Convergence of Nanotechnology and Cancer Prevention: Are We There Yet?

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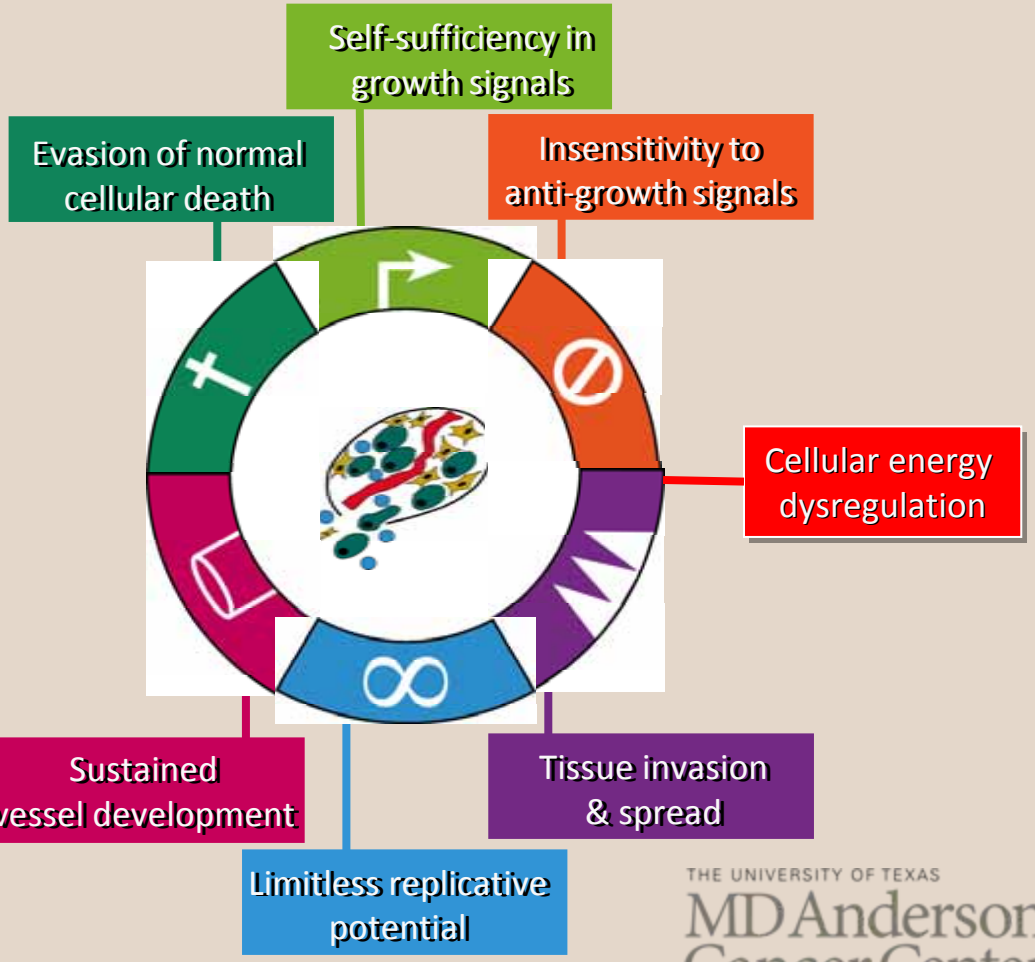
Principle #1 - Cancer Results From An Interplay of Inherited Factors & Exposures That Damage Cardinal Elements of Cellular/Tissue Growth Control & Identity

"Non-modifiable" Risk Factors

- Major defects in cancer-promoting/ inhibiting genes
- Subtle differences in genetic coding or expression

"Modifiable" Risk Factors

- Tobacco
- Poor diet
- Physical inactivity
- Viruses
- Occupational exposures



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Modified from Hanahan & Weinberg, Cell 100:57, 2000; Science 2006

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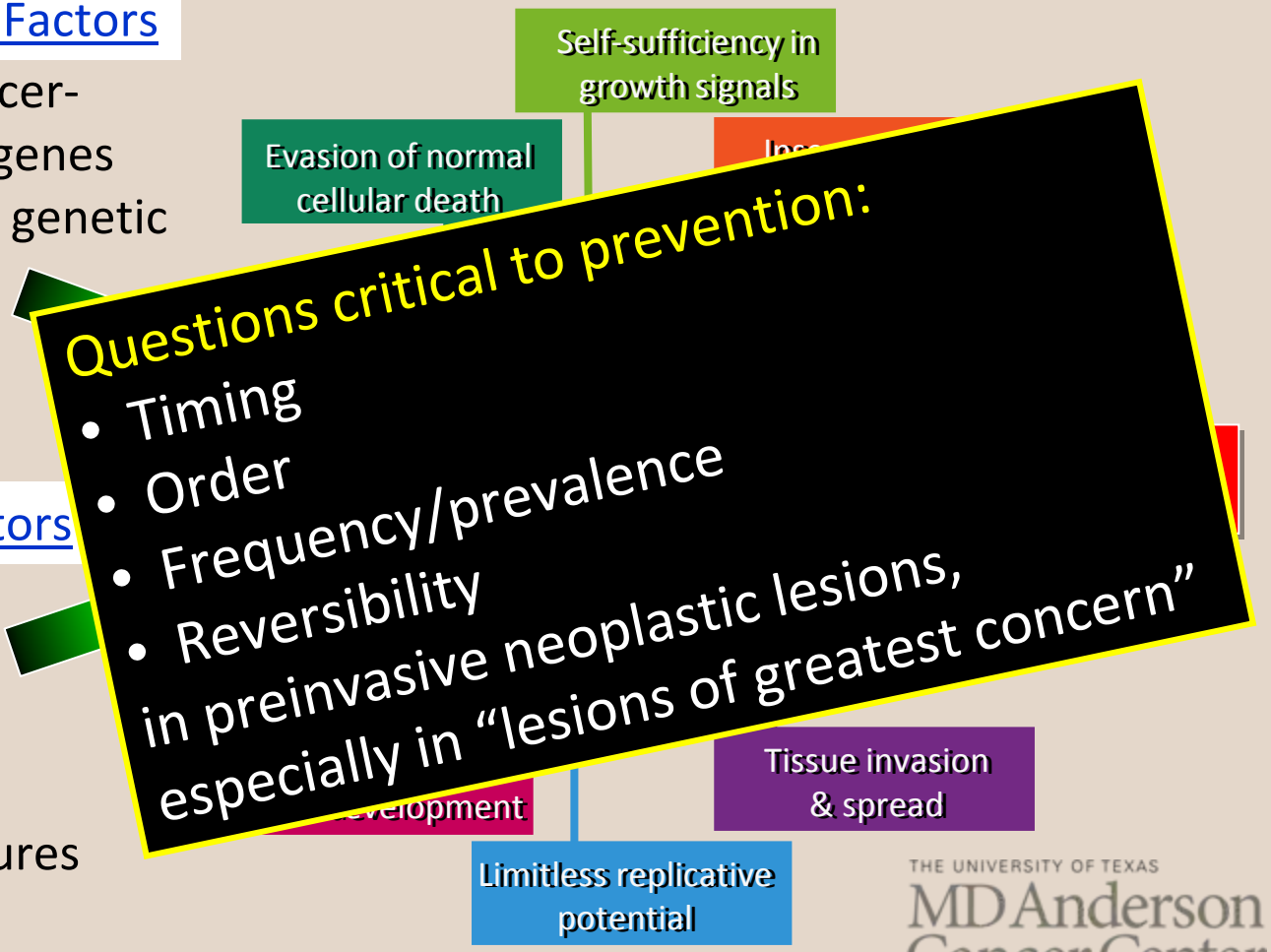

