

Foods Made with Special Whey Protein Help PKU Sufferers

by Jan Shepel

Food products made from whey are paving the way for healthier lives for people born with an inherited disorder that doesn't allow them to process phenylalanine, an amino acid found in most foods — including breast milk.

Specifically, the genetic disorder is called phenylketonuria, or PKU.

Thanks to a team at the University of Wisconsin-Madison, led by Dr. Denise Ney, a nutritional sciences professor, new foods have been created to help PKU sufferers eat better and stick with the strict diet required by their disorder. Ney believes the pieces needed to get that job done only exist in a few places in the world — and maybe only in Madison.

Screening of infants at birth — required in some countries, but not in others — allows parents to understand that they must feed children with PKU differently. One in 50 people carry the gene that causes the disorder, which affects about 15,000 people in the United States and 60,000 worldwide.

“This disease is completely democratic. It could happen to anyone,” she said. “Newborn screening was developed for this disease. PKU is the poster child for genetic diseases.” In the developed countries, every baby is screened. In Wisconsin, four to six babies are born each year with PKU. (In China and India there is a high incidence of children with PKU, she added. But babies in those countries aren't routinely screened.)

The goal, in using the whey protein called glycomacropeptide or GMP, was to try to improve nutrition for these people, Ney explained to *The Milkweed*. “Infants usually accept the diet readily but the problems start when they have to learn to drink from a cup rather than a bottle.” The traditional “medical foods” used by people with PKU are described as “smelling bad and tasting worse,” Dr. Ney clarified.

“The good news is that with treatment — the medical diet — these people can have pretty normal lives,” she said. But if they don't stick with the diet, intellectual disabilities, seizures and other serious health problems will result. Without the special diet, dangerous levels of phenylalanine build up in the body because PKU sufferers cannot metabolize that amino acid.

The problem in formulating that special PKU diet is that most naturally-occurring proteins contain phenylalanine. Avoiding naturally-occurring proteins presents difficulties for people with PKU to obtain adequate protein in their diets. Even a vegan diet doesn't work. That's because nuts and beans have too much protein for PKU sufferers. Small amounts of fruit and vegetables are allowed.

Before Ney and the UW specialists stepped in with their whey protein, the medical PKU diet was created with synthetic protein substitutes made from amino acids that afflicted individuals can metabolize. Because of the taste, smell and texture of the necessary PKU medical diet, adhering to that diet has traditionally been difficult.

“Their biggest challenge in life is following the diet,” according to Ney. Adults who go off their prescribed diet become irritable and get headaches as the phenylalanine builds up in their bodies. For children, mental retardation can result. “When researchers worked out the mechanism of PKU in the 1930s, they went into mental institutions and tested people and it turned out that 15-20% at that time had



Dr. Denise Ney is a professor of nutritional sciences at the University of Wisconsin-Madison. Dr. Ney coordinated a team of researchers at UW-Madison that developed a whey-derived protein as a food ingredient for individuals suffering from phenylketonuria (PKU). Her research continues UW-Madison's long history of PKU studies.

it [PKU]. The mental damage could have been prevented,” she said.

The Wisconsin connection with this disorder is a strong one. Dr. Harry Waisman, a pediatrician at the UW-Madison in the 1960s, treated PKU sufferers in Madison and testified before Congress urging lawmakers to require the testing of newborns for PKU. The Waisman Center at the UW Hospital is named for him.

Whey Protein (GMP) May Help With Weight Loss, Osteoporosis

by Jan Shepel

A special diet for people born with the genetic disorder phenylketonuria (PKU) has been improved with the use of a whey protein that lacks the amino acid that causes huge problems for these folks.

The genetic disorder affects a fairly small number of people worldwide — about 60,000. So these diet components created on the University of Wisconsin-Madison campus, with help from the farmer-funded Center for Dairy Research, are helping a small pool of people. But ongoing research has pinpointed another area that might be a huge boon for the patented product made from the whey-derived glycomacropeptide, or GMP.

Nutritional Scientist Dr. Denise Ney, who was a key figure in doing the research and developing the GMP products for people with PKU, has also found that it may be useful in promoting bone density and weight loss in people who don't suffer from PKU.

