

**B T
E R**

BIO-THERAPEUTICS EDUCATION & RESEARCH FOUNDATION

Advancing health care through education and research in biotherapy

ANNUAL REPORT

2014 - 2015



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Randall L. Sullivan, RN, BHSc.
January 4, 1931 - February 24, 2014

This year's Annual Report describes many achievements that should be joyously celebrated by the BTER Foundation members and the larger community. But we also want to note one of our greatest disappointments this year: the passing of one of our Founding Board Members, Randall L. Sullivan, RN, BHSc.

Ms. Sullivan was born in Birmingham, Alabama, on January 4, 1931, though she spent much of her childhood in Detroit, Michigan. She joined the U.S. Navy after high school, graduated from Navy Hospital Corpsman School, and was honorably discharged 5 years later. After discharge, Randall Sullivan obtained her LVN and then her RN, eventually becoming one of the first and premier skin integrity nurses and nurse educators. She retired from the Veterans Affairs Medical Center in Long Beach, California in 1991, but she never retired from the profession of nursing, nor from the field of wound care. Ms. Sullivan spent several years participating in maggot therapy during the 1990's, and helped establish the BTER Foundation in 2003, becoming the organization's executive board Secretary and taking a leading role on the Education Committee. Randall Sullivan published several papers on wound care and wound care education, including several on maggot therapy. She was also very active in her community, involved in numerous charity projects.

Randy Sullivan passed away peacefully at her home in Long Beach, California, on February 24, 2014. A memorial service was held by the Psi Eta Chapter of the Chi Eta Phi Nursing Sorority, of which she was an active leader.

The BTER Foundation has established the Randall Sullivan Memorial Fund for Therapist Education in her honor. Fund-raising has already begun, in the hopes of continuing her work in wound care education.

May her memory be a blessing to all.





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Mission Statement

The BTER Foundation was formed to advance health care through education and research in “biotherapy.” Biotherapeutic treatments are those that involve living animals, such as leeches (hirudotherapy), fly larvae (maggot therapy), honey bees (bee venom therapy), round worms (helminthic therapy), fish (ichthyotherapy), large animals like dogs and horses (service animals and pet therapy, hippotherapy) . . . And even microbes (phage therapy, bacteriotherapy, fecal microbiota transplants).



The BTER Foundation accomplishes its mission by: a) supporting research in biotherapy; b) making information about these modalities readily available to all; c) working to overcome the financial barriers which prevent individuals in need from accessing these services. To date, thousands of lives have been saved or improved as a result of these activities.

Message from the Chairman of the Board

Two years ago, publication of the BTER Foundation's Annual Report switched from a yearly calendar to a biannual calendar, not because we did not have enough to publish every year but because we were so busy serving our clients that we did not want to take time out to boast about it. Of course, we recognize that sharing our stories and accomplishments is important, too. Our members, our Directors, our supporters all want to hear every detail in a timely fashion. Indeed, they deserve to hear all about it, as do you.

As a result, we hired an assistant editor in 2014 to assist us in taking advantage of social media, in an effort to keep everyone up to date on our activities at the BTER Foundation, and what's going on in biotherapy in general. We now have a greater presence on social media, where we communicate on Twitter and Facebook. We expanded our other publications as well. **The BeTER LeTTER** is now published 10 - 12 times per year. We began a new publication, **Biotherapy Journal Review**, which now brings critical biotherapy publications to the attention of readers who may not otherwise find these works. Our website was given another overhaul, as we typically do every 3 or 4 years. Its faster, sleeker design helps ensure that the rapidly growing content remains easily accessible to all.

If you have been with us for the past two years you will already be aware of most of the achievements described in this report. If you are new to the Foundation — or if you simply have not had time to follow our communications on a monthly basis — you can now read about our recent activities and our plans for the coming year. Join us in our bi-annual celebration as you turn the pages of this report. Be inspired with us as we dream of all that has yet to be accomplished. Journey with us as we explore and bring to fruition the many health benefits of living with other animals.