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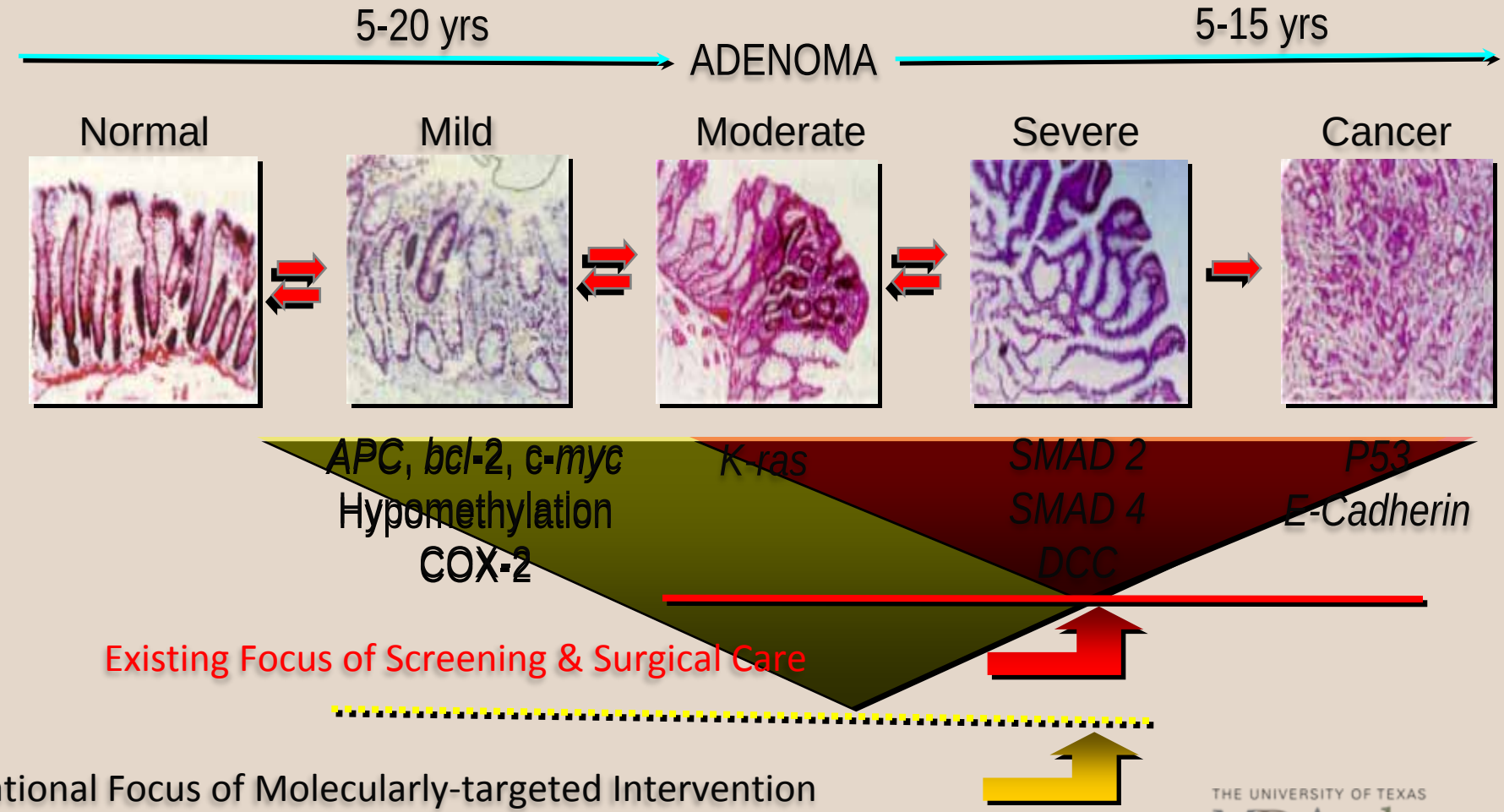
Modified from Hanahan & Weinberg, Cell 100:57, 2000; Science 2006

Principle #2 – Carcinogenesis is a Chronic Disease – From Molecular Defect to Dysplasia to Cancer



Adapted from Ilyas et al. Eur. J. Cancer 1999; 35:335-351

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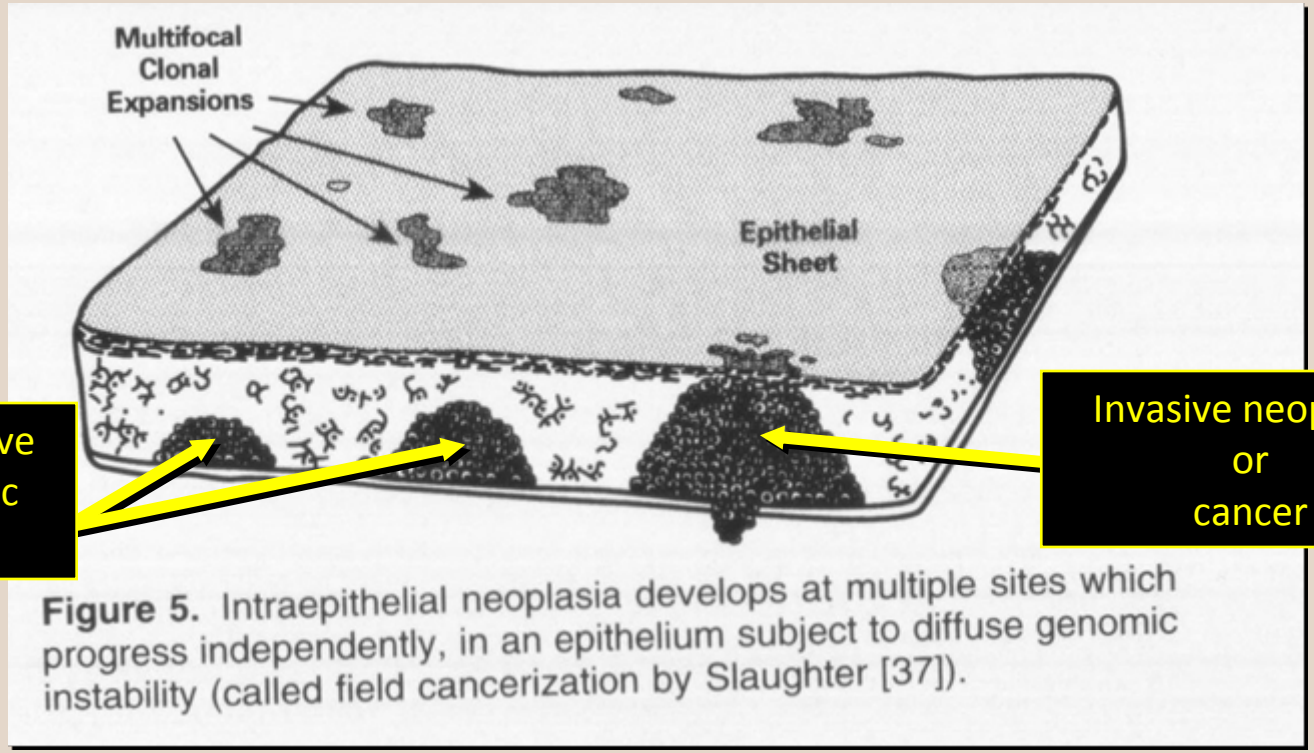
Principle #3 – Carcinogenesis is Typically Polychronotropic in Nature



