

My prog-MS ezine

For people with progressive MS and other interested people

Issue number 44, July-September 2022

Hello and welcome to the latest edition of my ezine about progressive Multiple Sclerosis and MS progression in general. My name is Ian Cook. I'm a secondary progressive MSer from Birmingham, UK. I'm 63.

In this issue are eight pages of prog-MS news stories. There are also two features. One on page 5 is about new research into an antiseptic drug Hiprex which has helped me prevent utis for the past five years.

There's also a feature on the present research on grit also known as resilience or courage and a research paper which looks as whether these admirable qualities can help us in our battle with progressive MS. See page 10 for details.

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Second SPMSer sees big benefit with Foralumab nose spray

Treatment with foralumab nasal spray has resulted in “marked clinical improvements” after three months in the second secondary progressive multiple sclerosis (SPMS) patient treated in the US, raising hopes for the drug’s use in this type of prog-MS.

The positive findings were consistent with those seen in the first SPMS patient and have led to a decision by the U.S. Food and Drug Administration (FDA) to allow up to eight more patients to receive the experimental treatment.

“We are excited about the positive clinical responses seen in 2 out of 2 SPMS patients treated so far. Clinical data from both patients further validate our novel intranasal therapy with foralumab, which seems to overcome the blood-brain barrier to allow therapeutic action of the drug,” Kunwar Shailubhai, CEO and chief scientific officer of Tiziana Life Sciences, said in a press release. Foralumab is designed to reduce inflammation by targeting the CD3, a protein receptor on T-cells. In animal models, this binding suppressed the activity of inflammatory T-cells, which are known to contribute to MS damage. It also boosted the function of regulatory T-cells, which can dampen the inflammatory activity of other immune cells.

The first SPMS patient who received the treatment was having continuous disease progression despite taking several MS disease-modifying therapies. After six months of treatment, improvements were seen in validated measures of walking ability, cognition, and dexterity. Microglial cells — the resident immune cells of the brain that have been shown to contribute to nerve damage and disability in SPMS — were also less active on positron emission tomography (PET) scans across all parts of the brain. Depending on the brain region, reductions ranged from 20%–25% at three months and 36%–50% at six months.

The second patient was diagnosed with SPMS in 2014, and had progressively worsening disability for the next eight years. PET scans also showed a 10%–30% reduction in microglia activation after three months of treatment, comparable with the changes seen in the first patient. A neurological examination of the patient also showed improvements after three months, along with gains in the 25-foot walk test time. Both patients are continuing their treatment regimen with the experimental therapy; they have been receiving treatment for 13 and four months. The treatment has been well-tolerated by both. Tiziana, the bio-pharma behind the research anticipates enrolling the third patient in July, and data from all 10 patients are expected in 2023, it announced as we went to press.

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News

Hunt for EBV Vaccine Gets a Boost From prestigious US body - NIH

The US National Institutes of Health (NIH) is joining the search for a vaccine to attack the Epstein-Barr virus (EBV). This is a big step for people with MS because research published earlier this year by Harvard scientists concludes that a previous EBV infection may increase a person's MS risk by 32 times.

The NIH study carries with it the considerable weight of this major research institution. The study plans to enrol 40 healthy adults ages 18 to 29, half of whom have evidence of prior EBV infection. Over a six-month period, they'll receive three injections of an experimental vaccine called EBV gp350-Ferritin, developed by the National Institute of Allergy and Infectious Diseases' (NIAID) Laboratory of Infectious Diseases, which is part of the NIH. It targets a glycoprotein found on the surface of the virus and virus-infected cells. This investigational vaccine showed encouraging results in an EBV mouse model about four years ago.

"A vaccine that could prevent or reduce the severity of infection with the Epstein-Barr virus could reduce the incidence of infectious mononucleosis and might also reduce the incidence of EBV-associated malignancies and autoimmune diseases," NIAID Director Anthony S. Fauci, MD, said in a press release .EBV can cause mononucleosis and other illnesses, so it's good news that the NIH is joining multiple efforts already underway to develop EBV vaccines and therapies. An investigational therapy called ATA188 is among those being researched, and a small study has indicated that this treatment may have an impact on MS. Researchers hope to enroll up to 80 non-active primary and secondary progressive MS patients with evidence of past or current EBV infection in their study's second phase.

