



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

INFOCUS

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Dr. Noel Rose

AARDA MOURNS THE LOSS OF DR. NOEL ROSE, “THE FATHER OF AUTOIMMUNITY”



Dr. Noel Rose (December 3, 1927 – July 30, 2020) Together, we mourn the loss of Dr. Noel Rose. Among his peers, Noel R. Rose, M.D., was a giant. To the American Autoimmune Related Diseases Association (AARDA), he was a friend, mentor, advisor, leader, and champion for nearly 30 years.

A prominent figure at board meetings, public forums and Congressional briefings, in webinars, and national and international conferences, Dr. Rose shared his vast knowledge and expertise with millions, always with great charm, clarity, and his signature bow tie.

Dr. Rose was a founding member and served as chair of AARDA's Scientific Advisory Board. He championed the AARDA mission; led the renowned Scientific Colloquia; and headed the AARDA-supported Center for Autoimmune Disease Research at the Johns Hopkins University Bloomberg School of Public Health. For his incomparable and dedicated service, AARDA presented Dr. Rose with its first Champion Award in 2016, and named him an Autoimmune Hero in 2017. Last year, AARDA renamed its series of scientific meetings he established and convened, the Noel R. Rose Scientific Colloquia. Dr. Rose received dozens of other honors and awards from prestigious institutions throughout his career. He was once nominated for a Nobel Prize, and was awarded the American Association for the Advancement of Science Golden Goose Award in 2019 for his pioneering work in autoimmunity.

“Words cannot express the magnitude of my feelings for this man who was both intellectually and in his personhood a giant,” according to Virginia T. Ladd, AARDA founder, past president, and current advisor to the president. “Noel Rose leaves an incredible legacy and will be remembered always by AARDA and the autoimmune community. His willingness to always take time to respond to patient calls and emails, which he continued to do until just prior to his death, is a tribute to his respect for patients and their need for information.”

Dr. Rose was recognized as the “father of autoimmunity” for his groundbreaking discovery of thyroid autoimmunity in 1956. With this discovery, he would effectively establish the field of autoimmunology and usher in a new era of autoimmune disease research that today impacts one in every five Americans.

“Our patients with autoimmune diseases of the skin will remember [Dr. Rose] and will be forever grateful for his contributions in understanding their illnesses,” said Luis A. Diaz, M.D., UNC School of Medicine, and member, AARDA Scientific Advisory Board.

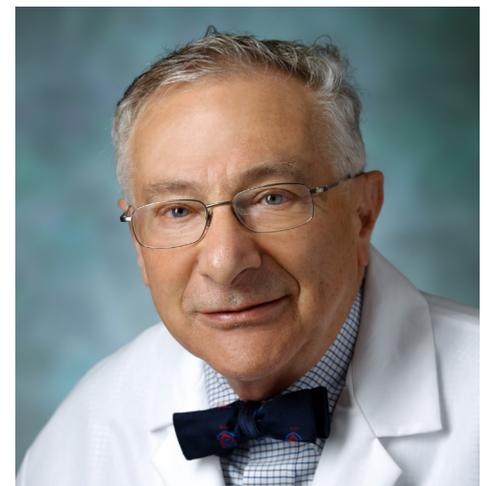
“He was one of those giants on whose shoulders we have all stood,” said Robert Eisenberg, M.D., professor emeritus, University of Pennsylvania, Division of Rheumatology.

“We have decided to name a session in the Congress of Autoimmunity after Noel R. Rose,” said Yehuda Shoenfeld, M.D., FRCP,

MaACR, professor emeritus of the Zabludowicz Center for Autoimmune Diseases, Sheba Medical Center, Tel-Aviv University. “We will all remember and memorialize him.”

As a tribute to Dr. Rose, AARDA Board Member, author, and clinical psychologist Dr. Bob Phillips has re-released his 2009 podcast episode, “Dr. Noel Rose: An Immunologist Affectionately Called “The Father of Autoimmunity.” [Listen here.](#)

The family of Dr. Rose has established a memorial fund in his honor through AARDA. Proceeds will go to continuing the Dr. Noel R. Rose Scientific Colloquia. Donations can be made by mail or by visiting the [memorial gift page](#) on the AARDA website.