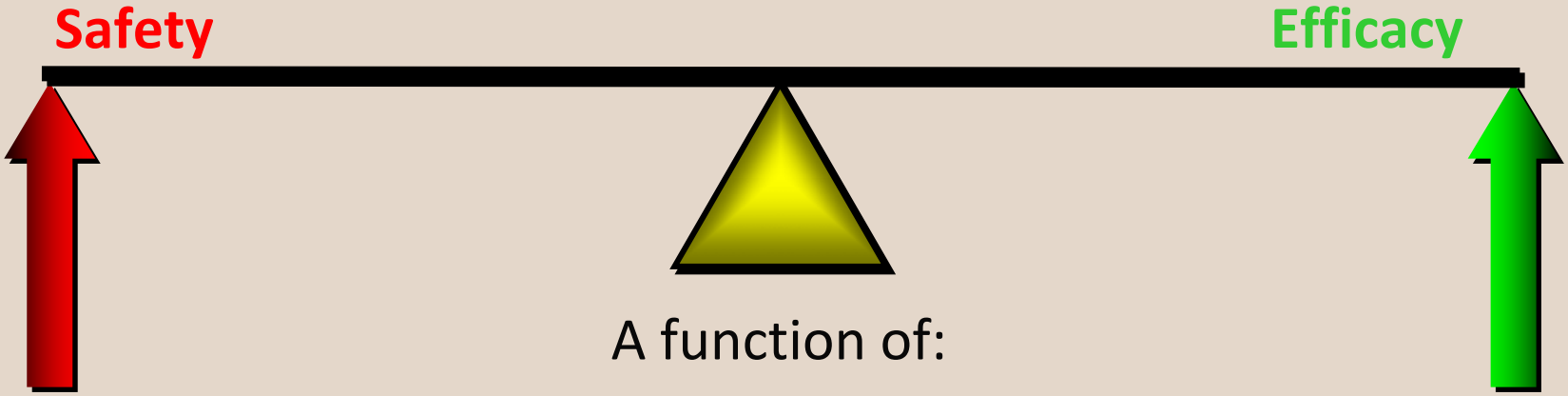
Pre-invasive neoplastic lesions

Invasive neoplasia or cancer

Figure 5. Intraepithelial neoplasia develops at multiple sites which progress independently, in an epithelium subject to diffuse genomic instability (called field cancerization by Slaughter [37]).

Boone et al 1997

Principle #4 - The Therapeutic Index Drives Preventive Applications



A function of:

- Agent's intended & unintended effects
- Individual/cohort's susceptibilities to both the disease and the agent's effects
- Disease of interest

Achieving balance is particularly critical in prevention

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Major Challenges in Cancer Prevention & Control – 2010

Effective Delivery of What Already "Works"

- Increasing diversity – race/ethnicity, geography, SES
- Growing numbers of those "at-risk"
  - Aging
  - Unhealthy lifestyles
  - Screening
  - Cancer survivors
- Limited public understanding of cancer development, risk, and prevention
- Increased coverage/reimbursement for prevention in health care reform legislation

Research & Translation to Improve Insights & Options

- Advances in –omics, biospecimen-based risk assessments & prevention
  - Limited impact to date
  - Flood of biomarkers without clear criteria for validation/clinical application
  - Flood of potential targets for intervention
  - Concerns over risk:benefit balance
- Advances in molecular and clinical imaging
- Paucity of dedicated research & researchers
- Paucity of private investment

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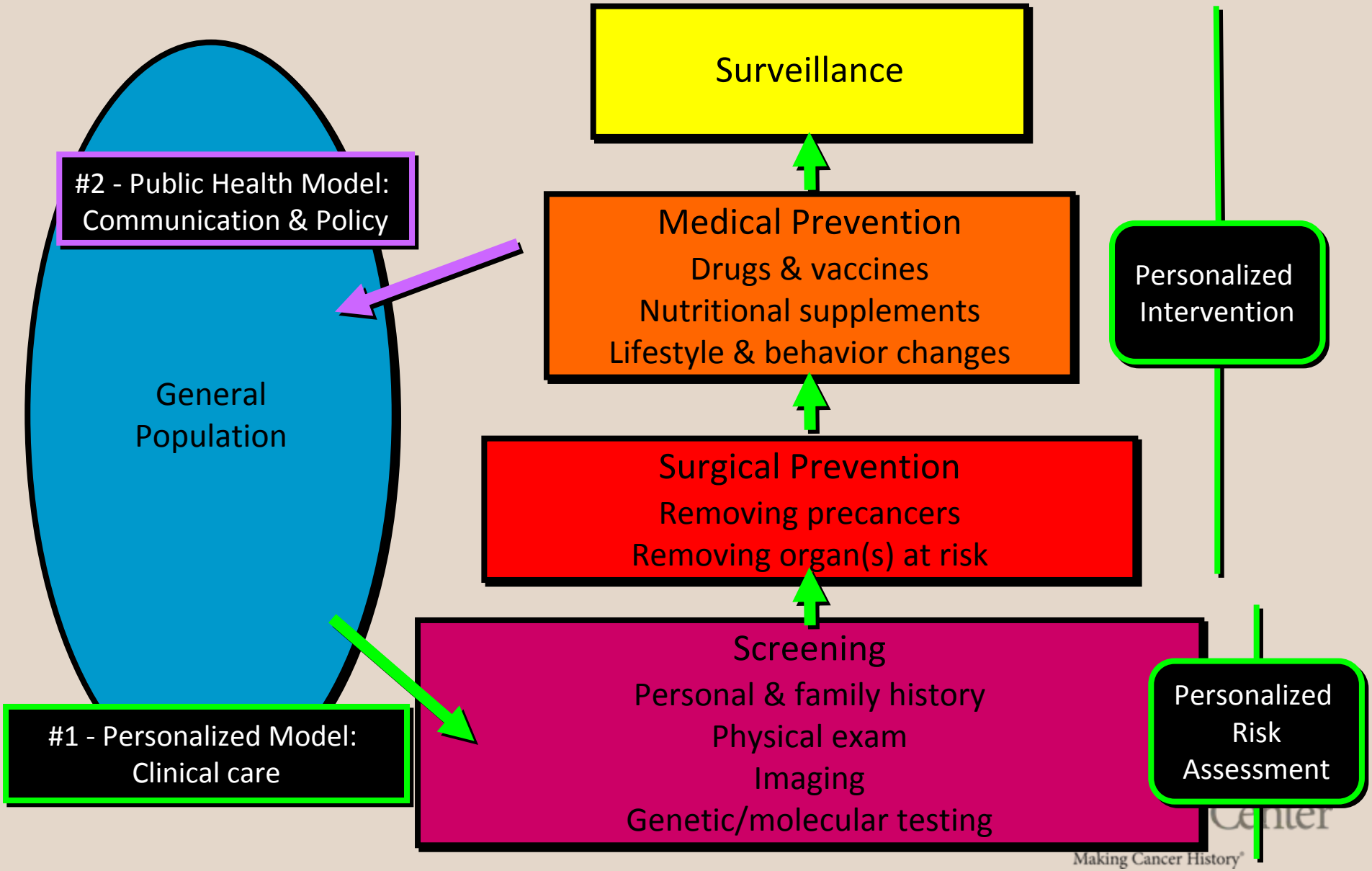
Cancer Prevention Strategies



Approaches to the Development and Marketing Approval of Drugs That Prevent Cancer

Gary J. Kelloff,[1] John R. Johnson, James A. Crowell, Charles W. Boone, Joseph J. DeGeorge, Vernon E. Steele, Menul U. Mehta, Jean W. Temeck, Wendelyn J. Schmidt, Gregory Burke, Peter Greenwald, and Robert J. Temple

National Cancer Institute, Division of Cancer Prevention and Control, Bethesda, Maryland 20892 [G. J. K., J. A. C., C. W. B., V. E. S., P. G.], and the Food and Drug Administration, Center for Drug Evaluation and Research, Rockville, Maryland 20857 [J. R. J., J. J. D. G., M. U. M., J. W. T., W. J. S., G. B., R. J. T.]

The examples given of chemopreventive approaches primarily involve intraepithelial neoplasia (dysplasia) since the majority of human cancers are epithelial in origin. However, in the future, the chemopreventive approach may be applied to dysplasia in mesenchymal tissue as well, such as in premalignant lesions of connective and hematopoietic tissues leading to the sarcomas, leukemias, and lymphomas. It must be emphasized that this is not a regulatory document but rather a summary of consensus views of the participants.