Moderna, which produces one of the mRNA-based COVID-19 vaccines, is further along in its quest. The company is sponsoring a clinical trial for a possible EBV vaccine that uses the same mRNA technology as the COVID-19 vaccine. Researchers hope to enrol about 270 participants across 15 sites in the U.S. Other researchers are investigating whether an experimental COVID-19 T-cell therapy called TVGN-489 can be used against EBV for the treatment of MS. **For details of all news stories go to page 13**

Fibroblast Cell Therapy Shows Early Promise in MS Patients

A single infusion of FibroBiologics' investigational cell therapy, CYMS101, was able to inhibit disease activity and restore nerve cell loss in a mouse model of MS and appears safe in early MS clinical trials, the company has said.

Data from the mouse and human studies were presented at the 2022 Consortium of Multiple Sclerosis Centers Annual Meeting, held from June 1–4, in National Harbour, Maryland.

Cell-based approaches to restore nerve cell loss are of great interest for treating MS and other neurodegenerative diseases. Two types of cells in the human body have such regenerative capacity, stem cells and fibroblasts.

Stem cells, or more specifically mesencyhmal stem cells (MSCs), have received much attention in recent years as a treatment approach for MS. But despite promising results, they are scarce in the body, making them difficult and expensive to obtain, maintain, and grow for therapeutic use. Fibroblasts, the main cell type in connective tissue, are involved in wound healing and tissue regeneration. They are able to reduce inflammation. In contrast to MSCs, they are abundant, easier to harvest from the body, and cheaper to maintain.

CYMS101 is a cell-based therapy made of fibroblasts collected from the skin of a healthy donor that do not cause unwanted activation of the recipient's immune system. These cells are delivered regularly via into-the-vein infusions.

In the recent presentation, FibroBiologics showed that CYMS101 treatment led to a number of beneficial cellular responses that inhibited disease in mice with experimental autoimmune encephalomyelitis (EAE), a commonly used MS model. The fibroblast therapy specifically caused an expansion in regulatory T-cells — immunosuppressive cells that dampen responses from other cells of the immune system while inhibiting other damaging types of immune cells. The number of myelin-producing oligodendrocytes, and the production of myelin, were also increased in the animals.

An early Phase 1 trial (NCT05080270) also evaluated the safety of a single CYMS101 infusion, containing about 100 million fibroblasts, in five people with MS — four with relapsing-remitting MS and one with secondary progressive MS. Blood and cardiovascular tests revealed no significant safety concerns, and no side effects were reported up to 16 weeks (about four months) after the infusion. Pending approval from the U.S. Food and Drug Administration (FDA), the company is planning to launch a Phase 1/2 clinical trial testing multiple infusions of CYMS101 in a larger population. Patients will be followed for 18 months.

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Hiprex are as good as antibiotics in treating recurring utis

Anyone who is prone to recurrent Urinary Tract Infections (UTIs) knows well the misery they cause as well as the difficulty of getting rid of them for good.

As a long-term self-catheteriser and recurrent UTI sufferer I was therefore hugely relieved some years ago when I read about a drug called methenamine Hippurate (Hiprex) that might be a long term UTI solution. Hiprex isn't an antibiotic and technically speaking you don't need to get a prescription for it. You can buy it online.

If, like me, you prefer to seek a doctor's advice before taking a new drug and want to go down the more orthodox medical route rather than buying drugs online then there are one or two urologists prepared to see long term sufferers and prescribe Hiprex. So, a few years ago I decided to search out one of these urologists. I booked a private appointment to see a urologist called Professsor James Malone-Lee who was happy to see me, listen to me and put me on a repeat prescription for Hiprex. The UTI problem more or less cleared up immediately and permanently.

As mentioned earlier Hiprex is not an antibiotic. It is actually an antiseptic. This means it works by attacking the environment that bacteria live in (the bladder and its stale urine) rather than directly on the bacteria that thrive in this toxic place.

