

Dr. S. K. Dash

President & Director of Innovations
DD Innovations, Inc. (USA)

Chairman & Founder
UAS Laboratories, Inc (USA)

INNOVATIONS, INC.

Any statements and/or claims made in this presentation have not been reviewed or approved by FDA.

About Dr. Dash

- **Ph.D. (Nutrition & Biochemistry), 1973**

  South Dakota State University, Brookings

- **MS (Nutrition), 1970**

  South Dakota State University, Brookings

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About Dr. Dash

- Former **Director of Food and Drugs**

  South Dakota State (USA)

- **Chairman National Probiotic Committee** (USA)

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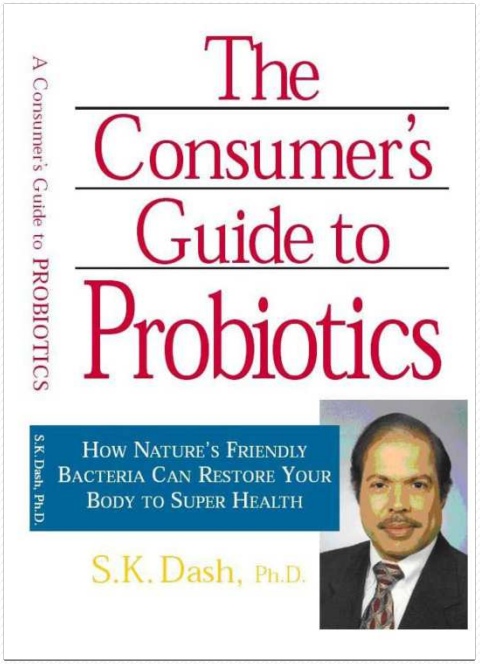
About Dr. Dash

- **Served as Scientific Advisor & Vice-President** of International Probiotics Association
- **Adjunct Professor at**
  - Minnesota State University
  - South Dakota State University

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About Dr. Dash

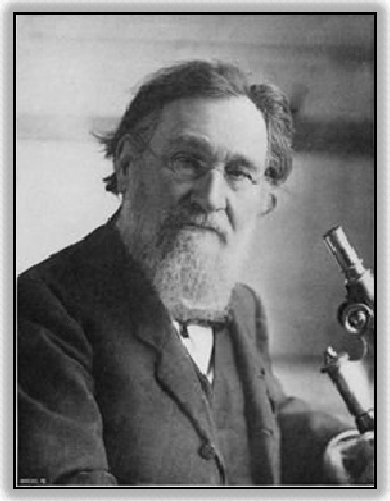
- Author of more than 40 Scientific Articles
- Author of 4 books
- Recipient of various National and International Awards



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History Of Probiotics

- Probiotics are not new. Probiotics have been used for a long time
- The probiotic concept was postulated in early 20th century by Russian Scientist Eli Metchnikoff (Nobel Prize, 1908)



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Probiotics as a Drug

While working as the Director of Food and Drug at South Dakota during 1973 to 1979, Dr. Dash found a probiotic product was licensed by the US Government (USDA) as a drug to treat *E. coli* infection (scour) in pigs.

Probiotics effective against infections

- Further research by Dr. S. K. Dash revealed that probiotics were 97% effective against *E. coli* infection in pigs, a cure rate as effective as the antibiotic, Neomycin Sulfate.

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Probiotic Industry lacked funds

- Antibiotic industry had resources for research and marketing and prevailed.
- Probiotic industry lacked funds to compete with antibiotics and lost the battle.

Probiotics regain its importance

- Later Dr. S. K. Dash found that people were concerned about drug residues in meat, milk & eggs and antibiotic resistance and other side effects of the drugs.
- Unlike antibiotics, probiotics had no harmful effects.

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Probiotics regain its importance

- People were looking for **nutrition not prescription**
- He also realized that there were no high quality probiotics commercially available at that time

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Continued…

- Dr. Dash rediscovered and reintroduced probiotics in the USA in 1979.
- He left the Food & Drug Director position in 1979 to establish UAS Laboratories in Minneapolis, Minnesota (USA)

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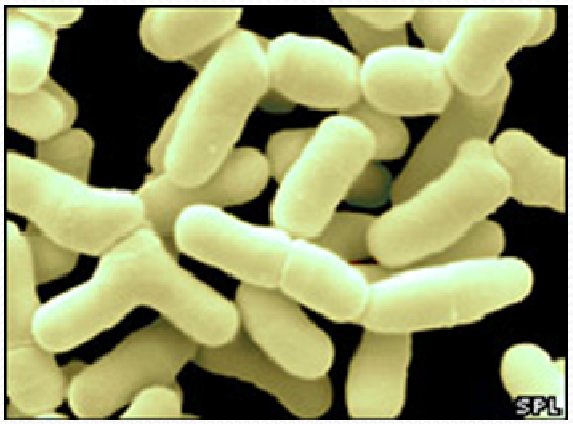
Continue…

- UAS Laboratories has been at the forefront of Probiotic Industry since 1979.
- Dr. Dash commercially manufactured and introduced a strain of *Lactobacillus acidophilus* DDS®-1 which is backed by 40 years of University Research, US patent and trademark.

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Definition of Probiotics

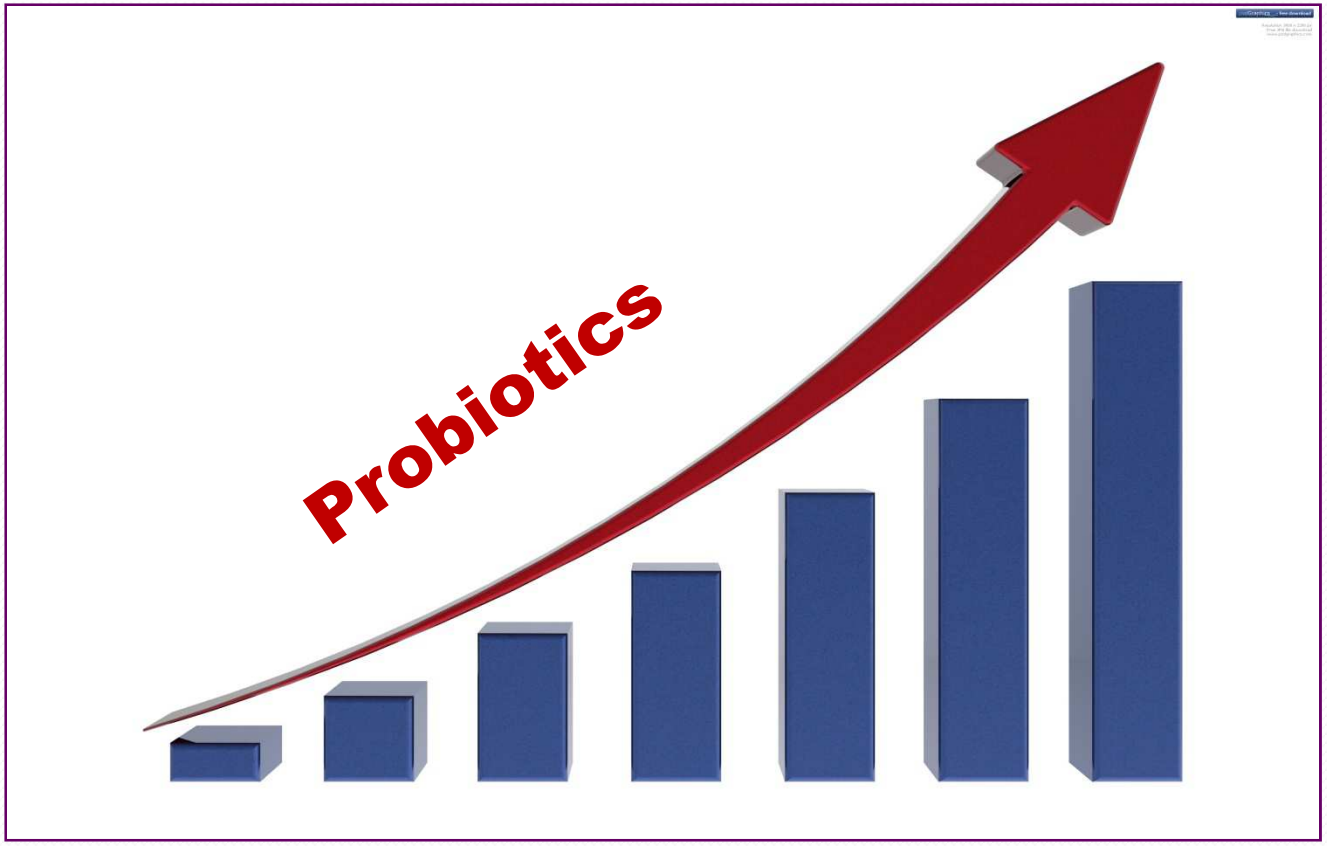
- Probiotics are “Live microorganisms which when administered in adequate amounts confer a health benefit on the host”