Dr. Noel Rose



PRIORITIZING CLINICAL TRIALS AND AUTOIMMUNE RESEARCH

President/CEO Message: Randall Rutta

NEW AARDA HEADQUARTERS IN MI!

After more than two decades in Eastpointe, AARDA is moving to a new location in Southeast Michigan. AARDA's new offices are modern and features ample space for its highly dedicated and talented team of professionals to carry-out our important mission of service and advocacy to people with autoimmune diseases – and room to expand! Check us out at 19176 Hall Road, Suite 130, Clinton Township Michigan 48038.



For 50 million Americans living with autoimmune diseases, the focus on research and innovation is critical and potentially life-changing. The COVID-19 pandemic has added a new level of urgency. Scientists are racing to develop a COVID-19 vaccine as well as transforming facilities to focus on testing and treatment options for people infected by the virus. Therapies to treat and prevent the novel coronavirus can't come soon enough.

Yet, research at companies, academic institutions, and health systems are supporting clinical trials of promising treatments that, due to the COVID-19 pandemic, have been interrupted, suspended, and otherwise challenged. This is a serious concern. Safely restarting this critical drug development pipeline will help deliver lifesaving medicines to some of our nation's most vulnerable patients. Read more about this urgency and the importance of continued forward progress on research in a recent op-ed in [The Buffalo News](#).

AARDA remains committed to research through the Virginia T. Ladd Young Investigators Program which offers awards to support young

researchers in basic autoimmune disease discovery. Currently, AARDA is supporting five dedicated researchers with two-year grants of \$20,000 each. In addition, [Autoimmune Research Network](#) – ARNet – supports patients in learning about and participating in clinical trial design and trials that may lead to breakthrough treatments. More than 18,000 individuals with one or more diagnosed autoimmune conditions are part of this network and that number continues to grow – upwards 200 new patients each month. These individuals are matched to researchers and given the opportunity to participate in trial design and/or clinical trials themselves, often receiving a stipend to take part. To participate, access: www.aarda.org/who-we-help/patients/arnet/.

Our commitment is particularly relevant in the recent weeks as we mourn the loss of Dr. Noel Rose, the “father of autoimmunity,” founding member of AARDA, and long-time and chair of AARDA's Scientific Advisory Board. He championed the AARDA mission and led the renowned Scientific Colloquia. Read more about Dr. Rose – our friend, mentor, advisor, and leader (see front page).

KEEP UP WITH AARDA!



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(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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NEW COALITION HIGHLIGHTS INFECTIOUS DISEASE CONCERNS



PFCD recently launched the [Partnership to Fight Infectious Disease \(PFID\)](#), a new initiative focused on advancing awareness and driving policy changes to address the growing problem of antimicrobial resistance (AMR, aka “superbugs”). All PFCD partners are welcome and encouraged to join. In case you missed it, click [HERE](#) for a webinar and presentations on the PFID effort.

This new initiative is a strategic awareness opportunity to partner with the infectious disease community and continue to build on AARDA’s public health collaborations. We have heard loud and clear from the [Infectious Diseases Society of America](#) (IDSA) and other experts that additional

voices are welcome and needed from the chronic disease community about the importance of addressing antimicrobial resistance. Our ability to prevent and cure infections underpins modern medicine, but many of the advances we’re making on cancer treatments, major and minor surgeries and transplants, wound care from treating accident victims to people living with diabetes are being undermined by the growth of antibiotic-resistant infections. There is considerable work continuing on these issues, but much more needs to be done.

For more information and how to engage, contact Candace.DeMatteis@fightchronicdisease.org.



AN ALTERNATIVE VIEW TO DIET AND AUTOIMMUNE DISEASE

As the saying goes, “Let food be your medicine.” Researchers at the Van Andel Research Institute, in Grand Rapids, Michigan, found that significantly reducing dietary levels of the amino acid methionine could slow onset and progression of inflammatory and autoimmune disorders such as multiple sclerosis in high-risk individuals.