When I told the NHS doctor at the the urology department of my local hospital about my experiences with Hiprex I expected to be greeted with an enthusiastic reception. Sadly, this was not the case. I was told rather bluntly that Hiprex was a rather old-fashioned drug (It dates back to the 1960s) and there were more modern and effective drugs available. In other words I needed modern antibiotics.

Imagine my surprise, therefore, when I read about an academic paper titled: "Antiseptic Drug Hiprex May Be as Effective as Antibiotics at Preventing Recurring UTIs" published in the British Medical Journal (BMJ) in March this year.

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Continued from page 5 In the abstract the paper's authors say Hiprex is nearly as effective as antibiotics in treating urinary tract infections (UTIs) in women. They add that Hiprex, being an antiseptic, also doesn't contribute to the problem of antibiotic resistance.

The study, called "ALTAR (Alternative to Prophylactic Antibiotics for the treatment of Recurrent Urinary Tract Infections) was published in the British Medical Journal, and looked at 240 women over the age of 18 with recurrent UTIs. The participants randomly received either Hiprex or a low dose antibiotic. The trial lasted 18 months and the women had a follow-up visit every 3 months. Between 50 and 60 percent of adult women experience at least one UTI in their life. Around 25 percent have recurrent infections.

In their study, the ALTAR researchers concluded that Hiprex could be a viable alternative to daily antibiotics for women with recurrent UTIs. Women taking antibiotics had .89 incidents and those taking Hiprex had 1.38 incidents. Although there were slightly more UTI episodes in women using Hiprex, the researchers determined Hiprex to be "non-inferior to antibiotic prophylaxis (prevention)."

"This trial provides the highest quality evidence to date detailing the clinical benefit of a non-antibiotic preventive treatment," said Dr. Christopher Harding, the lead author of the study, a urological surgeon and the chairman of the European Association of Urology Guidelines. "Our results could support a change in practice in terms of preventive treatments for recurrent UTI and provide patients and clinicians with a credible alternative to daily antibiotics," Harding added. "The information provided by this trial will allow clinicians and patients to undertake a shared decision-making process relating to UTI preventive treatments. The study showed a small numerical difference in UTI incidence between the daily antibiotics and methenamine hippurate (Hiprex) groups but the potential trade-off includes the avoidance of antibiotic consumption, which is closely associated with antimicrobial resistance development,"

Jane Stapleford, a member of Bladder Health UK and a patient representative on the Hiprex study as well as a long-time sufferer from UTIs, said that one advantage of taking Methenamine Hippurate was that the information gained from the study will help patients with repeated UTIs like her (and me) to decide on the different options for treatment especially, if they wish to avoid taking prolonged courses of preventative antibiotics.

I certainly wanted to do this, and for this reason have been taking Hiprex for a long time and will continue to do so. As Jane Stapleford says patients with repeated UTIs need options and Hiprex is a pretty good option so I will continue opting for it rather than for antibiotics as there is clearly no problem with Hiprex resistance developing, unlike antibiotics.

More information on page 14

Ekso's Wearable Exoskeleton Cleared in US for MS Walking Rehab

The U.S. Food and Drug Administration has given Ekso Bionics clearance to market its wearable robotic exoskeleton to improve gait and mobility in people with walking problems associated with MS.

Dubbed EksoNR, the device had been approved by the regulatory agency for stroke and spinal cord injury patients in 2016 and those with acquired brain injury in 2020. Now, it is first of its kind to be cleared for rehabilitative use in MS, Ekso reported.

Gait and balance problems are among the most common symptoms of MS, which can significantly affect a person's ability to walk independently. The use of robotic devices during gait training are thought to be one way of maximizing rehabilitation gains in these patients.

EksoNR, a next-generation version of the Ekso GT device, is worn over a patient's clothing and fitted to their body during physical rehabilitation. It has specialized sensors and motors that manipulate a person's legs and waist to assist them while they practise standing, walking, and sitting. EksoNR's goal is to enable individuals with limited standing and walking ability to perform these movements during therapy.

A number of studies have demonstrated the therapeutic potential of Ekso's device. A pilot study (NCT04000373), sponsored by the Cleveland Clinic, evaluated the safety and feasibility of Ekso GT during rehabilitation training in five people with MS and moderate or severely limited mobility. All underwent three weekly sessions consisting of stretching and gait training with the device for eight weeks.