FAO/WHO

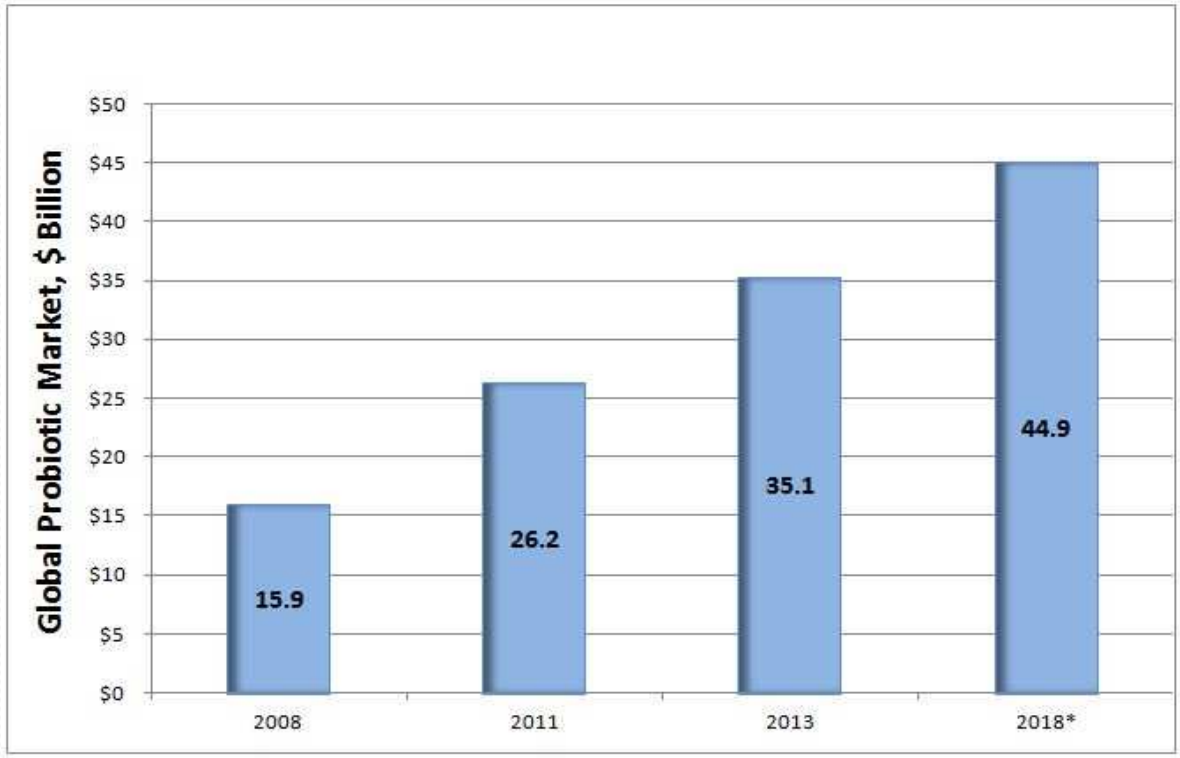
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Probiotics are now top Selling Supplements in the world



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Global Probiotic Market



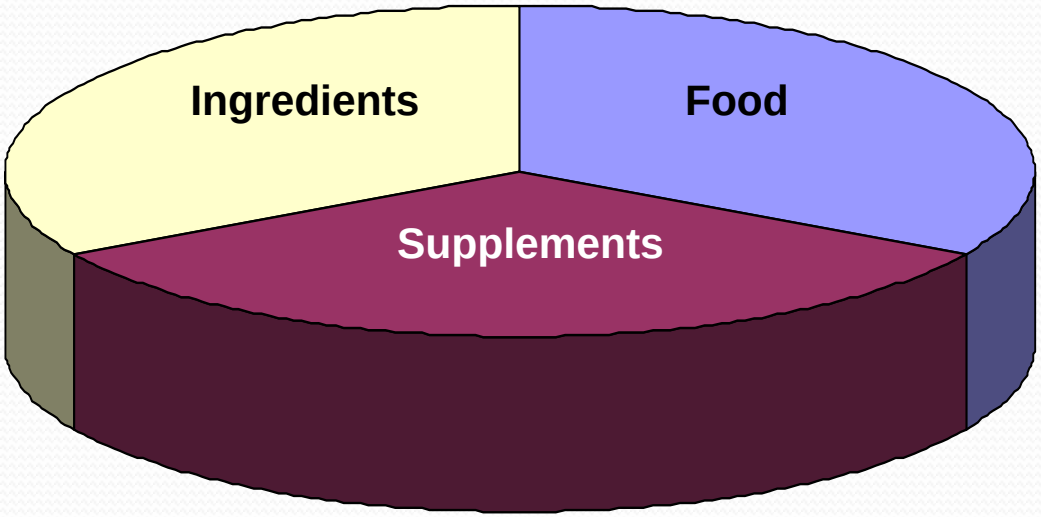
* Expected forecast

Source: Transparency Market Research titled “Probiotics Market (Dietary Supplements, Animal Feed, Foods & Beverages) - Global Industry Analysis, Market Size, Share, Trends, Analysis, Growth and Forecast, 2012 – 2018.

