

WHITE PAPER



THE "JUST IN TIME" EVOLUTION OF NUTRACEUTICAL CRANBERRY

2007





U.S & Global Supplement Trends:

If you're reading this White Paper there's a certainty that you have considerable interest in the world of natural health care. It's also most likely a certainty that you are affiliated with one or another company who acts as a developer and marketer of dietary supplements. It's well known that the current marketplace for supplements has its own history and chronology of events which have led to the prevailing trends unfolding within the industry at large. Tipping point legislation, embodied by the Dietary Supplement Health and Education Act (DSHEA) in 1994; has served to shape the industry not only in terms of its rules, but its raison d'être. Supplement sales have reached \$21.3 billion in the US and \$66.6 billion globally and now account for 28% and 32% of total Nutrition Industry sales respectively. Herbal sales comprise a significant portion of dietary supplement sales, approximately \$4.5 billion overall. However, over the last 9 years their trend has slowed considerably with only a select number of favored herbals in growth mode, cranberry being one of them.

A growing number of consumers worldwide have jumped on the natural supplement bandwagon to help maintain their health and well-being, but require that the Natural Products Industry police itself and strive to elevate the level of its clinical support and product quality. The bar labeled "safety & efficacy" has been elevated to unprecedented levels.

<i><u>Industry Segment</u></i>	<i><u>USA</u></i>	<i><u>GLOBAL</u></i>
<i>Dietary Supplements</i>	<i>21,310</i>	<i>66,550</i>
<i>Natural & Organic Food</i>	<i>20,840</i>	<i>47,730</i>
<i>Natural & Organic Personal Care & Household Products</i>	<i>6,560</i>	<i>18,210</i>
<i>Functional Food</i>	<i>25,660</i>	<i>77,890</i>
<i>Total Nutrition Industry</i>	<i>\$ 75,370</i>	<i>\$ 210,380</i>

SOURCE: Nutrition Business Journal; 2006, Represents All Trade Classes

An Industry "Herbally" Challenged:

Greater awareness of the natural end-benefits found in a multitude of different dietary supplements has yielded increased retail distribution and consumer usage. Consumers instinctively believe that "natural is better". During the period from 1994-1998, herbal products exploded into the natural food and FDM retail marketplaces and were welcomed as a new source of incremental sales. Consumers were drawn towards the world of herbals and to products containing such ingredients as Ginseng, Garlic, St. Johns Wort, Saw Palmetto, Echinacea and Ginkgo as a means of promoting good health and well-being. Herbals were clearly on the fast track and seemed invincible to a category slow down.

However there are always two sides to every coin. A broad and inconsistent range of quality, coupled with an increased incidence of contrary side-effects, resulted in their being questioned and subsequently doubted for their safety and efficacy by industry watch dog groups and the media at large. The overall effects of these actions have been two-prong. First, a flattening of the overall growth curve for herbals in



various retail sales channels, while at the same time a concerted effort by many responsible manufacturing entities to prove the safety and curative worth of these products clinically.

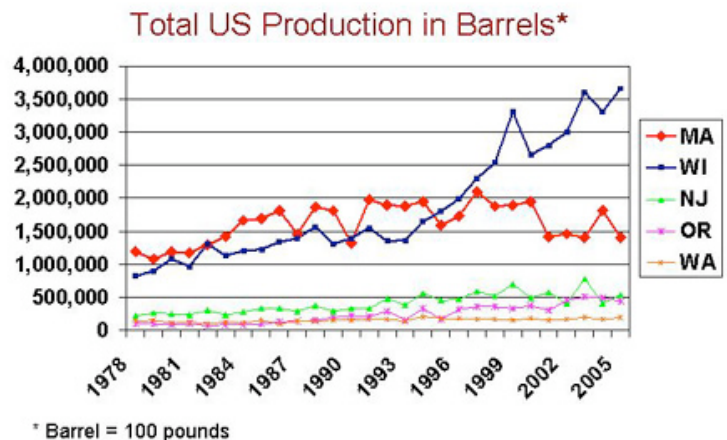
The industry has struggled with a negative consumer “trust factor”. Many want to supplement their health with natural medicinals, but there’s that little voice inside each consumer that says, “Do these really work? Will they truly make a difference? Will they act as promised or for that matter do me harm? Should monies I’ve budgeted towards wellness be spent this way or should I go at it differently?”

Consumer trust is gained as a by-product of the Corporate drive towards excellence. Reputable companies in the industry willing to elevate and sustain the caliber of their products while dedicating the necessary time and resources towards clinical affirmation are the new breed of industry leaders. Although this process is far from over, there has been significant improvement in the quality of natural medicines available to the general public as well as an accelerating drive to substantiate them scientifically. It’s believed that natural medicines are now on the cusp of another upward trend due in part to greater satisfaction with their users worldwide.

