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Prader-Willi
SYNDROME ASSOCIATION | USA
SAVING AND TRANSFORMING LIVES

PWSA | USA
THE PULSE

Vol. 21 | June 4, 2021

FAMILY SUPPORT & ADVOCACY

24/7
365

"PWSA | USA and their family support team has helped us at times where we were desperate for assistance. Their immediate response for help with medical issues have made the difference between a critical medical issue and immediate help to resolve and correct the problem. No words can say how appreciative we always will be."

Tammie, Mom to Victor (27) of Arizona

pwsausa.org/get-involved-donate/

"PWSA I USA is a soft place to land, a light shining in the darkness and a community that cheers us on this grand adventure. We are so thankful to be a part of the PWSA I USA family and blessed to know they are here for us 24/7."

Christina, Mom to Oaklyn (2) of Maryland

pwsausa.org/get-involved-donate/

To help sustain our life-saving Family Support Program, give generously below!

DONATE NOW

FAMILY SUPPORT

PWSA | USA is excited to announce an opportunity to participate in a new series that elevates the variety of voices and experiences in our community. ***Stories of Resilience & PWS*** will

share personal stories from around the community with a focus not only on the challenges but on the joys, victories and opportunities of the journey.

We're currently looking for Dads to help us kick off this campaign! If you are interested in participating in a brief audio interview to share your story of resilience, please email info@pwsausa.org to arrange an interview time that works for you.

Thank you for using your voice to help us bring attention to PWS!

Hunter's Story

"If Hunter wasn't born with Prader-Willi Syndrome, he wouldn't be Hunter, which would be a shame because I have never met a happier person than him. He constantly has a smile on his face, always! I believe our kids can do anything they put their mind to. Prader-Willi Syndrome will not hold my child back and it shouldn't hold yours back either! Together we can all get through this. One day at a time."

- Nicolette, mom to Hunter (2)

READ THE FULL STORY HERE

Virtual National Convention

Time is running out to register for this year's Virtual National Convention **Hope's on the Horizon**!

There's so much to learn and so many ways to connect (and reconnect) with our PWS community. Whether you have a loved one with PWS, are a professional provider, a Physician, or Scientist . . . this year's convention has something for everyone!

Over 700 individuals have already registered and remember - this year, **registration to our General Conference is FREE**!

PWSA | USA's **virtual** National Convention will be held **June 22-26, 2021.** Our dedicated staff and convention volunteers are hard at work putting together an exciting lineup of educational, informative, and fun sessions for the PWS community.

Download the Convention flyer here, and don't forget to share with your loved one's medical and care providers! Watch the Convention video here.

REGISTER HERE

Announcing This Year's Conference Agenda + Keynote Speakers

Virtual Medical & Scientific Convention

Wednesday, June 23, 2021 | 11:15 a.m. - 12:15 p.m.

Keynote Speaker: Deepan Singh, MD
Topic: Behavior Problems in Prader-Willi Syndrome – What to Expect

Virtual General Convention

Friday, June 25, 2021 | 11:15 a.m. - 12:15 p.m.

Keynote Speaker: Clint Hurdle, Former Major League Baseball Manager
Topic: Hello World – Ready or Not Here I Come!

Virtual Professional Providers Convention

Tuesday, June 22, 2021 | 11:15 a.m. - 12:15 p.m.

Keynote Speaker: Lisa Graziano, MA, LMFT
Topic: PWS Behavior Management Strategies & Solutions

LEARN MORE ABOUT OUR KEYNOTE SPEAKERS

Superhero BINGO Family Fun Night

Registration to receive a Superhero Kit has been extended to Sunday, June 6th!

REGISTER FOR SUPERHERO BINGO


SUPERHERO BINGO FAMILY FUN NIGHT

SATURDAY, JUNE 26TH | 6-8PM EST

To participate, you must be registered by June 20th

Presented by: Leaving Legacies Foundation

- BINGO
- Live Entertainment
- Superhero Guests
- Prizes + Trivia

ADVANCED REGISTRATION REQUIRED FOR VIRTUAL EVENT

- FREE to PWSA Families (Includes 1 Superhero Kit + 2 Bingo Cards) *Check your email for your free code*
- General Public: $25 (Includes 1 Superhero Kit + 2 Bingo Cards)
- Additional Kits ($15) and Bingo Cards ($5) can be purchased at Registration
- Prizes for best individual and family/group costumes!

The Superhero Bingo Family Fun Night, June 26th from 6-8pm EST, is ***ABSOLUTELY FREE*** for PWS Families and Residential Homes. If you register between now and **June 6th**, you will be entered to win a PWSA | USA Family Summer Fun Kit!


WIN A FAMILY SUMMER FUN KIT!

- PWSA | USA Logo Beach Tote
- 2 Towels
- 2 Waterbottles!
- Beachball

Don't forget about the incredible auction items up for bid!

The Superhero BINGO Auction features brand-name toys, accessories, jewelry, a golfing adventure in Florida (perfect for Father's Day!), and items for everyone in your family to enjoy - all donated with proceeds benefitting PWSA | USA!

SEE ALL AUCTION ITEMS

THE MOUNTAINS ARE CALLING... GETAWAY FOR

IPAD AIR / 4TH GENERATION

HELLO SUMMER FAMILY FUN

TWO PACKAGE

LEARN MORE

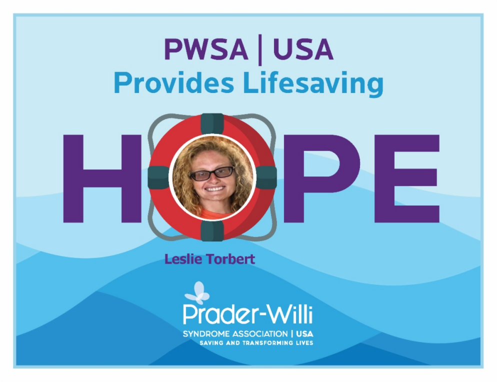
LEARN MORE

PACKAGE

LEARN MORE

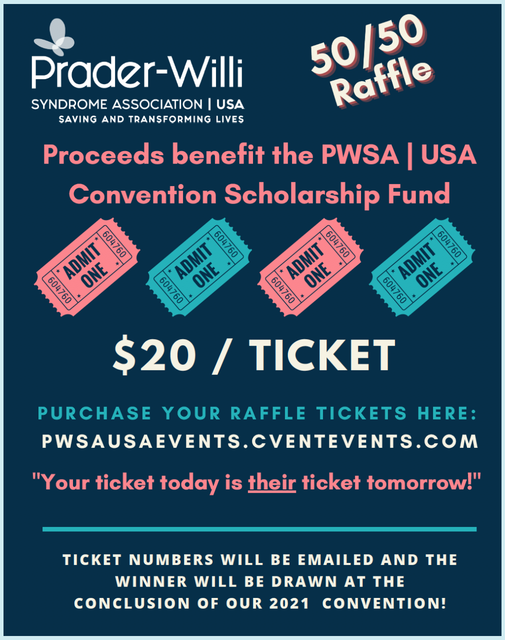
To register as a family, select 1 Superhero Deluxe Kit and enter discount code **"BAM"** at checkout**.** To register a group at a residential facility, contact Stacy Ward at **sward@pwsausa.org** for your special free registration code!

