



NEW ENGLAND The BEACON

A Publication of Scleroderma Foundation New England

Fall 2020

SEARCHING FOR HEALTH by Jane Ladas, SFNE Vice President

Since the beginning of time, man has sought ways to treat illness and improve health. Archeological artifacts from around the world show our earliest human ancestors harnessed resources from nature to treat sickness. Clay was used to set broken bones while plants, herbs, trees, and minerals were used for common maladies such as diarrhea, infection and pain.

Even some wild animals selectively seek out remedies to alleviate illness. Chimpanzees in Tanzania deliberately eat sharp, prickly leaves from the *Aspillia* bush to scour parasitic worms from their GI tracts while heavily pregnant African elephants wander far from home to eat leaves from a bush that induces labor.

For nearly 20,000 years the average human lifespan across the globe hovered at 30 years because nearly all humans lived in poverty, suffered high infant and child mortality rates, and lacked meaningful medical resources.

Coinciding with the Industrial Revolution, the average human lifespan started to increase but occurred only in countries connected to the Industrial Revolution. This is significant because

it's the first time in human history that lifespans varied across the globe. By the 1850's, the average human lifespan in industrialized countries rose to 40 years and by 1900 reached 46. Citizens of wealthy nations lived longer than citizens of poor nations – a disparity that continues on.

Today, Japan has the longest average lifespan of 83 years and the Central African Republic the shortest at 53. As of September 2020, our world's population reached 7.8 billion people up from 2 billion in 1900 and 1 billion in 1800. The exponential growth in our world's population combined with increased longevity makes the need for safe, effective, accessible, and affordable drugs as great today as ever before.

It's likely that every one of us has taken a prescription drug at some point in time. But, before that drug became available for your healthcare provider to prescribe, it underwent a long, complex and uncertain journey through Research and Development. Historically, it took 15 years from the time a drug was discovered in the lab to the time it received regulatory approval which, in the US, is granted by the Food and Drug Administration.

Today this process takes about 10 years.

There are two pivotal timeframes associated with creating a new drug and each time frame has its own set of complex research components. The first time frame is called *Discovery* and the second is called *Development*. Before Discovery scientists search for potential new compounds to treat a disease, they amass as much knowledge as possible about its biology. Advances in technology enable Discovery scientists to study the disease on a molecular level where they can identify factors that contribute to the disease's onset and progression forward.

They search for genetic, cellular and biochemical aberrations seen only in patients with the disease and explore if any of these molecular abnormalities could be a target a drug could hit. The reason to hit a molecular target with a drug is to either activate (green light) or deactivate (red light) the target and, in doing so, disrupt a key component of the disease process.

Once a molecular target has been identified, Discovery scientists screen thousands of compounds from their

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COVID-19 UPDATE . . .

Out of an abundance of caution related to the coronavirus, the New England Chapter has decided to cancel all face-to-face support group meetings and education days through the end of 2020. We encourage patients and caregivers

to stay in touch with us via the free virtual support group meetings listed on our website.

Please make sure you are following SFNE on Facebook and that we have your email so we can continue to reach you!

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Scleroderma Foundation

New England Chapter

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DISCLAIMER: SF/New England Chapter in no way endorses any drugs or treatments reported in this newsletter or at SFNE sponsored meetings. Information is provided to keep readers informed. Because the manifestations and severity of scleroderma may vary among individuals, personalized medical management is essential. Therefore, it is strongly recommended that all drugs and treatments be discussed with the reader's physician(s) to assure proper evaluation and treatment.

A MESSAGE FROM THE SFNE OFFICE

2020 has been a year of pivots. Whether it's how we get groceries, how we learn or teach, or how we communicate, we have all had to find ways to keep moving forward in the face of so many obstacles caused by the global COVID-19 pandemic.

The New England chapter is no different. Although our fundraising year looks much different, we still have an amazing and dedicated group of volunteers who have continued to support our mission through their efforts.

Our support groups are the backbone of our organization. For those who have participated, you know how much the support and encouragement means to your mental health during your most difficult times. Although so many in our community struggle with chronic pain, our support group members serve as a listening ear, a shoulder to cry, and often times a wealth of information for those navigating through unfamiliar times. Knowing how critical those connections are, we have had many of our support groups move to ZOOM meetings. Although this is a new concept for some, we have seen the benefits of maintaining those connections. If you have ever wanted to join a support group or learn more about what it can mean to you, now is a great time to participate from the comfort of your own home!

