



**American
Autoimmune**
Related Diseases Association, Inc.

INFOCUS

A quarterly newsletter of the American Autoimmune Related Diseases Association, Inc.

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Rocky (Lee-Anna's husband), Lee-Anna, AARDA President & CEO Randall Rutta

AARDA LAUNCHES INSIGHT: CONVERSATIONS WITH THOUGHT LEADERS

AARDA is pleased to announce a new channel of bringing new information and compelling perspectives on issues of critical importance to people with autoimmune diseases and stakeholders. Through a series of interviews hosted by AARDA President & CEO Randall Rutta, **INSIGHT** contributes to our understanding of issues and ideas, best practices, and strategies for change in support of the autoimmune community and society.

INSIGHT launches with an interview with Lee-Anna, a nurse practitioner by training and a person with multiple autoimmune diseases, who is an effective patient advocate in her home state of Tennessee and nationally. Lee-Anna was forced to plan her own funeral at the age of 36 due to the nearly overwhelming challenge of managing her diseases in the current, imperfect health care system. She battled the harmful effects of step therapy, and this battle continues. She is

a dedicated advocate who travels the country to encourage changes in access restriction policies that so often prevent autoimmune patients from getting the prescribed medicines and care that are best for them.

Visit www.aarda.org to learn more about Lee-Anna's efforts to educate decision-makers and support others in becoming effective patient advocates, and to access future **INSIGHT** conversations with thought leaders.

AUTOIMMUNE DISEASE AWARENESS: A TIMELY, NATIONAL PRIORITY; RESOURCES TO HELP HIGH-RISK PATIENTS DURING GLOBAL PANDEMIC

Autoimmune Disease Awareness Month (ADAM) is our time to speak up to increase understanding of the prevalence, impact, challenge, and opportunity facing an estimated 50 million Americans living with autoimmune diseases. The stakes have never been higher. People with one or more of the 100+ specific autoimmune conditions have stories to tell, contributions to make, commitment to research, and hope for new treatments. Yet, too many confront a too-long list of barriers between them and the medicines and care that they need to lead healthy, full lives.

The American Autoimmune Related Diseases Association – AARDA - is dedicated to breaking down these barriers. ADAM is a call to action, and everyone is encouraged to participate.

Raising awareness about the presence of autoimmune disease is especially critical in this time of global pandemic. People with autoimmune conditions are among those with underlying health conditions that put them at greater risk of experiencing serious consequences if they contract this novel coronavirus, COVID-19. AARDA has relevant information and resources on our website, www.aarda.org, including

links to government, academic, patient group, and other sources of advice and expertise.

For nearly 30 years, AARDA has been a pioneer and leader in advocating for all autoimmune diseases, actively collaborating with patients, doctors, and other stakeholders to raise awareness about autoimmunity, drive public policy changes, and promote increased investment in research and discovery.

AARDA is committed to advocating for those living with autoimmune diseases, and we welcome your help. Join us to raise awareness, engage, advocate, and support our cause. Visit www.aarda.org/adam for ideas and opportunities to get involved.



MARCH 2020: ADVANCING AUTOIMMUNE AWARENESS & ACTION

President/CEO Message: Randall Rutta

Autoimmune Disease Awareness Month is our time to speak up to increase understanding of the prevalence, impact, challenge, and opportunity facing an estimated 50 million Americans living with autoimmune diseases. The stakes have never been higher, especially now with the COVID-19 pandemic and the higher risk that this novel coronavirus poses to persons with autoimmune diseases and other underlying conditions.

People with one or more of the 100+ specific autoimmune conditions have stories to tell, contributions to make, commitment to research, and hope for new treatments. Yet, too many confront a too-long list of barriers between them and the medicines and care that they need to lead healthy, full lives.

AARDA is dedicated to breaking down these barriers. And, as CEO, I am privileged to engage with amazing patient advocates, patient groups, practitioners, researchers, legislators, and others whose lives, careers, and decisions affect people throughout the autoimmunity community. ADAM is a call to action, and everyone is encouraged to participate.