Explore All That Our Convention Has To Offer



Recognize your loved one or family member with a Lifesaving Hope display image to be showcased during the 2021 Virtual National Convention for just $30!

LEARN MORE HERE


Prader-Willi
SYNDROME ASSOCIATION | USA
SAVING AND TRANSFORMING LIVES

50/50 Raffle

Proceeds benefit the PWSA | USA Convention Scholarship Fund

$20 / TICKET

PURCHASE YOUR RAFFLE TICKETS HERE:
PWSAUSAEVENTS.CVENTEVENTS.COM

"Your ticket today is their ticket tomorrow!"

TICKET NUMBERS WILL BE EMAILED AND THE WINNER WILL BE DRAWN AT THE CONCLUSION OF OUR 2021 CONVENTION!

PURCHASE RAFFLE TICKETS

Thank You to Our Convention Sponsors!

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of Alachua County

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Prader-Willi California Foundation

Calling all New Englanders!

THE 12TH ANNUAL

HUNTER LENS GOLF TOURNAMENT

SATURDAY, OCTOBER 2ND 2021 - 1 PM

THE BACK NINE CLUB

17 HERITAGE HILL - LAKEVILLE, MA

TO REGISTER:

WWW.PWSAUSA.ORG/LENSGOLF/

$150 / Adult Golf & Dinner
$80 / Youth (16 + under) Golf & Dinner
$60 / Dinner Only
Can't Attend? Donations are Welcome!

Hunter is 23 years old and has Prader-Willi Syndrome. He leads a happy and active life despite his daily challenges. He has friends, a loving family and his weight is under control. Supporting PWSA | USA, a national non-profit, will open more doors for Hunter and others who live with PWS, which ultimately means a better life. Hunter deserves a better life. Please join us on this special day in honor of Hunter and all families living with PWS.

Prader-Willi Syndrome (PWS) is a rare, lifelong, non-inherited, genetic disorder. It is the most common known genetic cause of life threatening obesity. Currently, there is no cure but early diagnosis and intervention saves lives.

Proceeds Benefit:

Prader-Willi
SYNDROME ASSOCIATION | USA
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REGISTER HERE

ADVOCACY & AWARENESS

PHONE 2 ACTION

DCCR COMMUNITY EFFORTS

May 27, 2021 - June 2, 2021

94 NEW ADVOCATES

693 Total Legislator Connections

Thank you for using your voice to spark change! With your continued support and efforts, the possibility of DCCR becoming available to our loved ones is in reach!

Prader-Willi SYNDROME ASSOCIATION | USA SAVING AND TRANSFORMING LIVES

Join the Voices for Change and Contact Your Elected Officials on the Importance of DCCR

Our PWS community recently learned that the FDA is recommending an additional clinical trial for DCCR (Diazoxide choline controlled-release tablet), which is manufactured by Soleno Therapeutics.

DCCR is a therapy that our community desperately needs and we hope that it can quickly become available to anyone with PWS who would benefit from it. While the PWS community might not have the resources of groups with greater numbers, change is still possible!

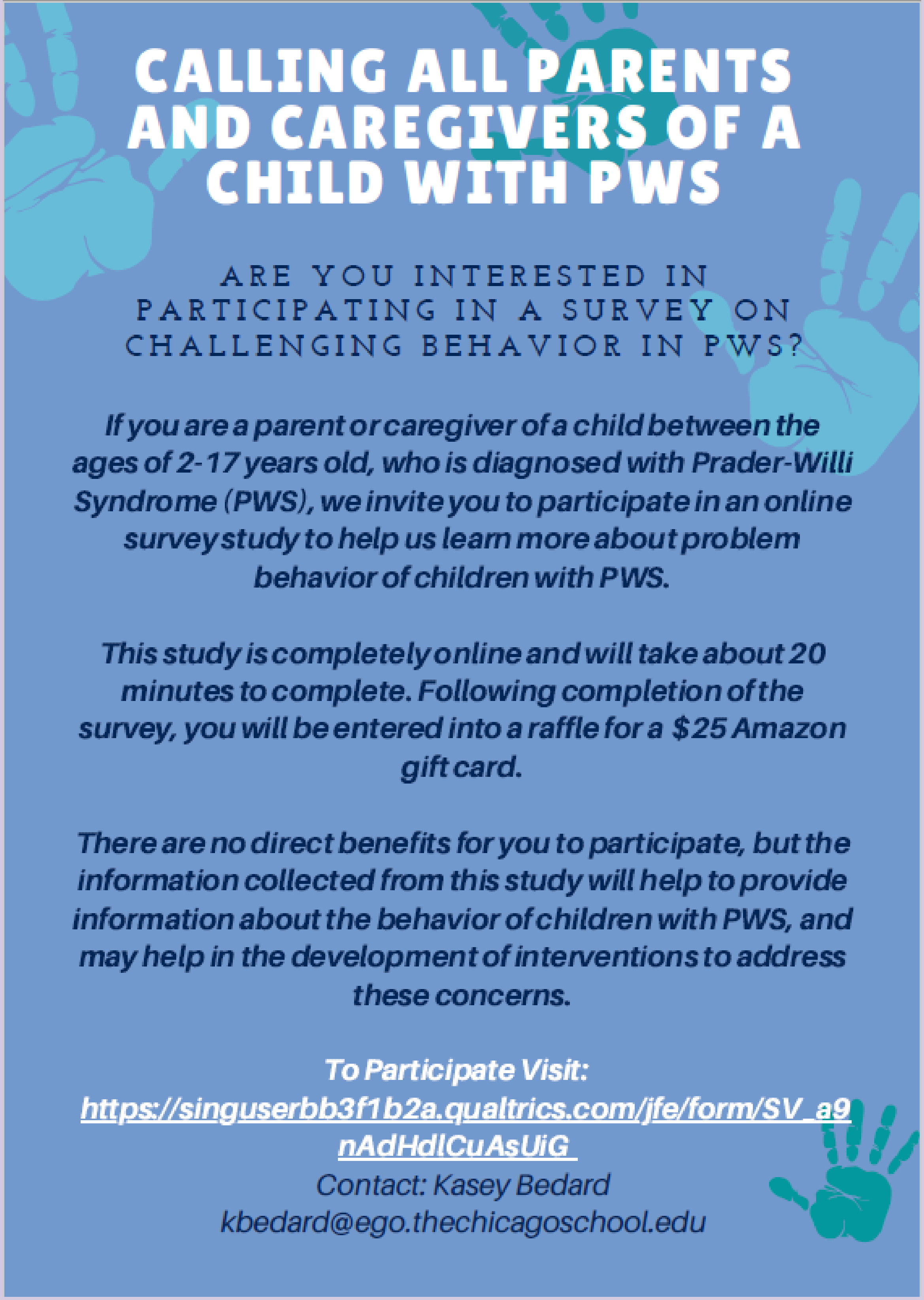
Please take the time to contact your elected officials TODAY and inform them of this issue facing our community.

