THE CANCER LETTER

Vol. 35 No. 23
June 12, 2009

PO Box 9905 Washington DC 20016 Telephone 202-362-1809

FTC Report Disagrees With Key Provision Of Biologics Bill Backed By Companies

By Paul Goldberg

A report by the Federal Trade Commission disagreed with a key provision of the follow-on biologics bill supported by the innovator companies.

That measure, introduced by Rep. Anna Eshoo (D-Calif.) gives innovators 12 years of exclusivity, but the term can be increased to 14 years if the company develops additional indications.

A competing measure, introduced by Rep. Henry Waxman (D-Calif.), chairman of the Committee on Energy & Commerce, caps the innovators exclusivity period at five years.

According to the FTC report, the 12- to 14-year regulatory exclusivity period is too long to promote innovation.

The report, which was released June 10, also points out that regulation of

(Continued to page 2)

In the Courts:

Judge Sentences Former BMS Exec Bodner To Write Book Reflecting On His Experience

By Paul Goldberg

The travails of former Bristol-Myers Squibb executive Andrew Bodnar appeared to have a certain novelistic quality.

Prosecutors alleged that Bodnar attempted to make an unwritten side deal with a Canadian company in order to delay introduction of the blood thinner Plavix, and—worse—that he lied to government officials about it. The Plavix imbroglio led to the ouster of BMS chief executive Peter Dolan.

Now—as part of his punishment—Bodnar has to tell his story. At length. In a book.

Judge Ricardo Urbina of the U.S. District Court for the District of Columbia last week sentenced Bodnar "to write and complete a book reflecting upon the experience associated with the criminal behavior in this case so that others similarly situated may be guided in avoiding such behavior."

The book-writing project, ordered by Urbina on June 8, is a special condition of a two-year unsupervised probation. Bodnar will also pay a $5,000 fine.

Last April, Bodnar pleaded guilty to a single count of making a false certification to federal officials.

Under sentencing guidelines, Bodnar was facing up to six months of incarceration, a one-year supervised release and the $5,000 fine. His

(Continued to page 4)

Follow-On Biologics Dispute Defined In Two Competing Bills

(Continued from page 1)

follow-on biologics—FOBs—would differ substantially from regulation of to generic small molecule drugs.

"The report completely disposes of the drug industry's argument that they need 12 to14 years of exclusive marketing, indeed that they need any additional exclusivity, to sustain innovation," Waxman said in a statement June 11. "The FTC has provided an unbiased, expert analysis of all the arguments and has definitively concluded that patents and market-based pricing provide more than enough incentive to invest in important new medicines. This is good news for consumers, who will have early access to affordable versions of life-saving drugs without compromising future breakthroughs."

Rebutting Waxman's statement, the Biotechnology Industry Organization offered to arrange interviews with patient groups that favor longer exclusivity.

"Many patient groups recognize that limiting the period of data exclusivity to achieve minimal savings on today's therapies will greatly hamper the ability of biotech companies to develop the next generation of products for the many diseases for which no treatment, or insufficient treatment options, exist," said Stephanie Fischer, BIO's director of communications. The only cancer-related group on her list was Men's Health Network.

In 2007, biologics accounted for $40.3 billion of the $286.5 billion Americans spent on prescription drugs. Biologics tend to be more expensive than small molecule drugs. As an example, the report cites the cost of a year's worth of Herceptin: about $48,000.

According to industry figures, generic drugs cost between 30% and 80% less than branded drugs. Nobody expects so dramatic a price drop for FOBs. The Congressional Budget Office estimates that mandatory health programs could save $19.6 billion between 2010 and 2019 by switching to FOBs.

For now the dispute is defined in two bills, Waxman's H.R. 1427, which has 11 co-sponsors, and Eshoo's H.R.1548, which has 92 co-sponsors. The Senate counterpart of the Waxman bill, S. 726, is co-sponsored by Sen. Charles Schumer (D-NY) and has seven co-sponsors. The Eshoo bill has no Senate version.

