

**B T
E R**

BIO-THERAPEUTICS EDUCATION & RESEARCH FOUNDATION

Advancing health care through education and research in biotherapy

ANNUAL REPORT

2012 - 2013





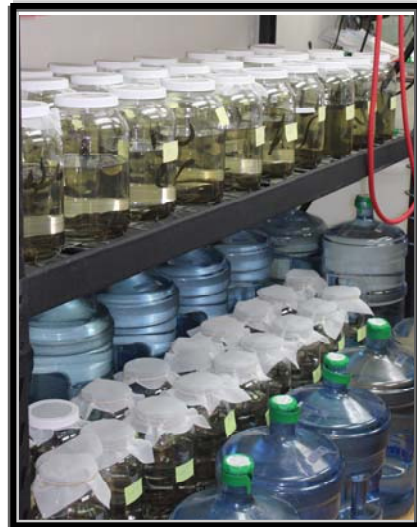
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Mission Statement

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

The BTER Foundation celebrated its 10 year anniversary in 2013. I say “celebrated,” but only a small part of the year was spent celebrating. There was so much to do that we hardly had time to stop and notice our anniversary. Besides, it is not usually the passage of time that we celebrate, but above all, what we accomplish within that time.

In the pages that follow, you can read many more reasons to celebrate: the BTER Foundation continues to provide grants and services to health care providers and patients, to researchers and students. In addition to convincing insurance companies to reimburse for proven biotherapeutic treatments, we are inspiring companies that provide such services to lend financial assistance to clients who have no insurance.

The demand for our educational programs has steadily increased, and our research is published with increasing frequency. Examples can be found in this year’s report, along with a description of our widening impact.

All of these successes suggest that we are on the right track. However, we still have a long way to go in reaching some of our goals. For every animal whose medical benefits are well-accepted and utilized, there are three more that are unproven, and possibly countless more unrecognized. Thus far, we focused intently on public education, but now that bio-therapeutic products and therapists are sprouting up, we must focus also on their quality.

Yes, we have come a long way over the past ten years, and our team is growing. We have many adventures still ahead, and we hope that you will join us on our exciting and challenging journey.

Turn the pages of this report, read about our accomplishments, and know that our dreams for the future can become a reality. And YOU can help us make it Your Reality.

A stylized, handwritten signature in black ink that reads "R. Sherman". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Ronald A. Sherman, MD
Chair, Board of Directors

The Year in Review

Advances in Education

The BTER Foundation led the way in biotherapy education again, producing and presenting lectures, workshops, webinars and scientific publications. In fact, 2012 and 2013 were the sixth and seventh years in a row that we were invited back to the Wild on Wounds Annual Conference to present the “Principles and Practice of Maggot Therapy” lecture and workshop. In 2013, we also introduced wound care therapists to hirudotherapy. Additionally, the BTER Foundation presented lectures and workshops to therapists attending the Annual Palliative Wound Care conference in Stevenson, Washington (5/17/2012) and Indianapolis (5/16/2013); Paralyzed Veterans of America Summit in Las Vegas (8/29/2012), and the Superbones Podiatric Conference in Las Vegas (10/18/2012). The Foundation presented a poster at the 2013 meeting of the National Pressure Ulcer Advisory Panel. We were also invited to speak at the University of British Columbia (November 20 and 21, 2012), and the California State University, Long Beach (December 5, 2013). The BTER Foundation presented two lectures and a workshop this past year at the Canadian Association of Wound Care (November 7-10, 2013; Vancouver).



Archived presentations from our Webinar series on maggot therapy, as well as recorded lectures from the 2010 International Conference on Biotherapy (Los Angeles) continue to be downloaded from the BTER Foundation’s website. Our lecture slides from the Principles & Practice of Maggot Therapy course, while a little outdated, also are still being downloaded regularly.

2013 also marked the beginning of a new program in health care education: the BTER Foundation Internship. 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.