Cranberry...A Rising Star in Herbal Sales:

In addition to its historical place at the Thanksgiving table and its consumption as a great tasting and refreshing juice drink consumed casually, the cranberry fruit is currently used by millions for its overall health benefits. Here are some interesting facts on cranberries (Source: Cape Cod Cranberry Growers Association, 2006):

- Cranberries are one of only three commercially grown fruits native to North America. The other two are blueberries and concord grapes.
- On average, every planted acre of cranberries is supported by three to four acres of surrounding wetlands and uplands. These supporting wetlands and uplands provide open space, wildlife habitat and groundwater recharge in an area otherwise stressed from urbanization.
- Most of the world’s cranberries are cultivated on 39,000 acres in just five states: Massachusetts, Wisconsin, New Jersey, Oregon and Washington. Another 8,000 acres are cultivated in the provinces of British Columbia and Quebec, Canada. Delaware, Maine, Michigan, New York, Rhode Island, as well as the Canadian provinces of New Brunswick, Nova Scotia, Ontario and Prince Edward Island also produce cranberries. Recently, cranberries have been produced in Chile, South America.
- Of the approximately 1,000 cranberry growers in North America, 500 are in Massachusetts. Approximately 70 percent of these growers are small family farms with less than 20 acres of bog. The cranberry is Massachusetts' number one agricultural commodity crop and employs about 5,500 people.





Sales of cranberry nutraceutical products are rapidly accelerating at retail. Whereas just a few years ago distribution for these products were sparse, it's not uncommon these days to see an expansive on-shelf choice of various cranberry products covering a wide array of quality and cost. Not too long ago, the cranberry category was absent from top 10 herbal sales, while today it's poised to be #1 with Garlic currently trending downwards at almost 14%. The chart below illustrates current herbal standings in FDM outlets:

<i>Rank</i>		<i>Dollar Sales</i>	<i>Dollar Sales % Chg YA</i>	<i>Dollar Sales Chg YA</i>
	TTL HERBS	\$56,378,800	(3.5)	(\$2,065,620)
1	Cranberry	\$5,340,377	20.6	\$911,330
2	Garlic	\$4,932,349	(17.5)	(\$1,043,734)
3	Soy Products	\$4,783,063	(39.5)	(\$3,125,757)
4	Ginkgo	\$4,321,837	9.7	\$383,007
5	Saw Palmetto	\$4,050,406	(6.6)	(\$287,843)
6	Ginseng	2,668,179	(4.9)	(\$136,058)
7	Milk Thistle	\$2,178,631	2.4	\$50,887
8	St. Johns Wort	\$2,039,054	(2.6)	(\$54,426)
9	Black Cohosh	\$1,990,570	2.3	\$44,065
10	Echinacea	\$1,746,090	(11.8)	(\$233,316)

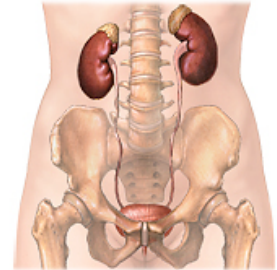
SOURCE: IRI. Latest 13 weeks ending May 27, 2007. No Wal-Mart

The Cranberry herbal category is currently +20.6% in FDM outlets across the U.S. So the question is why the sharp increase of sales within the world of nutraceuticals? To answer this question, it's important to understand the direction from "where" this trend has evolved. Cranberry is a category whose basis historically is in food consumption. Not too long ago, those who wished to gain the healing benefits of this special fruit did so by either ingesting the whole natural fruit or its juice. As awareness of the health benefits of cranberry has broadened over the last 10 years, (in tandem with the escalation of supplement sales) the desire to gain the health benefits inherent in this super food in the form of herbal supplementation was a natural segue for a multitude of consumers. This certainly is not difficult to understand given the large amounts of fruit or juice that need to be consumed to equal the benefits supplied by products that deliver cranberry's essential elements effectively in supplement form. There are a preponderance of women consumers globally who now recognize the benefits of cranberry for the maintenance of good urinary tract health, and prefer its benefits be delivered in nutraceutical form, void of the excessive calories, sugar and costs incurred in the digestion of its food and juice forms.

Cranberry bares fruit for Good Urinary Tract Health:

The strong growth in cranberry nutraceutical sales is directly related to a high prevalence of urinary tract infections (UTI's) predominantly effecting women. The following are key statistics: (Source: National Kidney Foundation and the NIH).