Many cell types in the body produce methionine, however, the immune cells responsible for responding to threats like pathogens – agents that cause disease – do not produce methionine. Instead, the methionine that fuels these specialized cells called T cells must be obtained through ingesting foods. Most foods contain methionine, but animal products such as meat and eggs, contain particularly high levels.

During an immune response, T cells flood the affected area to help the body fight off pathogens. Dietary methionine,

through ingested foods, fuels this process by helping reprogram T cells respond to the threat by quickly replicating and differentiating into specialized subtypes. Some of these reprogrammed T cells cause inflammation. This is a normal part of an immune response, but if it lingers, it can cause damage—such as nerve damage that occurs in multiple sclerosis, for example.

While methionine is critical for a healthy immune system, the Van Andel Institute study results suggest that for people predisposed to inflammatory and autoimmune disorders, reducing methionine intake can dampen the immune cells that cause disease. Russell Jones, Ph.D., the study’s senior author and program leader of Van Andel Institute’s Metabolic and Nutritional Programming group stated: “These findings provide further basis for dietary interventions as future treatments for these disorders.”

According to Dr. Jones: “By restricting methionine in the diet, you’re essentially removing the fuel for this over-active inflammatory response without compromising the rest of the immune system.” He cautions that the findings must be verified in humans before dietary guidelines can be developed. The team will also investigate whether new medications can be designed to target methionine metabolism.

In studying methionine-restricted diets as possible treatments for disease, researchers at Duke University in 2019 showed that reducing methionine could improve the effects of chemotherapy and radiation in fighting cancer.

Source: Excerpted from “Dietary interventions may slow onset of inflammatory and autoimmune disorders,” Van Andel Research Institute, February 4, 2020.

AARDA HONORS MEMBERS OF CONGRESS FOR LEADING EFFORTS TO SAVE PATIENT COPAY ASSISTANCE

This month, AARDA presents its Outstanding Autoimmune Advocate Award to four deserving lawmakers who have been steadfast in their work to preserve critical copayment coupon support for patients. This award is given to policymakers who demonstrate extraordinary effort to advance an issue or action that is critically important to Americans with autoimmune diseases and to AARDA. This year, four Members of Congress met this criteria for recognition:

- Representative Don McEachin (D-VA)
- Representative Rodney Davis (R-IL)
- Representative Bonnie Watson Coleman (D-NJ).
- Representative John Joyce (R-PA)

Copay coupon assistance programs are offered by drug manufacturers and others to help patients pay for their prescription medicines. They are a life-line to drug affordability that patients need, including Americans with an autoimmune disease, who may not otherwise be able to cover copays to access medicines and adhere to their treatment regimens. This is especially

true now, as the COVID-19 pandemic threatens jobs, erodes personal finances, and undermines the overall health for millions of families. People are more strapped and stressed than ever.

Earlier this year, the Centers for Medicare and Medicaid Services (CMS) proposed and then implemented a rule to allow insurance plans and others to no longer count the value of copay assistance coupon programs offered by manufacturers of prescription drugs against annual cost-sharing limitations. This policy can prevent patients from meeting out-of-pocket caps, subjecting them to extended cost-sharing and financial hardship, causing many to defer or delay taking their medicines as prescribed and resulting in set-backs to their health and wellness.

AARDA strongly urged CMS to withdraw the rule through comments and a campaign urging patients to also weigh-in on this problematic policy change, called [Patients Deserve Better](#). The campaign continued in July, when a Medicaid pricing rule proposed a provision applying unworkable

requirements to drug manufacturers with copay coupon assistance that undermines continuation of this essential support for autoimmune patients and others.

Throughout this process, Representative Don McEachin (D-VA) called on his Capitol Hill colleagues to urge CMS to withdraw and then delay this problematic rule that puts patients at risk of financial hardship and the inability to access their medicines as prescribed. Joining Congressman McEachin in this effort were Representative Rodney Davis (R-IL), Representative John Joyce (R-PA), and Representative Bonnie Watson Coleman (D-NJ).

