Speaker: Dr. Nancy Rawson

Dr. Nancy Rawson from WellGen, Inc. gave a presentation entitled "Can Food be Medicine?" on April 13th at Penn State Abington. Nancy is the Chief Scientific Officer at WellGen, North Brunswick, NJ, making use of her classic nutrition background and later training in molecular biology. She began by defining the continuum of therapeutic nutrition. There are dietary supplements (such as Osteo-Biflex), which are a $23.7 billion market in the US and lower volume/high profit products (profit margin of 42%). They have very little oversight and few requirements for safety and efficacy (only recently required to be made under good manufacturing practices [GMP] regulations). The next category is functional foods and beverages. These are foods with additives, such as Activia (a yogurt containing additional species of probiotic cultures) or calcium-fortified beverages. These have a huge market ($34.3 billion US market). They can make structure-function claims (that are not related to a particular disease) and approved health claims (such as the importance of calcium in preventing osteoporosis). Such claims have very restricted options for marketing and are not proprietary (no differentiation between similar products). Lastly, there is an emerging high-growth market of medical foods. These can make strong disease claims that are supported by peer-reviewed clinical trials in a targeted patient population. In addition they have an IP (Intellectual Property) defense. Medical foods are generally prescribed by an M.D. and have high revenues and a profit margin of 55%.

Nancy went on to describe medical foods in more detail, since most of the audience was unfamiliar with this category. To be a medical food, the ingredients have to be designated as"generally recognized as safe" or GRAS. (Some functional food supplements are GRAS, but they don't have to be.) They must meet FDA/FTC labeling guidelines, be manufactured under GMP conditions, supported by clinical trials, and have a mechanistic understanding of how a product works. Interestingly, the FDA does not "approve" GRAS applications. A "Self-Affirmation" data dossier is given to a panel of expert consultants. This includes full characterization of the physical and chemical properties. The process can take two years and cost between $1 00K to $1 million. This is for a specific quantity and use and requires the unanimous recommendation of the panel. This is a private process, protecting the IP status of the product.

What makes a medical food different from a pharmaceutical? One aspect is that the active ingredient must be present or derived from food. Because of this requirement it is generally more complex and may be active on multiple targets in a pathway. Like some drugs, it must be provided in an oral dosage form.

Because the ingredients are GRAS, the safety profile is greater. Nancy gave three examples of medical foods currently on the market: Metanx, which consists of the active forms of three vitamins targeted to endothelial dysfunction in diabetic neuropathy;
Axona, an alternate food source for the brain instead of glucose, targeted for mild to moderate Alzheimer's disease; and Limbrel which works by dual inhibition of arachidonic acid metabolism and anti-oxidant action rather than COX-2 selective inhibition for those with osteoarthritis. One advantage of medical foods is that they afford greater potential for preventive action, since they are so safe. Another distinction from a pharmaceutical is the time to market. For a new chemical entity to product launch as a pharmaceutical generally takes 10-12 years and costs $800 million. Once a medical food receives its GRAS designation, the time to launch is 4-5 years and costs less than $50 million.

Lastly, Nancy gave a short description about WellGen, Inc. The company is focused on treating inflammation, based on plants with a therapeutic history. They identify bioactives in cell models of inflammation, develop methods for enriching them and conduct much of the same testing as a pharmaceutical (animals models, pharmacokinetics, clinical trials). They have a theaflavin black tea extract that has received the GRAS designation and is first being targeted towards diabetes. One recent report shows promise for the role of inflammation in Type 2 diabetes. In an NIH study, researchers evaluated the impact of salsalate, an anti-inflammatory drug related to aspirin, on glycemic control in patients. The study confirms that treatment with salsalate lowered HbA1c and improved other markers of glycemic control in patients with diabetes. At WellGen, testing of their black tea extract (WG0401) in diabetics rats showed a greater decrease in HbA1c (0.96%) and in fasting glucose (30% decrease). The dosage had no adverse effect, unlike the extremely high dose of salsalate used in the human study, and is the equivalent of 26 cups of tea, but without the caffeine.

Nancy ended with this quote from Hippocrates "Let food be thy medicine and medicine be thy food." This dates from around 400 BC, but is still true today. The presentation was followed with many questions from the audience. Nancy can be reached at nerawson@wellgen.com. For more information on information on WellGen, Inc., you can go to their website: http://wellgen.com.

Drs. Alice Marcy and Deb Cortese listening to the speaker

Dr. Ellie Brown looking at a sample of a nutritional supplement

Article by Dr. Sheryl Meyer; photos by Drs. Sheryl Meyer and Edyth Malin.
http://www.awisphl.org/April2010meetingreport.pdf