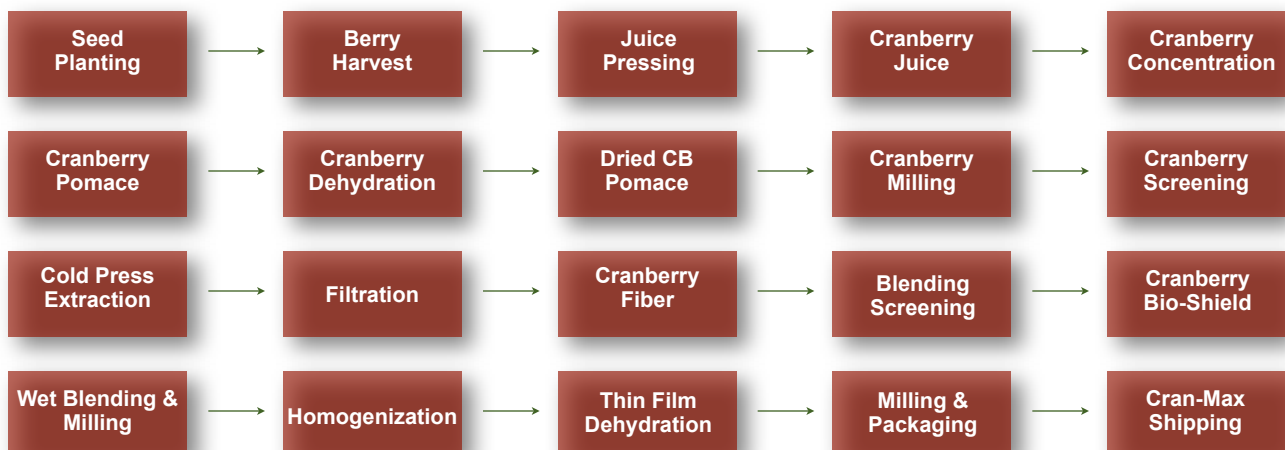
- Urinary tract infections are responsible for nearly 10 million doctor visits each year
- Over \$1 billion dollars are spent per year on UTI's.
- One in five women will have at least one UTI in her lifetime.
- Nearly 20 percent of women who have a UTI will have another, and 30 percent of those will have yet another. Of this last group, 80 percent will have recurrences.
- Total number of cases involving UTI's are approximately 40 million per year, of which 30 million are unreported and involve self medication.
- UTI's are the 2nd leading cause of lost work days for women.
- More than 1.5 million hospitalizations are related to UTI's



Indigenous peoples have used cranberry preparations to treat urinary tract infections and other illness for centuries. Modern medical research has revealed the chemical and physiological effects cranberries have on the urinary tract and in its natural ability to inhibit the growth of E. Coli bacteria responsible for urinary tract infections (UTI's). It's important to understand the natural mechanism of action of cranberry. The E. Coli bacteria are never "destroyed" by the cranberries, but "physiologically changed", thereby disallowing their attachment within the urinary tract. In contrast to the use of pharmaceutical medication, these harmful bacteria are essentially whisked away, all within the flow of natural bodily processes.

Cran-Max[®] and the Evolution of Nutraceutical Cranberry:

Nutraceutical supplements are in fact medicines of the natural kind. As with any medicine, they must deliver an end-benefit as promised. The process by which a phyto-medicine is developed and prepared during manufacture is crucial to its efficacy. The innate goodness of plant medicines must be hermetically sealed and delivered with optimum efficiency in the body. If a phyto-remedy is compromised by natural bodily process it will not deliver on its consumer promise. In the case of cranberry, it's imperative that its synergistic healing elements remain intact and in greatest abundance while being delivered most efficiently to their targets. Cran-Max has been developed to deliver on both counts. Nothing within the cranberry fruit is ever tampered with or wasted. The "whole fruit and nothing but the fruit" is utilized within a unique 20-step manufacturing process outlined below.



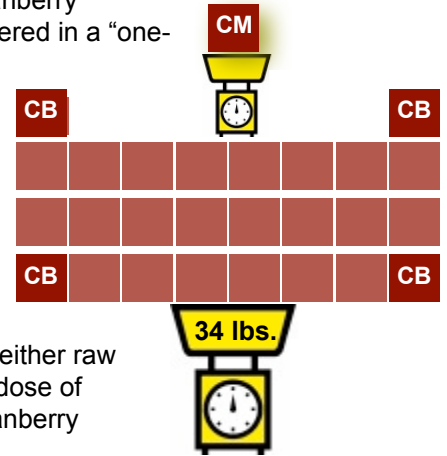


The Benefits of Cranberry Magnified:

Cran-Max is a highly concentrated herbal supplement. A high multiple of whole fresh cranberries are required to produce finished product for sale. It takes 34 pounds of raw cranberry material to produce a single pound of Cran-Max® natural cranberry. While most other cranberry products on the market require a daily “multi-dose” regimen, Cran-Max is delivered in a “one-per-day” dose.