Earlier this year, I took part in a Food and Drug Administration (FDA) Advisory Committee hearing to encourage consideration and approval of a breakthrough medicine to treat Thyroid Eye Disease (TED). TED is a rare and debilitating autoimmune condition that is painful, often disfiguring, that frequently leads to vision problems and loss. I joined a dozen TED patients, patient advocates, and physicians in urging the Advisory Committee and FDA to approve this new drug.

My comments were stronger because of the compelling input of many patient advocates who shared their views with me in advance of the hearing. I shared Seth’s comments in full:

At the age of 30, my appearance slowly morphed due to TED. In my “moderate” case of TED, the proptosis I experienced was coupled with dry eyes that were red/bloodshot. Where did the person I’d come to identify as go? How long will this last? Is this permanent? There really were no answers. I’ll never forget

when I attended a function and someone asked if I was high on marijuana (I was sober). My self-confidence plummeted during this time. I constantly hid behind eye glasses or sunglasses. After two years of waiting for the active phase of the disease to pass, I opted for orbital decompression. This improved the appearance of my eyes; however, I still miss the old me. If the eyes are windows to the soul then TED is a soul crusher. The FDA should keep an open mind when considering treatments for TED.”

Seth’s compelling words commanded the attention of everyone at the FDA hearing and were echoed in the statements of many others. A few weeks later, ahead of schedule, the FDA approved TEPEZZA to treat TED. Thank you Seth and all the other advocates who gave voice to their experience with autoimmune disease and urged action by the FDA to consider new treatments.

Autoimmune Diseases Awareness Month or ADAM is a time to celebrate and amplify advocacy – for personal health, for research into the underlying causes and treatment of autoimmune diseases, for access to innovative medicines, and for public policies that support people living with autoimmune diseases. For AARDA, every month is Autoimmune Disease Awareness Month, and we welcome and appreciate your leadership, partnership, and donations to advance our shared cause.

KEEP UP WITH AARDA!



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www.aarda.org



[\(586\) 776-3900](tel:(586)776-3900)

OUR MISSION

The American Autoimmune Related Diseases Association is dedicated to the eradication of autoimmune diseases and the alleviation of suffering and the socioeconomic impact of autoimmunity through fostering and facilitating collaboration in the areas of education, public awareness, research, and patient services in an effective, ethical, and efficient manner.

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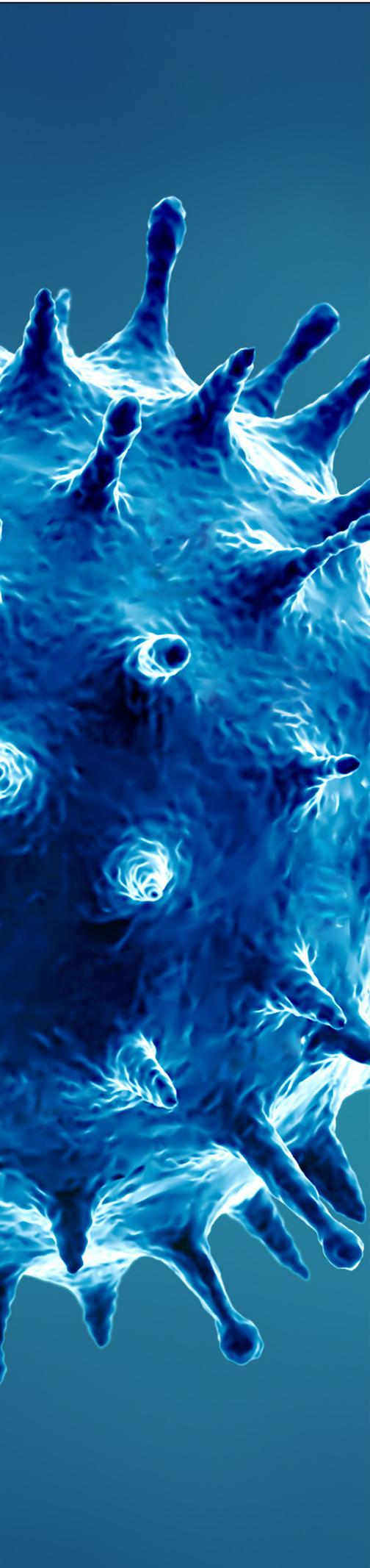
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PEOPLE WITH AUTOIMMUNE DISEASE AND THE COVID-19 PANDEMIC

