Having trouble viewing this email? Click here

Like

To download or read a pdf version of this newsletter, click here. **December 2014**

BioMarketing Insight Newsletter

Creating Markets and Marketing Strategies

Dear Regina,

Welcome to BioMarketing Insight's monthly newsletter.

Last month I covered " The Facts about Ebola and What is Being Done." If you missed last month's article, click here to read it. This month will be the first of a two (2) part series on genetic engineering and today's advances with genome engineering. I will cover Genetically Modified Organisms (GMO) Food: Good or Bad? And next month I will cover "Today's Advances with Genome Engineering."

Read on to learn more about this topic and other current news. On the right are quick links to the topics covered in this month's newsletter. The next newsletter will be published on January 15th.

We encourage you to share this newsletter with your colleagues by using the social media icons at the top left, or by simply forwarding the newsletter via email.

Please email me, Regina Au, if you have any questions, comments, or suggestions.

Sincerely,
Regina Au
Principal, Strategic Marketing Consultant
BioMarketing Insight

In This Issue

Join Our Mailing List!

Join Our Mailing List - For Mobile

BioMarketing Insight Services

Product Development

Market Development

Marketing Strategies

Previous Newsletters

Regulatory Challenges - Rapid Response

I'm pleased to announce that my article on regulatory challenges entitled "Rapid Response" has been published in the October 2014 issue in European Biopharmaceutical Review. To read an electronic version, please click here, my article is on page 10. To learn more about EBR, click here.

Top

The Paradigm Shift to an "Open" Model in Drug Development

I'm pleased to announce that my article "The Paradigm Shift to an 'Open" Model in Drug Development" was published in the December 1st, 2014 issue of Applied and Translational Genomics. To read an electronic version, please click here

Top

Save the Date: Medical Informatics World Conference - May 4-5, 2015

At the Medical Informatics World Conference, I will present "Designing Your Wearable Technology with Mobile Apps: What is Needed for Successful Product Adoption and Impact" on Tuesday, May 5th at 9:25 am under Track 5, Leveraging mHealth, Telehealth and the Cloud. For more information on this track click here. For conference details, click here.

Top

Genetically Modified Organism (GMO) Foods: Good or Bad?

Genetic engineering, or genetically modified organisms

(GMO): are they good or bad? It depends on who you ask.

DNA Structure
Source: National Institue of Health

History of Genetic Engineering

Genetic Engineering dates back to 1953, when James Watson (American), Francis Crick (British), and Maurice Wilkins (New Zealand/ British) first developed a 3D model of DNA. This opened the door to understanding what we know today about genes and gene traits in organisms such as plants, animals, humans and microorganisms. The discovery of the DNA structure changed many areas of science, particularly in the agriculture industry. The three shared the 1962 Nobel Prize for physiology/medicine.

With the growing worldwide population and the demand for more food, scientists have tried to improve crop yields by modifying specific genes to induce specific desirable traits and produce better yields by improving resistance to insects, disease, herbicides and harsh weather conditions such as drought, flood, and freezing weather. Some scientists are also trying to add more nutritional value to food products.

Gene modifications were accomplished by inserting a single desired gene from one species into another non-related species, in hopes that the host would acquire the desired trait, resulting in transgenic organisms (plants, animals and microorganisms). Bacillus thuringiensis (Bt), a soil bacterium, its gene is used in plants to produce a toxin that would kill certain insects when the insect eats the plant in building insect resistance. Another bacterium was used to build herbicide resistance and viruses were used for disease resistance.

Repercussions

Crop yields have prospered, but many consumers were not in favor of GMO foods when they discovered that foods contained a gene from a bacterium called Bt that produced a toxin. One anti-GMO advocate describes the Bt as producing "a protein that ruptures the stomach when ingested by pests," implying that this may occur when humans ingest the food that contains this bacteria and toxin.