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Probiotics and Major Market Segments

There are major three market segments of probiotics:



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Probiotics and Major Market Segments

- **Food**
  - Yogurt products accounted for the largest share of sales, representing 36.6 %

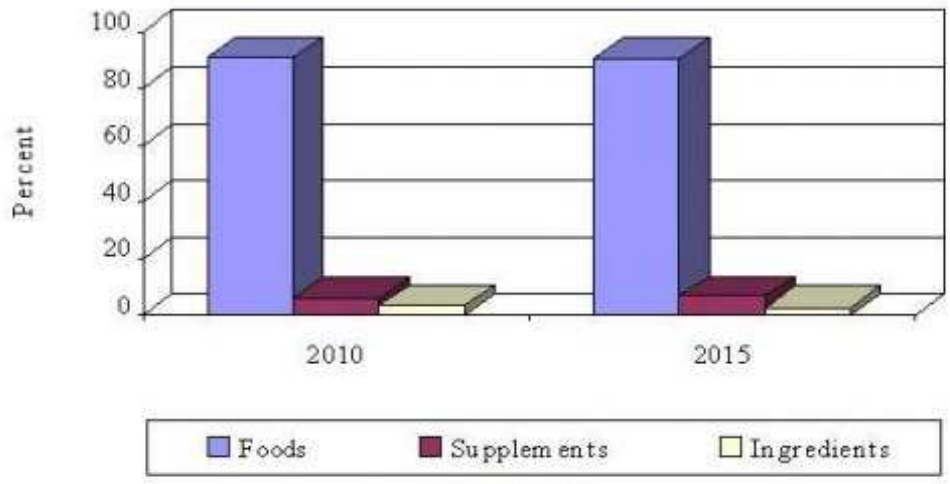
- **Probiotic Supplement**
  - US supplements' segment is the largest segment in the world
  - Probiotics are sold as dietary supplements. Now we have two additional categories: **Medical Foods and Drugs**

- **Probiotic Ingredients**
  - *Lactobacillus* genus account for the largest share representing 61.9%

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Global Probiotic Market by Segment

SUMMARY FIGURE
PROJECTED SHARES OF GLOBAL SALES OF PROBIOTIC INGREDIENTS, SUPPLEMENTS, AND FOODS, 2010 AND 2015
(%)



LEGEND

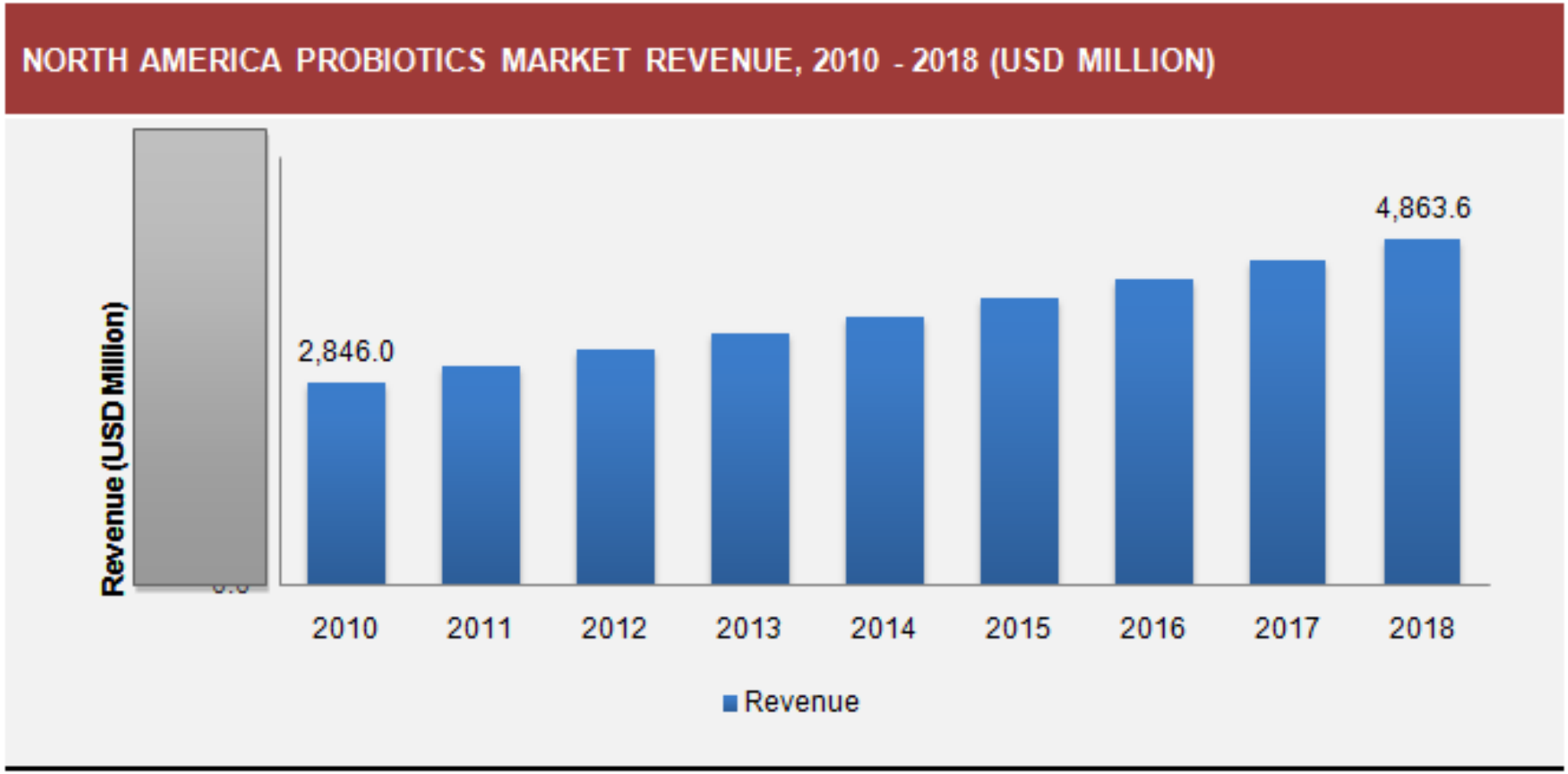
Probiotics	2010	2015
Foods	90.7	90.3
Supplements	6.1	6.7
Ingredients	3.2	3.0
Total	100.0	100.0

Source: BCC Research: The Probiotics Market: Ingredients, Supplements, Foods, June 2012

*** Expected forecast**

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North American Probiotic Market



Source Transparency Market Research

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Why Probiotic Market is growing?