Dr. Betty Diamond, Chair, AARDA Scientific Advisory Board

The worldwide spread of COVID-19 has disrupted all our lives. Unfortunately, the lack of information, and the slow engagement of scientific leadership, has enabled rumors and misinformation to spread. Fortunately, we all still exercise some control over our own health during this crisis. We, at AARDA, take this opportunity to offer some advice for individuals with autoimmune diseases during this pandemic.

It is clear that social distancing is an important component of infection control. Stay away from crowded venues. If you must use public transportation, try to travel during non-peak hours. Postpone gatherings with friends and family. Most importantly, wash hands often and thoroughly. Each individual's unique circumstances will be different, but the principle that should apply to everyone is to minimize contact with other people to the extent possible – for your own health, your family's health, and for the sake of public health. We each have a responsibility to minimize the spread of the virus in the community even if we are willing to take risks for ourselves.

The CDC has recommended against wearing a mask if you are well. However, if a family member is ill, they should wear a mask and avoid being in the same room with you.

It is a certainty that those on immunosuppressive medication and corticosteroids are more at risk for infections. It is also likely that individuals on immunosuppressive therapy who develop the virus may not exhibit a fever. Corticosteroids and immunosuppressive therapies lessen the activation of those

immune cells which are responsible for a fever. Therefore, individuals with autoimmune diseases requiring these therapies need to know that a cough, fatigue, and certainly any difficulty breathing are reason enough to contact your physician with or without a fever. Try to establish in advance how you will contact your doctor should you develop symptoms or have concerns that you were or might have been exposed to a person infected by the virus. Emergency rooms and triage centers are not good places to be. Alternative ways to access care is preferable if possible.

Unfortunately, some misinformation is being circulated online. There is no current treatment or cure for COVID-19 apart from supportive measures. There are a few specialized hospitals that are starting clinical trials of anti-viral drugs, and there are efforts underway to design vaccines. These will need to be tested for safety and effectiveness before they can be distributed to the general public. This takes time and is why health officials think it will be about a year before a vaccine is available.

Catch up on your reading.

As we learn more, we will share with you. There are many online sites that will give you accurate and frequently updated information about COVID-19. These can inform you about new developments and new knowledge. Here are a few:

- www.cdc.gov/coronavirus/2019-ncov/index.html
- www.hopkinsmedicine.org/coronavirus
- who.int/news-room/q-a-detail/q-a-coronaviruses

Betty Diamond, MD
Head, Center for Autoimmune and Musculoskeletal Diseases



ADVANCING THE FRONTIERS OF AUTOIMMUNE RESEARCH:

*Virginia T. Ladd Young Investigators Program
Founder and Advisor to the President*

AARDA's **Virginia T. Ladd** Young Investigators Program was established in 2015 to provide funding to young researchers studying basic autoimmune disease. Under the program, one-year grant terms of \$20,000 are awarded to applicants who have a senior mentor and demonstrate the skill and dedication required to research

autoimmune disease. AARDA's Scientific Advisory Board reviews applications for this funding, which, since 2015, has totaled \$320,000 to support thirteen researchers.

This program speaks to AARDA's core value of supporting autoimmune research. It is named in honor of AARDA

founder Virginia T. Ladd in recognition of her passion for promoting research. Currently, AARDA is supporting five dedicated researchers with second year grants of \$20,000 each. Checkout the profiles and areas of research for two of these grantees: Beth Wallace and Tarun Sjharma. Stay tuned for information on our additional grantees.