With the help of some of our interns, 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>
5/17/12: Lecture & Workshop	Annual Palliative Wound Care Conference	Stevenson, WA
8/29/12: Lecture	Paralyzed Veterans of America Conference ("PVA Summit")	Las Vegas, NV
9/12/12: Lecture & Workshop	Wild on Wounds	Las Vegas, NV
10/18/12: Lecture	Superbones	Las Vegas, NV
11/20/12: Lecture & Workshop	University of British Columbia	Vancouver, British Columbia
11/21/12: Lecture & Workshop	University of British Columbia	Vancouver, British Columbia
2/22/13: Research Poster	National Pressure Ulcer Advisory Panel (NPUAP)	Houston, TX
5/16/13: Lecture & Workshop	Annual Palliative Wound Care Conference	Indianapolis, IN
9/11/13: Lecture & Workshop	Wild on Wounds	Las Vegas, NV
11/9/2013: Lectures & workshop	Canadian Association of Wound Care, An- nual Conference	Vancouver, British Columbia
12/5/2013: Lecture	California State University (CSULB)	Long Beach, CA



The Year in Review

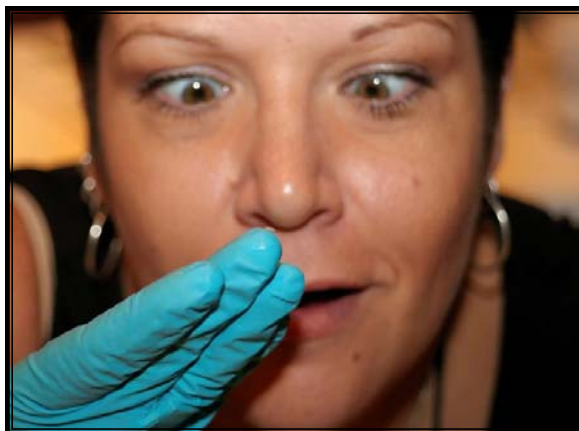
Current and Recent Trainees

<i>Interns:</i>	Communications –	Juan Castellanos Lynn Wang Deboshree Roy
	Research –	Yasmin Anoushiravani Krisha de Jesus Borna Khavari Matthew Monaco Christopher Truong Katherine Watt
	Regulatory Affairs / Quality Control – Videography –	Tim Cole, BS, MSc Raheem Maddox

Fellow: Tarek Tantawi, PhD

High School Trainees:

Yiping Lin



Advances in Patient Care

Knowledgeable, well-trained therapists translate directly into better patient care, so our therapist training programs are one way that the BTER Foundation has been improving patient care. We directly enhance patient care when we educate therapists and build their skills.

We also improved patient care this year by:

- Translating our patient information brochure (*Is MDT for Me?*) into Spanish;
- Updating the **MDT Policy and Procedure Template**;
- Creating downloadable Patient Consent documents for maggot therapy and leech therapy;
- Continuing to issue Patient Assistance Grants to those who can not afford proven biotherapy practices.

The Year in Review

Advances in Research



The BTER Foundation has long contributed to biotherapy research through its own activities and by supporting or disseminating the research of others. The years 2012 and 2013 marked a new era in BTER research support, with the establishment of the Leech Therapy Research Center, a collaborative effort between the BTER Foundation and Monarch Labs. As a producer of therapeutic animals, Monarch Labs contributed the facilities and the majority of funding, while the BTER Foundation contributed faculty, volunteers and interns to drive the research. Together, these two organizations fostered innovations in the way medicinal leeches are raised, stored, and applied — developments which are especially important to therapists who use leeches only infrequently. Recently, the Center received 3,000 *Hirudo medicinalis* from the International Medicinal Leech Center near Moscow to advance our work. In addition to supplying others who are performing research, the BTER Foundation will use these animals in clinical studies of leech therapy to treat severe pain syndromes.

Laboratory Skills Training and in-house research have been major components of the BTER Foundation Internship program, and several interns have already presented and/or published their work. Most notably, Borna Khavari co-authored a paper on the concurrent use of maggot therapy with hyperbaric oxygen (HBO).

Additionally, Foundation Intern Katherine Watt co-authored a paper on maggot-induced wound healing, which was presented at the prestigious National Pressure Ulcer Advisory Panel conference in 2012.

UHM 2013, VOL. 40, NO. 5 – DO MAGGOTS THRIVE WHEN THEY TAKE A DIVE?