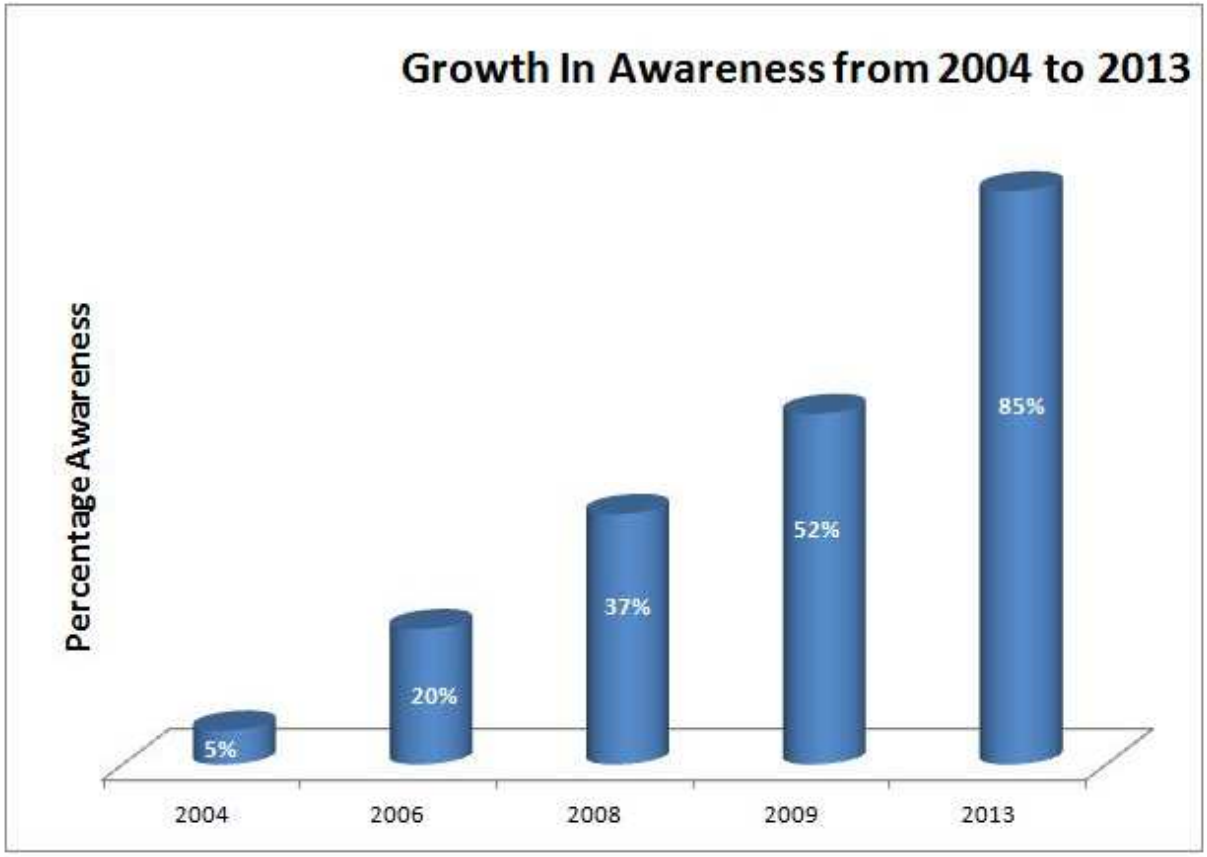
Major drivers for market growth



- Increasing consumer awareness
- Rising healthcare costs
- Specific health benefits
- Consumer interest towards preventive healthcare
- Increasing population of baby boomers

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Increased Awareness of Probiotics



- **Less than 10% Consumers knew Probiotics 10 years ago**
- **Now more than 85% Consumers know and most use probiotics**
- **Source: Food product design.com**

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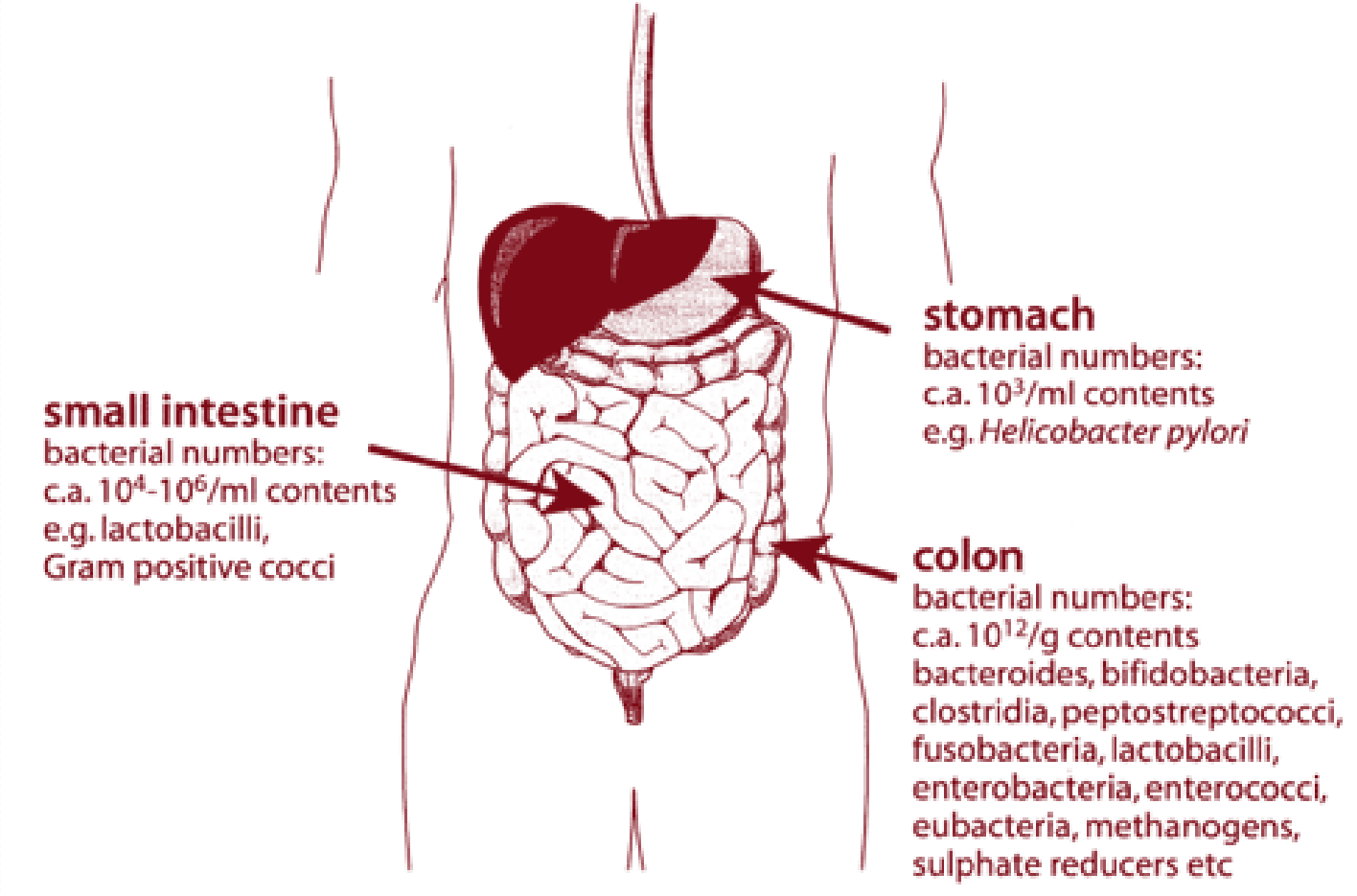
The name Probiotics doesn't mean anything unless it is

- Strain Specific 
- Dose Specific 
- Condition Specific 
- GRAS* 

* Generally Recognized As Safe

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Human GI Tract showing approximate bacterial numbers

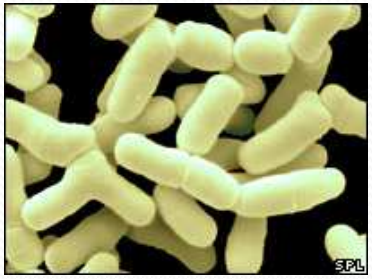


Types of Probiotic Strains

- *Lactobacillus acidophilus*
- *Lactobacillus bulgaricus*
- *Lactobacillus casei*
- *Lactobacillus paracasei*
- *Lactobacillus plantarum*
- *Lactobacillus lactis*
- *Bifidobacterium longum*
- *Bifidobacterium infantis*
- *Bifidobacterium bifidum*
- *Streptococcus thermophilus*
- *Saccharomyces boulardii*
- *and others*