2019 YOUNG INVESTIGATOR GRANT RECIPIENTS



BETH WALLACE
University of Michigan

"Glucocorticoid Prescribing within a Cohort of Veterans with Rheumatoid Arthritis"

I am a rheumatologist and early career investigator at the University of Michigan. My career goal is to optimize the treatment of autoimmune diseases by designing personalizable medication regimens that keep symptoms under control while reducing side effects. My current work focuses on better understanding how doctors are using oral steroids, like prednisone, to treat rheumatoid arthritis (RA), which is the most common type of autoimmune arthritis. Over three-quarters of RA patients use steroids, even though they are known to cause serious side effects like heart attacks, infections, and bone fractures. Treatment guidelines for RA recommend that steroids be tapered off, but cannot provide clinicians with data-based instructions on how to taper. Because tapering can lead to RA flares or steroid withdrawal symptoms, clinicians often avoid tapering steroids in RA patients who have been on them long-term. As a result, a quarter of RA patients on long-term steroids remain on them even when their RA is in remission.

This Young Investigator Grant will allow me to (1) develop an evidence-based definition of steroid tapering, informed by real-world practice, and (2) identify the patient characteristics most associated with successful steroid tapering in RA. This work will provide me with the information I need to design and test personalizable steroid tapering regimens, first for RA patients and later for patients with other autoimmune conditions.



TARUN SHARMA
Alleghany Health Network

"Rheumatoid Arthritis Biologic Tapering Initiative (RABTI): A Real World, Prospective, Cohort Analysis of Biologic Tapering in Stable, Well-Controlled Rheumatoid Arthritis by Implementing a Multi-Faceted Tapering Strategy"

In this study at the AHN Autoimmunity Institute, investigators are analyzing success of a biologic tapering strategy and hoping to identify predictors of and impact of successful tapering in stable, well controlled rheumatoid arthritis (RA). Established RA patients in stable remission on biologics are being identified for a dose or dosing frequency reduction where appropriate. In addition to studying successful tapering, investigators plan to measure events of infection and malignancy as part of the study as well. To follow patients longitudinally and collect and analyze data involves significant resources and time (e.g. database creation, maintenance, data entry, validation, statistical analyses). The AARDA grant award will help support this longitudinal study and help answer the vital question, "What are the outcomes of biologic tapering in stable RA and what can we learn from this multi-faceted biologic tapering strategy?" This funding means a lot not only to the study team, but also to all RA patients who are trying to answer this question concerning their long-term RA care.

ADVOCATING FOR AUTOIMMUNE DISEASE RESEARCH

More than 100 conditions are currently recognized as autoimmune diseases or closely related diseases, and the majority are considered rare diseases. Decades of research has contributed to a much better understanding of autoimmunity, yet there is still much work to be done to discover the underlying cause of autoimmune disease and a wide-range of condition-specific treatments.

Since its founding nearly 30 years ago, AARDA has been a proponent of increased investment in autoimmune disease research. Over the years, AARDA has actively encouraged government funding research into the underlying causes of autoimmune disease and specific and related diseases by the National Institutes of Health, the

Department of Defense (DoD), and in other agencies. Members of Congress are currently being encouraged to increase investment in these critical areas as part of the FY 2021 Budget and Appropriations campaign spearheaded by autoimmune and health advocates, including AARDA. Advocates are urging Congress to increase support for these programs.

As part of this effort, AARDA is urging Congress to allocate specific funding at NIH for the expanded role of the Autoimmune Diseases Coordinating Committee, which supports learning and collaboration on autoimmunity among researchers across multiple Institutes. AARDA is also asking Congress to reinforce the need for DoD to restore priority and funding

for autoimmune disease research in its Congressionally-Directed Medical Research Program.

AARDA actively promotes comparable investments in academic and health systems research, and encourages a climate of investment and incentives to promote innovation and discovery in private sector. Research and exploration of autoimmunity leads to advancements in specific autoimmune diseases, fostering breakthroughs in new and more effective diagnostic and treatment options for people living with these diseases.