RESEARCH

DCCR Shows ‘Life-changing’ Potential in Troubled Trial, Doctor Says in Interview

Dr. Jennifer Miller, a pediatric neuroendocrinologist at the University of Florida who is a lead investigator of the DESTINY PWS Phase 3 clinical trial of DCCR, shares updates on the trial's findings and some of the positive responses from participants.

READ THE FULL ARTICLE HERE



CALLING ALL PARENTS AND CAREGIVERS OF A CHILD WITH PWS

ARE YOU INTERESTED IN PARTICIPATING IN A SURVEY ON CHALLENGING BEHAVIOR IN PWS?

If you are a parent or caregiver of a child between the ages of 2-17 years old, who is diagnosed with Prader-Willi Syndrome (PWS), we invite you to participate in an online survey study to help us learn more about problem behavior of children with PWS.

This study is completely online and will take about 20 minutes to complete. Following completion of the survey, you will be entered into a raffle for a $25 Amazon gift card.

There are no direct benefits for you to participate, but the information collected from this study will help to provide information about the behavior of children with PWS, and may help in the development of interventions to address these concerns.

To Participate Visit:
https://singuserbb3f1b2a.qualtrics.com/jfe/form/SV_a9nAdHdlCuAsUiG
Contact: Kasey Bedard
kbedard@ego.thechicagoschool.edu

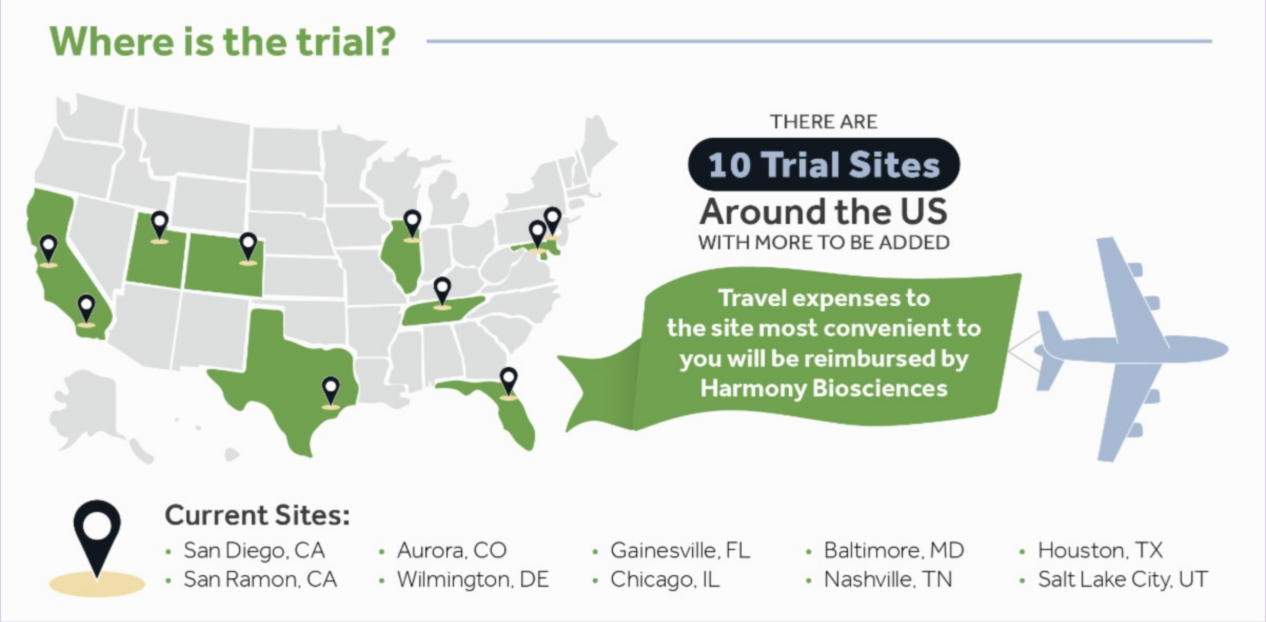
CLICK HERE TO PARTICIPATE IN THE SURVEY

Harmony Biosciences is seeking people with PWS between the ages of 6 – 65 to enroll in Clinical Trial

Harmony Biosciences will be studying the safety and impact of an investigational medication on excessive daytime sleepiness, cognition, and behavioral function in people with PWS.

Participation in the trial lasts approximately four months. During that time, there are five planned visits.

Read more here.



Where is the trial?

THERE ARE
10 Trial Sites
Around the US
WITH MORE TO BE ADDED

Travel expenses to the site most convenient to you will be reimbursed by Harmony Biosciences

Current Sites:

- San Diego, CA
- San Ramon, CA
- Aurora, CO
- Wilmington, DE
- Gainesville, FL
- Chicago, IL
- Baltimore, MD
- Nashville, TN
- Houston, TX
- Salt Lake City, UT

Important Message About This Newsletter

The information provided in this email is intended for your general knowledge only and is not intended to be a substitute for professional medical advice, diagnosis or treatment. Always seek the advice of your physician or other qualified healthcare provider with any questions regarding a medical condition. Never disregard professional medical advice or delay in seeking it because of something you have read in this publication.

Prader-Willi
SYNDROME ASSOCIATION | USA
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Your gift to PWSA | USA ensures individuals and families living with Prader-Willi syndrome have the connection, guidance, and hope they so desperately need. Thank you!

Visit Us Online!
www.pwsausa.org

Give Now

View as Webpage

Prader-Willi
SYNDROME ASSOCIATION | USA
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PWSA | USA
THE PULSE

Vol. 22 | June 11, 2021

"PWSA | USA has made a world of difference for all of us. From connecting us with a parent mentor to helping us navigate social services and providing connections with other families, PWSA has supported us on this journey from day one."

Emily, Mom to Olivia (9) of California
pwsausa.org/get-involved/donate/

"Without PWSA | USA as an anchor of support and resources, we would not have gotten very far on our PWS journey. Over the years, as a single homeschooling mother, things have not been particularly easy... Navigating the systems, finding the right doctors and learning about PWS became SO much easier once our family connected with PWSA! I am so grateful for the information and continued advocacy for our children."

Skye, Mom to Trevor (19) of Arizona
pwsausa.org/get-involved/donate/

To help sustain our lifesaving Family Support Program, please give generously below!

DONATE NOW

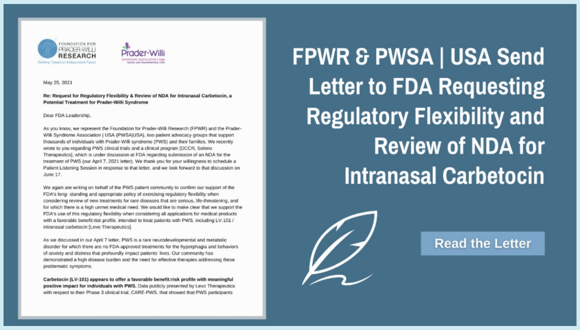
BREAKING NEWS

FPWR and PWSA | USA Announce Upcoming Meeting with FDA

We are excited to share that The

Foundation for Prader-Willi Research and Prader-Willi Syndrome Association USA will be meeting with the FDA next week to discuss the treatment needs of the PWS community. Thank you supporters!

