications to consider. For example, including patient perspectives could prove dangerous if it results in the approval of treatments or therapies that have no proven efficacy. Lantos et al identified more than thirty alternative treatments marketed towards Lyme disease patients on the internet, categorized as oxygen and reactive oxygen therapy, energy and radiation-based therapies, nutritional therapy, chelation and heavy metal therapy, or biological and pharmacological therapies. Upon review of medical literature, none of the identified treatments were supported by evidence, and many were identified as potentially harmful.⁶² These inappropriate therapies have the potential to prolong appropriate treatment, cause severe side effects, or in some cases, death.⁶³ As noted above, patient advocacy groups, and even physicians, are lobbying the government to amend the guidelines to allow long-term antibiotic use, for months, years, or even indefinitely.⁶⁴ There is no concrete evidence to support this as a valid treatment option, and it fails to consider the very serious individual and community-wide side effects that such rampant and careless use of antibiotics could cause.⁶⁵ Further, if they are successful in changing clinical guidelines for treating Lyme disease, this could set a precedent for other advocates to similarly pursue changes to clinical guidelines in absence of any evidence, creating a system of patient-guided medical guidelines.

Advocates also expressed a desire to grant immunity for physicians and alternative medicine practitioners who practice outside of the recommended guidelines by imposing a “moratorium on penalties/professional consequences for physicians diagnosing and treating Lyme disease” as well as imposing penalties on medical colleges that prosecute physicians who treat Lyme disease patients.⁶⁶ Moreover, they sought to have physicians who have lost their medical license “due to treating Lyme disease” reinstated. This goal also fails to comprehend the wide-spread implications of such a policy. If this were to be incorporated into the Framework, it would remove safeguards that are in place to prevent exploitative behaviour and ensure patients are protected from either unqualified or misinformed physicians.

Patient-sought changes to Lyme disease research are also indicative of Lyme-disease tunnel vision. Patients advocated to loosen the diagnostic criteria for involvement in research, while researchers identified the need to have clearly articulated cohorts to ensure the results are as useful

⁶² Lantos, Paul M. et al. “Unorthodox Alternative Therapies Marketed to Treat Lyme Disease” (2015) 60:12 *Clinical Infectious Diseases* 1776.

⁶³ See e.g. Robin Patel et al, “Death from Inappropriate Therapy for Lyme Disease” (2000) 31:4 *Clinical Infectious Diseases* 1107 (a 30 year old woman died from a septic thrombus on a catheter that was in place for over 2 years to administer antibiotics to treat an unproven case of Chronic Lyme disease).

⁶⁴ See e.g. Canadian Lyme Science Alliance, online: <<http://www.lymesciencealliance.org>> (the CLSA is an organization of scientists and clinicians that started a petition requesting “sound, science-based policy from the FFLDA including long term antibiotic treatment for chronic Lyme disease).

⁶⁵ Paul G. Auwaerter & Michael T. Melia, “Bullying Borrelia: When the Culture of Science is Under Attack” (2012) 123 *Transactions of the American Clinical and Climatological Association* 79.

⁶⁶ Conference Summary, *supra* note 48.

and accurate as possible. Allowing patients without a clear diagnosis of Lyme disease to participate in research could undercut the research process and slow down the advancement of knowledge. Furthermore, providing “interim relief” for those suffering from Lyme disease, as requested at the Conference, could result in the same impediments experienced by AIDS researchers.⁶⁷ If patients are granted access to long-term antibiotics funded by provincial health plans, the desire to participate in clinical trials will presumably suffer, effectively slowing down the research that patients and physicians are advocating for, as well as decreasing motivation for alternative research efforts that could prove to be more promising.

All of this is not to suggest that the patient involvement did not contribute important insights. Patients stressed the need to further understand the different strains of Lyme disease, the need to fund more clinical research, and the need to ensure physicians across the country are aware of how to diagnose and treat Lyme disease.⁶⁸ These suggestions were echoed by policy makers, researchers, and physicians present at the conference. However, most of the constructive suggestions raised at the Conference were also discussed at the BBE, which occurred prior to the Conference. This undermines the effectiveness of holding such large patient consultation events. Upon review of the draft Framework, it does not appear that patient perspectives from the Conference had much impact on the Framework, which further supports the suggestion that such exhaustive endeavors to involve patients adds little value to the process.

IV. Conclusion

Patient advocacy is pervasive in Canadian health policy, and will likely continue to be. The Lyme disease case study provides valuable insight as to how to better manage the involvement of patient advocacy in developing health policies in the future. While the Conference provided a much-needed outlet for frustrated patients and allies to have their voices heard, it does not appear that the patient input influenced the draft Framework. The draft Framework confirms many of the conclusions made at the BBE, primarily that research and awareness should be the primary focus until more evidence is available to support new diagnostic or treatment guidelines. This experience has left patients and advocates feeling betrayed as they double-down to fight back against the draft framework. This highlights the importance of managing expectations when patient advocates are involved in the policy-making process. It is clear that policy-makers and patient advocates had different expectations as to what their involvement signified. While patient advocates are fighting to have their perspectives incorporated into the Framework, the lack of patient concerns represented in the Framework suggests that the intention of patient involvement was to obtain a holistic view of the impact of Lyme disease on Canadians; not to create patient- driven policy.