Capitol Hill insiders say they are expecting introduction of another measure, by Sen. Edward Kennedy (D-Mass.)

The Kennedy bill would likely be largely similar to the measure he introduced in 2007, and would fall roughly in the middle, between the Waxman and Eshoo legislation.

In its 2007 version, the Kennedy bill capped exclusivity at 12 years, compared to Eshoo's cap of up to 14 years and Waxman's five. Insiders speculate that it could be introduced in the context of broader healthcare reform legislation.

Barriers to Entry

The standards for approval of FOBs appear to be less stringent in the Waxman bill.

The bill requires that the FOB be "biosimilar" to and "interchangeable" with the pioneer agent.

"Biosimilar" means that "no clinically meaningful differences between the biological product and the reference product would be expected in terms of the safety, purity, and potency if treatment were to be initiated with the biological product instead of the reference product."

"Interchangeable" means that the agents are biosimilar and that patients "can be switched one or more times between the reference product and the biological product without an expected increase in the risk of adverse effects, including a clinically significant change in immunogenicity, or diminished effectiveness, compared to the expected risks from continuing to use the reference product without such switching."

Under the Waxman bill, approval for FOBs would be granted based on:

THE CANCER LETTER

® The Cancer Letter is a registered trademark.

Editor & Publisher: Kirsten Boyd Goldberg
Editor: Paul Goldberg

Editorial: 202-362-1809 Fax: 202-379-1787
PO Box 9905, Washington DC 20016
Letters to the Editor may be sent to the above address.

Subscriptions/Customer Service: 800-513-7042
PO Box 40724, Nashville TN 37204-0724
General Information: www.cancerletter.com

Subscription $385 per year worldwide. ISSN 0096-3917. Published 46 times a year by The Cancer Letter Inc. Founded Dec. 21, 1973, by Jerry D. Boyd.

—Information derived from chemical, physical, and biological assays, and other non-clinical laboratory studies; and

—Information from any necessary clinical study or studies sufficient to confirm safety, purity, and potency.

The measure leaves it up to the HHS Secretary to determine when clinical studies are necessary.

The Eshoo bill gets into greater detail in laying out the approval criteria for FOBs. Under that proposal, biosimilarioty would be demonstrated based on analytical studies, animal studies, and "a clinical study or studies (including, but not limited to, the assessment of immunogenicity and pharmacokinetics or pharmacodynamics) that are sufficient to demonstrate safety, purity, and potency for each condition of use for which the reference product is approved."

However, the HHS Secretary would have the authority to waive these studies.

There are other differences between the Waxman and Eshoo bills:

—The Waxman bill doesn't require FDA to issue a guidance document on determination of interchangeability. The Eshoo bill does.

—The Waxman bill allows the FOB to keep the same name as the pioneer agent. The Eshoo bill requires a new name for the FOB.

Neither the Eshoo bill nor the Waxman bill deals with patent rights and regulation of patent disputes.

FTC: Percentage of Cost Savings Smaller Than With Generic Drugs

The FTC report argues that follow-on biologics would be very different from makers of generic drugs. According to the agency, competition would be more like brand-to-brand competition than brand-to-generic drug competition. The report states that FOB doesn't necessarily result in steep price discounting or rapid acquisition of market share, by FOB manufacturers.

According to the report, this would be the case for the following reasons:

—The substantial costs to obtain FDA approval, plus the substantial fixed costs to develop manufacturing capacity, will likely limit the number of competitors that undertake entry with FOB products.

FOB products are likely to take eight to ten years to develop, and their evelopment will likely cost between $100 and $200 million. These amounts differ substantially from the product development costs for small-molecule generic drugs, which typically take three to five years to develop and cost between $1 and $5 million.

—Given these high entry costs, FOB entrants are likely to be large companies with substantial resources, and it is likely that only two to three FOB entrants will seek approval to compete with a particular pioneer biologic drug.