READ THE FULL ARTICLE HERE



May 25, 2021

Re: Request for Regulatory Flexibility & Review of NDA for Intranasal Carbetocin, a Potential Treatment for Prader-Willi Syndrome

Dear FDA Leadership,

As you know, we represent the Foundation for Prader-Willi Research (FPWR) and the Prader-Willi Syndrome Association | USA (PWSA|USA), two patient advocacy groups that support thousands of individuals with Prader-Willi syndrome (PWS) and their families. We recently wrote to you regarding PWS clinical trials and a clinical program [DCCR, Soleno Therapeutics], which is under discussion at FDA regarding submission of an NDA for the treatment of PWS (our April 7, 2021 letter). We thank you for your willingness to schedule a Patient Listening Session in response to that letter, and we look forward to that discussion on June 17.

We again are writing on behalf of the PWS patient community to confirm our support of the FDA's long- standing and appropriate policy of exercising regulatory flexibility when considering review of new treatments for rare diseases that are serious, life-threatening, and for which there is a high unmet medical need. We would like to make clear that we support the FDA's use of this regulatory flexibility when considering all applications for medical products with a favorable benefit:risk profile, intended to treat patients with PWS, including LV-101 / intranasal carbetocin [Levo Therapeutics].

As we discussed in our April 7 letter, PWS is a rare neurodevelopmental and metabolic disorder for which there are no FDA-approved treatments for the hyperphagia and behaviors of anxiety and distress that profoundly impact patients' lives. Our community has demonstrated a high disease burden and the need for effective therapies addressing these problematic symptoms.

Carbetocin (LV-101) appears to offer a favorable benefit:risk profile with meaningful positive impact for individuals with PWS. Data publicly presented by Levo Therapeutics with respect to their Phase 3 clinical trial, CARE-PWS, that showed that PWS participants

READ THE FULL LETTER HERE

FPWR and PWSA | USA Request Regulatory Flexibility & Review of NDA for Intranasal Carbetocin

FPWR and PWSA | USA have submitted a petition letter to the FDA requesting regulatory flexibility & review of an NDA for intranasal carbetocina, a potential treatment for PWS. Levo Therapeutics recently completed a Phase 3 clinical trial evaluating the safety and efficacy of the drug in PWS.

FAMILY SUPPORT

Keep Your Loved Ones Safe in the Summer Heat with These Tips from Family Support

PWSA | USA's Family Support Team is always there for you – in fact, as the weather gets warmer, Director of Family Support Stacy Ward wants to make sure your PWS loved ones are safe in the summer heat.

- **Capitalize on the cooler temperatures** in the early morning and evening and plan your outdoor activities during those times.
- **Carry an umbrella** with you to block out the sun's direct rays.
- **Always wear sunscreen!**

READ MORE HERE

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Stories of Resilience & PWS will share personal stories from around the community with a focus not only on the challenges but on the joys, victories and opportunities of the journey.

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Thank you for using your voice to help us bring attention to PWS!

We're Less Than Two Weeks Away from the 2021 Virtual National Convention - Register TODAY!

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Download the Convention flyer **here**, and don't forget to share with your loved one's medical and care providers! Watch the Convention video **here**.

REGISTER HERE

DON'T MISS THIS OPPORTUNITY!

The **2021 PWSA | USA National Virtual Convention** will Highlight the Newest Research and Resources in PWS

Get to Know This Year's Special Education Advisory Board Panel

Barbara J. (BJ) Goff, Ed.D.

Barbara J. (BJ) Goff, Ed.D., is a Professor of Special Education at Westfield State University in Massachusetts. She has 40 years of experience working with individuals with Intellectual or Developmental Disabilities (IDD) in a variety of settings, with 30 years devoted to individuals with Prader-Willi syndrome. She provides training and consultant services to schools and adult service providers throughout the US and is a frequent presenter at state, national, and international conferences. She is the author of *Supporting Adults with Prader-Willi Syndrome in Residential Settings,* co-author of *The Student with Prader-Willi Syndrome: Information for Educators,* authored two chapters on educational issues and co-authored a chapter on sexuality in the third edition of *Management of Prader-Willi Syndrome.* She is a contributor to the international *Best Practice Guidelines for Standard of Care in PWS.*

Amy McTighe, PhD

Dr. McTighe has over 20 years of experience supporting persons with diverse learning needs in various settings. This experience has included supporting children and their families in public and private school settings, hospital rehabilitation programs, and inpatient and outpatient behavioral health programs. Additionally, she has provided support to adults in community day programs, group homes, and supported living environments. Dr. McTighe is a graduate of William and Mary Law School's Institute for Special Education Advocacy and is a certified Mental Health First-Aid trainer. She has presented at the state, national and international level about Prader-Willi syndrome. She has published many articles on Prader-Willi syndrome and recently authored a children's book titled *Penny: A Tale of Lost Currency.*

Staci Zimmerman, M.Ed

Staci Zimmerman has over 20 years of experience in special education, teaching and consulting in various school districts in Colorado. She supports private clients, and contracts with The Prader-Willi Syndrome Association of Colorado (PWSACO), Prader-Willi Syndrome USA (PWSA | USA), and Rocky Mountain Down Syndrome Association (RMDSA), as an IEP Consultant.

Staci collaborates with the PWS Multi-Disciplinary Clinic at the Children's Hospital CO, supporting patients, families, providers, and school districts in Colorado. Additionally, Staci collaborates with educators from Jewish Day Schools, integrating students with learning needs in a dual-curriculum education.

Staci is an Adjunct Professor in the Office of Clinical Experiences and Partnerships, School of Education, at Metropolitan State University of Denver. She teaches undergraduate Special Education, and supervises student teachers in various school districts in CO. Staci attended The University of Kansas and graduated with a B.A in sociology and a Master's in Special Education. She continued post graduate work at The University of Kansas Medical Center in Autism Spectrum Disorder.

Staci has lived in Denver, CO for the past 21 years. She lives with her husband and ten-year-old daughter. Staci enjoys teaching fitness classes, and keeping a healthy, active lifestyle in Colorado.

Brittni Kliment, M.Ed

Brittni Kliment started at Latham Centers in 2012 as a classroom teacher. She quickly became the Assistant Principal, and then Director of Education, serving as an administrator while working with the students for seven years. Brittni has worked with hundreds of students with Prader-Willi Syndrome during her tenure at Latham Centers and has created innovative plans for staff to best meet the needs of our students, as well as strategies for the students who are learning how to cope with the challenges of a PWS diagnosis. She now leads the Admissions team, bringing her educational background to the parents with whom Latham Centers works. Brittni serves on the Special Education Advisory Board of PWSA | USA where she works with a team that advises on special ed. issues, develops and reviews special ed. resources, and offers guidance on support services. In 2020, during COVID-19, Brittni, along with Patrice Carroll and Katrina Fryklund, created and currently facilitates a PWS Virtual Community to strengthen relationships for individuals with PWS around the world.