Approved Agents for Treatment of Precancerous Lesions or Cancer Risk Reduction - 2010

Disease	Intervention
Breast cancer	Tamoxifen Raloxifene
Cervical intraepithelial neoplasia & cancer	Human Papillomavirus vaccines
Esophageal dysplasia	Photofrin + PDT*
Colonic adenomas	Celecoxib
Bladder dysplasia	Bacillus Calmet Guerin Valrubicin
Actinic keratosis	Fluorouracil Diclofenac sodium 5-aminolevulinic acid + PDT* Masoprocol

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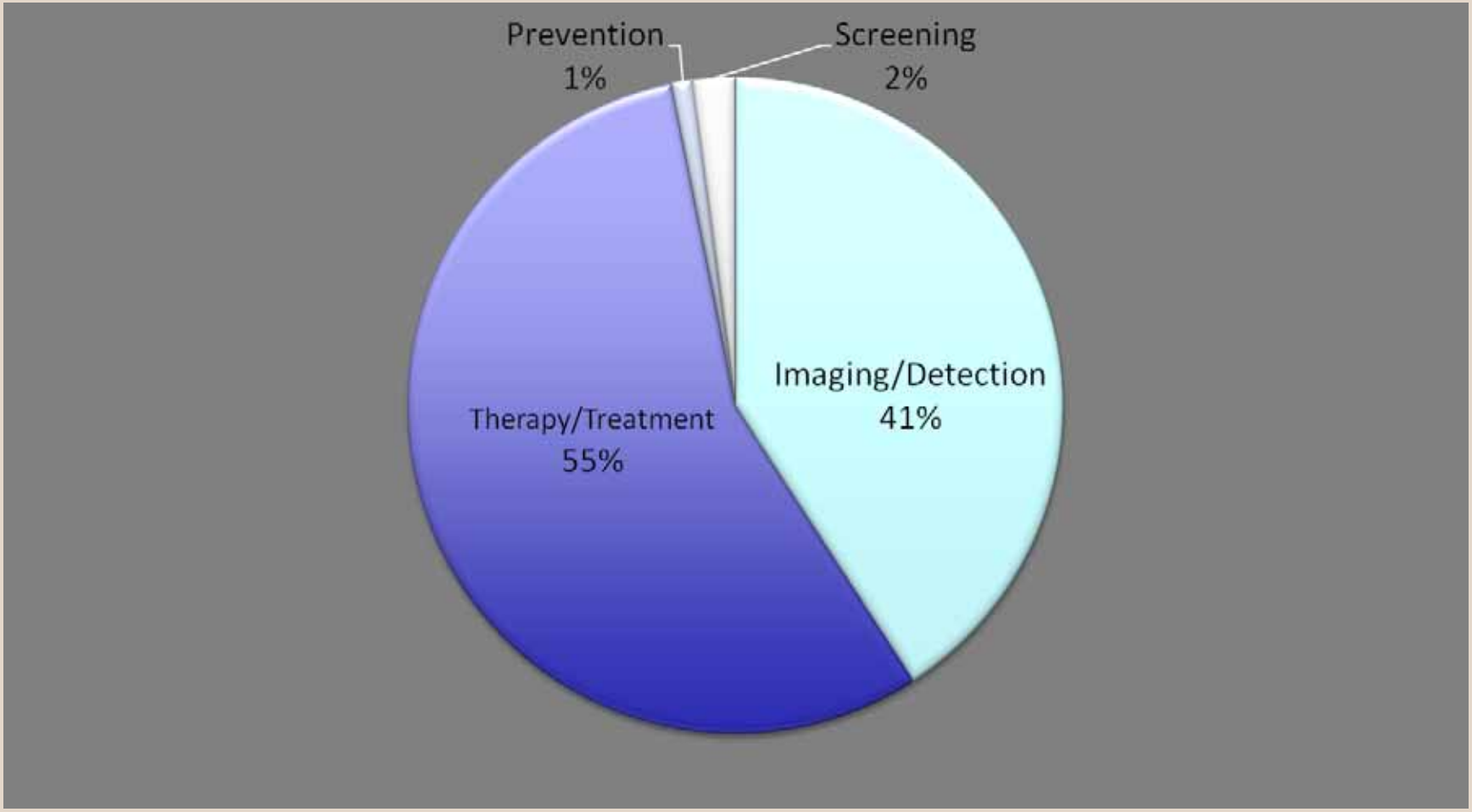
*PDT – Photodynamic therapy

NIH-Funded Cancer Nanotechnology Grants

(n=191)



NIH RePORTER accessed on July 6, 2010; search terms = "nanotechnology" and "cancer". www.http://report.nih.gov

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NIH Portfolio in Nanotechnology Relevant to Cancer Screening & Prevention

Project Number	Project Title	PI	Awardee Organization
PREVENTION			
5U54CA119343-05	CAROLINA CENTER OF CANCER NANOTECHNOLOGY EXCELLENCE	JULIANO, RUDOLPH	UNIVERSITY OF NORTH CAROLINA, CHAPEL HILL
5U54CA119342-05	AN INFORMATICS RESOURCE FOR TARGETED NANOPARTICLE THERAPEUTICS	SEPT, DAVID	WASHINGTON UNIVERSITY
SCREENING			
5R41CA132256-02	ENDOSCOPICALLY-GUIDED OPTICAL COHERENCE TOMOGRAPHY FOR EARLY CANCER SCREENING	IFTIMIA, NICUSOR	PHYSICAL SCIENCES, INC
5R41CA135911-02	ENHANCED CONTRAST FOR SCREENING OF EARLY PANCREATIC CANCER	IFTIMIA, NICUSOR	PHYSICAL SCIENCES, INC
5R01CA119402-05	INTEGRATED SYSTEM FOR CANCER BIOMARKER DETECTION	MANALIS, SCOTT	M.I.T.
5R21EB008520-02	NANODEVICE FOR DIGITAL IMAGING OF PALPABLE STRUCTURE AT HUMAN-FINGER RESOLUTION	SARAF, RAVI	UNIVERSITY OF NEBRASKA, LINCOLN

NIH RePORTER accessed on July 6, 2010; search terms = “nanotechnology” “cancer prevention” and “nanotechnology” “cancer screening’, www. http://report.nih.gov

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Cancer Biomarkers & Screening – Potential for Nanodetection?

nature biotechnology

LETTERS

Integrated barcode chips for rapid, multiplexed analysis of proteins in microliter quantities of blood

Rong Fan[1–3,5], Ophir Vermesh[1–3,5], Alok Srivastava[1,4], Brian K H Yen[1–3], Lidong Qin[1–3], Habib Ahmad[1–3], Gabriel A Kwong[1–3], Chao-Chao Liu[1–3], Juliane Gould[1–3], Leroy Hood[1,4] & James R Heath[1–3]

As the tissue that contains the largest representation of the human proteome[1], blood is the most important fluid for clinical diagnostics[2–4]. However, although changes of plasma protein profiles reflect physiological or pathological conditions associated with many human diseases, only a handful of plasma proteins are routinely used in clinical tests. Reasons for this include the intrinsic complexity of the plasma proteome[1], the heterogeneity of human diseases and the rapid degradation of proteins in sampled blood[5]. We report an integrated microfluidic system, the integrated blood barcode chip that can sensitively sample a large panel of protein biomarkers over broad concentration ranges and within 10 min of sample collection. It enables on-chip blood separation and rapid measurement of a panel of plasma proteins from

We first present an overview of the IBBC and then discuss control of assay sensitivity, extension of a single protein assay to an assay for a large panel of biomarkers and, finally, integration of plasma separation from whole blood, followed by the rapid measurement of a panel of protein biomarkers. **Figure 1** shows the design of an IBBC for blood separation and *in situ* protein measurement. We designed a polydimethylsiloxane (PDMS)-on-glass chip to perform 8–12 separate multiprotein assays sequentially or in parallel, starting from whole blood.