“AARDA applauds Representatives McEachin, Davis, Joyce, and Watson Coleman for their tenacious efforts in opposition of this harmful, unnecessary change and urging the revision, withdrawal, and delay of the proposed rule that, if fully implemented, will undermine the ability of patients to access, afford, and adhere to prescribed medicines that assure their health and well-being,” said Randall Rutta, AARDA President and CEO.

PLANNING YOUR LEGACY

[Caring.com](#) reports in its 2020 Estate Planning and Wills Survey that 68 percent of American adults do not have a will or estate plan, and the number is growing. AARDA is ready to help. Our new planned giving web site — [aarda.giftlegacy.com](#) — is a free service we are now providing to our friends and supporters that can help you find up-to-date, helpful information that could impact your quality of life, your finances, and your legacy.

The new site includes dozens of videos, brochures, and an Estate Planning Guide that you can fill out and share with your financial advisor, a planned gifts calculator, and the latest news. We hope that you find the resources and tools helpful as you plan to provide for your loved ones and support the causes you care about.

If you have questions, feel free to contact Deb Patrick, Senior Manager, Individual Giving and Events, at dpatrick@aarda.org. We are pleased to assist you in this journey.

ROLLOVER YOUR IRA FOR GOOD

You have worked hard and saved for your retirement, and your hard work has paid off. If you are looking for a tax-wise way to secure your legacy and are at least 70½ years old, you can use your individual retirement account (IRA) to support AARDA. It's easy, and there are a number of benefits:

- You can avoid taxes on transfers of up to \$100,000 from your IRA to our organization.
- You can make a gift that is not subject to the deduction limits on charitable gifts.
- You can help further the work and mission of AARDA.

The CARES Act waived Required Minimum Distributions (RMDs) for 2020, but future year benefits include:

- Satisfying your RMD for the year
- Reducing your taxable income, even if you do not itemize deductions

To learn more, visit [aarda.giftlegacy.com](#).



24 YEARS OF CONNECTION AND COMMITMENT

DONOR PROFILE

| | | | | | |
|-------|---------------------|--------------|---------------------------|------------|---------------------------------|
| Name: | Vicki T. | Profession: | ICU Nurse, retired | Interests: | Research & Education |
| From: | Milpitas, CA | Donor Since: | 1996 | | |

Vicki T.'s autoimmune story began early in her life. She had rheumatic fever at age four and again at age eight. At 21, Vicki celebrated the birth of her first baby, a daughter. Three or four months later, Vicki had a miscarriage; then another, and another. Looking back, Vicki thinks she may have been in remission for a time, followed by the birth of two sons. Following their births, Vicki again started to experience worrisome symptoms.

"They didn't know back then that autoimmune conditions could have more than one trigger," Vicki said, "and that pregnancy and childbirth could be one of them."

Her symptoms did, in fact, reemerge. "My teeth and my jaw hurt all the time," said Vicki. "I saw several dentists, but none had any good answers, and the X-rays were negative."

At first, the dentists dismissed her symptoms, telling her she just needed to floss regularly and take better care of her teeth. An ICU nurse by profession, Vicki knew better. In 1996, one dentist sent her to an oral and maxillofacial surgeon. His diagnosis: neuralgia-inducing osteonecrosis caused by a blood-clotting disease. He based this diagnosis on an article he had read in a professional journal. The disease was called antiphospholipid syndrome (APS), and in Vicki's case, that meant too much blood clotting.

"My oral surgeon ordered an antibody panel that wasn't done in most labs. I went to Smith-Kline. In 1996, the tests were expensive and not covered by insurance," said Vicki. "I paid \$2,500 out-of-pocket, which was a whole lot of money in those days. But I had to know. When the labs came back, they showed the antibodies. That's when my internist sent me to a hematologist."

The hematologist told Vicki that she did not have an autoimmune disease. He did,

however, put her on a blood thinner which did not address the pain in her teeth and jaws, but did slow the progress of her disease.

That same year, a friend showed Vicki a women's magazine which included an article by Virginia Ladd, founder and then executive director of AARDA. Vicki read it, and then called Virginia and spoke with her at length.