Current pioneer biologic drug manufacturers are likely to become FOB competitors in those markets in which they do not currently compete. Moreover, high entry costs are likely to limit FOB drug entry to markets with sales in excess of $250 million per year. The small number of likely FOB entrants contrasts significantly with the 10 or more generic entrants seen in many markets for small-molecule drugs.

—The lack of automatic substitution between an FOB product and a pioneer biologic drug will slow the rate at which an FOB product can acquire market share and thereby increase its revenues.

In small-molecule drug markets, automatic substitution erodes a branded manufacturers' market share quickly once the first generic product enters the market. This situation is unlikely to occur in FOB markets. Unlike small-molecule generic drugs, FOB products will not be designated as "therapeutically equivalent" with the pioneer biologic drug product. The lack of therapeutic equivalence means that, like pioneer manufacturers, FOB manufacturers will have to market their products and negotiate individual contracts with purchasers.

—An FOB drug also may have difficulty gaining market share due to concerns about safety and efficacy differences between a pioneer biologic drug and the competing FOB.

Physicians and their patients who have been taking a pioneer biologic drug may be reluctant to switch to an FOB due to a risk that the patients will react differently to the FOB than to the pioneer drug. Concerns such as these may limit FOB market opportunities to newly diagnosed patients.

—The specialty pharmaceutical characteristics of FOBs also are likely to constrain the ability of an FOB entrant to obtain market share.

Specialty drugs, including biologic drugs, are commonly used to treat patients with severe, chronic diseases and sometimes fatal conditions. These drugs, which are primarily injected or infused, are combined with ancillary medical services and products that require specialty training for proper handling and administration. Because most biologic products are delivered to patients in clinics, hospitals, doctor's offices, or other medically

supervised settings, shifting to another biologic product is typically more costly because it requires restocking of inventory and retraining of nurses and healthcare providers.

—**Biologic drugs currently are not reimbursed pursuant to strategies that payors often use to incentivize the use of lower-priced drugs; this, too, may limit market share acquisition by FOBs.**

Biologic drug products are typically delivered to patients by healthcare providers as part of medical treatments (*e.g.*, dialysis treatments or oncology treatments) and reimbursed by health insurers as part of patients' medical benefits rather than pharmacy benefits. Consequently, traditional payor strategies to incentivize utilization of lower-priced drugs, including the use of co-pays and tiered formularies, are unlikely to apply to drive up the market share of FOBs. FOB pricing and market shares also are likely to be affected by the reimbursement methodologies used by Centers for Medicare and Medicaid Services for infused and injected drugs, which may not effectively drive share to lower-priced drugs.

—**As a result of these factors, FOB competition against a pioneer biologic drug is likely to develop as follows**:

FOB entry is likely in biologic drug markets of greater than $250 million. Only two or three FOB manufacturers are likely to attempt entry for a given pioneer drug product. These FOB entrants are unlikely to introduce their FOB products at price discounts any larger than between 10 and 30 percent of the pioneer products' price.

Although not as steep a discount as small-molecule generic drugs, a 10 to 30 percent discount on a $48,000 drug product represents substantial consumer savings. Pioneer manufacturers are expected to respond and offer competitive discounts to maintain market share. This price competition is likely to lead to an expanded market and greater consumer access.

Nonetheless, the lack of automatic substitution will slow significant market share acquisition by FOB products. As a result, pioneer manufacturers are likely to retain 70 to 90 percent of their market share and, therefore, will likely continue to reap substantial profits years after entry by FOB drugs.

The document is available at www.ftc.gov/opa/2009/06/biologics.shtm

Waxman To Obama: Act Now

Two days before FTC issued its the report, Waxman wrote a letter urging the administration to start approving FOBs based on existing law, prior to any new legislation.

The text of the letter, dated June 8, follows:

I am pleased that your FY 2010 Budget provides a substantial increase for the Food and Drug Administration and includes a proposal to establish a pathway for FDA approval of generic biologics.