The Zweifach-Fung effect describes highly polarized blood cell flow at branch points of small blood vessels[14–16]. A component of the IBBC, redesigned from a previous report[14], exploits this hydrodynamic effect by flowing blood through a low-flow-resistance primary channel with high-resistance, centimeter-long channels that branch off it at right

- **Potential for inexpensive, non-invasive, informative detection**
- **Rapid assays for multiple cancer biomarkers from a finger prick of blood**

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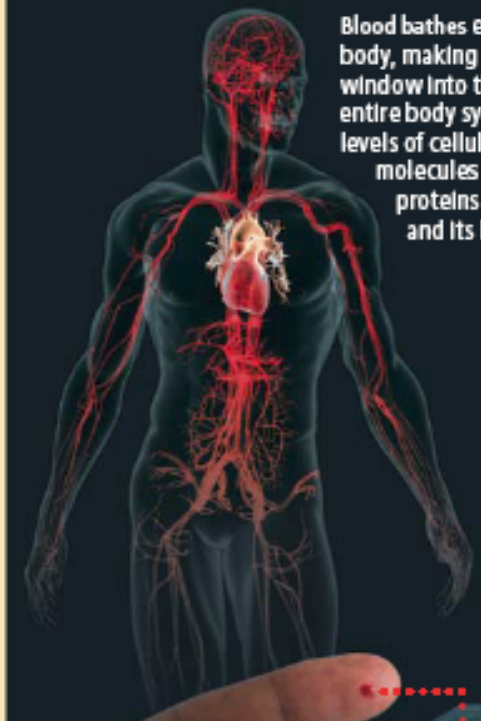
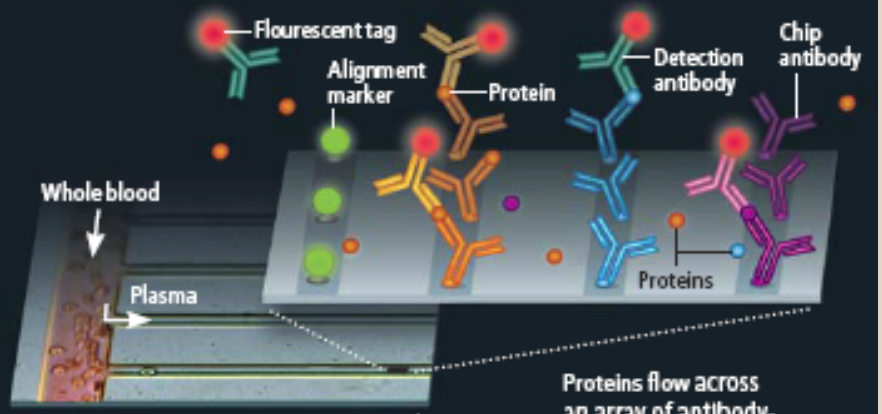
PENNIES PER PROTEIN

Information is the most valuable commodity in a systems approach to medicine, so diagnostic tests will have to easily and accurately measure large numbers of biological molecules for a few cents or less per measurement. Extreme miniaturization allowed the authors and their colleagues to produce a prototype chip that can measure concentrations of a panel of cancer-associated proteins in a droplet of blood in 10 minutes, at a cost of five to 10 cents per protein.



Blood bathes every organ in the body, making it an excellent window into the state of the entire body system. Abnormal levels of cellular signaling molecules or organ-specific proteins can flag a problem and its location.

Sample barcode containing 12 strips for detecting proteins associated with inflammation and prostate function. Results of a test of blood from a prostate cancer patient show high concentrations of prostate-specific antigen (*center*) and interferon-gamma (*right*).



Proteins flow across an array of antibody-studded bars. Each bar contains antibodies that will bind only to a specific protein. After the plasma has been sampled, fluorescent tags washed across the "barcode" array attach only to protein-bound antibodies.

Microfluidic channels within a four-centimeter-wide chip can take up a droplet of whole blood and separate plasma from cells. The plasma and proteins suspended within it flow down the narrower channels.

Heath JR, et al: SciAm 300:44-51, 2009

Promise of Nanoscale Interventions – Relevance to Prevention?

Nanoparticle Advantages[1]	Prevention Relevance
• Carry large "payloads" to improve efficacy – Including novel effectors, such as siRNA	• Yes[2] – Demonstrated 10x dose advantage in prostate cancer model with EGCG
• Improve targeting to bolster efficacy and/or reduce toxicity – Passive – based on enhanced vascular permeability and retention, differential pH/temperatures, etc. – Active – antigens, cell surface receptors, vasculature targets	• Probably – Although relevance of differential vascular EPR and active targeting strategies would require confirmation in preinvasive neoplasia
• Provide a combinatorial platform to improve efficacy	• Probably – Strong rationale based on success of combinations elsewhere in prevention
• Bypass efflux pump-based resistance	• Possibly

[1] *Heath JR, et al: Ann Rev Med 59:251-265, 2008*
[2] *Siddiqui I, et al: Cancer Res 69:1712-1716, 2009*

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DFMO + Sulindac Combination
Markedly Reduces Colon Adenoma Recurrence

Variable	Placebo N=129	Treatment N=138	Relative risk (Reduction)	P-value
Total adenoma recurrence (%)	53 (41.1)	17 (12.3)	0.30 (70%)	<0.001
Advanced adenoma recurrence (%)	1 1 (8.5)	1 (0.7)	0.085 (92%)	0.001
Large (>1cm) adenoma recurrence (%)	9 (7.0)	1 (0.7)	0.10 (90%)	0.004
Patients with >1 adenoma recurrence (%)	17 (13.2)	1 (0.7)	0.055 (95%)	<0.001

Meyskens F, et al: Cancer Prev Res, 2008

Blood Vessels in Normal & Cancerous Tissues

EPR = Enhanced Permeability & Retention

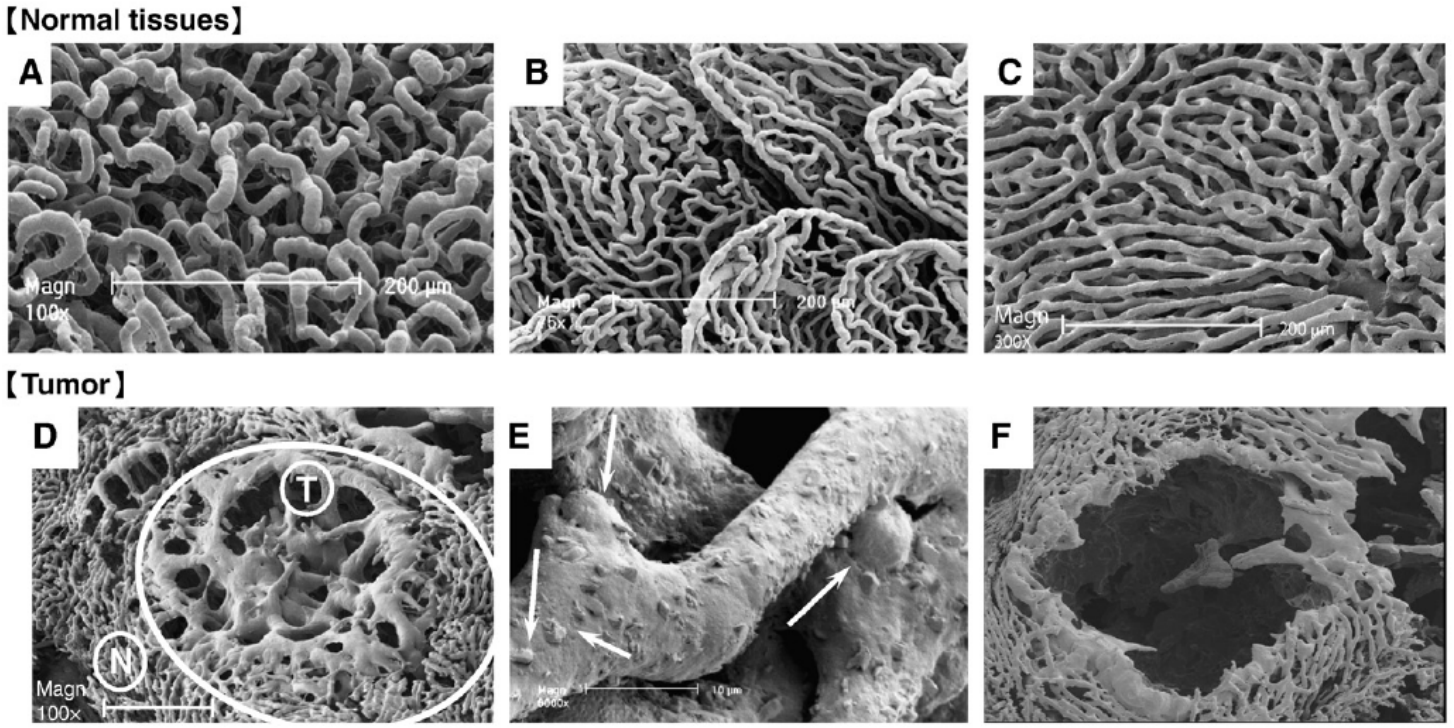

Fig. 4. SEM images of blood vessels in various normal tissues (A–C) and metastatic liver tumors (D–F). Normal capillaries of the pancreas (A), colon (intestinal villi) (B), and liver (sinusoid) (C) are shown. (D) Metastatic tumor nodule (circled area identified with T) in the liver, the normal liver tissue is indicated with "N." (E) Tumor vessels at the capillary level (larger magnification), with a rough surface and an early phase of polymer-extravasating vessels (arrows). Normal tissues show no leakage of polymeric resin (A–C), whereas the tumor nodules clearly demonstrate tumor-selective extravasation of polymer (via the EPR effect) (D, E). After i.v. injection of the macromolecular anticancer drug (SMA-pirarubicin micelles), the tumor vascular bed (visible in D) was completely disintegrated, as shown by an empty void (F).
Modified from Ref. [11] with kind permission of J. Daruwalla and C. Christophi.