Join us vicariously by reading this report. Join us in real time by keeping up with our newsletters and posts on social media (www.facebook.com/bterfoundation/ or <https://twitter.com/bterfoundation/>). Or you can literally join us as an integral part of the team, by becoming a member or contributor. Either way, I think you will be amazed by what we are learning, what we are sharing through our educational programs, and how we are transforming the practice of medicine. Thank you for helping us help others.



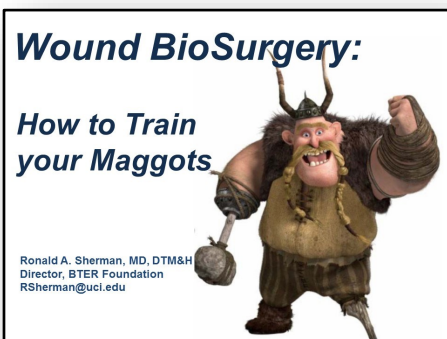
A stylized, handwritten signature in black ink that reads "R Sherman".

Ronald A. Sherman, MD
Chair, Board of Directors

The Year in Review

Advances in Education

The BTER Foundation continued to produce and present lectures and workshops, including the Long Term Care Nursing Continuum Symposium (Lake Geneva, Wisconsin; 2/22/2015) and the Academy of Physicians in Wound Healing (Philadelphia; 10/2/2015). Other new audiences include the Eastern Idaho Wound Care Conference (Idaho Falls; 4/11/2014) and the Medical Surgical Nursing Conference (San Francisco; 4/16/2015). We also had the pleasure of returning to speak at some of our long-time sponsoring conferences: University of California (Irvine; 11/3/2014), California State University (Long Beach; 11/6/2014), Superbones West (Las Vegas; 10/22/2015), and Desert Foot (Las Vegas; 11/20/2015). As always, our staff enjoyed the great reception we received at Wild on Wounds during our eighth and ninth yearly workshops in Los Vegas (9/20/2014 and 9/4/2015).



The BTER Foundation Internship Program continued to grow, offering college students and recent graduates opportunities in biotech research, writing and communications, regulatory affairs and quality. Since January, the Foundation placed young college graduates (and even a few high school students) in positions where they could learn by working on real projects in the fields of communications, research, education, writing, business, and filmmaking. Several interns have already had their work published or their documentary footage aired on national television.

The BTER Foundation moved forward with its Maggot Therapy Competency Initiative. A highly accomplished committee was assembled to work on the program. The committee identified specific knowledge and skill sets as essential for an accomplished maggot therapist. These competencies will be incorporated into future educational programs.



The Year in Review

Lectures, Workshops, and Presentations:

<u><i>Date & Presentation</i></u>	<u><i>Audience / Sponsor</i></u>	<u><i>Location</i></u>
4/11/14: Lecture	Eastern Idaho Wound Care Conference	Idaho Falls, ID
9/20/14: Lecture & Workshop	Wild on Wounds	Las Vegas, NV
11/03/14: Lecture	University of California, Irvine	Irvine, CA
11/06/14: Lecture	California State University, Long beach	Long Beach, CA
2/22/15: Lecture	Long Term Care Nursing Continuum Symposium	Lake Geneva, WI
4/16/15: Lecture	Medical Surgical Nursing Conference	San Francisco, CA
5/14,16/15: Lecture & Workshop	Palliative Wound Care Conference	Orlando, FL
9/04/15: Lecture & Workshop	Wild on Wounds	Las Vegas, NV
10/02/15: Lecture & Workshop	Academy of Physicians in Wound Healing (APWH)	Philadelphia, PA
10/22/15: Lecture	Superbones West	Las Vegas, NV
11/20/15: Lecture	Desert Foot	Phoenix, AZ



The Year in Review

Recent Trainees

<i>Interns:</i>	Communications –	Deboshree Roy
	Research –	Matthew Monaco Christopher Truong Katherine Watt
	Regulatory Affairs / Quality Control –	Margarita Finley Wesley Nye Victoria Pido Claudia Davidson
<i>Fellows:</i>	Tarek Tantawi, PhD Claudia Davidson, MS	

Selected Biographies . . .

. . . as published in **The BeTER LeTTER** (www.BTERFoundation.org/tbl_index).