AARDA invites patient advocates and others to support our policy initiatives to boost public and private investment in autoimmune disease research. Visit www.aarda.org to learn more.



ADVOCATING FOR POLICIES IMPORTANT TO AUTOIMMUNE PATIENTS

Congress and Federal Agencies are considering changes in a number of federal policies and programs that threaten patient access to the medicines and care prescribed by their physicians. AARDA is actively promoting proposals to protect and improve key policies.

Safe Step Act Promotes Reform

AARDA is actively promoting passage of the Safe Step Act, bipartisan federal legislation to reform insurance-mandated step therapy practices. This legislation, H.R. 2279 and S. 2546 in the House and Senate, respectively, would require timely and medically-appropriate appeals processes and other reforms needed to assure that patients get the treatment that is best for them.

Step therapy isn't a therapy at all, but an insurance industry practice that often denies, delays, and even blocks access to the medicines prescribed for patients by their physicians. All too often, step therapy and other utilization management techniques force patients to try and fail on one or more lower cost medications before they will provide coverage for the prescribed medication. Medicines are often placed on special formularies or require access through specialty pharmacies, frequently increasing costs and limiting access to treatments most appropriate to individual patients.

AARDA is a member of the Safe Step Coalition and recently joined other organizations in writing to Members of Congress to urge their support for passage of this critical legislation. Please join us: visit www.aarda.org to send an advocacy message to your

legislators encouraging them to support passage of the Safe Step Act.

Lastly, AARDA and other organizations are promoting step therapy reform in dozens of states under the banner of the [Let My Doctors Decide](#) national campaign. This initiative was launched two years ago to promote policy reforms to address the challenge of unwarranted step therapy, other utilization management, and insurance practices that interfere with patient access to appropriate and timely care.

Visit www.LetMyDoctorsDecide.org to learn more about Let My Doctors Decide and get involved in state-level step therapy policy reform and implementation efforts critical to the autoimmune patient community.

Proposed Rule Threatens Copay Assistance for Patients

Protecting patients' ability to have third-party financial assistance count towards their insurance plan cost-sharing requirements is being threatened. On January 31, the Centers for Medicare and Medicaid Services (CMS) released a proposed rule that

would allow health plans to exclude the value of third party financial assistance used to purchase prescriptions – often from drug manufacturers and patient health charities – from the calculation of deductibles and out-of-pocket costs.

If this proposal is finalized, it would result in major financial setbacks for patients and create undue interference with the physician-patient relationship. Negative effects would likely undermine patients' access to prescribed therapies and disrupt medication adherence.

We are concerned that the proposed rule change is inconsistent with the Administration's goal of making prescription drugs more affordable for patients. And, lastly, we know that the threat of losing critical copay assistance coupon support will add to already high levels of stress among patients with autoimmune diseases and other underlying conditions struggling to understand and take precautions against COVID-19. As a group, these individuals are at greater risk of suffering significant, maybe life-threatening health consequences, should they contract this novel coronavirus during the current global pandemic.

AARDA recently led an effort called Patients Deserve Better, and with the support of 43 partner organizations, submitted comments to the U.S. Department of Health and Human Services (HHS) in opposition to the proposed rule. While the official HHS comment period is closed, we invite your input on this issue to inform ongoing advocacy with HHS, Congress, and others to preserve copay assistance support that counts towards patient cost-sharing limits.

AARDA continues to collect comments, personal examples, or other information from patients, family members, practitioners and others to better understand and oppose this proposed rule.

Promoting step therapy reform and opposing the proposed rule that would allow health insurers to not count copay assistance coupon support from drug manufacturers against patient cost-sharing limitations are just two of nearly dozen AARDA federal and state policy priorities. Additional information on these policies and action steps are available to you at www.aarda.org.