Currently unclear when abnormal vessel architecture & EPR occur in carcinogenesis…estimates = 0.8 – 1 mm vs. < 0.2mm

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Fang J, et al: Adv Drug Delivery Rev, 2010

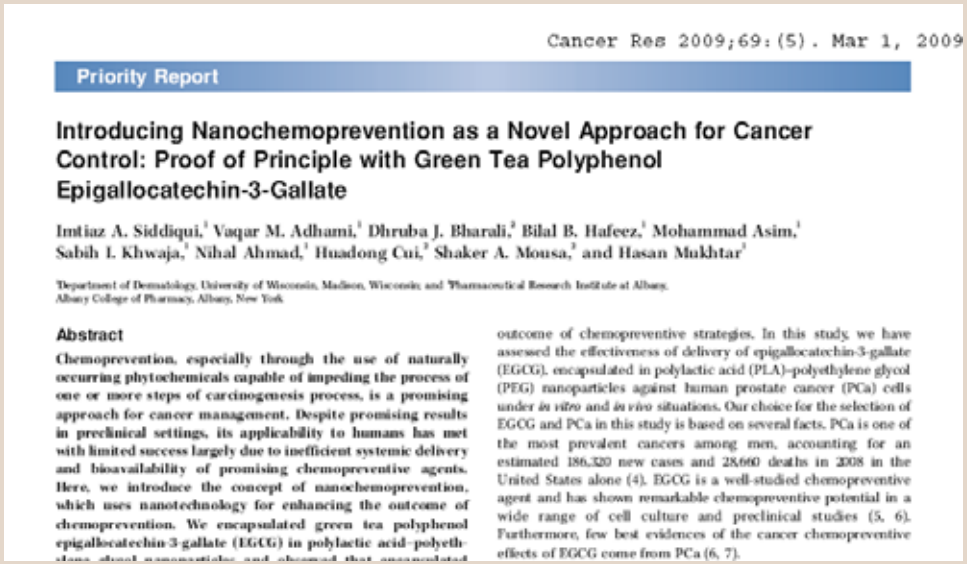
Nano-EGCG

- Epigallocatechin-3-gallate – a green tea polyphenol
- Chemopreventive potential in human breast, pancreatic, colon, esophageal & lung cancers
- Poor oral absorption (<1%) requiring high doses (~ 8-10c/d) for chemopreventive benefit
- Caffeine-related GI & neurological side effects

- EGCG in PLA-PEG nanoparticles to improve therapeutic density

-Efficient uptake by murine prostate cancer cells *in vitro & in vivo*

-At significantly lower doses than those required with typical EGCG
  - Reduced cellular penetration barriers
  - Induced apoptosis
  - Retained mechanistic identity
  - Inhibited angiogenesis
  - Decreased tumor volume
  - Inhibited serum PSA



Cancer Res 2009;69:(5). Mar 1, 2009

Priority Report

Introducing Nanochemoprevention as a Novel Approach for Cancer Control: Proof of Principle with Green Tea Polyphenol Epigallocatechin-3-Gallate

Imtiaz A. Siddiqui,[1] Vaqar M. Adhami,[1] Dhruba J. Bharali,[2] Bilal B. Hafeez,[1] Mohammad Asim,[1] Sabih I. Khwaja,[1] Nihal Ahmad,[1] Huadong Cui,[3] Shaker A. Mousa,[2] and Hasan Mukhtar[1]

[1]Department of Dermatology, University of Wisconsin, Madison, Wisconsin; and [2]Pharmaceutical Research Institute at Albany, Albany College of Pharmacy, Albany, New York

Abstract

Chemoprevention, especially through the use of naturally occurring phytochemicals capable of impeding the process of one or more steps of carcinogenesis process, is a promising approach for cancer management. Despite promising results in preclinical settings, its applicability to humans has met with limited success largely due to inefficient systemic delivery and bioavailability of promising chemopreventive agents. Here, we introduce the concept of nanochemoprevention, which uses nanotechnology for enhancing the outcome of chemoprevention. We encapsulated green tea polyphenol epigallocatechin-3-gallate (EGCG) in polylactic acid–polyeth-

outcome of chemopreventive strategies. In this study, we have assessed the effectiveness of delivery of epigallocatechin-3-gallate (EGCG), encapsulated in polylactic acid (PLA)–polyethylene glycol (PEG) nanoparticles against human prostate cancer (PCa) cells under *in vitro* and *in vivo* situations. Our choice for the selection of EGCG and PCa in this study is based on several facts. PCa is one of the most prevalent cancers among men, accounting for an estimated 186,320 new cases and 28,660 deaths in 2008 in the United States alone (4). EGCG is a well-studied chemopreventive agent and has shown remarkable chemopreventive potential in a wide range of cell culture and preclinical studies (5, 6). Furthermore, few best evidences of the cancer chemopreventive effects of EGCG come from PCa (6, 7).

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Nano-EGCG – Effective at 10-fold Lower IP Doses Measuring Tumor Volume and PSA Secretion in a Murine Xenograft Model Using Androgen-responsive 22Rv1 Prostate Cancer Cells