Meet **Wesley Nye**, an Intern with the BTER Foundation! Wesley graduated from the University of California Riverside in 2014 with a B.S. in Bioengineering. During his quality control internship with the BTER foundation, he has written a 510k submission to the FDA, crafted validation reports, written a Device master file, and maintained adverse event and CAPA registries. Wesley's current career goal is to become a validation engineer in the field of biotechnology. His hobbies include computer building, as well as outdoor activities such as hiking and tennis.



Margarita Finley completed a Bachelor's of Science in Biology with a concentration in Molecular Biology and Biotechnology in May 2014 at California State University, Fullerton. While at CSUF, she participated in independent research in a biochemistry lab which focused on inhibiting methanogenesis by targeting critical steps involved in methanopterin biosynthesis. She also has paralegal studies certification from Fullerton College. Participating as a quality control intern at Monarch Labs has allowed Margarita to utilize the skill sets developed during her education. While at Monarch, she is learning valuable skills such as policy development, writing, and implementation. She is also assisting with documentation that is required by regulatory agencies. In her spare time, Margarita likes to ride motorcycles with her husband and watch horror movies.



Claudia De Novaes Davidson was born in Rio de Janeiro, Brazil. She first came to the United States in 1981, and fell in love with the country. Following that life changing trip, her dream was to return to the U.S. to study and develop a better quality of life for herself. She received her bachelor's degree from Universidade Federal Fluminense school of Pharmacy, and worked for eleven years as the manager of Pharmacy Leme pharmacy. Finally, in 2001, she received an F1 Visa to study at Irvine Valley College in California. Claudia graduated from the Honors Program, and went on to study at Santa Ana College. She received her Masters in Biotechnology at California State University, Fullerton. Claudia's quest for knowledge and skill in the pharmaceutical industry led her to an internship with Gilead Sciences, and ultimately

to the BTER Foundation, where she just finished an internship in Regulatory Affairs and Quality Control, honing her abilities at Monarch Labs in Irvine, CA. We applaud Claudia's hard work and are grateful for her dedication to the BTER Foundation and the advancement of bi-therapy.

The Year in Review

Advances in Patient Care

The BTER Foundation continued its mission to advance patient care by increasing the staffing of its e-mail and phone center to help address over 200 new consultations. Our most commonly received request was for a local therapist, so we continued to solicit care providers to submit their contact information as a source for patients looking for biotherapeutic care options.

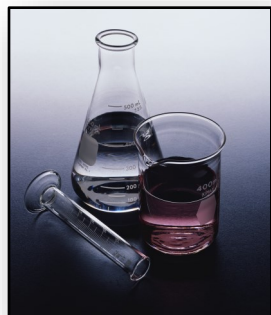
Of course, one of the best ways to improve patient care is to train therapists to the highest standards. To that end, therapist training continues to be one of the BTER Foundation's foremost efforts, and one of our most highly acclaimed contributions. When we educate therapists and build their skills, we directly enhance patient care.

Other patient care efforts included the continuation of our Patient Assistance Grants program, which subsidizes the costs of biotherapy for those with limited financial resources.



Advances in Research

Research is how we move the field forwards, and how we make sure that we optimize care and education. During these past two years, the BTER Foundation focused its research and research training efforts in the fields of leech therapy (hirudotherapy) and maggot therapy.



In 2012, the BTER Foundation joined with Monarch Labs (Irvine, CA) to establish the California Leech Therapy Research Center. Early progress from that collaborative project was described in a previous issue of these Annual Reports. After years of studying leech biology, behavior, and rearing, we developed a less expensive and easier-to-deliver system for providing leech salt (now available through the BTER Foundation) and a system of leech jars that make it easier to clean and care for the animals (and effectively kill the germs that might otherwise contaminate the leeches).

One of our greatest advances, thanks to a team of collaborating clinicians, was the development of a clinical study protocol aimed at expanding the indications (approved uses) of hirudotherapy. We are now seeking funding to embark on the clinical trial. Anyone interested in participating as a leech therapist or as a sponsor of the trial is invited to contact the BTER Foundation.