Participants were generally satisfied with the device, reporting scores ranging from 3.4 to 4.8 out of five on the Quebec User Evaluation of Satisfaction with Assistive Technology, version 2 (QUEST 2.0), with higher scores reflecting greater satisfaction. Improvements in gait speed and step height were also seen after training, the Cleveland Clinic reported.

Another pilot study, published by Kessler Institute researchers last year, showed that four weeks of exercise rehabilitation using the Ekso GT device worked better than conventional gait training at improving mobility and cognitive function in MS patients with substantial walking difficulties. The Kessler Foundation is now sponsoring a trial (NCT04855825) to further investigate the effects of Ekso's device on mobility, learning and memory, and walking ability compared with conventional gait therapy in adults with MS.

EKsoNR is also CE-marked — meaning it has met safety, health, and environmental protection requirements — and available in Europe.

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News

$3.9M Grant to Study Effects of Low-glycemic Diet in MS

The U.S. Department of Defence (DOD) has awarded $3.9 million to fund clinical research to test the impact of a low-glycemic diet on physical, cognitive, and psychological function in people with MS including those with secondary progressive MS.

A diet with a low glycemic load, or one with carbohydrates that cause fewer blood sugar spikes, is thought to enable fat loss while maintaining or increasing muscle mass, and could be a promising diet for MS patients. Examples of low-glycemic foods include green vegetables, most fruits, beans, and nuts. These diets are generally low in calories

The four-year project, called "Impact of diet quality and calorie restriction on physical function and patient-reported outcomes in multiple sclerosis," will take the form of a clinical trial (NCT05327322) that's expected to launch in November 2022.

It will be spearheaded by Brooks Wingo, PhD, and Amy Goss, PhD, along with colleagues at the University of Alabama (UAB) and Washington University in St. Louis, the two sites where participants will be enrolled. "This study is unique because it is highly translatable," Goss said in a university news release. "We not only have the potential to change the lives of the people directly involved in the study but hopefully to improve health outcomes for all people living with MS. Our findings could possess the potential to change clinical care when it comes to multiple sclerosis," Goss said.

Diet can significantly influence energy, strength, gastrointestinal function, mood, and immune health, among other things. In MS patients, an unhealthy diet has been linked to worse health outcomes. While healthy eating is advised, and many dietary guidelines exist, a standardized diet for MS has not been established.

Previously, Wingo and Goss were involved in a pilot trial (NCT03372187) that evaluated the feasibility of delivering a calorie-restricted diet with low glycemic load via telehealth in 20 patients with relapsing-remitting MS (RRMS). Results showed the diet is feasible and may be associated with positive effects on symptoms and cardiac health. The upcoming FOOD for MS trial will be conducted to test the effectiveness of the diet over eight months in 100 secondary progressive or relapsing remitting MS patients who are overweight or obese.

The study's primary goal is to assess changes in physical function, as assessed with the Multiple Sclerosis Functional Composite (MSFC) scale. **For more details go to page 14**

Phase 1/2 Trial Tests Immunotherapy in prog MS Patients

A Phase 1/2 clinical trial is looking at the safety and effectiveness of a cutting-edge immunotherapy called “extracorporeal photopheresis” in people with secondary progressive MS.

The study, dubbed PHOMS (NCT05168384), is enrolling up to 45 adults with MS including those with secondary progressive MS (SPMS) at a single site, the Abu Dhabi Stem Cells Center (ADSCC), in Dubai. Extracorporeal photopheresis (ECP) is a cutting-edge, cell-based immunotherapy used for certain T-cell lymphomas, complications of bone marrow and stem cell transplants, organ transplant rejection, and other autoimmune conditions linked to abnormal immune T-cells, a type of white blood cell involved in the fight against infections.

ECP involves drawing blood from a patient and separating the white blood cells. These cells are then combined with a natural molecule called psoralen exposed to ultraviolet light to activate it, and then infused back into the patient. When activated, psolaren becomes a highly reactive molecule that binds to DNA, cell membranes, and proteins that together lead to cell death and other toxic effects.