On March 11, 2009, my colleagues and I introduced H.R. 1427, the "Promoting Innovation and Access to Life-Saving Medicine Act," a bipartisan bill to allow the FDA to approve affordable generic biologic drugs. Biotech drugs, while often life-saving, are the fastest growing and most expensive components of the nation's prescription drug costs. Many of them cost tens and thousands of dollars a year and impose an unsustainable burden on patients, employers, and the federal and state governments. This legislation, which I believe is consistent with the principles outlined in your budget is one of my highest priorities this year.

When this legislation passes, it is important for FDA to begin implementing the program as soon as possible. I urge the Administration to consider what steps can be taken under existing authority to prepare and even begin to use a pathway for generic biologics. The speed of FDA's action will determine how quickly safe and effective generic biologics become available to patients.

In addition, I would be interested in your Administration's analysis of long-term savings generated from generic biologics not only for Medicare and Medicaid, but also for businesses, insurers, and families. Generic biologics are a significant way to control costs and I agree with you that controlling costs is integral to reforming our health care system.

With your support I am hopeful we can achieve our shared vision for Americans to get access to safe, effective, and affordable generic biologic therapeutics.

In the Courts:

Bodner Sentenced To Write "Something Instructive"

(Continued from page 1)

sentencing was delayed once because he had suffered a heart attack.

"He is going to write the book," said Bodnar's attorney Elkan Abramowitz, of the New York firm of Morvillo, Abramowitz, Grand, Iason, Anello & Bohrer. "It is probably going to discuss how this case was handled in the [Department of Justice] antitrust division.

It's an unusual case, and one in which the government may have acted precipitously."

Will Bodnar also shed light on disastrous moves by the company's former management?

"We will see when he writes the book," Abramowitz said.

The transcript of the sentencing hearing shows an extraordinary exchange in which Urbina and Bodnar appear to talk like a literary agent and a client, brainstorming ideas for books, finally zeroing in on one that both agree is worth pursuing:

URBINA: "Let me ask you something that may seem like an unrelated question. You have very vast experience in the non-profit sector, and I have noted carefully all the involvement you've had with community work in one form or the other: Is there a book or a publication that addresses the task of non-profit organizations to reach out to the community and to conduct itself in a way that would permit it to acquire more support and funds, what would that book be like?"

BODNAR: "You mean is there such a book?"

URBINA: "Yeah. All right. Is there such a book?"

BODNAR: "Not that I'm aware of, Your Honor."

URBINA: "Would you be competent to write such a book?"

BODNAR: "One of the things I haven't done in addition to wanting to become a rabbi is writing a book, and I majored in English literature when I was in college and always thought about being a doctor and being a lawyer, and I became both of those, and one of the things that I have always wanted to do was write a book."

URBINA: "What about?"

BODNAR: "Well, it's changed with time. When I was younger, it was going to be about Jewish guards in Nazi concentration camps who were collaborators and who in later life had to deal with that. I thought that probably has been written since then, so I've kind of given up on that. And as I have gotten older, even though I have not yet read "The Mystery of Edwin Drood," which is the Dickens novel that I haven't read because I'm kind of saving it for the last thing I do, I have gotten more and more away from fiction as reading and fiction in my fantasies about what I'm going to write to more and more about life, and, although, I will never say that I think that this experience is something that I would have liked to have, had I had a choice going in, I actually have given a lot of thought to writing about it."

After stating that had decided to impose a fine and probation, Urbina, said he would retain supervision of the case instead of transferring it to New Jersey, where Bodnar lives.

"I will retain this case," Urbina said. "And one of the things, Mr. Bodnar, that I would like to see you do is to write a book. That's going to be one of the conditions of your probation. Hopefully, you'll finish it before the probationary term expires, but I was thinking more along the lines of, well, what you've just stated, which is what occurred under these circumstances, that would be fine; something that would be instructive so that other individuals don't find themselves in a situation that you have just indicated is unpleasant and unforeseen."

The entire transcript of Bodnar's sentencing hearing is posted at http://www.cancerletter.com/publications/special-reports.