Effect of hyperbaric oxygen on the growth and development of medicinal maggots

Ronald A. Sherman M.D., M.Sc.¹, Borna Khavari², Darryl Werner M.D.³

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² University of California, Irvine, Calif. USA

³ Medical Director, Orange County Wound and Hyperbaric, Santa Ana, Calif. USA

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ABSTRACT

Some wound care therapists use both maggot debridement therapy (MDT) and hyperbaric oxygen (HBO₂) therapy to treat non-healing wounds. Some practitioners have reported success using both MDT and HBO₂ therapy concurrently; others have not. To begin evaluating the utility of using MDT and HBO₂ therapy concurrently, we assessed the effects of hyperbaric oxygen (HBO₂) on maggot growth and development, as a surrogate for debridement capacity.

Replicate sets of medical-grade blowfly larvae were placed on liver-agar wound models and exposed to HBO₂ at 2.0 atmospheres absolute (atm abs) for 90 minutes on 0 (control), 1, 2 or 3 sequential days. The effects of

HBO₂ exposure were quantified by measuring the maggots' subsequent growth and development. Exposure to HBO₂ was most lethal to young larvae (second instars), but not to older larvae (third instars). There was no dose-relationship between the number of HBO₂ treatments and rate of larval survival.

Our findings suggest that maggot therapy and HBO₂ therapy may be administered concurrently, as long as the larvae are not too immature (that is, as long as they are beyond the second instar) by the time they take their first dive. A clinical trial evaluating the clinical benefits of concurrent HBO₂ therapy and MDT is warranted.

Maggot-Induced Wound Healing – What is the Evidence?

Ronald A. Sherman, MD; Katherine Watt, BS
BioTherapeutics, Education & Research Foundation

The Year in Review

Publications & Presentations

Over the past two years, the BTER Foundation facilitated the publication of several biotherapy research projects.

Of particular note is the publication of five years of research by the Foundation into the coordination of hyperbaric oxygen (HBO) with maggot debridement therapy for wound care. In recent years, some therapists have used the two modalities together with great success at cleaning the wounds, killing infection, and stimulating wound healing. Other therapists noted that the maggots did not survive the HBO treatments. Even our own studies could not make sense of these two conflicting reports until we discovered that maggot survival in the HBO chamber was age-dependent. Slightly older, more mature larvae were able to tolerate HBO quite well, and accomplished their work of dissolving dead tissue, while most of the larvae that were still very young did not survive. This work was published in the journal: ***Undersea and Hyperbaric Oxygen*** (2013, Vol 40, No. 5; pages 377-380), and was co-authored by BTER Foundation Director Ronald Sherman, intern Borna Khavari, and Dr. Darryl Werner, MD, Director of Orange County Wound and Hyperbaric in Santa Ana, CA.

Perspectives on Palliative Wound Care:

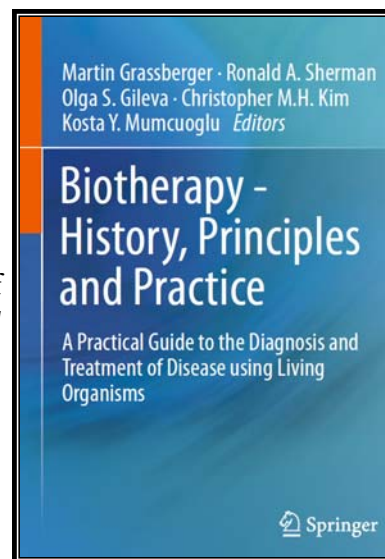
Interprofessional Strategies for the Management of Palliative Wounds

Aletha Tippet, MD
Ronald Sherman, MD, MSC, DTM&H
Kevin Y. Woo, BSc, MSC, PhD, RN, GNC(C), ACNP, FAPWCA
Laurie Swezey, RN, BSN, CWCN, CWS, FACCWS
Mary Ellen Posthauer, RD, CD, LD

Go to www.woundsource.com to download this document
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BTER Foundation member Dr. Aletha Tippet, MD, along with several colleagues, authored ***Perspectives on Palliative Wound Care: Interprofessional Strategies for the Management of Palliative Wounds***. Published in 2012 through Kestrel (and available for free, from www.woundsource.com), this white paper includes a chapter from the BTER Foundation about biosurgery (maggot therapy) for palliative wound care.

The BTER Foundation also contributed to the writing and editing of the first biotherapy textbook: ***Biotherapy – History, Principles and Practice***. The editorial team was led by Martin Grassburger, MD, PhD of Vienna, and organized in Los Angeles at the 2010 International Conference on Biotherapy. The book, published in 2013 by Springer, and available through book sellers everywhere, has already been used and cited by therapists, students, and researchers throughout the English-reading world.