"I remember when I first talked with Vicki and always enjoyed our conversations over the years," said Virginia. "Antiphospholipid disease was one of the reasons I founded AARDA, and I also have it. I felt that research in this area was lacking, and diagnosis came too late considering the seriousness of the manifestations of the condition."

Virginia sent Vicki some materials and resources. In 2001, the two met at the Annual Meeting of the American Association for the Advancement of Science in San Francisco. Dr. Noel R. Rose (see cover page), chair of AARDA's Scientific Advisory Board, was a featured speaker, as was Dr. J. Lee Nelson. Vicki found Dr. Nelson's report about antibody titers and scleroderma with pregnancy most interesting, and learned much from Dr. Rose, who would come to be known as "the father of autoimmunity" for his groundbreaking research.

Over the years, Vicki kept asking questions, kept reading, and learning more. "I enjoy getting InFocus and finding out new bits and pieces on autoimmune disease," she said.

Information and resources are not just for Vicki. Autoimmunity impacts both sides of her family. A cousin has lupus. A nephew and another cousin have type 1 diabetes. A niece and her daughter have Hashimoto's. Two cousins have MS. Her mother- and sister-in-law both have rheumatoid arthritis. Vicki is a committed, influential

advocate for family, friends, and others who have autoimmune conditions.

Asked what it is about AARDA that has kept her interest and support, Vicki said, "I really like the mission. I really like Virginia Ladd and her gusto! I admire her — her vision and her energy and ability to get out and find people and get things done!"

"And research! I think research is the most important part of the AARDA mission," Vicki commented. "What's kept me going and giving all these years is knowing that someone is working on what I've got. We need a lot more research. And a lot more education — especially among doctors across all disciplines. I was fortunate to have an MD who would listen," she said, "and who kept learning." They are teaching about APS and autoimmune in dental schools now! Researchers need to publish more of their findings for physicians to read and learn."

Vicki's advice to those seeking a diagnosis: "Just because you don't have a diagnosis now, doesn't mean you won't get one in the future. Keep your ear to the ground. Take good care of yourself as best you can. Sometimes, the experts may not know; they may not agree! You have to keep educating yourself and advocating for yourself. The answer will come. I'm 78 and still alive! Most people who have what I have don't last this long."

"Vicki has been a long-time and loyal supporter of AARDA's work," said Virginia, "and it is support like hers that keeps us working passionately to reach our goal — a cure."

Vicki is currently sheltering in place at her home in Santa Clara County, the early epicenter of the COVID-19 pandemic in California. She connects with friends and family through Facebook and remains in close contact with friends and colleagues at AARDA.



AARDA SURVEY: CHRONIC PAIN A REALITY FOR PEOPLE WITH AUTOIMMUNE DISEASE

In June, AARDA conducted a **Patient Experiences with Chronic Pain Survey** to provide patients with a platform to share their experiences living with chronic pain and inform our understanding of how best to meet treatment needs. Nearly 500 individuals responded, and several key trends emerged:

PATIENT CHALLENGES WITH CHRONIC PAIN HAVE PERSISTED THROUGH THE COVID-19 PANDEMIC.

60% of respondents rated the intensity of their pain as 6 out of 10 or higher since COVID-19 began.

As the COVID-19 pandemic has required many individuals to follow stay-at-home orders and social distance guidelines, it has disrupted many patients' normal activities and intensified their pain symptoms.

"My pain goes up and down, and COVID-19 has been especially hard as I am unable to have regular massages and use the health club food for therapy. I have been having trouble with my hip, and therefore, have not been able to get out and walk as my muscles tense so much."

"Chronic pain makes life much more complicated. My regular exercise routine has been disrupted by COVID-19 restrictions on gyms."

CHRONIC PAIN HAS BOTH DIRECT AND INDIRECT COSTS FOR PATIENTS.

60% of respondents said their chronic pain increased their healthcare costs.

86% of respondents said their chronic pain causes sleep disruptions and decreased their quality of life.

66% of respondents said their chronic pain caused them to miss time with family and friends.