In the Cancer Centers:

Nevada Cancer Institute, University Renew Partnership

NEVADA CANCER INSTITUTE and the University of Nevada's University Medical Center have renewed a partnership under which the institute will provide outpatient oncology services at the medial center. The cancer center and the medical center had a previous agreement for outpatient services that ended in 2008.

A $3 million donation from The Lincy Foundation will be used to renovate space at UMC to build a state-of-the-art clinic for outpatient services, including medical oncology and radiation oncology. Radiation oncology provides additional revenue that will enable the clinic to be financially sustainable over the long term.

"We are humbled by this extraordinary gift from The Lincy Foundation, a long-term supporter of Nevada Cancer Institute. This gift allows us to partner with UMC to offer high-quality, patient-centered care through the NVCI oncology clinic at UMC," NVCI CEO and Director **John Ruckdeschel** said. "We can put our arms around patients and give them everything they need all in one location. This is about the community coming together and finding a solution that improves healthcare."

Patients will see the reinstatement of services that previously existed at UMC, most notably outpatient chemotherapy treatments, plus a higher level of service and care once the new clinic opens. NVCI will provide outpatient services including medical oncology, malignant hematology and radiation oncology; certain inpatient cancer services including patient consults and

inpatient cancer coverage; and oversight of residents and fellows on their cancer rotations at UMC through separate agreements with the University of Nevada School of Medicine. NVCI and UMC will offer access to cancer support groups, case management and financial counseling among other services. Also, NVCI will provide physician services. It is estimated that the outpatient cancer services will require additional dedicated medical oncologists/internists and a radiation oncologist. These physicians may be jointly recruited and funded by NVCI, UMC and possibly UNSOM using a salary shortfall funding structure.

Unlike the previous agreement, NVCI will not be in a sub-contractor relationship with UMC. NVCI is leasing the space at UMC, and this will be a satellite location of NVCI.

In another development, NVCI's Board of Directors has elected **Stephen Cloobeck** as its next chairman, effective July 1. Cloobeck is the chairman & CEO of Diamond Resorts International. He succeeds founding Chairman of the Board **Heather Murren**. Murren has served as the institute's only chairman since NVCI was founded eight years ago. Murren will continue to be involved with NVCI as a board member.

* * *

NEWYORK-PRESBYTERIAN HOSPITAL/Weill Cornell Medical Center will establish the LeFrak Center for Robotic Surgery with a $3 million gift from the Richard S. and Karen LeFrak Charitable Foundation. The LeFrak Center will focus on robotic treatments for patients with prostate cancer and other urologic conditions, and will support innovative procedures in areas including otolaryngology, obstetrics and gynecology, and ophthalmology. **Ash Tewari** will lead the new center as the newly appointed director of robotic surgery at NewYork-Presbyterian/Weill Cornell. The gift will make possible the purchase of a new da Vinci surgical robot, the third such device at NewYork-Presbyterian/Weill Cornell. The LeFrak Center will also support multidisciplinary research toward innovations in robotic surgery, including support toward the creation of a center to train other physicians in robotic surgical techniques. Since joining NewYork-Presbyterian/Weill Cornell in 2004, Dr. Tewari has performed more than 2,000 robotic procedures for prostate cancer. . . . **JOHN "DREW" RIDGE**, chief of head and neck surgery at Fox Chase Cancer Center, has been elected president of the American Head and Neck Society. Ridge has been Fox Chase's chief of head and neck surgery since 1991. Ridge has held many positions within the AHNS. At Fox Chase, Ridge directs clinical research on head and neck cancer and has a strong role in translational research. His clinical practice focuses on head and neck and endocrine tumors, including nonsurgical management, organ preservation, new surgical techniques and early and advanced thyroid tumors. Ridge co-chairs the Previously Untreated Locally Advanced Head and Neck Cancer Task Force for the NCI. He has been a member of numerous federal advisory groups, including NCI grant review panels, NCI review group for Specialized Program of Research Excellence grants, and think tanks on head and neck cancer for NCI and NIDCR. . . . **M. D. ANDERSON CANCER CENTER'S** history is the subject of a new book by historian **James Olson**. "Making Cancer History: Disease and Discovery at The University of Texas M. D. Anderson Cancer Center" (Johns Hopkins University Press). "With remarkable truth and clarity, Jim has captured the stubborn spirit, heroic attempts, colossal setbacks and glittering achievements we have faced—as a nation and an institution—in cancer care and research," said **John Mendelsohn**, president of M. D. Anderson. "This is no dry institutional history, but a record of the will and courage to confront and conquer cancer." . . . **MEMORIAL SLOAN-KETTERING CANCER CENTER** awards and appointments: **James Eastham** was named chief of the Urology Service in the Department of Surgery and the incumbent of the Florence and Theodore Baumritter/Enid Ancell Chair of Urologic Oncology. He also serves as co-leader of the Genitourinary Disease Management Team and chair of the Department of Surgery Protocol Committee. He joined MSKCC in 2000 and has directed the Urology Service's clinical research program for the past five years and has been associate director of the fellowship program in urologic oncology since 2003. **Tari King** was named to the new Jeanne E. Petrek Junior Faculty Chair. King is the principal investigator of the Breast Surgery Research Laboratory. She came to MSKCC as a breast surgery fellow in 2001 and joined the faculty in 2003. Petrek was a breast surgeon and clinical investigator whose career at MSKCC spanned more than 20 years, from 1984 until her death in 2005. The chair was endowed with funds from more than 500 donors, many of whom were Petrek's patients. . . . **MEHARRY MEDICAL COLLEGE** said **Billy Ballard** was appointed interim dean of the School of Medicine. Ballard, associate dean for Graduate Medical Education and professor and chair of the Department of Pathology, has been a tenured professor at Meharry since 2000. Former dean of the School of Medicine, and senior vice president of health affairs, **Valerie Montgomery Rice**,