However, Bt has been used as a microbial spray pesticide to control caterpillars, certain types of beetles, as well as mosquitoes and black flies for years. In 1995, the EPA registered the first Bt plant-incorporated protectants for use in the United States and 11 more since then. According to the Environmental Protection Agency (EPA), the use of conventional pesticides for control of the European corn borer has dropped by about one-third since Bt corn was introduced.

Bt may also have been confused with DDT, organochlorine insecticide, the first insecticide on the market that did create a lot of health problems, most notably reproductive problems and cancer in animals. The use of DDT as an insecticide was cancelled in 1972 by the EPA.

Organic food advocates were certainly not in favor of GMO foods and organic farmers feared that GMO grains could potentially cross - contaminate fields located nearby to a GMO farm.

More negative publicity for GMO foods occurred when Monsanto's GMO corn did not kill the rootworm and the rootworm formed resistance in four mid-west states. Additionally, there was fear of the potential to create "super weeds" that might be born due to cross - resistance that could occur over time.

Environmentalists were concerned that Bt corn was responsible for the death of the Monarch Butterfly. University scientists found that Bt corn pollen, like natural corn pollen, can blow onto milkweed leaves, which are the exclusive diet of Monarch caterpillars. Steps were recommended to avoid cross - contamination of crops.

Another issue was the introduction of StarLink, a GMO corn derived from Bt that produces a protein,

Cry9C, that acts as a pesticide, protecting the plant from pests such as the European Corn Borer. StarLink corn was registered for use in animal feed only and not for human consumption due to unresolved questions concerning StarLink's potential allergenicity.

In 2000, taco shells were tested to find traces of StarLink corn DNA. Confirmed by the FDA, a number of food companies implemented a voluntary recall of taco shells and other products manufactured with yellow corn meal.

The USDA, FDA, and EPA worked to test corn grain for the presence of StarLink and remove any potentially contaminated corn seeds from the market. Since then, the EPA will no longer issue split registrations (animal feed only and not for human consumption) for pesticide products.

The EPA has incorporated regulation of biopesticides to address gene transfer and outcrossing (transfer from one field to another) to ensure the safety of plants crops. Currently the EPA has found no gene flow or outcrossing for corn and potato due to differences in chromosome number, phenology and habitat. There is a possibility, however, of gene transfer from Bt cotton to wild or feral cotton relatives in Hawaii, Florida, Puerto Rico and the U.S. Virgin Islands.

Overall, the EPA encourages the use of biopesticides vs. synthetic pesticides, which fall into 3 major classes:

1) Microbial pesticides consist of a microorganism (e.g., a bacterium, fungus, virus, or protozoan) as the active ingredient which includes Bt.
2) Plant pesticides are pesticidal substances that plants produce from genetic material that has been added to the plant or GMO plants such as corn, cotton, and potato.
3) Biochemical pesticides are naturally occurring substances that control pests by non-toxic mechanisms such as insect sex pheromones, that interfere with mating, as well as various scented plant extracts that attract insect pests to traps. This excludes conventional pesticides that are synthetic chemicals.

The goal of producing GMO foods was to yield better crops, resulting in lower food prices, greater benefit (longer shelf life or nutritional value), or both. But according to the World Health Organization (WHO), when the first GMO foods were introduced onto the European market, the products were not perceived by the consumer as having any direct benefit (not significantly cheaper, no increased shelf life, no better taste).

The three main health concerns regarding GMO foods according to the WHO are:

1. Allergenicity - "...the transfer of genes from commonly allergenic organisms to non-allergic organisms is discouraged unless it can be demonstrated that the protein product of the transferred gene is not allergenic."
2. Gene transfer - "Gene transfer from GMO foods to cells of the body or to bacteria in the gastrointestinal tract would cause concern if the transferred genetic material adversely affects human health. This would be particularly relevant if antibiotic resistance genes, used as markers when creating GMOs, were to be transferred."
3. Outcrossing - "The migration of genes from GMO plants into conventional crops or related species in the wild (outcrossing), as well as the mixing of crops derived from conventional seeds with GM crops, may have an indirect effect on food safety and food security. Cases have been reported where GMO crops approved for animal feed or industrial use were detected at low levels in the products intended for human consumption."