⁶⁷ *Ibid.*

⁶⁸ See e.g. Cécile Ferrouillet et al, “Lyme Disease: Knowledge and Practices of Family Practitioners in Southern Quebec” (2015) 26:3*Canada Journal of Infectious Diseases and Medical Microbiology* 151 (results shows a moderate lack of knowledge and suboptimal practices).

Moving forward, it is important to continue to research patient advocacy and how it can be most effective in drafting ethical and effective health policy. One way to improve the experience of patient advocates is to develop federal or provincial guidelines for how to involve patients in the policy-making process, including appropriate limitations to their involvement. This will ensure that different advocates are afforded the same opportunities regardless of their size or influence, and will ensure that all parties involved are conscious of their roles in the process, as well as their limitations. This would help to avoid repeating the experience of Lyme disease advocacy, who argue that the government has failed to incorporate their perspective. However, the *FFLDA* does not mandate that the Framework include all the demands sought by patients, it only mandates that patient representatives be included in the Conference, which they were. Somewhere along the way, patient advocates interpreted the *FFLDA* to mean that the government had a duty to consult patient advocates at every stage of the process. Had the relationship between patient advocacy and policy-makers been better defined, most of the antagonism that current exists between patient groups and policy makers could have been avoided. Such guidelines would ensure that patients are included in a meaningful way but are not afforded absolute deference.

Second, increasing the capacity of advocates to be critical of scientific and medical research will permit advocates to participate more meaningfully in policy discussions. In doing so, I do not suggest that experts should go unchallenged; pushing back against expert evidence is a necessary function of a democratic society that ensures government funded agencies remain accountable to the population it serves. To conclude, I do not suggest putting limitations on patient advocacy as a method for silencing patients; this paper has shown that there is great value in including patients in various aspects of health policy. Rather it is to ensure that patients can be assured that their concerns will be genuinely considered in a cost-effective manner, and that evidence-based information will prevail in an informational environment increasingly dominated by pseudoscience and unethical promotion of services that take advantage of vulnerable persons.

References

- Auwaerter, Paul G. et al. "Antiscience and Ethical Concerns Associated with Advocacy of Lyme Disease" (2011) 11:9 *Lancet Infectious Disease* 713.
- Auwaerter, Paul G. & Michael T. Melia. "Bullying Borrelia: When the Culture of Science is Under Attack" (2012) 123 *Transactions of the American Clinical and Climatological Association* 79.
- Bill C-442, *An Act Respecting a Federal Framework on Lyme Disease*, Canada, 2nd Sess, 41st Parl, 2013 (assented to 16 December 2014).
- Canadian Institutes of Health Research. "Best Brains Exchange Report – Lyme Disease Diagnostics" (31 March 2016) online: <<http://www.cihr-irsc.gc.ca/e/49713.html>>.
- Canadian Lyme Disease Foundation. "About", online: <<https://canlyme.com/about/>>.
- Canadian Lyme Disease Foundation. "Draft of report to parliament regarding Bill 442 now online and open to public input" (7 February 2017) online: <<https://canlyme.com/2017/02/07/draft-of-report-to-parliament-regarding-bill-442-now-online-and-open-to-public-input/>>.
- Canadian Lyme Disease Foundation. "The Federal Government of Canada NOT Acting in Good Faith so Far on Bill C-442", (6 June 2015) online: <<https://canlyme.com/2015/06/06/the-federal-government-of-canada-not-acting-in-good-faith-so-far-on-bill-c-442/>>.
- Canadian Lyme Science Alliance. Online: <<http://www.lymesciencealliance.org>>.
- Colombo, Cinzia et al. "Patient Organizations' Funding from Pharmaceutical Companies: Is Disclosure Clear, Complete and Accessible to the Public? An Italian Survey" (2012) 7:5 *PLoS ONE*.
- Dresser, Rebecca. *When Science Offers Salvation: Patient Advocacy and Research Ethics* (New York: Oxford University Press, 2001).
- Epstein. Steven. *Impure Science: AIDS, activism, and the Politics of Knowledge* (Berkeley: University of California Press, 1996).
- Federal Framework on Lyme Disease Act*, SC 2014, c 37.
- Gilkey, Melissa B., Jo Anne L. Earp & Elizabeth A. French. "What is Patient Advocacy" in Jo Anne L Earp, Elizabeth A. French & Melissa B Gilkey, eds, *Patient Advocacy for Health Care Quality: Strategies for Achieving Patient-centered Care* (Mississauga: Jones and Bartless Publishers, 2008).
- Grilli, Roberto. "Media Have Key Role in Shaping Use of Health Services" (1999) 319:7212 *British Medical Journal* 786.