During the last several months, we have introduced virtual walks and I am pleased to share that the Worcester walk not only met – but exceeded – its fundraising goal. Our Maine walk also was a great success! We have hosted an online sports auction that was used as a replacement for our Annual Golf Tournament for our sports enthusiasts.

Our Stroll for Scleroderma, organized by the daughter of our President Don Legere in his honor, Maria Bartoszewicki, surpassed their goals and included fun challenges to inspire their virtual teams. They also were able to inspire virtual walkers from all over the country to support their efforts!

Needless to say, although we will not meet the goals we set last December for 2020, we continue to prove that the New England chapter is mighty and our community stands behind our mission. To that, we say THANK YOU. We truly could not continue without your support and commitment. Our fight continues thanks to your efforts!



Team Roberta



Team Skippy

LOBSTER SHOOT – REIMAGINED!

Last year a group of members of Team Skippy from our Worcester Walk organized a successful lobster shoot. Like so many other events, the 2020 event was cancelled. But that didn't stop our amazing volunteers! Team Captain Kathy Chaves and her sister Michelle Monteiro had already collected more than 30 baskets and prizes donated by friends and local businesses. So the sisters brainstormed how to transition the lobster shoot to a calendar raffle and promoted this through social media and word of mouth. Chance holders had more than 30 chances to win a prize throughout the month of August.

Team Skippy exceeded their goals for the raffles and were excited at the response for the community. Not only were people excited for prizes, they were also learning more about scleroderma and the importance of finding a cure for this disease! Team Skippy is looking to host another raffle in the future thanks to the positive response.

This is just another example of how our community rises to the occasion in the face of adversity. Thank you Kathy, Michelle, and Team Skippy for all you do!

CORBUS PHARMACEUTICALS RELEASES TOPLINE RESULTS FROM PHASE 3 TRIAL

On September 8, Corbus Pharmaceuticals released topline results from RESOLVE-1 Phase 3 study of lenabasum for treatment of systemic sclerosis. Topline data showed no significant differences in the primary and secondary endpoints when comparing lenabasum to placebo, both added to background drug therapy. Three hundred and sixty-five patients were dosed in the study with baseline characteristics of patients across

groups balanced. Further analyses of these data are underway, and once Corbus has a fuller understanding of the data, the Company would like to engage with the FDA to determine potential next steps in this clinical development program. The data will be presented at upcoming medical conferences. Lenabasum is currently being evaluated in a Phase 3 DE-TERMINE study in dermatomyositis, a Phase 2 study in systemic lupus

erythematosus, and a Phase 2b study in cystic fibrosis.

Our Chapter has worked closely with Corbus in the past and given their location in Massachusetts we have a strong synergy. Although this is disappointing news for our community, the New England Chapter continues to be partners with Corbus Pharmaceuticals and looks forward to continued updates.

CENTRAL NH SUPPORT GROUP – STEPPING OUT TO FEEL BETTER!

Although not always possible, getting some form of exercise can be helpful in addressing symptoms related to scleroderma. Since many people with scleroderma experience joint and muscles stiffness, low-impact activities like walking, cycling, swimming, yoga, dancing, water aerobics and Pilates are all good choices for activities. However, everyone with scleroderma is different, and so exer-

cise intervention will be very person dependent.

At their July meeting, the Central New Hampshire Support Group was challenged by the Rheumatology department at Dartmouth-Hitchcock Medical Center to a steps challenge. Members of the support group logged their weekly steps for a month and in the end, they were the champions

and won a gluten free pizza party (when it's safe to gather, of course). This was a wonderful motivation to get moving and an example of how just a few steps can make a difference as a team.

Remember to consult your physician before starting any exercise routine or program and always listen to your body and take it slow!

SCLERODERMA FOUNDATION
NEW ENGLAND CHAPTER
MASSACHUSETTS

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- Fall River/Bristol County Support Group**
donnabdab2shotmail.com, 774-488-6775
- North Shore Support Group**
781-324-7426
- Worcester Area Support Group**
508-869-2997

NEW HAMPSHIRE

- Granite State Support Group (Hampstead)**
carla.kingecomcast.net, chappybear@charter.net
- Central NH Support Group**
603-566-3145, donlegerescomcast.net
- VERMONT**
- Burlington Vermont Support Group**
802-324-4826, blythe.leonard62@gmail.com
- Brattleboro Area Support Group**
802-464-5847, jlenewax@gmail.com

MAINE

- Maine Support Group**
207-420-3337, slunners@aol.com
- South Berwick Support Group**

ONLINE

- ScleroMen Support Group**
ScleroMen@scleroderma.org

Support Group Meetings are being held via Zoom at this time, contact the SFNE office or group leadersto get more information and connect today!