Mary K. Ziccardi, B.S.

Mary K. Ziccardi has worked providing services and supports to people with developmental disabilities for over three decades. She is currently employed as the Regional Director at REM Ohio, a partner of The MENTOR Network, overseeing programming in sixteen counties in northern Ohio. Ms. Ziccardi is the Co-chair of PWSA (USA)'s Professional Providers Advisory Board (PPAB) as well as Co-chair of the 2019 Provider's Day. Along with the PWSA (USA) provider, special education advocacy and family resource activities, Mary K. has remained active with the international provider community, co-chairing IPWSO's Professional Provider Caregiver Board.

Find the full list of speakers and topics for each convention by clicking on the images below.

PWSA | USA 2021

Virtual Professional Providers Convention Schedule

DOWNLOAD AGENDA HERE

PWSA | USA 2021

Virtual Medical & Scientific Convention Schedule

DOWNLOAD AGENDA HERE

PWSA | USA 2021

Virtual General Convention Schedule

DOWNLOAD AGENDA HERE

Join us Saturday, June 26th from 6-8 p.m. for a night a family of fun for *ALL AGES!*

REGISTER FOR SUPERHERO BINGO

SUPERHERO BINGO FAMILY FUN NIGHT

SATURDAY, JUNE 26TH | 6-8PM EST

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Presented by: Leaving Legacies Foundation

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Superhero BINGO Family Fun Night will be the epic closing event to our Virtual National Convention, complete with special guest appearances, trivia and prizes, a live auction, and, of course, BINGO! Register here by June 20, 2021. Bonus - this super event is **FREE** for PWS families when you enter the discount code **"BAM"** at checkout.

Don't forget about the incredible auction items up for bid!

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SEE ALL AUCTION ITEMS

SUPER DAD PACKAGE

LEARN MORE

BOCA RATON GOLF GETAWAY PACKAGE

LEARN MORE

ROOM MAKEOVER PACKAGE

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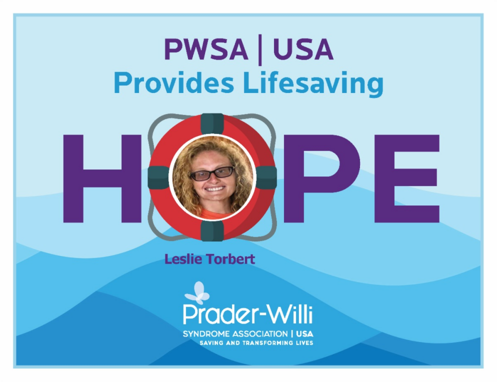

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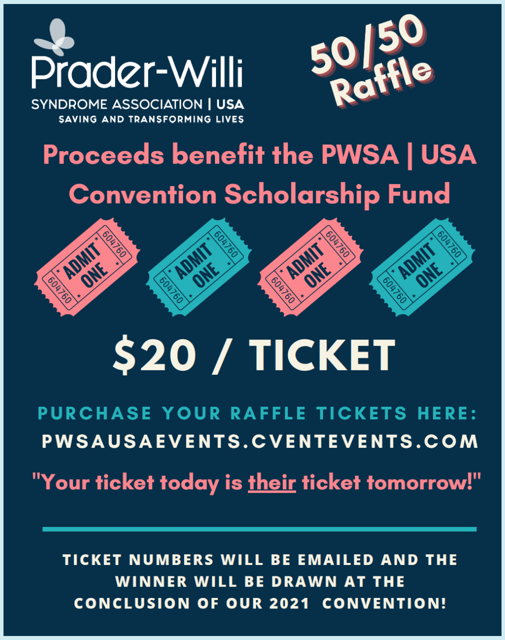
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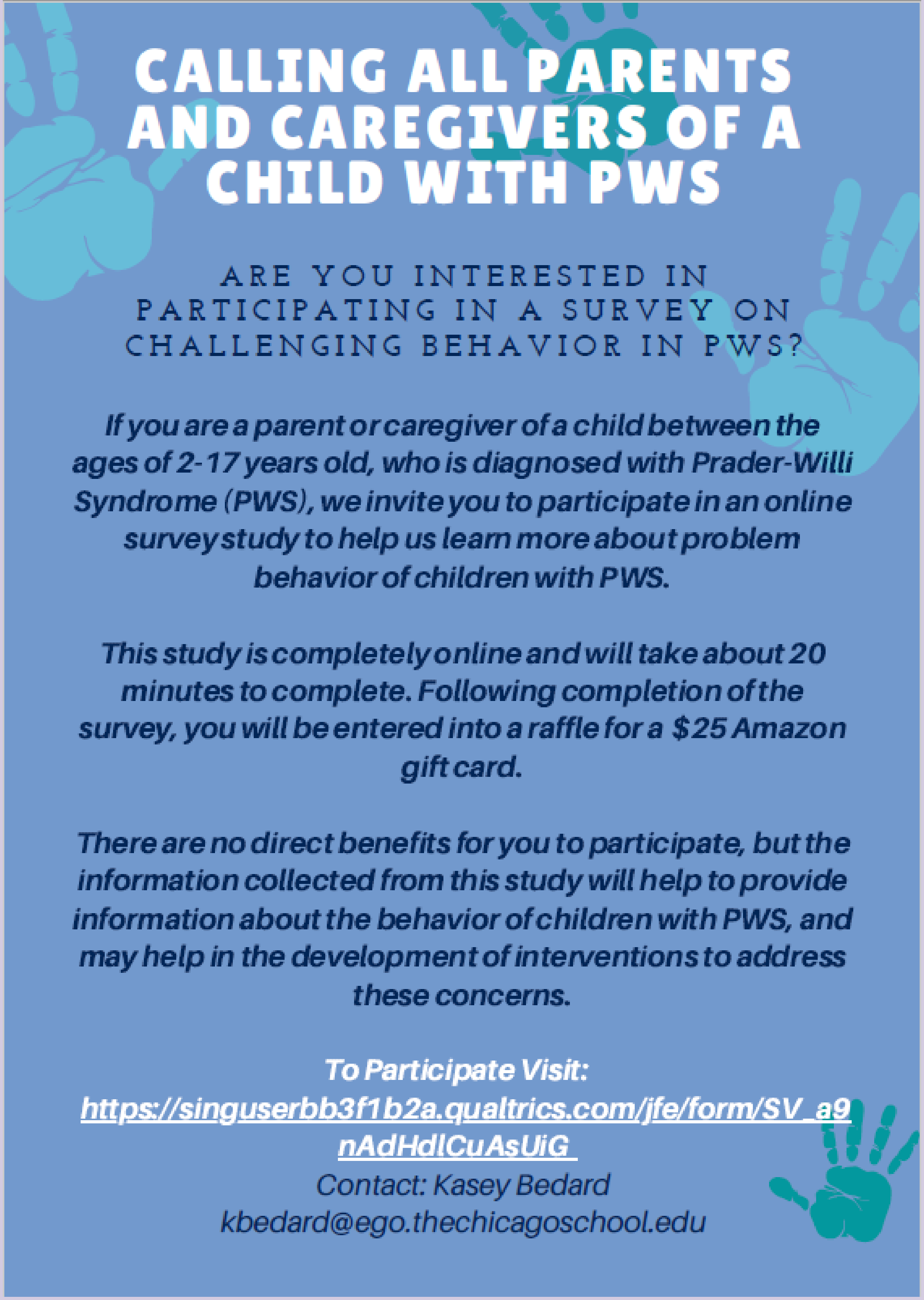
RESEARCH

DCCR Shows ‘Life-changing’ Potential in Troubled Trial,

Doctor Says in Interview

Dr. Jennifer Miller, a pediatric neuroendocrinologist at the University of Florida who is a lead investigator of the DESTINY PWS Phase 3 clinical trial of DCCR, shares updates on the trial's findings and some of the positive responses from participants.