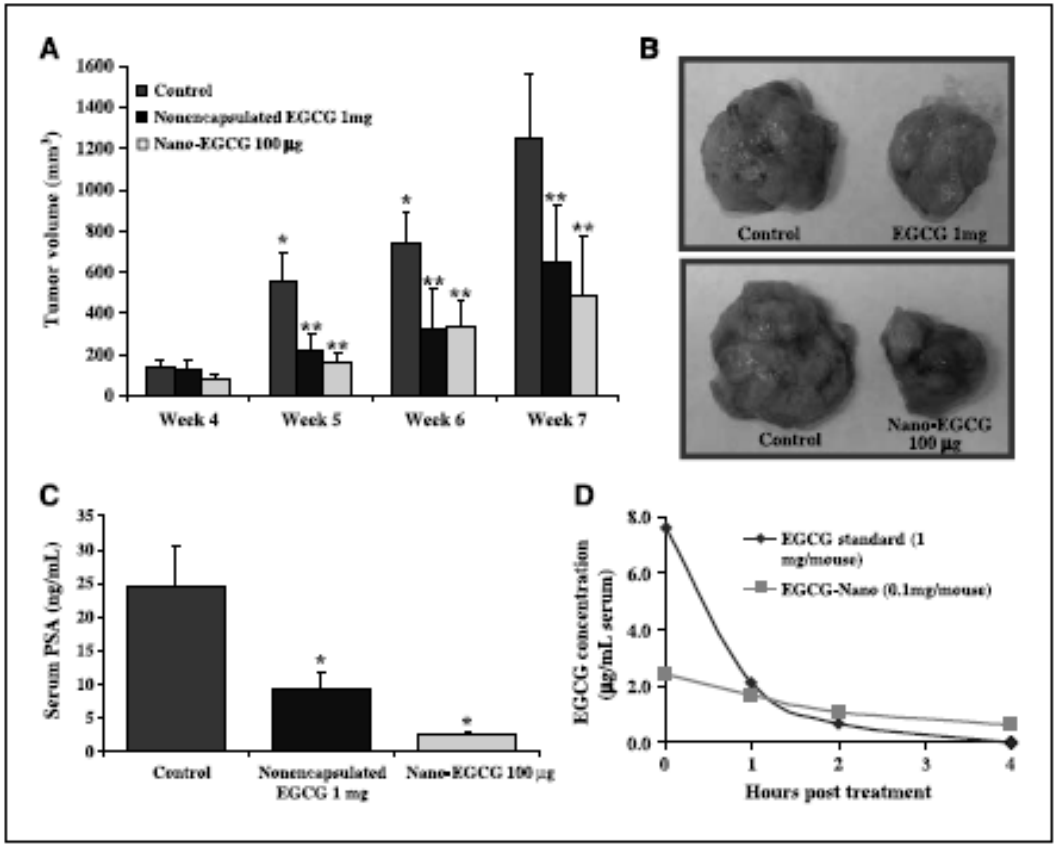
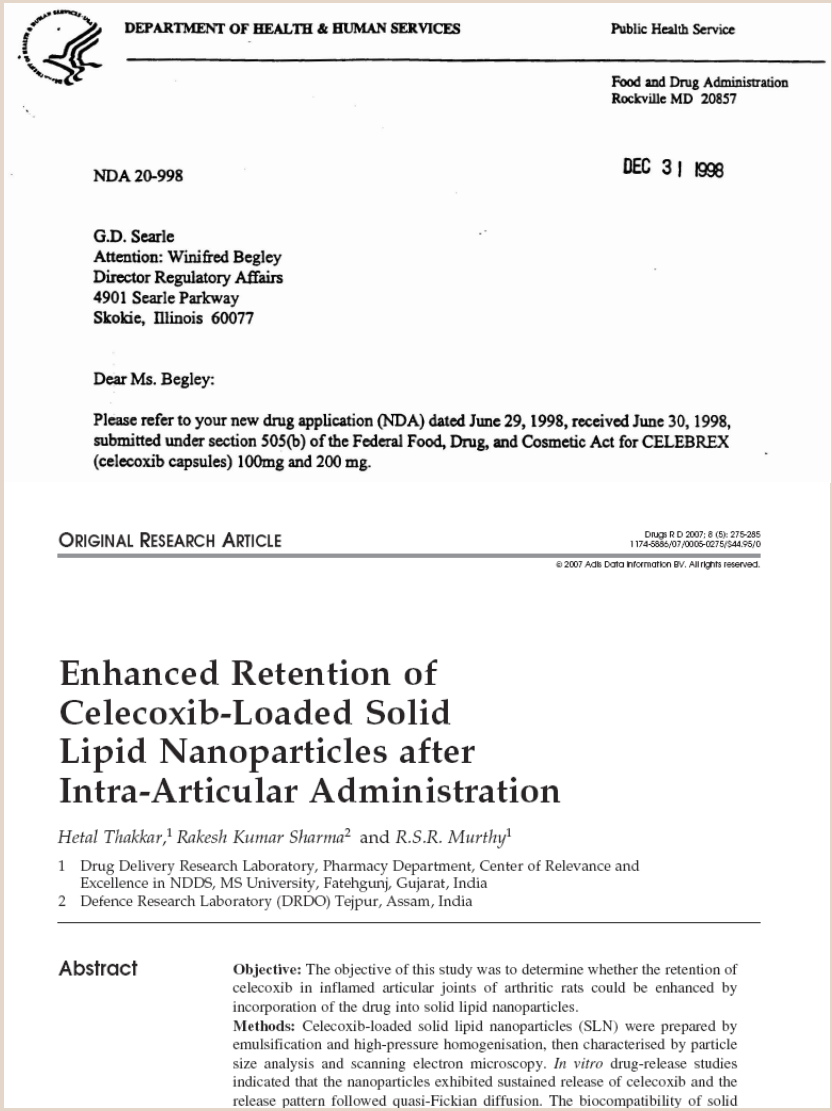


Figure 4. Comparative effects of nonencapsulated EGCG and nano-EGCG on tumor growth and PSA secretion in a xenograft model. *A*, effect on the growth of tumor xenografts. Details of the experiments are given in Materials and Methods. *Columns*, tumor volume (mm^3) of seven mice; *bars*, SE. *, $P < 0.05$ compared with the data from control group at previous time point. **, $P < 0.01$ compared with the control group at the respective time point. *B*, photographs of tumors. Photographs were taken of the excised tumors at the termination of the experiment. Typical tumors from control and treated groups. *C*, effect on the serum PSA levels. The levels of PSA were determined by ELISA assay and expressed as serum (in ng/mL) ± SE of five mice. *, $P < 0.05$ compared with the vehicle-treated controls. *D*, EGCG serum levels. Four mice in each group were treated with the agents and bled immediately and 1, 2, and 4 h after treatment. Serum was separated, and EGCG concentration was determined. Results are expressed as EGCG concentration (µg/mL serum).

Siddiqui I, et al: Cancer Res 69:1712-1716, 2009

Celecoxib



DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-998

DEC 31 1998

G.D. Searle
Attention: Winifred Begley
Director Regulatory Affairs
4901 Searle Parkway
Skokie, Illinois 60077

Dear Ms. Begley:

Please refer to your new drug application (NDA) dated June 29, 1998, received June 30, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for CELEBREX (celecoxib capsules) 100mg and 200 mg.

ORIGINAL RESEARCH ARTICLE

Drugs R D 2007; 8 (5): 275-285
1174-5886/07/0005-0275/$44.95/0

Enhanced Retention of Celecoxib-Loaded Solid Lipid Nanoparticles after Intra-Articular Administration

Hetal Thakkar,[1] *Rakesh Kumar Sharma*[2] and *R.S.R. Murthy*[1]

1 Drug Delivery Research Laboratory, Pharmacy Department, Center of Relevance and Excellence in NDDS, MS University, Fatehgunj, Gujarat, India
2 Defence Research Laboratory (DRDO) Tejpur, Assam, India

Abstract

Objective: The objective of this study was to determine whether the retention of celecoxib in inflamed articular joints of arthritic rats could be enhanced by incorporation of the drug into solid lipid nanoparticles.

Methods: Celecoxib-loaded solid lipid nanoparticles (SLN) were prepared by emulsification and high-pressure homogenisation, then characterised by particle size analysis and scanning electron microscopy. *In vitro* drug-release studies indicated that the nanoparticles exhibited sustained release of celecoxib and the release pattern followed quasi-Fickian diffusion. The biocompatibility of solid

1998: first FDA-approved COX-2 inhibitor to treat signs/symptoms of osteo- & rheumatoid arthritis

1999: approved as adjunct treatment for FAP

After 1 & 3 years of Celebrex at 200 & 400 mg BID, or 400mg QD vs. placebo in adenoma patients:

- 2004: inc risk of serious CV events up to 2-3x
- 2006: 30-60% red'n in recurrent adenomas

2007: Celecoxib-loaded solid lipid nanoparticles delivered directly to arthritic joints in rats

- Articular concentrations of celecoxib 15x higher 24h post-injection
- Reduced drug clearance into systemic circulation, potentially mitigating CV risks