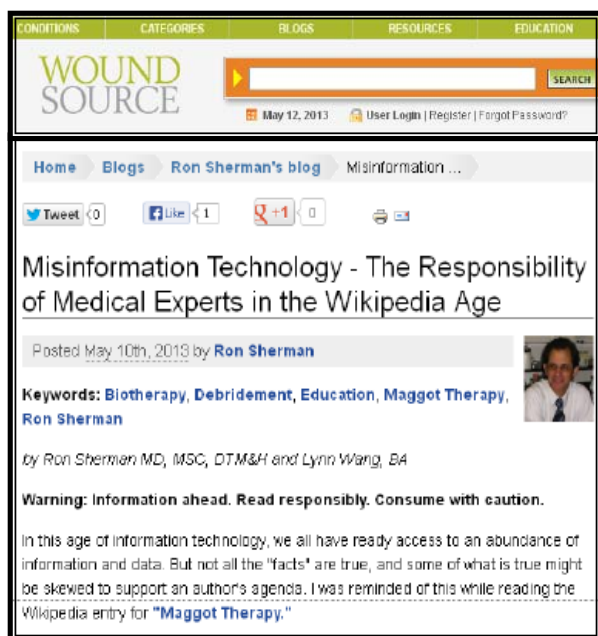


The BTER Foundation also presented another research project on maggot-induced wound healing at the 2012 National Pressure Ulcer Advisory Panel conference. This project was part of the work of Foundation Intern Katherine Watt.

The Year in Review

Everything changes with time, including biotherapy. Accordingly, BTER Foundation publications must be updated as well. In 2012, the Foundation's **Maggot Therapy Procedures and Policy Template** was updated to include new methods and products. This document continues to be a popular download for therapists and health care facilities wanting guidance regarding the writing of policies that permit them to practice biosurgery safely and effectively.

The Foundation's newsletter, **The BeTER LeTTER**, continues to update subscribers to the research, clinical and political advances in biotherapy. There are now nearly 3,000 subscribers, and many more who download the newsletter from the website.



The frequency of this publication recently increased to over six issues per year.

The Biotherapy Blog, formerly on the BTER Foundation's website, moved to a more prominent spot on Kestrel's **WoundSource** blog page. Written by the Foundation's director, staff and interns, the blog now goes out to thousands of wound care therapists, and can be viewed at: www.woundsource.com/blog/ron-sherman.

Grants

A total of fourteen grants were awarded, including patient assistance grants and research publication grants. There was a marked decrease in the number of requests for maggot therapy grants in comparison to prior years. While most insurance companies are now reimbursing for maggot therapy, the decrease in grant requests may have had other causes as well. In large part, the reason for a decrease in requests for maggot subsidies is that the North American supplier of medical grade maggots, Monarch Labs, initiated its own Patient Assistance Grants program to address the financial needs of its clients. This is exactly what the BTER Foundation aims to achieve within the biotherapy community. By insisting that suppliers and therapists who participate in our Patient Assistance Grants program reduce the costs of their own services, we try to inspire therapists, suppliers, and community leaders minimize socioeconomic barriers to receiving biotherapy. Kudos to Monarch Labs for establishing its own patient assistance program; and Double Kudos to the BTER Foundation, for teaching by example.

The Year in Review

International Activities & Collaborations

Therapists, patients, researchers and students continue to seek out the BTER Foundation's educational materials, publications and referrals. While our mission and focus is in North America, we never turn down the opportunity to assist anyone in need. Indeed, the fact that we are asked to assist in distant lands is a testament to the growing international thirst for biotherapy information and support.



In the past two years, requests for assistance have come from dozens of countries, including: Argentina, Brazil, Columbia, Croatia, Czech Republic, Egypt, France, Germany, India, Iran, Israel, Kenya, Liberia, Malta, Malaysia, Mexico, Morocco, Nigeria, Peru, Poland, Russian Federation, Saudi Arabia, Serbia, Singapore, South Africa, Turkey, United Kingdom, United States of America and its territories, and Venezuela.