When patients are not able to find an effective treatment plan to manage their pain, it can require additional visits to the doctor, lab tests, and prescription costs. For those same patients, chronic pain can have a significant negative impact on all aspects of an individual's life.

"I can't live the kind of life I would like to live. I miss time with my children and family, and time with my friends. There are things I want to experience in life, but do not have the time or energy to do because of my chronic illness. I spend a lot of time resting, and it seems that whatever activities I engage in, I need to rest for twice that long afterwards. I feel like I'm missing out on life."

THERE IS AN OPPORTUNITY TO IMPROVE AND ENHANCE THE PATIENT-PHYSICIAN RELATIONSHIP.

23% of respondents agreed with the statement: "There are no doctors who understand my pain." Another 21% agreed with this statement: "I don't have access to a doctor who understands my pain."

The patient-physician relationship is important to ensuring that patients receive timely and effective care to treat their chronic pain. We must create an environment that allows patients to have open conversations with their providers about their pain and create a better treatment experience.

"I cannot even get a referral due to my doctor's attitude. He feels that my AI diseases are being treated, therefore, I cannot be in pain."

THERE IS A DIRECT CONNECTION BETWEEN MENTAL HEALTH AND CHRONIC PAIN.

66% of respondents said their chronic pain makes them feel sad or depressed. Another 60% said their chronic pain makes them feel withdrawn or isolated.

Patients who are not able to manage their chronic pain can experience depression and social isolation, and often chose to withdraw themselves from normal activities with friends and family.

"I am not the happy energetic person I once was. I am depressed and anxious especially because of a rare blood disorder with a high mortality rate. Living with daily chronic pain wears me out physically and mentally. I want my life back or at least as much of it as I can get."

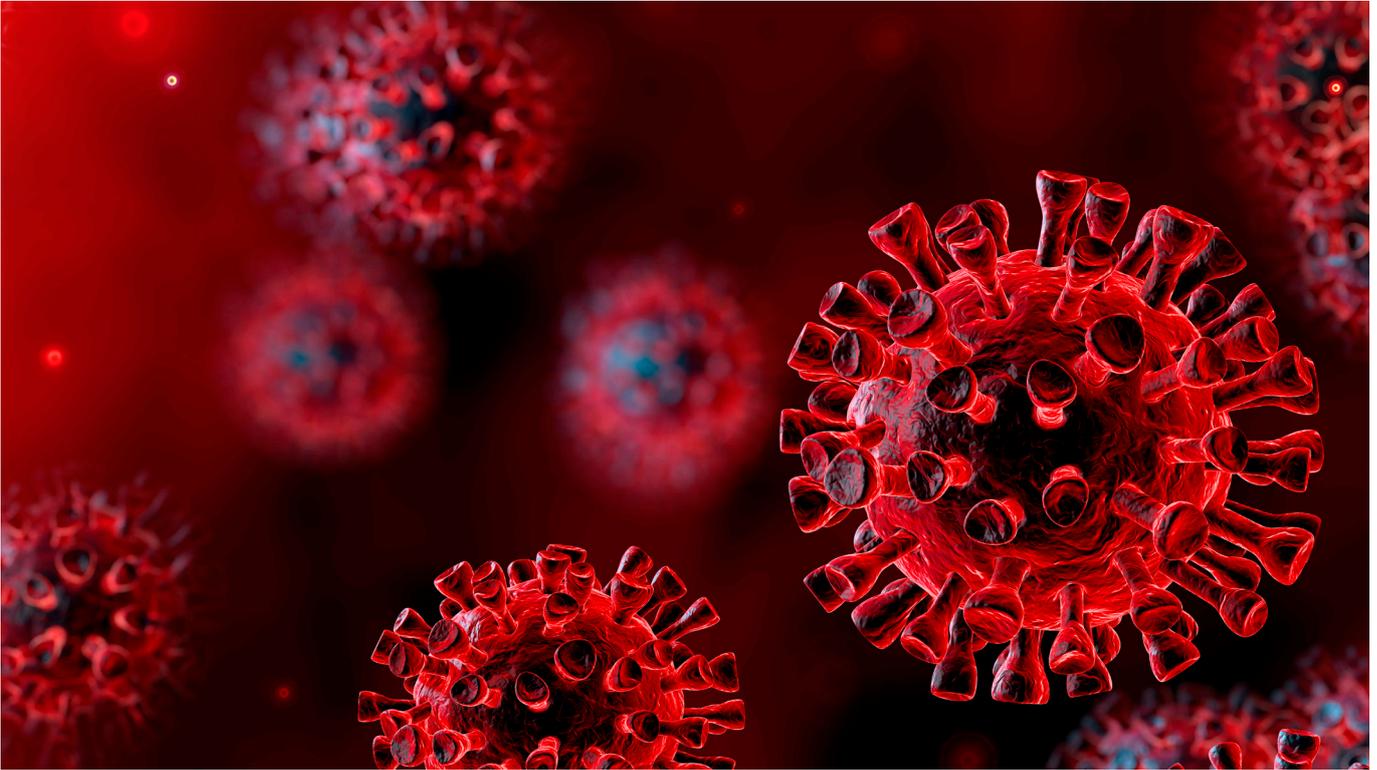
PATIENTS WANT NEW TREATMENT OPTIONS TO MANAGE THEIR CHRONIC PAIN.