NEW SUPPORT GROUP NOTICE

We are assembling a support group for patients on or around Cape Cod. Please contact our office if you are interested in participating. Spread the word!

If you would like to coordinate a support group in your area, or would like to join an existing group please contact Lindsay De Santis at the SFNE office.



SEARCHING FOR HEALTH *(continued from page 1)*

“molecular libraries” in a process called high throughput screening. Those that don’t hit the target are eliminated while those that do are subjected to further investigation to determine if hitting the target translates into the desired biological response. These tests take place in living cultures such as cells and tissues and eventually progress to animal models with the disease.

Scientists eventually narrow the field to one “lead candidate drug.” Often, they tweak the lead candidate drug’s chemical structure to make it less likely to interact in similar chemical pathways in the body. Many adverse events arise because a drug has “off-target” interactions and altering its chemical structure (creating analogues) helps reduce these off-target effects and enhance safety.

The lead candidate drug must demonstrate that it selectively hits the target, elicits the desired biological response and doesn’t raise serious safety concerns. Only then can it transition from Discovery into Development where testing in humans begins. Very few Discovery compounds make this transition and, of those that do enter Development, only 12% achieve regulatory approval. Drugs fail in the Development stage for two key reasons. They either lack efficacy or lack safety and sometimes lack both. Before it can be considered for regulatory approval, the drug must complete 3 phases of human research – each phase with increasingly larger numbers of participants.

Phase 1 studies are conducted in healthy volunteers to assess how the drug behaves in the human body (pharmacokinetics) and how well-tolerated it is at various dosing strengths. Phase 1 studies do not assess efficacy. The one exception to this rule relates to cancer trials. Phase 1 cancer trials enroll cancer patients who have exhausted all other treatment options and these studies assess, safety, tolerability, and efficacy by searching for evidence of tumor response.

Phase 2 studies enroll patients with the disease and assess safety, tolerability and efficacy. The data from Phase 2 studies shapes the design of the “pivotal” Phase 3 studies.

Phase 3 studies enroll thousands of patients (except when it involves a rare disease). These studies are large, costly, and time-consuming. It can take years to recruit all the patients and to accrue and analyze the data generated from them. Usually, the primary endpoint in a phase 3 trial is to demonstrate better efficacy compared to the current standard-of-care with equal or better safety and tolerability. As we know from the recently- failed trial of Lenabasum in Systemic Sclerosis, a phase 3 (late-stage) failure is hugely disappointing. But, sometimes failure in one study leads to success in another. Pfizer Pharmaceuticals was developing a new drug in the late 1990s for the treatment of high blood pressure and angina pectoris. The angina trial was a failure the hypertension trial a success. In both studies however, male patients reported a surprising but not unwelcomed side effect. This off-target side effect led to the birth of Viagra.

A lesser-known story is that of tamoxifen which was being developed in the 1960’s by ICI Pharmaceuticals (now AstraZeneca) as an emergency contraceptive. It failed when many women participating in the study became pregnant. Perplexed by this outcome, scientists discovered

that tamoxifen has two modes of action. In breast tissue it blocked (red light) estrogen but in uterine tissue it enhanced it (green light). These scientists realized they may have accidentally stumbled upon a treatment for estrogen-driven breast cancer and convinced AstraZeneca to fund their research. In the early 1970’s, tamoxifen became the first oral drug to reduce the risk of breast cancer recurrence and is still a mainstay of breast cancer treatment for many women today around the world.

Discovering and developing a drug is fraught with risk and high costs. A 2019 report from the Tufts Center for the Study of Drug Development estimates this cost at \$2.6 billion. Of this, \$1.4 billion represents direct, out-of-pocket costs and \$1.2 billion represents the research costs of thousands of failed compounds. Many health economists argue the \$1.2 billion failure cost should not be included in the overall price tag. But, all agree there is a high price for both success and failure.