It's highly concentrated content is significant when addressing the issue of quality. The natural synergistic elements of cranberry are untampered and condensed in Cran-Max resulting in a highly active and magnified dosage making it extremely convenient for the consumer to use and reap its benefits.

Testing has shown that its highly concentrated character makes it appealing to those who want the benefits of cranberry without the excessive ingestion of either raw fruit or juice. A recent study has shown that the anthocyanin content in a daily dose of Cran-Max (500/mg) is equivalent to 7 eight-ounce glasses of Ocean Spray Cranberry Juice Cocktail.

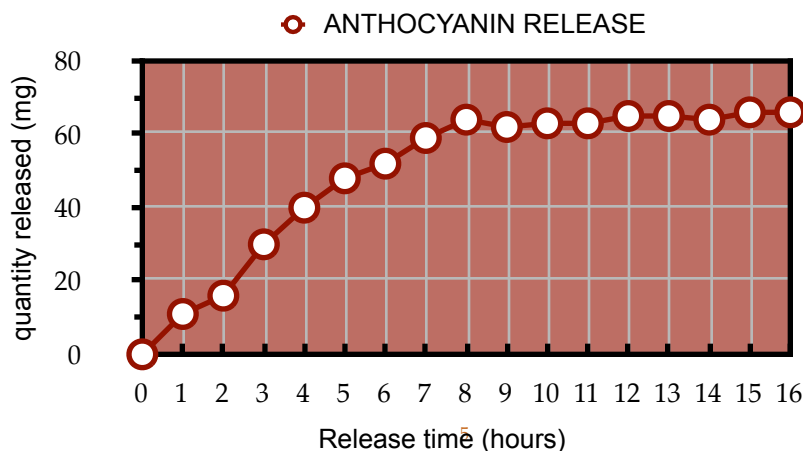


Nothing wasted. Everything Gained:

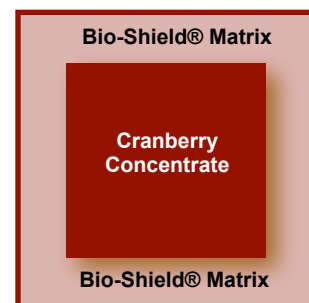
The efficacy of any nutraceutical remedy is dependent on its ability to survive the intrinsic acidic conditions of the GI tract. It's common for the innate goodness inherent in any natural medicine to be neutralized during this process and its potential health related benefits lost.

Cran-Max contains Bio-Shield® Technology which serves to “protect” the active healing elements found in cranberry, allowing them free and unhindered passage through the digestive tract to specific target receptor sites throughout the body. Bio-Shield is analogous to a protective vehicle, enveloping and safeguarding its important cargo within an impenetrable casing, delivering its payload intact and with optimum efficacy to its final site of action. Cran-Max® uses the patented Bio-Shield system to deliver its bioactives through the digestive tract’s acidic medium without deterioration.

Cran-Max is prepared as part of this unique, manufacturing process where “the whole fruit and nothing but the fruit”, (solids, seeds, skins and concentrated juices) are first highly concentrated, leaving the fruit’s natural and synergistic elements intact, then infused into the patented Bio-Shield carrier where these actives (anthocyanins) are escorted through the stomach acids to the lower intestines where they are released in controlled fashion, absorbed by the body over a 12-16 hour time period.



More specifically, the key benefit of Bio-Shield technology is to maintain the integrity of the anthocyanin to glucose bond which allows anthocyanins to be passed into the lower gastrointestinal tract intact and readily absorbed into the body from a non-acidic aqueous medium. It's the role of the Bio-Shield "envelope", comprised of natural plant fibers, derivatives of the natural fruit itself, that is credited with this activity. The genius of Bio-Shield and what makes Cran-Max truly unique is that nothing is wasted and everything gained in the process. Nothing is ever introduced into the manufacturing process that interferes with the intrinsic natural value or goodness of what nature has intended. Given the guarantee of a high concentration of fruit actives coupled with Bio-Shield protection, consumers are assured an optimum delivery of the nutritional benefits related to the cranberry fruit, even greater than ingesting such foods in their raw form.