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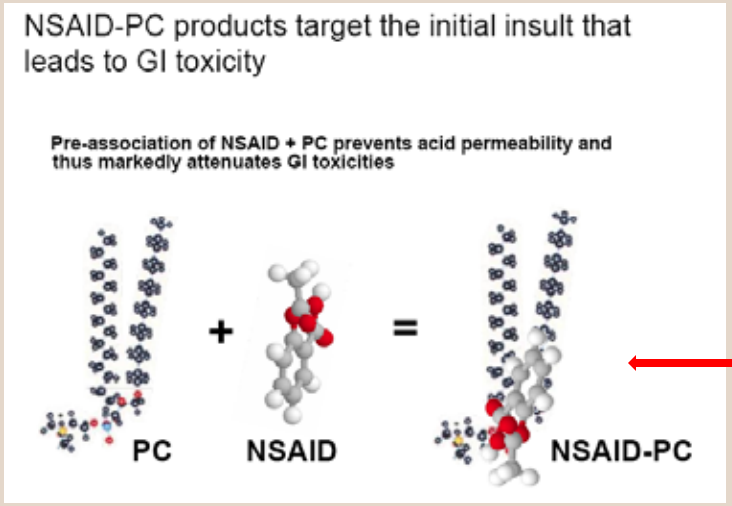
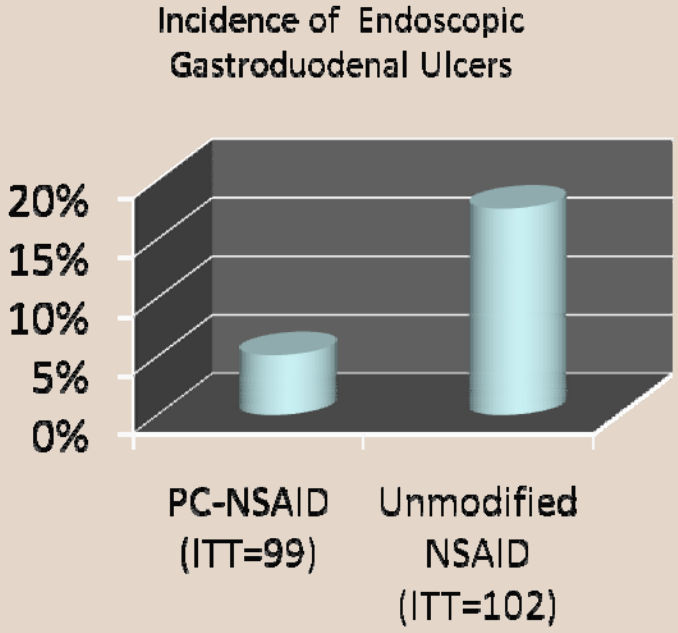
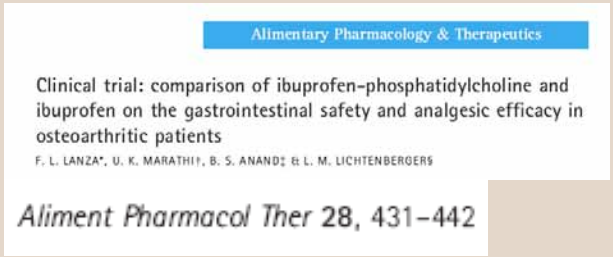
Phosphatidylcholine-associated NSAIDs



- Chronic inflammation is associated with CV, autoimmune & neurologic diseases, arthritis, diabetes and cancer
- NSAIDs are efficacious in reducing risk of these diseases, but can result in gastric erosions and CV complications
- Conjugating phosphatidylcholine (PC) to NSAIDs (NSAID-PC) could mitigate adverse effects without compromising protective properties



- In early clinical studies, a NSAID-PC conjugate demonstrated improved GI safety profile compared to unmodified NSAID in older OA patients at risk for NSAID-induced GI injury



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Current Challenges & Limitations of Nanotechnology in Cancer Prevention

- Debate over the merits of early detection of preinvasive neoplasia
- Insufficient sensitivity and specificity to detect preinvasive neoplasia or early-stage cancer
- Need to measure multiple markers for reliable detection at early stages
- Biodegradability of nano-delivery systems (carbon, silica)
- High cost
- Need for IV administration
- Human data severely limited

Nagahara LA, et al: Cancer Res 70:4265-4268, 2010

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Can Nanotechnology Improve Health More Broadly? Maybe Yes…

Functional Foods

- Addition of nanocarriers to transport vitamins, minerals and phytochemicals
- Infusion with nanoenhancers to improve taste and health benefits while reducing salt and sugar content

Food Packaging

- Nano-based, non-chlorine coating a barrier to preserve freshness
- Coating fruits and vegetables to protect from humidity and O_2 and to allow for harvesting of crops when they are riper

Food Storage & Preparation

articles imbedded in food storage
ers, plastic bags,
rds and cooking utensils retards growth of bacteria, mold and fungus

- Cookware coated with “nanoglaze” to prevent gaseous/toxic odors and
of cooking surface onto foods

Vitamins & Supplements

and precursors are insoluble in
when formulated as
es, bioavailability increases

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Can Nanotechnology Improve Health More Broadly? Maybe No…

Available online at www.sciencedirect.com
ScienceDirect
Appetite
Appetite 49 (2007) 459–466
www.elsevier.com/locate/appet

Research Report

Public acceptance of nanotechnology foods and food packaging: The influence of affect and trust

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[a]ETH Zurich, Institute for Environmental Decisions (IED), Universitätsstrasse 22, CHN J75.1, CH-8092 Zurich, Switzerland
[b]University of Zurich, Switzerland
[c]EMPA, St. Gallen, Switzerland
[d]ETH Zurich, Switzerland

Received 2 June 2006; received in revised form 7 February 2007; accepted 7 March 2007

Abstract

Nanotechnology is increasingly being employed in the areas of food production and packaging. Public perception will be crucial to the realization of these technological advances. We examined how lay people ($N = 153$) perceive nanotechnology foods and nanotechnology food packaging, and we examined the factors that influence willingness to buy these products. Participants received some general information about nanotechnology, and specific information about four nanotechnology applications. Overall, participants were hesitant to buy nanotechnology foods or food with nanotechnology packaging. Results suggest, however, that nanotechnology packaging is perceived as being more beneficial than nanotechnology foods. Results further suggest that social trust in the food industry is an important factor directly influencing the affect evoked by these new products. As suggested by the affect heuristic, affect had an impact on perceived benefits and perceived risks. Perceived benefit seems to be the most important predictor for willingness to buy.

- Public perception
  - – "Nano-inside" (e.g., foods) appears less acceptable than "nano-outside" (e.g., packaging)
- Unknowns
  - – Do nanoparticles migrate from packaging to food?
  - – What are the downstream environmental impacts during disposal?
- Social trust
  - – Acceptance of technology
  - – Assurance of regulatory oversight

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Are We There Yet?

Francis Collins, MD, PhD
Director, National Institutes of Health

CANCER IN AMERICA

The Cancer You Can Beat

by Dr. Francis S. Collins

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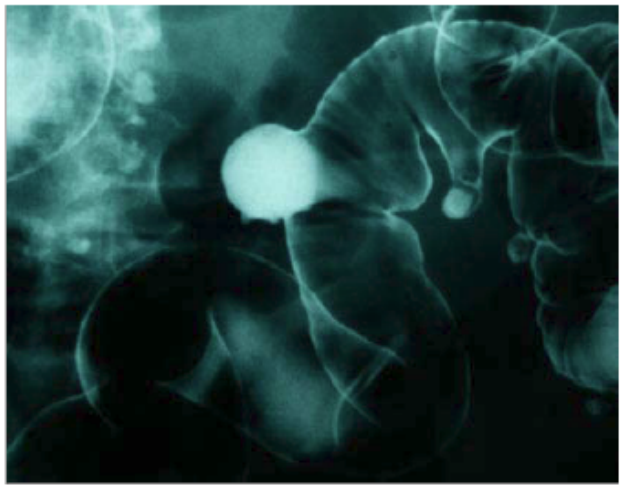

The incidence of colorectal cancer fell by more tha
between 1985 and 2005—mostly because more p
disease.

Yet colorectal cancer remains the second-leading
claiming the lives of nearly 50,000 Americans eac
these cases could be averted or caught in an early
started getting regular screenings when they hit th
if a family member has had the disease). Indeed, a
older have never been screened for colorectal can

Many experts consider a colonoscopy to be the m
cancer-screening tool available. In the procedure,
long, flexible tube equipped with a tiny camera) th
enables them to detect and remove polyps and les
cancerous.

6 Things You Can Do to Help Prevent Cancer

Another screening mainstay is the fecal occult blood test, in which stool samples are examined for microscopic specks of blood. (If you get this test, make sure it's the more accurate version that uses

Current imaging methods detect cancers once they are large enough to be visible. But imagine how great it would be if doctors could spot a single cancerous or even pre-cancerous cell. This may soon be possible through nanotechnology, the branch of engineering that deals with the manipulation of individual atoms and molecules.

Parade Magazine, June 20, 2010

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