Lactobacilli



Bifidobacteria

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Lactobacillus acidophilus

- Safe (GRAS) and effective
- Boosts immune function
- Aids digestion
- Produce natural antibiotics to inhibit pathogens
- Colonizes in the small intestine

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Bifidobacterium bifidum

Bifidobacterium lactis

Bifidobacterium longum

- Colonize in the large intestine
- Modulates immune system
- Safe (GRAS)

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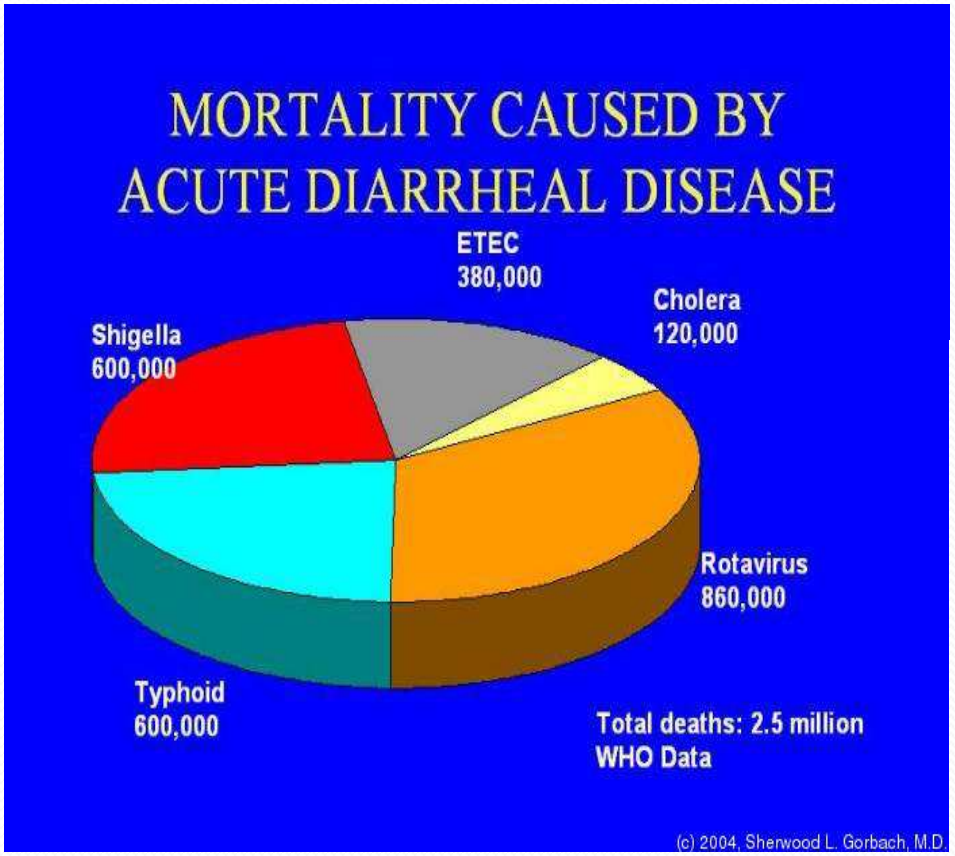
Fructooligosaccharides (FOS)

- Indigestible carbohydrate which feeds beneficial bacteria
- Promotes, stabilizes and enhances the proliferation of beneficial bacteria
- Called “Synbiotics” when mixed with probiotics

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Medical Conditions Helped by Probiotics – Diarrhea

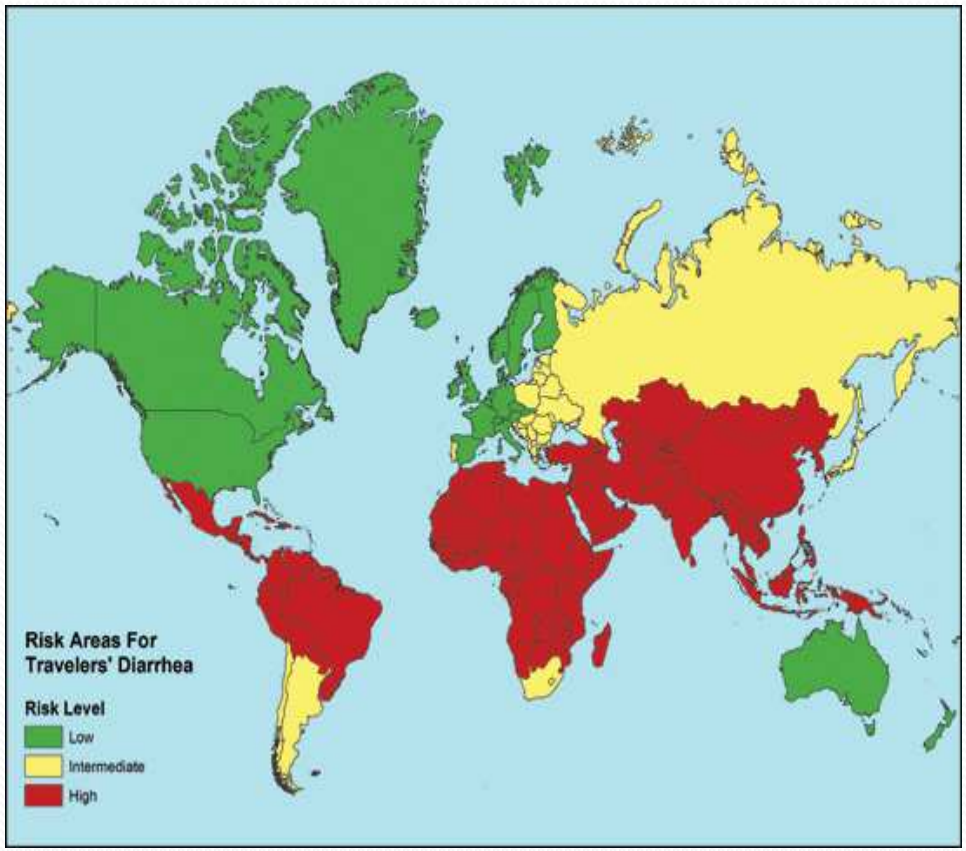
- #1 cause of sickness and death worldwide
- Diarrheal disease - #3 cause of sickness and death in US
- Dysbiosis costs $107 billion/yr in direct health care costs
- 200 million sick days, 50 million ambulatory visits
- 16.9 lost school days, 10 million hospitalizations



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Medical Conditions Helped by Probiotics – Diarrhea (cont.)