“This discovery on weight and bone density came along with the PKU study,” she said. A large study of mice that are known to develop PKU and control mice that don't get the disorder, led to the discovery that mice fed the GMP diet had bigger, stronger bones and less fat on their bodies. “And it was always more prominent in the females.”

Ney is pursuing more research to look into the possible connection between

GMP and resulting stronger bones and less obesity. If a connection can be authenticated, the market would expand exponentially — from female athletes to post-menopausal women concerned about weight loss and bone density.

“We are thinking that these people wouldn't need to alter their whole diet like PKU patients do, but could possibly take a GMP supplement and still get the benefits,” she said. The working theory as to how this mechanism might take place in the body is that the pre-biotic properties of the GMP affect the microbiome, which in turn results in stronger bones and weight loss.

Dr. Ney is now working on a research project titled, “Use of GMP to Promote Women's Health,” along with a medical team that includes an endocrinologist at the University of Wisconsin School of Medicine and Public Health — Karen Hansen, MD who is a specialist in osteoporosis and calcium absorption. “This next phase of research is the non-PKU phase,” Ney said.

The new study will focus on humans and how GMP could help burn fat and build bone. Early research shows that GMP may work in women by promoting satiety (the feeling of being full) and by helping the colon's microbiota by reducing inflammation.

If research establishes a link to provide a weight-loss supplement that also improves bone density, especially in women, the market could be a huge one in the United States. Ney also sees that this kind of a product stream would also make the production of GMP cheaper, and thus would help the PKU patients, for whom the whey-based diet was originally formulated to help.



Here are some consumer products offered by Cambrooke Therapeutics: Restore Powders, Complete Bars and Build.



Additional Cambrooke Therapeutic products: Restore Powders, Complete Bars and Build Glytactin Ready To Drink and Bettermilk.

(In 2010 a national non-profit advocacy group, the National PKU Alliance was formed and Christine Brown, a mother of three – two with PKU — from Tomahawk, Wisconsin, is the executive director. There is another Wisconsin connection: Turkey sends all of its PKU infant screenings to the Wisconsin Laboratory of Hygiene to be tested.)

In 2003, Ney started to get questions from dietitians at the Waisman Center about improving the diet of their PKU patients. Those dietitians knew she had conducted some earlier research on genetic diseases.

As the potential research focus began to come together, food scientist Mark Etzel came up with the idea of the GMP whey protein. GMP stands for Glcomacropetide, which comprises 15% to 20% of whey proteins found in cows' milk. Whey proteins equal about 20% of all proteins contained in cows' milk. A grant was secured from the dairy industry to investigate further. "GMP is the third most abundant protein in whey and he knew it didn't contain any phenylalanine," Ney said.

Nestle, S.A. — the global food corporation with widespread infant formula products — had a patent on the use of GMP for treating PKU. But Nestle's researchers had never done much with that patent, she explained. The initial UW-Madison research project zeroed in on a method to extract GMP from whey, which was then patented by the Wisconsin Alumni Research Foundation (WARF) — the entity which harbors all the intellectual property generated on the campus.

"When Mark had that, he went to food companies but nobody would touch it," Ney said. The Waisman Center's PKU dietician, Sally Gleason, understood the problem and she wouldn't let go Ney said. Her persistence helped to rally interest in the PKU community and form a task force with the goal of developing the GMP diet.

The research staff at the National Institutes of Health (NIH) advised Ney that she would need to develop foods with GMP and conduct taste tests to establish palatability, before she could even apply for one of their grants to study the proposed, whey GMP-based PKU diet.

UW-Madison's Center for Dairy Research was critical at this point in the project, she said. "It was just an idea and we needed some research. I went to the Center for Dairy Research and asked them if they could make some foods for me with GMP. Food scientist Kathy Nelson came up with drinks and crackers, fruit chews and yogurt-like mixtures." The Center for Dairy Research also had specialists who helped evaluate the sensory qualities and palatability of the foods as they were developed.