READ THE FULL ARTICLE HERE



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To Participate Visit:
https://singuserbb3f1b2a.qualtrics.com/jfe/form/SV_a9nAdHdlCuAsUiG
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kbedard@ego.thechicagoschool.edu

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- Nashville, TN
- Houston, TX
- Salt Lake City, UT

Important Message About This Newsletter

Prader-Willi
SYNDROME ASSOCIATION | USA
SAVING AND TRANSFORMING LIVES

Your gift to PWSA | USA ensures individuals and families living with Prader-Willi syndrome have the connection, guidance, and hope they so desperately need. Thank you!

Visit Us Online!
www.pwsausa.org

Give Now

View as Webpage

Prader-Willi
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PWSA | USA
THE PULSE

Vol. 23 | June 18, 2021

"Following Samantha's PWS diagnosis, I was filled with fear and questions. The support and guidance I received from the parent-mentors at PWSA | USA helped me shift out of fear and into hope. Now, at 8 months old, Samantha is making incredible progress and defying expectations. I'm glad she can benefit from all that has been - and continues to be - learned about this rare disease, and I'm grateful to have PWSA | USA keeping me apprised of those developments."

Mandy, Mom to Samantha (8 months) of California

pwsausa.org/get-involved-donate/

"Family support from PWSA | USA is such a critical part of our lives and for many others who have a loved one with Prader-Willi Syndrome. We are blessed to be able to help others while at the same time rely on our own family and friends to support us in our times of need. Helping loved ones that are impacted with Prader-Willi is absolutely a team sport."

John, Dad to Hunter (23) of Massachusetts

pwsausa.org/get-involved/donate/

To help sustain our lifesaving Family Support Program, please give generously below!

DONATE NOW

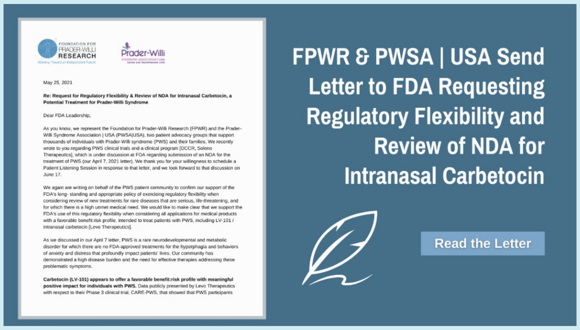
BREAKING NEWS

We are Pleased to Announce that Dr. Moris Angulo M.D. has Opened up a New Clinic Located in Babylon, NY, and Accepts Patients

Location: Center for Pediatric Specialty Care, 655 Deer Park Avenue, Babylon, NY 11702

To schedule an appointment, call 631-321-2100

Moris A. Angulo, M.D., was born in El Salvador, Central América and attended the School of Medicine, National University, El Salvador. He attended Nassau County Medical Center, Long Island, New York, for his post-graduate work. Dr. Angulo is American Board certified in Pediatrics, Medical Genetics & Pediatric Endocrinology. He is a member of the Clinical and Scientific Board at IPWSO and the Clinical Advisory Board for PWSA | USA. Dr. Angulo has been recognized by the Global Directory of Who's Who as a Top Doctor for outstanding contributions and achievements in Endocrinology. Dr. Angulo is a tireless advocate for PWS and has been instrumental in getting Growth Hormone approved for general use in PWS.



May 25, 2021

Re: Request for Regulatory Flexibility & Review of NDA for Intranasal Carbetocin, a Potential Treatment for Prader-Willi Syndrome

Dear FDA Leadership,

As you know, we represent the Foundation for Prader-Willi Research (FPWR) and the Prader-Willi Syndrome Association | USA (PWSA|USA), two patient advocacy groups that support thousands of individuals with Prader-Willi syndrome (PWS) and their families. We recently wrote to you regarding PWS clinical trials and a clinical program [DCCR, Soleno Therapeutics], which is under discussion at FDA regarding submission of an NDA for the treatment of PWS (our April 7, 2021 letter). We thank you for your willingness to schedule a Patient Listening Session in response to that letter, and we look forward to that discussion on June 17.

We again are writing on behalf of the PWS patient community to confirm our support of the FDA's long- standing and appropriate policy of exercising regulatory flexibility when considering review of new treatments for rare diseases that are serious, life-threatening, and for which there is a high unmet medical need. We would like to make clear that we support the FDA's use of this regulatory flexibility when considering all applications for medical products with a favorable benefit:risk profile, intended to treat patients with PWS, including LV-101 / intranasal carbetocin [Levo Therapeutics].

As we discussed in our April 7 letter, PWS is a rare neurodevelopmental and metabolic disorder for which there are no FDA-approved treatments for the hyperphagia and behaviors of anxiety and distress that profoundly impact patients' lives. Our community has demonstrated a high disease burden and the need for effective therapies addressing these problematic symptoms.

Carbetocin (LV-101) appears to offer a favorable benefit:risk profile with meaningful positive impact for individuals with PWS. Data publicly presented by Levo Therapeutics with respect to their Phase 3 clinical trial, CARE-PWS, that showed that PWS participants

READ THE FULL LETTER HERE

FPWR and PWSA | USA Request Regulatory Flexibility & Review of NDA for Intranasal Carbetocin

FPWR and PWSA | USA have submitted a petition letter to the FDA requesting regulatory flexibility & review of an NDA for intranasal carbetocina, a potential treatment for PWS. Levo Therapeutics recently completed a Phase 3 clinical trial evaluating the safety and efficacy of the drug in PWS.

FAMILY SUPPORT

We want to wish all of the amazing Dads out there a very Happy Father's Day! Thank you for all that you do.

PWSA | USA is excited to announce an opportunity to participate in a new series that elevates the variety of voices and

experiences in our community. ***Stories of Resilience & PWS*** will share personal stories from around the community with a focus not only on the challenges but on the joys, victories and opportunities of the journey.

We're currently looking for Dads to help us kick off this campaign! If you are interested in participating in a brief audio interview to share your story of resilience, please email info@pwsausa.org to arrange an interview time that works for you.