Special Projects

In 2012, submissions for our first Biotherapy Video Contest were evaluated by visitors to the website. We had two winners who each received \$300 and a year's free membership in the BTER Foundation: Dr. Aletha Tippet (Cincinnati, OH), and Dr. Kosta Mumcuoglu (Jerusalem, Israel). Congratulations to you both, and thank you for sharing your biotherapy videos with us. With everyone's participation, we can educate larger audiences and help more people.

Several times each year, news media production companies ask the BTER Foundation to assist in their production of programs that feature biotherapy. In 2013 there were two such programs. BTER Foundation staff and videography intern Raheem Maddox submitted footage for one of these documentaries (National Geographic, "Creepy Cures" in *World's Weirdest*, produced by Orion Multimedia), and the footage was included in the final cut. Congratulations, BTER photographers!



The Future: Great Expectations

We have accomplished a lot during the past ten years. We have even accomplished a lot just during the past two years. Nevertheless, we have the potential to do still more. Many lives could be improved, if only we could expand our efforts in education, research, and services. Here are some of our most pressing goals:

The BTER Foundation's Internship Program has no shortage of students, but rather a shortage of mentors. In particular, we are searching for clinicians willing to mentor young health care workers in the application of biotherapy.

The maggot therapy competency committee has already begun their work, but still must create a core curriculum and syllabus for accomplished therapists. This is one of the goals for 2014.

The BTER Foundation presents an average of six courses or lectures per year, but the demand continues to grow. We hope to increase our educational programs by recruiting more volunteers able and willing to teach.

In order to accomplish these goals, we will need to increase our ranks. Therefore, expansion of our Board Membership and expansion of the BTER Foundation membership at large are among our top priorities for 2014.



The BTER Foundation has a representative on the editorial board of the highly ranked journal, Evidence-based ***Complimentary and Alternative Medicine*** (“***eCAM***”). Biotherapists and researchers have always been encouraged to submit scholarly manuscripts to this journal, whether or not they are members of the BTER Foundation. In 2014, a special issue of ***eCAM*** will be devoted to medicinal invertebrates and their products, and several of these articles will be published by members and/or supported in part by the Foundation. Research published in ***eCAM*** will definitely have the high impact that we expect from all of our projects.



The BTER Foundation has always focused its limited research resources on projects with high potential but little attention. Beginning in 2014, we will enroll patients in our clinical studies of leech therapy (hirudotherapy). Once we secure the necessary funding, we will initiate clinical studies in “doctor fish” therapy (ichthyotherapy), in late 2014 or early 2015.

**Financial Status -
Profit & Loss, 2012 - 2013**

Income	<u>Jan - Dec 12</u>	<u>Jan - Dec 13</u>	<u>TOTAL</u>
Donated Funds	17,312.52	2,263.33	19,575.85
Membership Dues	425.00	121.95	546.95
Sales & Services	638.00	1,350.00	1,988.00
Interest Income	86.57	76.99	163.56
Total Income	18,462.09	3,812.27	22,274.36

Expense	Bank & Credit Card Processing Fees	16.70	4.64	21.34
	Insurance	1,085.00	948.00	2,033.00
	Internship Training Program	125.00	0.00	125.00
	Licenses and Permits	20.00	0.00	20.00
	Computer software	0.00	231.00	231.00
	Marketing	0.00	100.00	100.00
	Newsletter Service	454.50	0.00	454.50
	Patient Assistance Grants	2,500.00	1,016.95	3,516.95
	Postage and Delivery	0.00	48.31	48.31
	Professional (accounting) Fees	1,797.00	1,570.00	3,367.00
	Program Expense - Other	-147.84	0.00	-147.84
	Publication Costs	0.00	250.00	250.00
	Office Supplies & Equipment	0.00	266.97	266.97
	Rent	2,400.00	3,420.00	5,820.00
	Taxes (California State)	10.00	0.00	10.00
	Telephone	74.01	43.23	117.24
	Travel	210.00	0.00	210.00
	Total Expense	8,544.37	7,899.10	16,443.47

Net Income / Expense	3,676.27
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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

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Donna Beales
Lowell, MA

Programs & Grants Committee



Sharon Mendez, RN, CWS
Clayton, WA

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Alana Jolley, PhD
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Alison Schorger, CPA
Aletha Tippet, MD

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***... 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 Deboshree Roy (BTER Foundation Intern), Hillary Martinez (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 7, 8, and 13 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 8 years.

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