- Nearly 200,000 deaths per year, Diarrhea costs $4.7 billion per year
- Traveler's Diarrhea affects 30%-50% of 30 million U.S. travelers
- 80% of cases due to infectious agents



Source: USAF Public Health Info and Research

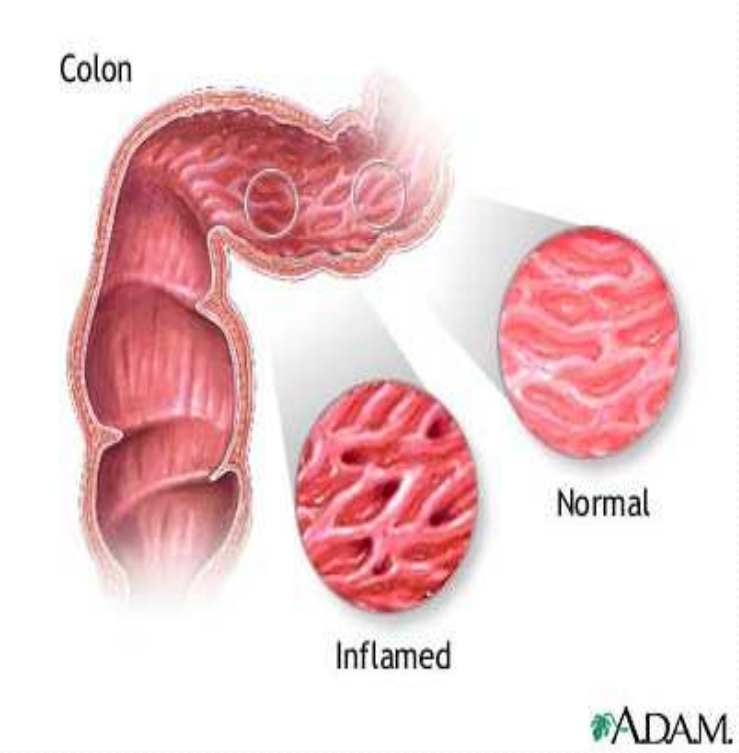
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Inflammatory Bowel Diseases

- 1.4 million people in U.S. and 2.2 million in Europe

- Crohn's Disease $1.3 billion in annual healthcare costs

- Ulcerative colitis: $868 million in annual healthcare costs



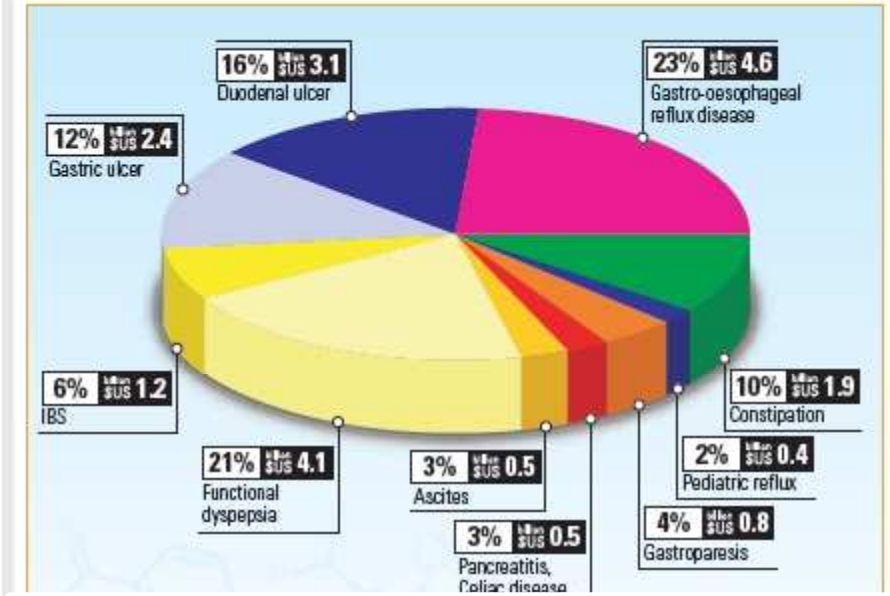
- Source: NIH - NIDDK

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Digestive Disease

- 22 Million acute digestive conditions/year
- Chronic Constipation – 6.3 million visits in 2004
- Peptic Ulcer – $3.1 billion
- Colorectal cancer - $9.5 billion

•Source: NIH - NIDDK



Global Incidence of GI market IMS Health Data 2006

***old data**

Breakdown of the global GI market based on ICD9 coding of sales figures
Movetis model based on IMS Health data (Q2 2006)

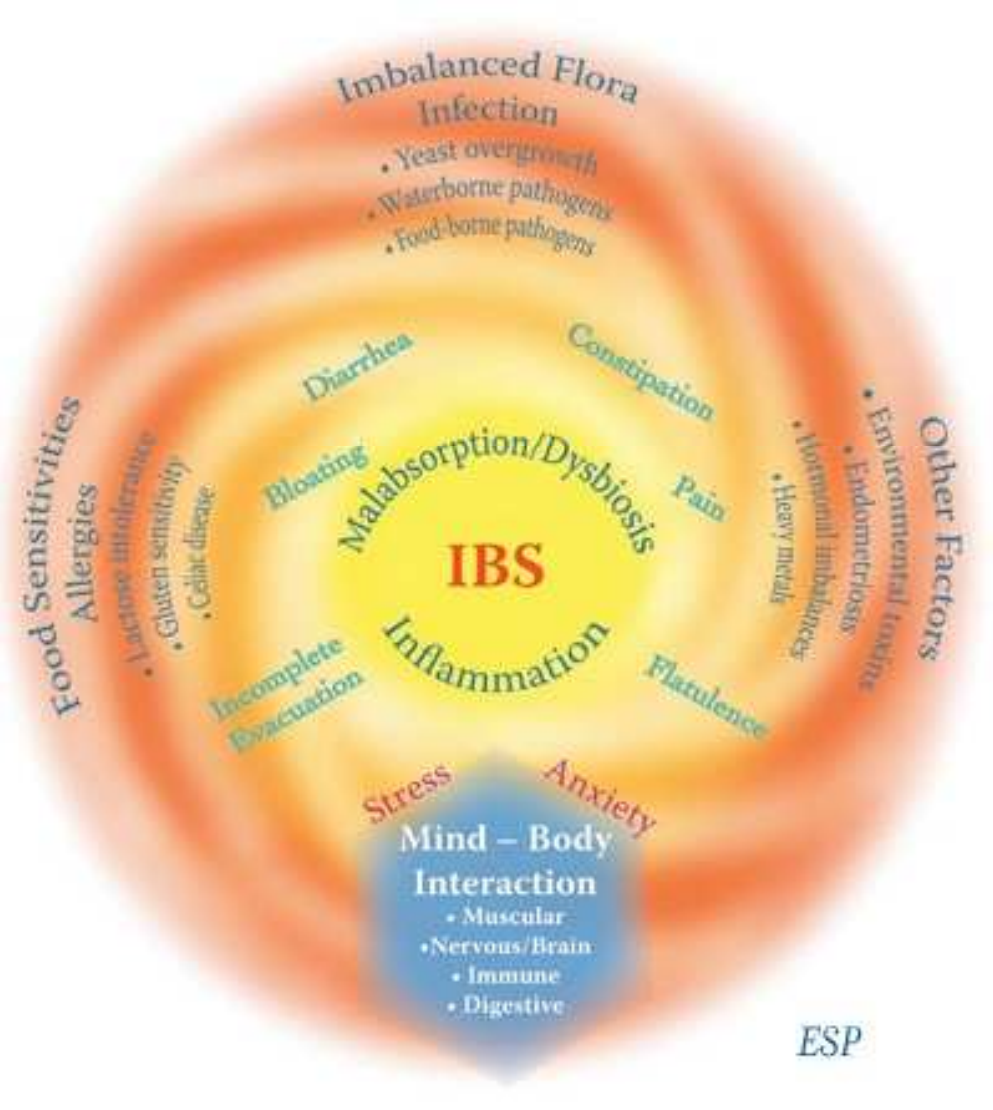
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IBS

- 3 million hospital visits per year
- $1 billion in total costs

- Possible actions of probiotics
  - Adherence prevents pathogens
  - Enhanced barrier function
  - Secretion of bacteriocins
  - Acidification of colon
  - Immune modulation
  - Altered mucosal response to stress
  - Inhibition of hypersensitivity