NEW INSTITUTE LAUNCHED TO ASSURE HEALTH SYSTEM READINESS FOR GENE THERAPY



The Institute for Gene Therapies (IGT) was launched in February to advocate for a modernized U.S. regulatory and reimbursement framework to assure that gene therapies can deliver their significant potential to patients. IGT will educate stakeholders across the healthcare community about the transformational nature of gene therapies and advocate for policies that help ensure patients who need them can benefit from them.

Gene therapy is poised to change human health as we know it. By altering non-functioning genes or replacing absent ones, gene therapies have the potential to reshape the way thousands of diseases are treated with long-lasting effects for patients. The

first of these transformative therapies have already been approved by the U.S. Food and Drug Administration (FDA) and hundreds more are currently being studied in clinical trials for rare and common diseases, including many types of cancer, neuromuscular diseases, blood disorders and infectious diseases, among others.

Gene therapies are fundamentally different from traditional pharmaceutical and biologic medicines in that they target the cause of the disease at the DNA level to create a change in the body. Further, some gene therapies are designed to be one-time treatments that offer life-long benefits. Today, the vast majority of medicines help manage the symptoms of disease

over time rather than address – or halt – diseases at their root.

The U.S. healthcare system – from the drug approval process to the way treatments are paid for – reflects this reality. The existing regulatory and reimbursement structures, which were established and adjusted over time to accommodate pharmaceutical and biologic medicines, need revisiting in light of gene therapies and their significant potential.

“The incredible scientific advancements in this space present unique opportunities to directly improve and save the lives of patients suffering from debilitating diseases,” said IGT Chairman, and former Congressman Erik Paulsen.

AARDA is among the stakeholder experts across the healthcare system will work together to ensure health policies reflect the latest medical advances, remove barriers that hinder patient access to

gene therapies and advocate for sustainable, long-term solutions. IGT will work to ensure a greater understanding about the value gene therapies bring to patients, families, the healthcare system, and our

society so that gene therapies can achieve their full potential. For more information, visit gene-therapies.org and follow us on Twitter [@gene_therapies](https://twitter.com/gene_therapies).



HONORING AARDA'S EXTRAORDINARY DONORS

For the third year in a row, Kimberly Trimble is leading a Virtual Autoimmune Walk for AARDA. The Georgia native has made it her mission to raise awareness and funding every March during Autoimmune Disease Awareness Month. Inspired by her energy and courage, her team — Kimmy's Krewe — walks with her.

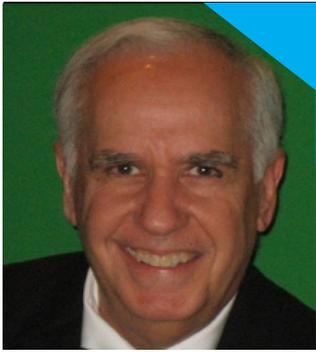
"In March 2017, I was diagnosed with a rare autoimmune disorder called

Relapsing Polychondritis," Kimberly says. "It resulted in several areas of my body being affected, with the most significant being my airway, and in December 2018 I had a tracheotomy. Thankfully, I am now on a course of treatment that is working! I am still able to work full-time as a School Psychologist and participate in activities with my families and friends, such as cheering on my Atlanta Falcons!

Of course, I still have my bad days, but I have vowed to never let this disorder slow me down!"

Kimberly and her "Krewe" had planned to walk on March 21 at Rhodes Jordan Park. The rise and spread of the novel coronavirus, COVID-19, necessitated a change in plan. The great thing about Virtual Walks, however, is that they can be done anywhere, on any day, at any time.





REDUCING STRESS

Robert H. Phillips, Ph.D., Director, The Coping Counselors at the Center for Coping, Hicksville, NY, Member, AARDA National Board of Directors

The current coronavirus (COVID-19) pandemic has been causing increased stress for most people. Both the known facts about the virus, as well as the unknown concerns, can be overwhelming and anxiety-inducing for adults and children.

It can be helpful to recognize that the way we are affected by anything going on around us is directly related to the way we think about it. Therefore, an important category of coping strategies involves working on your thinking.