"I don't think this project could have gone forward if it weren't for the Center for Dairy Research. They told me it's in their mission – to

find new markets for milk. They were so nice and so enthusiastic about this novel project."

That work set the stage for the NIH grant, which allowed Ney to conduct a study of 11 people with PKU. The protocol involved admitting the 11 to the hospital for six days to study their reactions to the GMP diet. Dr. Ney also studied mice known to develop PKU, and showed that these mice could grow on the GMP diet.

When the results of those tests were favorable, Ney went back to WARF. "I told them I think I've got something here and they said, 'you sure do.'" A new WARF patent was issued and the patent was licensed to a Boston company – Cambrooke Therapeutics. That firm was started by a mother with PKU kids. Cambrooke Therapeutics ran with the ball, creating a variety of beverages, pudding and snack bars using GMP.

So much of what has developed is due to the critical mass of specialists, knowledge and tenacity on the UW-Madison campus ... with an appreciative nod to dairy farmers whose check-off money funded the Center for Dairy Research, through the Wisconsin Milk Marketing Board, Ney said.

"I wanted to do research in nutrition that made a difference in people's lives and that's why I wanted to do this — solve a terrible problem for people with this disorder." Ney also credits the process of patenting and development through WARF. "I didn't realize the entrepreneurial part."

"A patent is the quickest way to get a discovery to the people it can help. I think I was very fortunate to be in Wisconsin when this idea came up. I'm pretty sure this couldn't have happened anywhere else. We had all the pieces here on this campus – the Waisman Center, the medical school, the hospital with a research unit, a professor who understood the applied nutritional biochemistry, food scientists and the Center for Dairy Research. How many places in the world have all of that?"

"We had the pieces. We have the culture where you can reach across departments and we have the Wisconsin Idea where we know we are here to help solve the problems of the people. Dairy farmers should be proud for having had a part in that."

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Growing First-Half Sales & Profits for The a2 Milk Company

by Ken Rabas

The a2 Milk Company continues to see large increases in both sales and profits. The New Zealand-based firm's 6-month financial report shows an 84% increase in overall revenue.

That growth includes a 150% increase in a2 Platinum infant formula revenue, and a 290% increase in profits. Stock prices continue to increase for The a2 Milk Company. The Australian market continues to grow with another 3% increase in fresh milk retail sales market.

The firm's most recent quarterly report details that a2 Platinum infant formula has achieved a 25% share of all infant formula sold in Australia. China is also a growing market for a2 Platinum infant formula. Meanwhile, sales in the United Kingdom have passed the breakeven point and are beginning to show a profit.

In the United States, The a2 Milk Company is showing a loss. But a major marketing push in the United States is planned for 2018. That expanded sales push in this country will include The a2 Milk company's entire product line — most notably a2 Platinum infant formula. As The a2 Milk Company expands its U.S. marketing effort, it will require larger volumes of fluid milk sourced from farms here in the US, but all of the powdered products will be imported from New Zealand.

In this writer's opinion, that last sentence clearly demonstrates that the U.S. industry is again lagging far behind New Zealand's imports ... particularly for the perceived, higher-value a2 materials. The a2 Milk Company's half-year report details a conservative management of infant formula production and inventory. That statement probably means that with increasing sales, the supply of a2 Platinum could get tight before the start of the next milk season in New Zealand.

Synlait — the New Zealand firm that partners with and produces The a2 Milk Company's Platinum infant formula — is scheduled to bring on line a brand new, wet-mix production line in November 2017. All the above-mentioned elements are looking positive for a2 Milk.

a2 Milk USA has added a reduced-fat Chocolate Milk to its product line. To the firm's credit, the reduced-fat Chocolate Milk label contains no carageenan. a2 has also announced that it will be offering a2 Milk in Publix, a chain of 1,100 stores in the Southeast. A third announcement from a2 USA is a non-exclusive marketing agreement with Prairieland Dairy in Firth, Nebraska.

Prairieland is a 1,400-cow dairy that has been supplying milk to a2 Milk USA. Prairieland Dairy also has its own milk bottling plant. Presumably, that deal allows Prairieland to label its own bottled milk as a2.