Thank you for using your voice to help us bring attention to PWS!

Last Chance to Register for the 2021 Virtual National Convention!

Registration for the 2021 Virtual National Convention CLOSES on Sunday, June 20th at 11:59 p.m. EST.

Don't miss this opportunity to connect (and reconnect) with our PWS Community! Whether you have a loved one with PWS, are a professional provider, a Physician, or Scientist, this year’s convention has something for everyone!

REGISTER HERE

Over 1,100 individuals have already registered and remember - this year, **registration to our General Conference is FREE**!

PWSA | USA's **virtual** National Convention will be held **June 22-26, 2021.** Our dedicated staff and convention volunteers are hard at work putting together an exciting lineup of educational, informative, and fun sessions for the PWS community.

Download the Convention flyer **here**, and don't forget to share with your loved one's medical and care providers! Watch the Convention video **here**.

Find the full list of speakers and topics for each convention by clicking on the images below.

PWSA | USA 2021

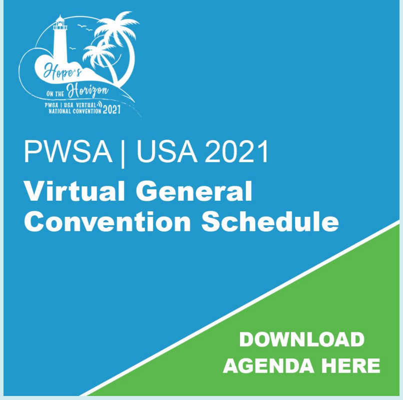
Virtual Professional Providers Convention Schedule

DOWNLOAD AGENDA HERE

PWSA | USA 2021

Virtual Medical & Scientific Convention Schedule

DOWNLOAD AGENDA HERE



PWSA | USA 2021

Virtual General Convention Schedule

DOWNLOAD AGENDA HERE

DON'T MISS THIS OPPORTUNITY!
Registration for Superhero BINGO Closes Sunday, June 20th at 11:59 p.m. EST

REGISTER FOR SUPERHERO BINGO

Superhero BINGO Family Fun Night will be the epic closing event to our Virtual National Convention, complete with special guest appearances, trivia and prizes, a live auction, and, of course, BINGO! Register here by June 20, 2021. Bonus - this super event is **FREE** for PWS families when you enter the discount code **"BAM"** at checkout.

Don't forget about the incredible auction items up for bid!

The Superhero BINGO Auction features brand-name toys, accessories, jewelry, a golfing adventure in Florida (perfect for Father's Day!), and items for everyone in your family to enjoy - all donated with proceeds benefitting PWSA | USA!

SEE ALL AUCTION ITEMS

SUPER DAD PACKAGE

LEARN MORE

BOCA RATON GOLF GETAWAY PACKAGE

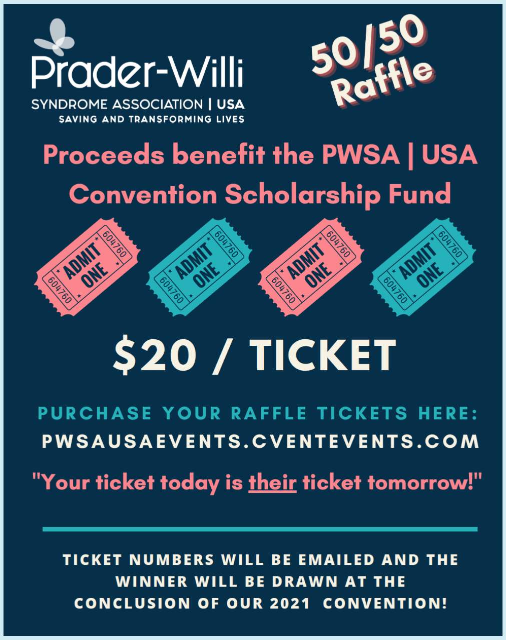
LEARN MORE

ROOM MAKEOVER PACKAGE

LEARN MORE

To register a group at a residential facility, contact Stacy Ward at **sward@pwsausa.org** for your special free registration code!

Explore All That Our Convention Has To Offer



Prader-Willi
SYNDROME ASSOCIATION | USA
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50/50 Raffle

Proceeds benefit the PWSA | USA Convention Scholarship Fund

$20 / TICKET

PURCHASE YOUR RAFFLE TICKETS HERE:
PWSAUSAEVENTS.CVENTEVENTS.COM

"Your ticket today is their ticket tomorrow!"

TICKET NUMBERS WILL BE EMAILED AND THE WINNER WILL BE DRAWN AT THE CONCLUSION OF OUR 2021 CONVENTION!

Help send families to our 2023 Convention by helping us raise funds for Scholarships! ***Raffle tickets are available for purchase until Friday, June***

25th at 12:00 p.m. EST.

*Learn more **here**.*

PURCHASE RAFFLE TICKETS

Thank You to Our Convention Sponsors!

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PWSA Arizona
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Prader-Willi California Foundation

Support PWSA | USA on Amazon Prime Day!

Amazon Prime Day is coming up on June 21st and 22nd, which means amazing deals for Amazon Prime members. Whether you're already a Prime member or planning to sign up, please consider logging in through Amazon Smile to make your purchases. The Amazon Smile Foundation will donate 0.5% of the purchase price from your eligible smile.amazon.com purchases. **Please consider selecting Prader-Willi Syndrome Association | USA in the "Supporting" tab on your Amazon Smile home page.** Thank you for making a difference!

LOG IN TO AMAZON SMILE

Calling all New Englanders!

THE 12TH ANNUAL

HUNTER LENS GOLF TOURNAMENT

SATURDAY, OCTOBER 2ND 2021 - 1 PM

THE BACK NINE CLUB

17 HERITAGE HILL - LAKEVILLE, MA

TO REGISTER:

WWW.PWSAUSA.ORG/LENSGOLF/

$150 / Adult Golf & Dinner
$80 / Youth (16 + under) Golf & Dinner
$60 / Dinner Only
Can't Attend? Donations are Welcome!

Hunter is 23 years old and has Prader-Willi Syndrome. He leads a happy and active life despite his daily challenges. He has friends, a loving family and his weight is under control. Supporting PWSA | USA, a national non-profit, will open more doors for Hunter and others who live with PWS, which ultimately means a better life. Hunter deserves a better life. Please join us on this special day in honor of Hunter and all families living with PWS.

Prader-Willi Syndrome (PWS) is a rare, lifelong, non-inherited, genetic disorder. It is the most common known genetic cause of life threatening obesity. Currently, there is no cure but early diagnosis and intervention saves lives.

Proceeds Benefit:
Prader-Willi
SYNDROME ASSOCIATION | USA
SAVING AND TRANSFORMING LIVES

REGISTER HERE

ADVOCACY & AWARENESS

PHONE 2 ACTION

DCCR COMMUNITY EFFORTS

May 27, 2021 - June 18, 2021

112 NEW ADVOCATES

821 Total Legislator Connections

Thank you for using your voice to spark change! With your continued support and efforts, the possibility of DCCR becoming available to our loved ones is in reach!