We are all dealing with the coronavirus and its impact on society. However, if you think about the people you know, you'll realize that they're all dealing with it differently. How can that be if we're all dealing with the same situation? It's because each person thinks differently. So if you work on your thinking, you can improve the way you deal with it, even while we're waiting for it to run its course.

So what can you do? Here are two simple suggestions for how you can start working on your thinking.

FOCUS ON POSITIVE THOUGHTS INSTEAD OF NEGATIVE THOUGHTS

If you were to have a "transcript" of every thought going through your mind, you'd be amazed to see how negative your thinking is. And you get into trouble if you are overwhelmed with negative thoughts, and you don't "fight back" with realistic positive thoughts.

So work on that. Try to identify as many of your negative thoughts as you can about what's going on. Then, instead of allowing them to become "a runaway train," try to jump in and come up with some positive responses. For example, Instead of thinking, "I can't deal with the stress; everything is falling apart," you might think, "I'm working to deal with the stress better, and I'm going to do the best I can until the problem peaks and then starts to wane."

USE POSITIVE AFFIRMATIONS

Positive affirmations are encouraging statements, directed at yourself, that you either say out loud or think to yourself. They are designed to strengthen you, help you to think more positively, and better offset debilitating negative thoughts.

It's important that these affirmations be realistic and believable, and that you keep repeating them to yourself. In this way, even if you don't believe them at first, the repetition will help them to become a greater part of the way you think.

Examples of positive affirmations that some people find helpful would be, "I am doing the best I can," "I can get through this one day at a time," and "I'm going to continue to focus on the positive things going on in my life."

TRY TO RELAX

Relaxation is the opposite of tension, so the more you're able to relax, the more you can your anxiety in check. The relaxation techniques I'm suggesting are clinical strategies, not the typical ways people think of relaxing such as walking, listening to music, reading, etc. Instead, I'm referring to strategies such as deep breathing, progressive muscle relaxation, meditation, among many others.

Here's the link to a simple relaxation technique that only takes two minutes to do. It's an effective technique that I developed more than 30 years ago, and has helped people all over the world.

www.coping.com/quickrelease

If you like the technique, I'd be happy to send you an mp3 file of the "Quick Release," at no charge. Just email me at drphillips@coping.com, and I'll make sure it's sent right back to you.

MOVING FORWARD...

These are skills that take practice, especially when you're surrounded by negativity. But they give you something to do, something to work on, to get your thinking in check... while we wait for this coronavirus crisis to run its course.

AUTOIMMUNE AWARENESS WALKS GO VIRTUAL



AARDA is transitioning our highly successful and fun Autoimmune Awareness Walks from in-person events to Virtual Walks to protect the health and safety of autoimmune patients and families. Our Walk events typically draw 100 to 300 participants, which exceed CDC, federal and state guidelines for gatherings during the pandemic.

Autoimmune Awareness Walks are critical for raising public awareness, helping patients and families, and generating community spirit. As important, our Walks are essential for raising funds to support AARDA's efforts on behalf of people with autoimmune diseases, especially now as we confront the devastating impact of the coronavirus COVID-19 pandemic.

Older persons and people with autoimmune disease and other underlying conditions are at greater risk of suffering dire health consequences if exposed and infected with COVID-19. Now, more than ever, AARDA's mission services and advocacy are necessary to support the autoimmune community in getting through this crisis. We need your donations, your partnership, and your engagement.

If you have already signed up for a Walk, AARDA will be contacting you with more details about how you can change your registration to a Virtual Walk. A Virtual Walk can be whatever you make it. You can walk on the treadmill in your home, walk around your own back yard, or don't walk at all! The main thing is reaching out to your networks of friends, family members, and colleagues to raise awareness and invite their support of AARDA.

Register at walk@aarda.org to join or host an Autoimmune Awareness Walk or another virtual activity that raises funds to support people with autoimmune diseases and our cause. You can make a difference in the lives of millions of others, today!

Contact Deb Patrick at walk@aarda.org or (586) 776-4493 with questions and ideas.