- Statistics source: NIH NIDDK



Probiotics for Other Digestive Tract Conditions

- Gingivitis and Thrush
- Halitosis (Bad Breath)
- Tooth Decay
- Canker Sores
- Colic
- Food Allergies
- Pancreatitis (acute)
- Malabsorption

Probiotics for Non-digestive conditions

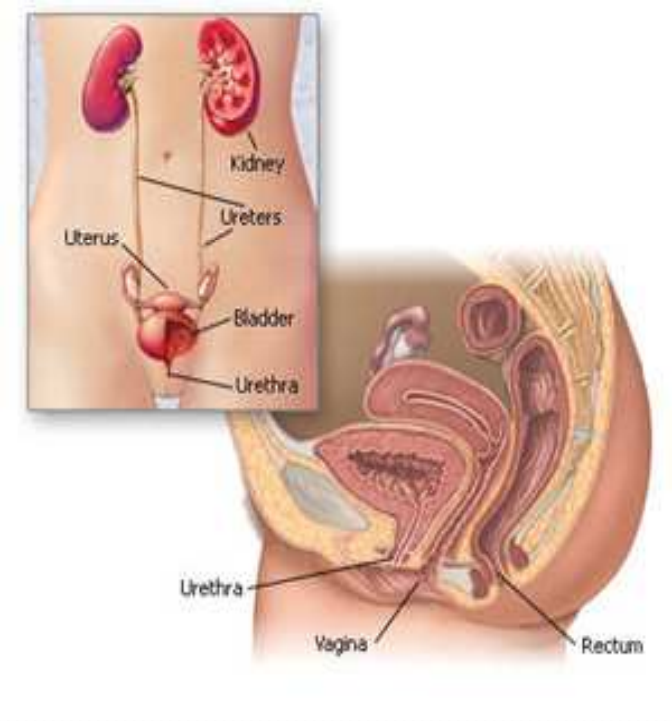
- Candida Yeast Infections
- Autism
- Chronic Fatigue Syndrome
- Urinary Tract Infections
- Elevated Cholesterol and Blood Lipids
- Allergies
- Damage from Smoking
- Cancer Prevention
- Toxic Shock Syndrome
- HIV Support
- Eczema
- Acne
- Infections and Immune Function

Probiotics and Cancer

- Lung, breast and prostate cancers are the most common
- The next most likely is colon cancer (95,000/yr and rising) and rectal cancer (35,000/yr and rising)
- Functional foods are an exciting hope for prevention and cure
- Faecal bacterial enzyme activity is linked to cancer incidence
- *L. acidophilus* and *Bifidobacterium* have shown positive anti-cancer effects.

Probiotics and UTIs

- Over 300 million cases
- Most common cause – fecal bacteria
- Most common treatment – antibiotics
- Natural biofilms
  - Antibiotics and spermicides alter microflora
  - Lactobacilli inhibit many fecal organisms
  - Production of hydrogen peroxide

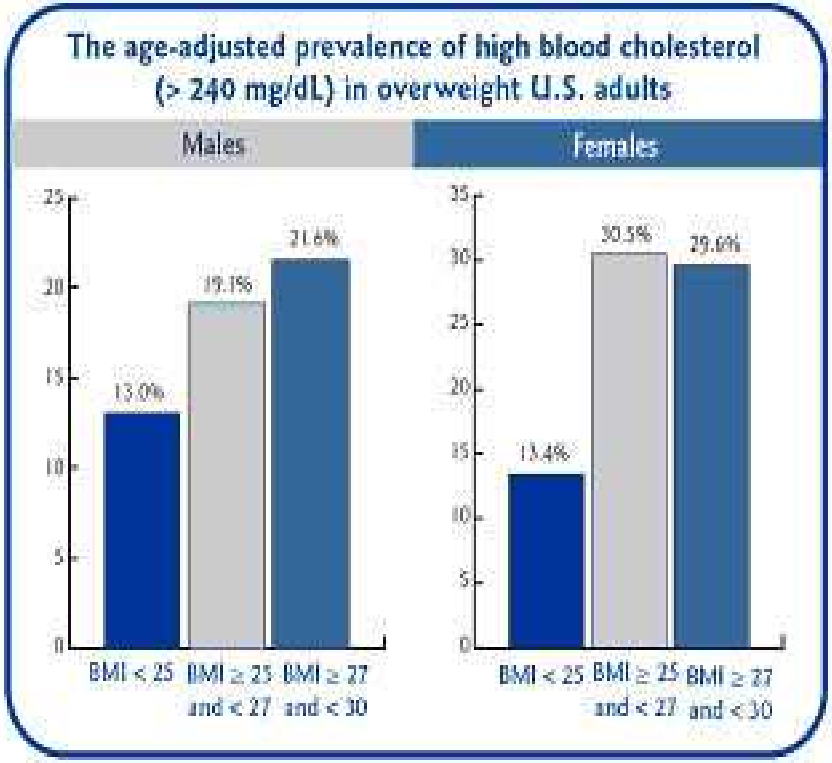


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Probiotics and Cholesterol

- British Journal of Nutrition finds *L. acidophilus* reduces cholesterol absorption

- Annals of Nutrition and Metabolism found that *L. acidophilus* and *B. lactis* had cholesterol lowering effects in hypercholesterolemic subjects.



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Role of L. acidophilus DDS-1 in various Health Conditions

Antibacterial Action

L. acidophilus DDS®-1 produced an antibacterial compound 'acidophilin' that demonstrates activity against

- *Bacillus subtilis*
- *Clostridium perfringens*
- *Proteus mirabilis*
- *Salmonella typhimurium*
- *Staphylococcus faecalis*
- *Clostridium botulinum*
- *E. coli*
- *Salmonella enteritidis*
- *Staphylococcus aureus*
- and others

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Antibacterial Studies

- *L. acidophilus DDS®-1* inhibits growth and adhesion of pathogens at vaginal and urethral mucosa.
- Shows positive effects in the prevention of urinary tract infection.

Ref:

- *Tramer J. Inhibitory effect of L.acidophilus. Nature 1966;211:204-5.*
- *Gerasimov SV. Probiotic prophylaxis in pediatric recurrent urinary tract infection. Clin Pediatr 2004;43:95-8*

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Effect on *Candida albicans*

- *L. acidophilus DDS*®-1 produces hydrogen peroxide that helps in the **inhibition of *Candida albicans***

Ref:

- *Senhert KW. Effect of DDS-acidophilus, A case study. 1989*
- *Attaie R, Whalen PJ, Shahani KM, Amer MA Inhibition of growth of S. aureus during production of acidophilus yogurt. J Food Protect 1987;50:224-8*

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Anti allergic Studies

- *L. acidophilus DDS®-1* was demonstrated to be effective in controlling **atopic dermatitis** in preschool children, improving child`s and family quality of life, and reducing use of corticosteroid medications.

Ref:

Perdigon, G., de Macias, M.E., Alvarez, S., Oliver, G., and A.P. de Ruiz Holdago. 1988. Systemic augmentation of the immune response in mice by feeding fermented milks with Lactobacillus casei and Lactobacillus acidophilus DDS-1. Immunology. 63: 17-23.