Clinical Affirmation of Branded Cranberry:

The developers of Cran-Max have made strong efforts to clinically affirm their product. Several studies have been conducted and others are underway to prove product efficacy. An overview of these studies follow:

Results of Completed Cran-Max Studies*:

- Results of a randomized, double-blind study on the prevention of recurrent cystitis with GynDelta. Dr Jean-Marc BOHBOT.
- A randomized trial to evaluate effectiveness and cost effectiveness of naturopathic cranberry products as prophylaxis against urinary tract infection in women. L. Strothers. June 2002. Can J Urol 2002 June: 9(3): 1558-62.
- The Effect of Prophylactic Administration of Cranberry Extract (Swiss Cran-Max™ 7500mg) on the Occurrence of Recurring Infections on the Urinary Tract. L.Hejzlar, Orology Clinic of PPCHC, SANUS in Hradec Kralove: J. Poduska, Urology Clinic of UNV, Prague.
- Initial Pilot Study. Jan Poduska, MD, Department of Urology, Central Military Hospital, Prague, Czech Republic, 1999.
- Dr. Ronald Wheeler Cran-Max Study. Outcome Study, Dr. Ronald Wheeler.

Preliminary Results and Abstracts of Cran-Max® Studies Under Way*:

- Preventive Treatment With Cranberry Extract Of Vesico-Ureteral Reflux (VUR) 14 In Children - Preliminary Report. Yosef Binyamini, Yuval Bar-Yosef, Mario Sofer, Haim Matzkin and Yaakov Ben Haim.; Children's Urology Unit, Urologic Department, Tel Aviv Medical Center
- Effectiveness of cranberry extracts as primary prevention of urinary tract 15 infections and evaluation of cost-effectiveness, amongst female soldiers.; Abstract of the trial procedure
- Evaluation of Cran-Max for the Prevention of UTI in Spinal Cord Injured 17 Patients with Neurogenic Bladders. Veteran Affairs, Boston Healthcare System.
- Can Cran-Max® Be Used To Treat Current Urinary Tract Infections. 18 McMaster University. Dr. Anil Kapoor. Treatment of urinary tract infection.

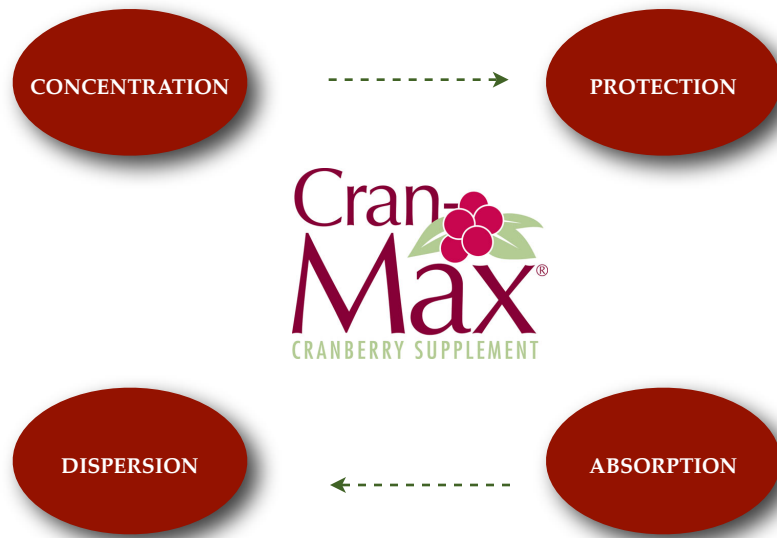
Independent Laboratory Results for BioShield®*:

- Proposed Mechanism of BioShield bound Anthocyanins, Integrated Biomolecule 22 Corporation. Tucson, Arizona
- Controlled Delivery of Components from CranMax-an In vitro Study, 25 Doddabele Madhavi, Ph.D,
- BioActives, Inc., Worcester, MA

****Clinical Study abstracts available upon request***

This White Paper has been written to provide an overview of the cranberry category, and highlights Cran-Max as one of its unique entries. It seeks to shine light on the importance of cranberry within a rapidly growing herbal marketplace, and to make a case for Cran-Max as a solution to a problem as old as the supplement industry itself: product consistency, quality and efficacy. The question all nutraceutical manufacturers are responsible to answer is whether their products are safe and efficacious and whether there is sufficient clinical evidence to confirm these claims.

In summation, the development of Cran-Max parallels important trends unfolding within the nutraceutical industry, and has come into existence due to a strong desire on the part of its developers to elevate cranberry to a higher level within the world of nutraceuticals. Cran-Max delivers the essential elements of cranberry in a natural, consistent and untampered fashion to consumers at large.



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