Efforts in maggot therapy research focused on improved dressings . . . in particular, reducing the pain that some patients feel when the maggots wiggle around an innervated tender wound. Stay tuned for more on this work in the near future . . .

The Year in Review

Publications & Scientific Presentations

Over the past two years, three BTER Foundation manuscripts were published. Another 2 manuscripts were submitted, but not yet published. Published studies can be viewed at the linked web-sites:

- [Sherman RA. Mechanisms of maggot-induced wound healing: what do we know, and where do we go from here? Evid Based Complement Alternat Med. 2014;2014:592419.](#)
- [Sherman RA, Mendez S, McMillan C. Using maggots in wound care – Part 1. Wound Care Advisor. 2014;3\(4\): 7-14.](#)
- [Sherman RA, Mendez S, McMillan C. Using maggots in wound care – Part 2. Wound Care Advisor. 2014;3\(6\): 27-30.](#)



Additionally, BTER Foundation staff assisted in extramural research, published in the International Journal of Lower Extremity Wounds:

- [Borst GM, Goettler CE, Kachare SD, Sherman RA. Maggot Therapy for Elephantiasis Nostras Verrucosa Reveals New Applications and New Complications: A Case Report. Int J Low Extrem Wounds. 2014 May 25;13\(2\):135-139.](#)



Announcements and current events continued to be published in our newsletter, **The BeTER LeTTER**. We returned to our previous publisher, Constant Contact, after a trial period of self-publishing in order to conserve limited funds (our director is always pre-occupied with spending donor's contributions wisely). But we could not provide the frequency, the timeliness, nor the in-depth news reporting that we could with the assistance of our prior e-mail management service, so we returned to Constant Contact with renewed confidence that it was the best option for serving our growing clientele, and well-worth our investment. We now have over 3,000 subscribers, and new subscribers are regularly joining the list through our website or through the newsletter links, when they receive forwarded copies of **The BeTER LeTTER**.

The Year in Review

Social media presence was expanded via the BTER Foundation's **Facebook** page and **Twitter** account.



Meanwhile, the Director continued to submit wound-related manuscripts to the WoundSource biotherapy blog at: www.woundsources.com/blogs/ron-sherman. These include such varied topics as:

- Contained and Free-Range Maggot Therapy Delivery
- How Different Maggot Therapy Dressings Work
- Want to Understand Your Wound Care Patient's Perspective? Just Ask!
- Understanding Patient Behaviors
- Even Medicinal Maggots Carry Warnings
- The Shortcomings of Systematic Reviews and Meta-Analyses of Wound Care Research



The year 2015 saw the creation of a new publication, devoted to biotherapy research: the **Biotherapy Journal Review**. The project began as an opportunity to share pivotal scientific papers with the biotherapy community in a timely fashion. Already it has grown into a compendium of current research, and will be a major focus of work in the coming years.

Grants

Supporting patients (Patient Assistance Grants) continues to be a mainstay of our grants program, but we also supported researchers with Publication and Presentation grants (to defray the costs of publication), and established the Randall Sullivan Memorial Fund for Therapist Education in honor of our Founding Board Member, to continue her efforts in training new clinicians in the methods of biotherapy.

The Future: Great Expectations

The value of reviewing past performance is that it offers an opportunity to learn from the past, thereby also providing the opportunity to optimize future. In putting together this annual report, we have attempted to take advantage of these opportunities. What follows is our realistic assessment of where we are headed and what the near future is likely to bring.

We will continue those programs that have performed well and which directly achieve our mission. Among our educational programs, these include keeping the public up to date through our website, newsletter and social media posts. We plan to expand the Biotherapy Journal Review into a multi-article compendium of recent literature that can be viewed readily from the Internet or as a standalone printed or digital journal. We intend to offer the opportunity to publish not just reviews but also original papers in biotherapy. Ultimately the success of this publication will depend on participation among the academic- and research-centered biotherapy communities.

We will continue to strengthen biotherapy education by offering more webinars and video lecture broadcasts, which allows us to reach those who can not travel to large conferences nor afford to invite one of our speakers to their area. We will resume efforts to establish guidelines for assessing biotherapist competency, thereby identifying the standard of care to which clinicians should aspire, and by which they can be evaluated.