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Diarrheal Illness Studies

- *L.acidophilus DDS®-1*, in combination with *Lactobacillus casei*, significantly reduced diarrheal duration and vomiting in children, aged 6-24 months, suffering from **persistent diarrhea**

Ref:

Gaon, D., Garcia, H., Winter, L., Rodriguez, N., Quintas, R., Gonzalez, S.N., and G. Oliver. 2003. Effect of Lactobacillus strains and Saccharomyces boulardii on persistent diarrhea in children. Medicina (B Aires). 63: 293-299.

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Diarrheal Illness Studies

- *L. acidophilus DDS*®-1 provided substantial protection against **traveler's diarrhea**

Ref:

Senhert KW. Effect of DDS-acidophilus, A case study. 1989

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Cholesterol Lowering Studies

- *L. acidophilus DDS®-1* demonstrated **cholesterol lowering effects** in a rat model.
- Relative to control milk, milk fortified with 4 million *L. acidophilus DDS®-1* cells per milliliter achieved significant reduction in cholesterol levels of the animals

Ref:

Sinha DK. Development of unfermented acidophilus milk and its properties. Ph.D. thesis, University of Nebraska, Lincoln, 1978

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Anti Carcinogenic Studies

- *L. acidophilus DDS®-1* stimulated the production of immune components (interleukin-1α and tumor necrosis factor-α) that are known killers or inhibitors of tumor cells.

- *L. acidophilus DDS®-1* performed this function better than three other strains of *L. acidophilus* or *Bifidobacterium bifidum*.

Ref:

- *Lee H, Rangavajhyala N, Grandjean C, Shahani KM. Anticarcinogenic effect of Lactobacillus acidophilus on N-nitrosobis (2-oxopropyl) amine induced colon tumor in rats. J Appl Nutr 1996;48:59-66.*
- *Rangavajhyala N, Shahani KM, Sridevi G, Srikumaran S. Nonlipopolysaccharide components of lactobacillus acidophilus stimulate the production in interleukin-1 alpha and tumor necrosis factor-alpha by murine macrophages. Nutr Cancer 1997;28:130-4*

Immune Health Studies

- *L. acidophilus DDS®-1,* fed via a fermented milk product, was demonstrated to increase phagocytic and lymphocytic activity, in mice

Ref:

Perdigon, G., de Macias, M.E., Alvarez, S., Oliver, G., and A.P. de Ruiz Holdago. 1988. Systemic augmentation of the immune response in mice by feeding fermented milks with Lactobacillus casei and Lactobacillus acidophilus DDS-1. Immunology. 63: 17-23

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Other indications where Probiotics are used

- Antibiotic associated Diarrhea
- Rotavirus Diarrhea
- Indigestion
- Constipation
- Inflammatory Bowel Syndrome

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Other indications where Probiotics are used

- Irritable Bowel Syndrome
- Peptic and Duodenal Ulcer
- Urinary Tract Infections (UTIs)
- Bacterial Vaginosis
- Lactose Intolerance

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World class
Manufacturing facilities



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Doctors prefer to have Probiotic Formulations which:

1. Contain Super strain DDS®-1 *L. acidophilus,* or such other proven Probiotic strains
2. Non Dairy, Gluten free, Wheat free, Corn free, Non GMO
3. High Potency
4. Human Origin, adapts to the human body
5. Acid and Bile resistant (survives stomach acid)

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Doctors prefer to have Probiotic Formulations which:

6. Produces Hydrogen Peroxide, Lactic Acid & Natural antibiotics
7. Fortified with Prebiotics (It is Synbiotic)
8. Stable at room temperature for 2 years
9. Freeze dried and packaged with Nitrogen to improve stability
10. Available in veggie capsules



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Doctors prefer to have Probiotic Formulations which:

11. Helps maintain a Healthy flora
12. Generally Recognized as Safe
13. Backed by University Research, US Patent and Trademark
14. Listed in Physicians' Desk Reference
15. America's Favorite Probiotic Since 1979

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About

UAS™ LABORATORIES

The Probiotic Company

Established since 1979

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UAS LABS
Credentials

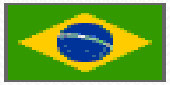
- Probiotic Pioneer since **1979**
- **First** to introduce **QC standard CFU**/gm, now used worldwide
- **First** to introduce **non dairy, gluten free, non GMO probiotics**
- **First** to introduce **nitrogen packaging** to enhance the stability
- **First** to introduce **acid & bile resistant probiotics**
- **First** to introduce the combination of **probiotics with Prebiotics**
- **First** to use University of Wisconsin technology to improve probiotic Stability.

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UAS Labs serves in over 55 Countries

United States 

Australia 

Brazil 

Chile 

Hong Kong 

Israel 

Japan 

Mexico 

Philippines 

Germany 

Kazakhstan 

Singapore 

Taiwan 

United Kingdom 

Austria 

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Finland 

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Baltic Republic 

New Zealand 

Russia 

South Africa 

Trinidad & Tobago 

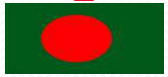
Vietnam 

Malaysia 

Norway 

Spain 

Republic of Georgia 

Bangladesh 

Uzbekistan 

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What is New in USA

- Establishment of Probiotic Innovation Laboratory
- Establishment of Endowed Probiotic Professor

At South Dakota State University, Brookings, South Dakota (USA)

SDSU

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Rebiotix
Microbiota Restoration Therapy

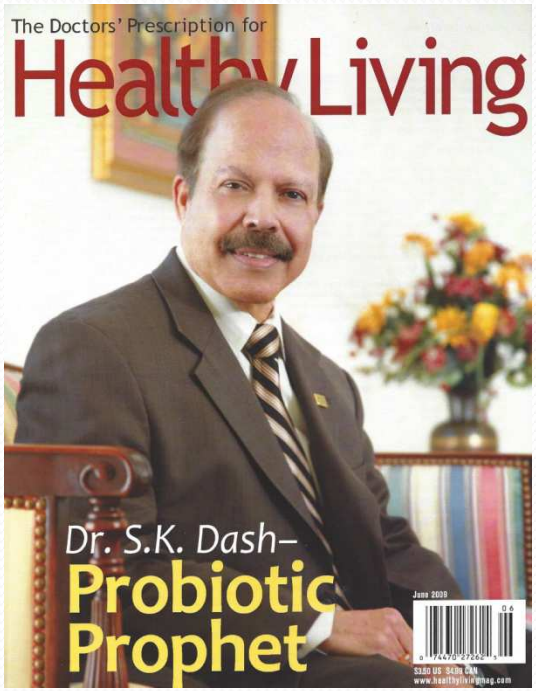


- NDA for Probiotic Drug
- FDA designated their product as Fast Track product for recurrent *C. diff* infection

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Achievements and Awards (2009)

Leading Consumer Magazine – Healthy Living honored Dr. Dash as “Probiotic Prophet”



The June issue of magazine has featured Dr. Dash and his many innovations, research and contribution to the growth of the probiotic sector and Philanthropy.

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Frost & Sullivan Award for Probiotic Innovation



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Honored by Minnesota State Senate for Outstanding Contribution to Probiotics



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Dr. Dash Emphasis

- "***Probiotics are more important than multivitamins and should be taken daily"*** *TM*

  Dr. S.K. Dash

- Since all probiotics are not the same, consumers should look for proven, well researched and documented probiotic supplements like DDS® Probiotics and such others.

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Thank You!

For additional information
please contact
drdash@ddinnovation.com

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