While its underlying mechanisms remain largely unclear, research suggests ECP promotes anti-inflammatory responses and reduces abnormal immune reactions through several processes, such as activation of regulatory T-cells (Tregs). Tregs are a subset of T-cells that dampen responses of other immune cells. This approach does not result in a global immunosuppression, as seen with several immunosuppressive therapies, meaning the body may still be able to effectively fight infections and cancer. Results from three ADSCC-based studies testing ECP were presented at the 2022 European Society for Blood and Marrow Transplantation (EBMT) Annual Meeting, held virtually, March 19–23.

The Phase 1/2 trial will test the therapy in 45 MS patients who are able to walk, even if only with help. Participants will be randomly assigned to receive either 28 ECP sessions plus standard disease-modifying therapies (DMTs; 30 patients) or DMTs alone (15 patients) for 24 weeks (nearly six months). The study’s main goals are to assess the ECP’s safety and effectiveness, while secondary goals include assessing MS patients’ immune response profile. Effectiveness measurements include changes in disability progression, walking ability, occurrence of clinical relapses, finger dexterity, and general health; all assessed with validated measures. The trial is expected to conclude in April 2024, and should it produce positive results, the researchers plan to launch a Phase 3 trial to confirm the findings in a larger group of patients.

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Grit: can it help you with your MS?

Resilience, hope, and grit (courage and bravery) are modifiable, and it is claimed these have an effect on outcomes in MS.

So, could it be further argued that people with MS who have low levels of these attributes could be given treatments that boost them and help their MS? That's an idea being discussed by Gavin Giovannoni, professor of neurology at Barts Hospital in London.

Prof. G explains the basic argument in the following way: "Arguably one of the most overused terms to emerge during the COVID-19 pandemic was the term resilience. Journalists and commentators have used the noun 'resilience' or the adjective 'resilient' when referring to countries, political, educational and healthcare systems, healthcare professionals and individuals with chronic diseases. These terms are even creeping into biology, for example, (1) his metabolic resilience protected him from developing diabetes and metabolic syndrome; (2) the resilience of the nervous system and its ability to recover function means the onset of the progressive phase of MS will be delayed by several years.

Giovannoni goes on: "I was therefore not surprised to read the research paper (see p14) showing that people with MS (pwMS) with higher resilience and hope scores tended to have higher grit scores. To be honest this is the first time I have heard the term grit applied to multiple sclerosis.

"Grit is defined as 'perseverance and passion for long-term goals despite adversity'. Grit is essentially a combination of perseverance of efforts and consistency of interests. Perseverance of effort is your ability to continue your efforts even when facing setbacks, while your consistency of interests is your ability to sustain an interest in achieving future goals over time.

"Higher levels of grit are associated with higher levels of achievements, such as educational attainment and fewer career changes, which go beyond your intrinsic abilities or talent.

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Continued from page 10 Not surprisingly grit is associated with improved health and mental health outcomes, and overall mental wellbeing.

“Other protective factors, including resilience and hope, are also associated with better health and mental health outcomes in people with disabilities. Resilience is a person with MS's ability to achieve growth and flourish in the face of having MS. In comparison, hope is a cognitive state that allows you to work toward your goals and formalise a path to meet your goals. “

So what, you may ask has this got to do with treating MS? Giovannoni says the overall conclusion of the study is that as resilience, hope, and grit are potentially modifiable traits, healthcare professionals (HCPs) should prescribe and use interventions to improve them in pwMS. In the study (on p14) resilience and hope seem to explain a significant amount of the variance in grit in pwMS.

“It shows that pwMS with higher levels of resilience and hope, not surprisingly, had higher grit scores. The obvious question is can you do something about this? I suspect yes. Despite the physical, cognitive, psychological and economic challenges of having MS, it should be possible for pwMS to positively influence their overall wellbeing.