is returning to the full time faculty to serve as executive director of the Center for Women's Health Research. She is also a tenured professor in the Department of Obstetrics and Gynecology. . . . **STEPHEN FESIK**, of Abbott Laboratories, joined Vanderbilt University Medical Center as professor of biochemistry. Fesik will lead the cancer drug discovery initiatives of the Vanderbilt Institute of Chemical Biology and the Vanderbilt-Ingram Cancer Center. Fesik earned his doctorate in medicinal chemistry at the University of Connecticut and did postdoctoral training in molecular biophysics and biochemistry at Yale Medical School. He then joined Abbott, where he developed and applied nuclear magnetic resonance methods in drug discovery. Divisional vice president of cancer research since 2000, Fesik built a pipeline of drug candidates showing promising anticancer activity in early clinical trials.

In Brief:

Blumenthal Said A Candidate For U.S. Surgeon General

SUSAN BLUMENTHAL, the controversial Clinton administration official, may be emerging as a leading candidate for the job of Surgeon General.

Rumors of Blumenthal's return to prominence have been circulating for about a week and were reported in the "In the Loop" column in The Washington Post June 12.

Blumenthal, a psychiatrist who is married to Rep. Edward Markey (D-Mass.), served as an Assistant Surgeon General and head of the PHS Office of Women's Health.

In that position, she antagonized key breast cancer groups, women's groups and top HHS officials.

Blumenthal obtained earmarks on NCI budget to fund non-peer-reviewed projects of the National Action Plan On Breast Cancer, a unit of HHS, which her office administered. In 1997, the project received a $14 million earmark, which critics said was an extraordinary amount of money to divert from peer-reviewed research. The action plan's steering committee voted unanimously to return the money to NCI (The Cancer Letter, Nov. 15, 1996).

Ultimately, the White House threw Blumenthal a lifeline, making her an advisor (The Cancer Letter, Oct. 3, 1997). But opposition from women's groups made that assignment untenable, and she never started the job (The Cancer Letter, Nov. 7, 1997).

At the time her White House assignment collapsed, Blumenthal was under investigation by the HHS Office of the Inspector General. The OIG investigation was focused in part on a Request for Proposals in which applicants were required to submit scientific papers that would be published under Blumenthal's name.