Prader-Willi SYNDROME ASSOCIATION | USA SAVING AND TRANSFORMING LIVES

Join the Voices for Change and Contact Your Elected Officials on the Importance of DCCR

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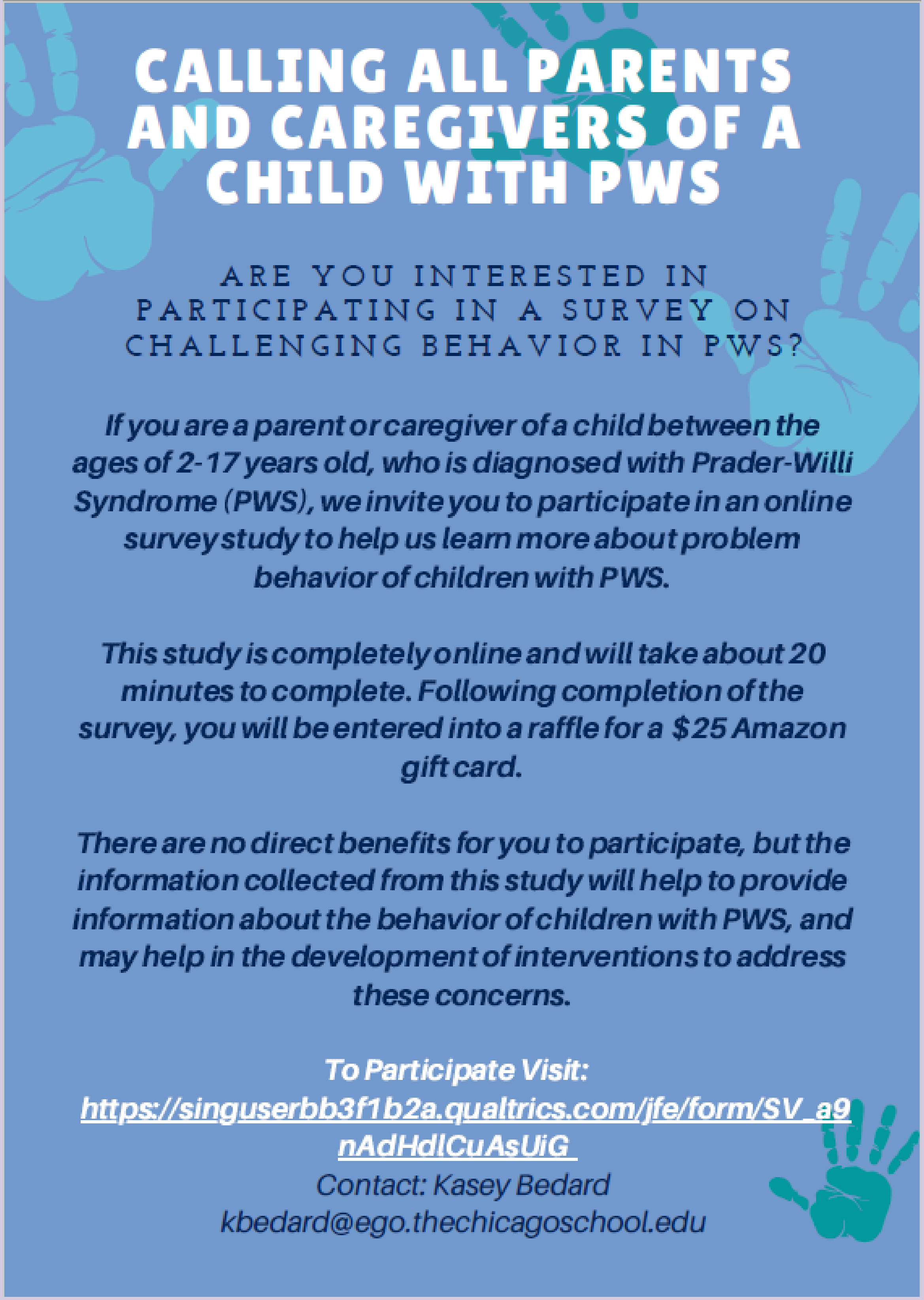

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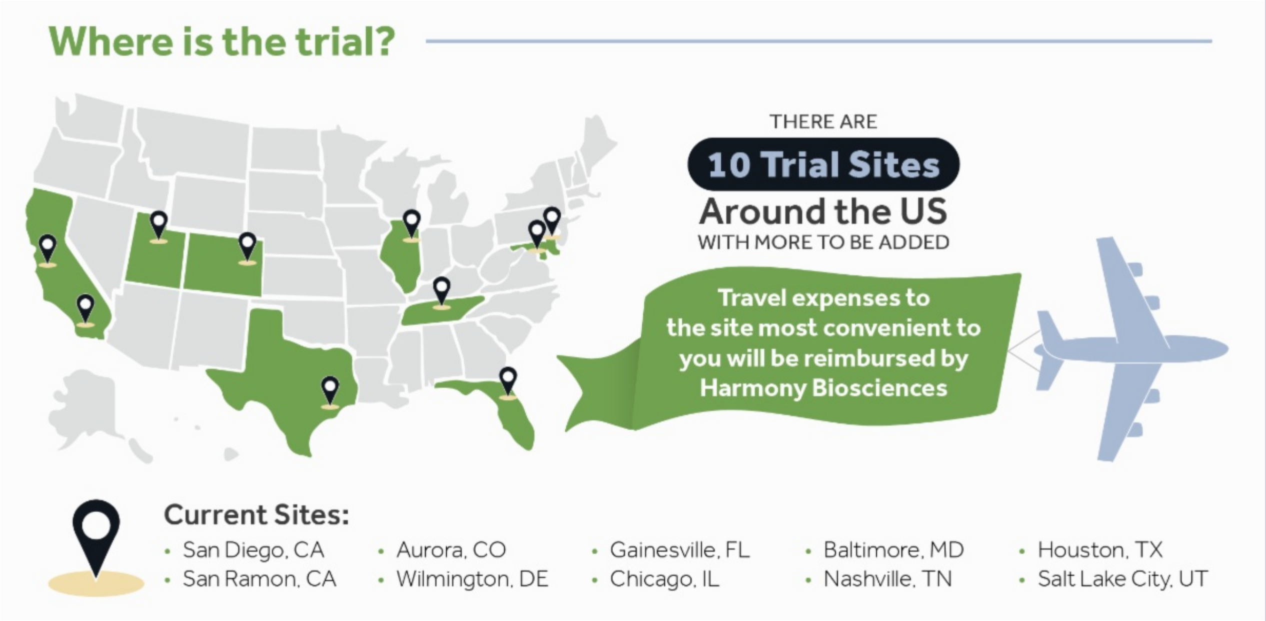

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Important Message About This Newsletter

The information provided in this email is intended for your general knowledge only and is not intended to be a substitute for professional medical advice, diagnosis or treatment. Always seek the advice of your physician or other qualified healthcare provider with any questions regarding a medical condition. Never disregard professional medical advice or delay in seeking it because of something you have read in this publication.

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