- Government of Canada. "Conference to Develop a Federal Framework on Lyme Disease May 15-17, 2016: Conference Summary Report" (October 20, 2016) online: <http://healthycanadians.gc.ca/publications/diseases-conditions-maladies-affections/summary-report-lyme-2016-conference-rapport-sommaire/index-eng.php?_ga=1.86750232.1497520611.1485190863>.
- Government of Canada. "Consultation on the draft Federal Framework on Lyme disease" (17 February 2017) online: <<https://www.canada.ca/en/public-health/programs/consultation-draft-federal-framework-lyme-disease.html>>.
- Government of Canada. "For Health Professionals: Lyme Disease" (02 August 2016) online: <<https://www.canada.ca/en/public-health/services/diseases/lyme-disease/health-professionals-lyme-disease.html#a3>>.
- Hall, J.G. "The Role of Patient Advocacy/Parent Support Groups" (2013) 103:12 *South African Medical Journal* 1020.
- Halperin, John J. "Prolonged Lyme Disease Treatment: Enough is Enough" (2008) 70 *Neurology* 986.
- Hatchette, T.F., I. Davis & B.L. Johnston. "Lyme Disease: Clinical Diagnosis and Treatment" (2014) 40:11 *Canada Communicable Disease Report* 194.
- Keller, Ann C. & Laura Packel. "Going for the Cure: Patient Interest Groups and Health Advocacy in the United States" (2014) 39:2 *J Health Pol* 331 at 335.
- Lantos, Paul M. et al. "Unorthodox Alternative Therapies Marketed to Treat Lyme Disease" (2015) 60:12 *Clinical Infectious Diseases* 1776.
- Lyme Action Group, online: <<http://lymeactiongroup.blogspot.ca/>>.
- Lyme Disease Association of Alberta: What We Do, online: <<http://www.albertalyme.org/about-ldaa/what-we-do>>.
- Lyme Disease Network, online: <<http://www.lymenet.org/SupportGroups/Canada/>>.
- Lyme Ontario: About Us, online: <<http://lymeontario.com/about/about-us/>>.
- Mackey, Tim K. & Virginia J. Schoenfield. "Going "Social" to Access Experimental and Potentially Life-saving Treatment: An Assessment of the Policy and Online Patient Advocacy Environment for Expanded Access" (2016) 14:17 *BMC Medicine*.
- Michaels, Margo & Deborah Collyar. "Research Advocacy in Traditional Research Settings: Questions of Influence and Legitimacy" in Jo Anne L Earp, Elizabeth A. French & Melissa B Gilkey, eds, *Patient Advocacy for Health Care Quality: Strategies for Achieving Patient-centered Care* (Mississauga: Jones and Bartless Publishers, 2008).
- Mayer, Musa. "Patient Advocacy in Research: Merely an Afterthought?" (2011) 4:2 *Patient* 69.

Nathanson, Constance A. *Disease Prevention as Social Change: The State, Society and Public Health in the United States, France, Great Britain, and Canada* (New York: Russell Sage Foundation, 2007).

Ontario Lyme Alliance. Online: <<http://www.ontariolymealliance.ca/aboutus.html>>.

Patel, Robin et al. "Death from Inappropriate Therapy for Lyme Disease" (2000) 31:4 *Clinical Infectious Diseases* 1107.

Public Health Agency of Canada. "Consultation on the Federal Framework on Lyme Disease" (28 July 2015) online: <http://www.phac-aspc.gc.ca/about_apropos/engagement-participation/lyme-consultation-eng.php>.

Rothman, Sheila M. "Health Advocacy Organizations and Evidence-Based Medicine" (2011) 305:24 *Journal of the American Medical Association* 2569.

Rose, Susannah L. "Patient Advocacy Organizations: Institutional Conflicts of Interest, Trust, and Trustworthiness" (2013) 41:3 *JL Med & Ethics* 680.

Stricker, Raphael B. & L. Johnson. "Lyme Disease: The Promise of Big Data, Companion Diagnostics and Precision Medicine" (2016) 9 *Infection and Drug Resistance* 215.

Stricker, Raphael B. & Marianne J. Middelveen. "Sexual Transmission of Lyme Disease: Challenging the Tickborne Disease Paradigm" (2015) 13 *Expert Review of Anti-Infective Therapy* 1306.

Sulik, Gayle A., Carrie Cameron & Robert M. Chamberlain. "The Future of the Cancer Prevention Workforce: Why Health Literacy, Advocacy, and Stakeholder Collaborations Matter" (2012) 27:Suppl 2 *Journal of Cancer Education* S165.

"Ticking Lyme Bomb in Canada. YOU are at RISK. Sign now!" Change.org online: <https://www.change.org/p/minister-philpott-ticking-lyme-bomb-in-canada-fix-canada-s-lyme-action-plan-now?source_location=topic_page>.

Wallack, Lawrence et al. *Media advocacy and public health: power for prevention* (Newbury Park, California: Sage Publications, Inc: 1993).