Over the past few years, the BTER Foundation's intramural research efforts have been primarily "translational" (basic science that is directly and immediately relevant to clinical medicine). In the coming years, greater effort will be spent on conducting clinical trials of treatment modalities . . . especially those that are not receiving significant funding from the private sector. Our efforts to obtain funding for clinical trials of hirudo-therapy bore no fruit these past two years. However, we will continue to seek new sources of funding, even if we must go where no seeker has gone before. We are preparing to solicit funding for a clinical trial of ichthyotherapy, which should finally clarify the value and mechanisms of action by which Dr. fish are said to treat psoriasis and related skin illness. Anyone with an interest to support or participate in such clinical studies is encouraged to contact our offices. While not our first or second choice for funding, we are even ready and willing to pursue crowd funding if necessary, in order to meet our financial challenges.

Our ability to fulfill our mission and advance healthcare is not limited by our vision nor by the current need. We are limited only by our financial resources and by the availability of our dedicated staff and volunteers. To that end, one of our most necessary (though least pleasant) responsibilities continues to be the generation of new and continuing support — financial, products, volunteer time, whatever. We will continue offering biotherapy products and services for sale, and selling donated goods to raise the funds we need to continue our work. We will continue our associates program with Amazon, GoodSearch, our gift store, etc. We welcome you to come along for the ride . . . sometimes bumpy, sometimes scary, but always rewarding and exciting. Just ask any of our recent colleagues, supporters, donors, or members.

**Financial Status -
Profit & Loss, 2014 - 2015**

Income	Jan - Dec 2014	Jan - Dec 2015	TOTAL
Donated Funds	13,707	7,106	20,813
Membership Dues		425	425
Sales & Services		558	558
Expense Other Income	55	175	230
Total Income	13,762	8,264	22,026
Computing & software	417		417
Grants	300		300
Insurance	1,093	2,186	3,279
Personnel, Staffing, Bookkeeping	5,453	7,140	12,593
Office Supplies	446	42	488
Program Expenses	942	1,030	1,972
Publication Expenses	1,750		1,750
Rent	3,420	3,420	6,840
Telephone	141	39	180
Other Expenses, asset disposal		102	102
Total Expense	13,962	13,959	27,921
Net Income / Expense			-5,895

The Board of Directors

The Foundation Directors have worked hard and tirelessly — OK, just hard — to support the needs of the Foundation's constituents: patients, therapists, students, members, and the lay community. Indeed, the Foundation is available to serve just about everybody. Thus, the Foundation Directors have been among the greatest donors of all. Building and sustaining the infrastructure of biotherapy is a big job; and it is getting bigger, as the number of patients and therapists continues to grow exponentially. Donna Beales is our newest Board Member, stepping in after Pamela Mitchell's untimely death. Please join us in thanking the Board Directors.



Ronald A. Sherman, MD
Irvine, CA

Chairman of the Board
Chief Executive Officer



Randall Sullivan, RN
Long Beach, CA
(Served 3/23/2003 - 2/24/2014)

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Education Committee



Samuel G. Kohn
Irvine, CA

Treasurer
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Programs & Grants Committee



Sharon Mendez, RN, CWS
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Programs & Grants Committee
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Amy Mendez, BA

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Aletha Tippet

***... and let us not forget the scores of
anonymous supporters!***

Thank you all!!

Credits

This Annual Report was designed and produced for the BTER Foundation's Board of Directors by Amy Lajiness (BTER Foundation Editorial Assistant) and Ronald Sherman (Foundation Director).

Artwork for this Annual Report was created from images owned or licensed by the BTER Foundation, unless otherwise noted. Images on pages 4, 7, 13 and 18 were provided through the courtesy of the Wound Care Education Institute, sponsor of Wild on Wounds, which has supported biotherapy and the BTER Foundation for the past 12 years.

Contact Information:

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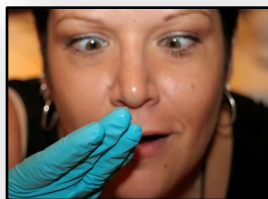
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May your life
be blessed



with a sense of awe
and wonder



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