53% of respondents agreed: "I want new treatment options for my pain."

It is critical that policymakers and regulators create vehicles to expand research and innovation to evaluate new, non-opioid treatment options for chronic pain and new approaches to manage acute and chronic pain.

"More medical research on how pain works and new medications with less dependence and side effects," when asked "what supports would help you in addressing your pain management needs."

AARDA's survey findings confirm the ways that chronic pain affects so many of the patients we serve and helps us prioritize our efforts to promote policies, resources, and patient experiences to ultimately improve outcomes for the millions of Americans who live with pain today. Please share your insights on pain and ideas for solutions on AARDA's website: www.aarda.org



AARDA CEO TALKS TO NATIONAL PHARMACEUTICAL COUNCIL ABOUT PATIENT ACCESS BARRIERS AND IMPACT OF COVID-19

The [National Pharmaceutical Council \(NPC\)](#) is a health policy research organization dedicated to the advancement of good evidence and science, and to fostering an environment that supports medical innovation. NPC talked with AARDA President and CEO, Randall Rutta, about the organization's efforts to raise awareness about step therapy, other access barriers, opportunities for patient-centered reform, and the impact of the COVID-19 pandemic.

NPC: People living with autoimmune conditions face many challenges when it comes to diagnosis, finding the right treatment, and getting coverage. How are those challenges unique to someone living with one or more autoimmune conditions? How did those experiences lead AARDA to work on issues with step therapy?

RANDALL: It is not uncommon for people with autoimmune disease to spend 3 to 5 to 7 years or more seeking a diagnosis, going to multiple specialists, enduring countless tests, and just suffering, before their disease is confirmed and they secure a treatment that works for them. Each person is different, what works for one person may not work for another in quite the same way. So patients who finally understand their illness and are prescribed medicines that support better quality of life and reconnect them to family, work, school and community – are the last people who should be asked to arbitrarily switch therapies to meet one-size-fits-all insurance requirements. AARDA hears from these people every day - they are afraid, they are angry, and they are being forced from treatments prescribed by their physicians. Their lives are at risk, and AARDA comes to their defense to push back on step therapy.

NPC: Is step therapy a problem that is unique to people living with autoimmune conditions? What are the risks associated with step therapy for these patients?

RANDALL: Many people experience step therapy, and for many it is not an issue. But for people with chronic conditions, mental illness, and health issues that require finely-tuned treatment regimens to maintain health and function, step therapy is a disaster. The consequences of step therapy when the best treatment is denied or deferred can be devastating, sometimes irreversible. Patients forced to wait 6 months to access a medicine that could work well for them can experience severe pain, loss of work, and frequently permanent joint or other tissue damage. →

NPC: Are there times when step therapy is appropriate? If so, what's the difference?