On May 29, 1992, The Food and Drug Administration (FDA) published its "Statement of Policy: Foods Derived from New Plant Varieties" in The Federal Registry (57 FR 22984) which includes GMO foods.

What about GMO wheat?

Wheat is used in numerous foods for human consumption such as cereal, bread, pasta, and desserts (cookies, cakes, pies, bread, etc.). Is there GMO wheat? Scientists have been working on GMO wheat for a long time but they've been unsuccessful, because wheat has a very complex DNA structure. Agriculture companies such as Monsanto have actually spent nearly a decade-and-a-half

researching GMO wheat. The company began field testing a variety starting in 1998, but suspended operations in 2005, after determining that a super-wheat strain wasn't quite ready to be launched.

Here is the reason why. A human cell (diploid) has two copies of 23 chromosomes for a total of 46 chromosomes, but a wheat cell (hexaploid) has six copies of its seven chromosomes (42 chromosomes total). Corn has 20 chromosomes total, and rice has 24. While wheat has fewer pairs of chromosomes than humans it has a greater number of genes, with an estimated 164,000 to 334,000 genes, compared to 20,000 to 25,000 genes for a human.

While there is no commercially approved GM wheat on the market, there has been an incident where GMO wheat was found in a farmer's unmodified wheat in Oregon. It was found that the GMO wheat came from Monsanto. Outcrossing can happen whether it's through nature (seeds blowing into another field) or through seeds clinging to someone's clothes and accidently transferring to another crop as that person travels.

In fact, due to the controversy about GMO products and the incident of GMO wheat being found in an unmodified wheat field where there is no commercially approved GMO, a ban of GMO products is in effect in 26 countries.

Top

Closing Thoughts

Two safety concerns cloud the potential usefulness and acceptance by the public of transgenic, or GMO foods. **First**, the insertion of a single foreign gene into a nonrelated species could set into motion a cascade of biological sequellae which we can neither predict nor manage. **Second**, the long - term effects that foreign genes might have on plants edible and inedible and the humans and animals that ingest those GMO foods, are completely unknown. The only test that regulatory authorities conduct is examining and testing how GMO foods are digested and in particular, whether GMOs survive human digestive acid. Yet those are short - term yardsticks. Toxins may be degraded, but what about DNA from the transplanted gene?

In my July newsletter, I spoke about the leaky gut and how it can affect our immune system when gluten (wheat) is not fully digested and short chains of amino acids cause zonulin to be released. It is zonulin that opens the junction doors of the intestinal lining, allowing large proteins to pass through into the blood stream and activating the innate immune system, which could cause symptoms relating to various autoimmune diseases. This process has led us to the theory of the leaky gut.

Is gluten or wheat not fully digested because it has been genetically modified and thereby causing leaky gut? In the preceding page, it is stated that developing GMO wheat has been an unsuccessful endeavor. We know that wheat has been genetically modified as stated above, but we don't know when. We know that research probably began in 1953 when Watson and Crick developed the DNA model. In 1973 Stanley Cohen and Herbert Boyer invented the technique of DNA cloning, which allowed genes to be transplanted between different biological species and in 1974, they created the first genetic modified organism. Could this explain why humans can't fully digest wheat? Or could it be because of the complex nature of wheat as opposed to corn and potatoes? Regardless of how or why, we know that wheat can't be digested. And if wheat can't be digested naturally, could modifying plants with foreign genes and DNA sequencing also create the same results, since our body can't recognize the DNA sequence to cleave off each amino acid?