The question is: what can you do about this to improve your “grit level”. As psychologists consider resilience, hope, and grit to be modifiable Giovannoni thinks we should be identifying pwMS with low levels of these attributes for interventions. Early interventions have shown promising results in improving resilience and mental health outcomes in pwMS. Similarly, hope-based interventions can increase your hope and meaning in life, and reduce anxiety and depression. Finally, interventions to improve grit, for example, cognitive-behavioural therapy (CBT), mindfulness and value-based or incentivised interventions which it is argued improve grit by helping you work on your thoughts and behaviours to make sure they are consistent with your long-term goals. I think here we are talking about what is called “social prescribing” rather than prescribing drugs.

On a personal note I am sympathetic to this idea but I am not yet totally convinced it will make a major impact on my MS. Grit may make me better able to deal with MS and the problems it creates but I don’t think it will modify my gradual descent into disability. That said, it costs nothing to be more gritty and given that it is unlikely to do me any harm it would be foolish to ignore the research. So from now on I am going to get more gritty.

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News

PoNS Device for MS-linked Gait Problems Now Available

The portable neuromodulation stimulator (PoNS) device, which improves walking abilities in people with MS is now available commercially in the U.S. for patients aged 22 and older who have a prescription from their healthcare provider. It is hoped that European countries including all of the UK (not just certain areas) will follow suit.

The device was approved last year by the U.S. Food and Drug Administration (FDA), which stipulated that it could be used for the short-term treatment of gait problems due to MS in conjunction with supervised physical therapy. The device may help MS patients in the U.S. see improvements in mobility, disability, and quality of life, according to its developer, Helius Medical Technologies.

"Approximately 40 percent of individuals with MS will need walking assistance within 15 years of the onset of the disease. PoNS therapy provides a unique opportunity for these patients to improve gait functionality and mobility," Antonella Favit-Van Pelt, MD, PhD, Helius' chief medical officer, said in a press release.

Walking difficulties are among the most common symptoms of MS. Often, walking can be improved with physical therapy, stretching, and assistive walking devices, sometimes in combination with medication.

PoNS is a non-invasive portable device consisting of a mouthpiece that's connected via a cord to a controller worn around the neck. When placed on the tongue, the mouthpiece delivers a light electrical stimulation to two nerves, called cranial nerves, which send electrical signals to the brain. These electrical signals promote neuroplasticity, a process wherein the brain adapts and rewires in response to new experiences. This is thought to promote the strength of brain circuits involved in movement and enhance the benefits of physical therapy in people with mild-to-moderate MS.

Helius is investigating PoNS use for treating gait and balance deficits after stroke, an indication for which the device also has a breakthrough designation. An upcoming clinical trial (NCT05135533) led by investigators at the Medical University of South Carolina will evaluate the effects of PoNS on gait recovery and stability after a stroke.

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Preclinical Data Support Remyelinating Potential of ABX-002

ABX-002, an experimental treatment for MS being developed by Autobahn Therapeutics, promoted the restoration of the myelin sheath – re-myelination - in preclinical models of the disease, new data show.

The research, which specifically tested an analog of ABX-002 called LL-341070, will be presented by Autobahn's academic collaborators at a pair of conferences this summer.

"We are excited to share new data with LL-341070, an analog of ABX-002, in partnership with these esteemed academic centres and leaders in neurodegeneration and remyelination in myelin-mediated diseases," Kevin Finney, chairman and CEO of Autobahn, said in a press release.

ABX-002 and LL-341070 both are thyromimetics, lab-made molecules designed to mimic the activity of thyroid hormone. This hormone stimulates the activity of oligodendrocytes, which are cells in the brain and spinal cord that can make and repair myelin, the fatty covering around nerve cells that helps them send electrical signals. MS is caused by inflammation that damages myelin in the central nervous system (CNS).

Ian Duncan, PhD, a professor at the University of Wisconsin-Madison, will present new data showing LL-341070 can promote remyelination (myelin repair) in an animal model at the 2022 Myelin Gordon Research Conference, being held May 22–27 in Barga, Italy. Duncan's talk is titled, "Promoting remyelination in a large animal model using the brain-enhanced thyromimetic LL-341070 drug."

"Our findings are highly encouraging and suggest that treatment with thyromimetics can lead to robust remyelination in the CNS, resulting in neurologic recovery," Duncan said. "I'm pleased to present these data in collaboration with Autobahn, which highlight a treatment approach that could have a significant impact on people suffering with MS."

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