Today, more than ever, scientists across multiple disciplines including medicine, biology, chemistry, engineering and even mathematics are working collaboratively to shed new light on ways we might target, disrupt, and eliminate disease. The author of *The Emperor of All Maladies*, Siddhartha Mukherjee, MD/PhD, wrote *Incremental advances can add up to transformative changes*. It is a time of great hope.



The New England Chapter Board is looking for new Board members with accounting and financial skills.

Please let us know if you are interested.

Contact

LDesantis@sfnewengland.org

See Back Cover for Raffle Ticket

| | SUN | MON | TUE | WED | THU | FRI | SAT |
|----|---|---------------------------------------|--|----------------------------------|---------------------------------------|---|--------------------------------|
| 6 | \$15 App Store & iTunes | 7 Whale Watch Passes | 8 Holiday Wreath | 9 \$20 TARGET | 10 Holiday Boxwood | 11 \$25 The Cheesecake Factory. | 12 \$20 |
| 13 | Baseball Collectibles | 14 \$20 | 15 Market & Steak Gift Card | 16 \$20 Holiday Boxwood | 17 \$20 Starbucks | 18 \$25 amazon.com gift card | 19 \$20 |
| 20 | \$20 | 21 \$25 amazon.com gift card | 22 \$20 Holiday Boxwood | 23 \$20 Bertucci's | 24 \$20 Holiday Boxwood | 25 \$25 SCRATCH TO WIN!!! | 26 \$20 Spring Wreath |
| 27 | \$20 Ninety Nine RESTAURANT & PUBS | 28 \$20 DUNKIN' DONUTS | 29 \$20 LEGAL SEA FOODS GOURMET GIFTS | 30 \$20 | 31 \$20 Total Wine Gift Card |  SCLERODERMA FOUNDATION SUPPORT · EDUCATION · RESEARCH NEW ENGLAND CHAPTER | |

See Back Cover for Raffle Ticket

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1. Visit smile.amazon.com in place of the www.amazon.com link and login to your account (make sure you visit smile.amazon.com every time you shop on Amazon.)
2. Type "Scleroderma Foundation New England" under "Or pick your own charitable organization" and click search.
3. Select Scleroderma Foundation New England as your designated organization

It's that simple!

SFNE Membership & Donation Form

You can improve the lives of individuals with scleroderma and help search for a cause and cure.
To join or make a donation by credit card, visit our website www.scleroderma.org/newengland.

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Phone : _____

Email address: _____

● Please check appropriate box(es): \$25.00 Membership Donation \$ _____

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To pay by cash or check, complete this form and mail to:

SFNE
462 Boston Street, Suite 1-1
Topsfield, MA 01983

Email us at Admin@SFNewEngland.org



MATCHING GIFTS

Corporate matching gifts are a type of philanthropy in which companies financially match donations that their employees make to nonprofit organizations. When an employee donates, they'll request the matching gift from their employer, who then makes their own donation. Companies usually match donations at a 1:1 ratio, but some will match at a 2:1, 3:1, or even a 4:1 ratio.

December 1, 2020 is giving Tuesday. Giving Tuesday is a global movement to create an international day of giving at the beginning of the holiday season. There's no better time to see if your employer will match your contributions for #GivingTuesday and year end giving. Check with your organization to see what their policies and programs are to maximize your contributions!



Percentage of match-eligible donors that have no idea whether their company offers a matching gift program.



Percentage of donors at companies with matching gift programs that actually submit a matching gift request.

Source: <https://doublethedonation.com/tips/corporate-matching-gift-programs/>

GIVING TUESDAY

December 1, 2020



SUPPORT ★ EDUCATION ★ RESEARCH
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Planned Giving

Consider joining our BEACON Legacies by making a major donation or creating a bequest provision to the Scleroderma Foundation New England Chapter in a will or trust.

- ✓ Leave a gift in your will
- ✓ Name SFNE as a charity beneficiary of IRA
- ✓ Give charitable gift annuities

To find out more about your planned giving options, please contact Lindsay De Santis at 978-887-0658

\$10 EACH
3 FOR \$25

CALENDAR RAFFLE

31 CHANCES TO WIN - RAFFLES DRAWN DAILY

DETACH THIS TICKET AND MAIL WITH YOUR CHECK OR CASH TO THE SFNE OFFICE - OR PURCHASE ONLINE AT SCLERODERMA.ORG/NEWENGLAND

SFNE
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NAME: _____

ADDRESS: _____

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EMAIL: _____

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