Another concern that arises is when one inserts a foreign gene for a desired trait, will this automatically alter our normal body function (other systems or pathways)? We don't fully understand how that process effects the rest of our biological system.

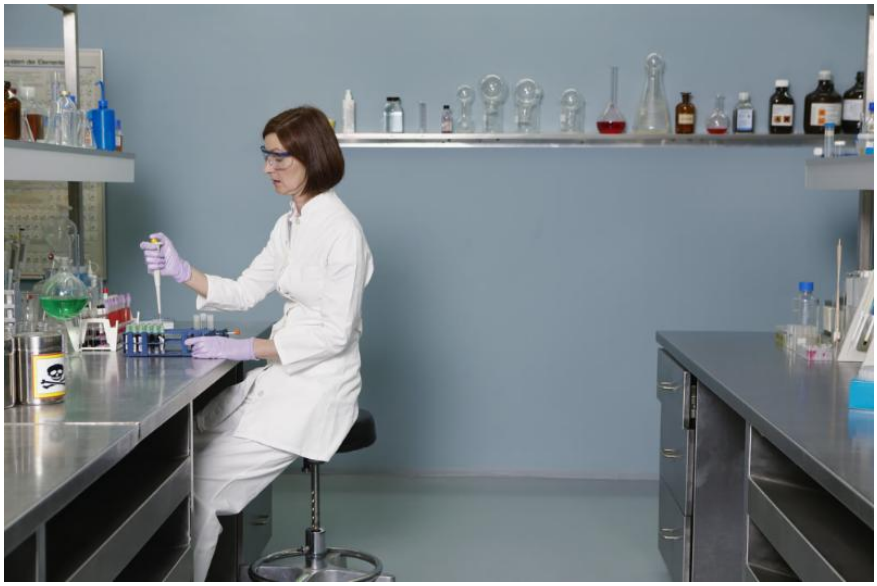
In terms of scientific technology and knowledge we've come a long way but like drugs, we don't

necessarily know early on the long - term effects of new formulations, which is why regulatory authorities are conservative in approving drugs for off - label use. Genetic engineering I suspect will probably take a long time before we understand the ramifications of their use. Due to this dilemma, scientists have developed technologies that aim to overcome these concerns and bring about a more complete understanding of the biology of genetic engineering and genome engineering.

I will be talking about genome engineering in my January 2015 newsletter, so stay tuned.

Top

Developing a Product?



If you are developing a product and have not conducted the business due diligence to determine commercial viability or success, contact me for an appointment. For successful commercial adoption of your product, contact me for an appointment.

Top

New Technology - Synthetic Biomarkers to Detect a Clot

Ideally, biomarkers are used to detect a disease before symptoms start. However, finding the right biomarker is difficult. Most natural biomarkers that are specific to a disease and easy to detect are rare. We don't always have the technology to detect them, particularly if they occur in very small quantities.

Sangeeta N. Bhatia of Massachusetts Institute of Technology and David R. Walt of Tufts University have developed an assay that causes diseased cells or tissues to produce a synthetic molecule that scientists could easily find. They combined their technology to accomplish this.

Bhatia's group had synthesized worm-shaped iron oxide nanoparticles that home in on diseased cells. Walt's team had developed single-molecule arrays (SiMoA) that allowed them to detect extremely low quantities of biological compounds of interest. The new assay consists of nanoworms with a peptide that can be cleaved by thrombin, an enzyme activated at high levels in clotting disorders. When the nanoparticles bump into active thrombin in a mouse with clotting problems, the enzymes clip off a labeled peptide that the mice then excrete in their urine. To read the full article in *Chemical & Engineering News*, click here.

Top

About BioMarketing Insight

We help companies de-risk their product development process by conducting the business due diligence to ensure that it is the right product for the right market and the market opportunity for the product meets the business goals of the company. We can then develop marketing strategies to drive adoption for the product.

Top

BioMarketing Insight | 39 Kilby Street | Woburn | MA | 01801