RANDALL: Doctors often apply step therapy to newly-diagnosed persons to test the efficacy of medicines with fewer side effects or that are less expensive before prescribing other medicines, eventually hitting on exactly the right treatment for that patient at that time. Step therapy is not appropriate in situations where the physician, though backed by available clinical evidence, is prohibited from prescribing the best option for treatment. And is certainly not appropriate in cases where a patient is stable and successful on a certain regimen and, due to a change in their insurance status – they change jobs, their employer changes insurance companies, or a formulary shifts – they are forced by step therapy to switch treatments, often with dire negative effects. Ironically, it is not unusual for step therapy to push patients back onto medicines that have failed them in the past.

NPC: What about the burden on providers? What do they experience, and what are the associated costs? How are provider groups working with AARDA in raising awareness of the problems and identifying solutions?

RANDALL: Doctors, nurses, and medical office staff spend nearly 2 days a week responding to requirements in making a case, submitting an appeal to navigate step therapy requirements to secure the most effective treatment for their patients. They face burnout and serious financial loss as they invest inordinate, unnecessary, and too often futile effort advocating on behalf of their patients' health. Provider groups, including the American Gastroenterological Association, Dermatology Nurses Association, and the National Organization of Rheumatology Managers, have joined with patient groups to promote awareness and reform of step therapy for just this reason under the banner of Let My Doctors Decide.

NPC: Tell us about AARDA's efforts in launching Let My Doctors Decide and how that led to you to develop an interactive experience relating to step therapy.

RANDALL: AARDA piloted Let My Doctors Decide in Michigan several years ago to educate and engage patients, providers, and decisionmakers in understanding the harmful effects of step therapy and the need for change. Since then, Let My Doctors Decide has grown into a nationwide campaign to tackle this issue, raising awareness through patient and physician stories, facts and statistics, and an array of resources and tools that interpret the harsh realities of step therapy and its undermining effects of patient health and well-being. We want the truths of step therapy to transcend words on a page to literally be experienced as a twisting, difficult maze of real-world requirements and barriers that may or may not lead to needed treatment. That is what led us to develop the "Escape the System" step therapy experience available both as an in-person exhibit and online.

NPC: What are the main features of the experience? Why did you think it was important to actually demonstrate what patients and providers are experiencing? What has the feedback been so far? How can people participate?

RANDALL: We created an interactive experience to demonstrate obstacles encountered in step therapy, including a highly engaging virtual version that takes the participants past the red tape, to confront face-to-face the unfilled prescriptions, impossible bureaucracy, and a system that feels rigged to prevent actual access to needed treatments. Everyone participating in our interactive presentation recognizes the frustrations of step therapy. Many patients coming through the exhibit actually cried as they relived the pain of the step therapy that they encountered and its harmful impact

on their health. Our experience ends on a hopeful note, with opportunities to endorse LMDD patient principles and a petition promoting step therapy reform, and a national map charting the progress of state efforts to reform step therapy, meant to inform and engage participants in home-state advocacy and advance passage of the Step Therapy Act by the U.S. Congress.

NPC: Has COVID-19 changed what patients and providers are experiencing with step therapy? What changes are patients and providers experiencing that you hope will continue when the crisis abates?

RANDALL: The coronavirus pandemic has exacerbated the difficulties already confronting people with chronic conditions and has created some flexibility that, if continued, may prove beneficial. Over the past several months, patients experienced severe shortages of critical medicines, disruptions caused by limitations or closure of treatment sites due to COVID-19 related patient care, testing, or precautions for at-risk persons with underlying conditions, and elevated stress leading to worsened health status. Federal and state policymakers responding to COVID-19, called on insurance plans to make changes that ameliorate some barriers typically found in step therapy, such as offering additional refills and authorized expanding coverage for telehealth and home-based therapies.

The impact of COVID-19 has been dramatic and devastating, particularly for persons with chronic health conditions who are routinely disadvantaged by step therapy and other impediments to needed care. It is my hope that the horror of this pandemic and revelation of health disparity in treatment and outcomes will drive recognition and lasting change so that patients and their doctors can, together, determine and secure the right treatments at the right time for optimal, lifetime health and well-being.