The outcome of the OIG investigation was never publicly disclosed.

MARCUS PLESCIA has accepted the position of director of the Division of Cancer Prevention and Control at the Centers for Disease Control and Prevention.

Plescia has been chief of the Chronic Disease and Injury Section of the North Carolina Division of Public Health since 2003. Under his leadership, North Carolina increased funding for cancer screening, tobacco cessation, and obesity prevention.

Cancer Statistics:

Colorectal Cancer Incidence Seen Rising Worldwide

A new study finds colorectal cancer incidence rates for both males and females increased in 27 of 51 countries worldwide between 1983 and 2002, and points to increasing Westernization as being a likely culprit.

The rise was seen primarily in economically transitioning countries including Eastern European countries, most parts of Asia, and some countries of South America. The study is the first in a peer-reviewed journal to present colorectal cancer incidence trends across all five continents. It appears in the June 2009 issue of Cancer Epidemiology Biomarkers and Prevention.

An accompanying editorial says the rise points toward a failed early detection and prevention strategy as well as failure to address lifestyle and dietary challenges of urbanization that affect most of the globe.

Colorectal cancer is the fourth most common cancer in men and the third most common cancer in women worldwide. Previous studies have reported rapid increases in colorectal cancer incidence rates in economically transitioning countries in many parts of the world, likely reflecting changing dietary and physical activity patterns. However, those studies used old data and examined regional or country-specific trends.

The new study, led by American Cancer Society epidemiologist Melissa Center, reviewed colorectal cancer incidence data from 51 cancer registries worldwide with long-term incidence data from the Cancer Incidence in Five Continents (CI5) databases created by the International Agency for Research on

Cancer. Researchers analyzed the change in incidence rates over the past 20 years; 1983-87 through 1998-2002.

Colorectal cancer incidence rates for both males and females increased for 27 of 51 cancer registries considered in the analysis between 1983-87 and 1998-2002. The increases were more prominent for men than for women. Some of the increases were dramatic. For example, in Slovenia, colorectal cancer incidence increased 70 percent among men and 28 percent among women. In Miyagi, Japan, rates rose 92 percent among men and 47 percent among women.

The researchers also observed substantial regional and ethnic variations in colorectal cancer incidence trends within countries such as Japan, Israel, and Singapore. The U.S. was the only country where colorectal cancer incidence rates declined in both males and females.

The authors say the increase in colorectal cancer in economically transitioning countries may reflect the adoption of Western lifestyles and behaviors. Many of the established and suspected modifiable risk factors for colorectal cancer, including obesity, physical inactivity, smoking, heavy alcohol consumption, a diet high in red or processed meats, and inadequate consumption of fruits and vegetables, are also factors associated with economic development or westernization.

The authors say male colorectal cancer incidence rates in the Czech Republic, Slovakia, and Japan have not only exceeded the peak incidence observed in the U.S. and other long-standing developed nations, but continue to increase.

An accompanying editorial by Asad Umar and Peter Greenwald of the NCI Division of Cancer Prevention calls the rising rates "alarming," saying "this increase points toward a failed early detection and prevention strategy as well as failure to address lifestyle and dietary challenges of urbanization that affect most of the globe."

Funding Opportunities:

Lustgarten Foundation Seeks Grant Applications

The Lustgarten Foundation for Pancreatic Cancer Research provides funding for research into the biology, diagnosis, treatment and prevention of adenocarcinoma of the pancreas. Grant applications in all areas related to adenocarcinoma of the pancreas are welcomed.

Applications will be accepted from individual investigators as well as from collaborating institutions. Grants will be awarded for a one-year period for a maximum amount of $100,000, of which no more than 10% can be used for indirect costs. National and international applications will be considered.

Mandatory Letters of Intent are due by July 24. The application deadline is Aug. 7. Funding will commence January 2010.

Applications may be obtained from www.lustgarten.org or by contacting The Lustgarten Foundation 1111 Stewart Avenue, Bethpage, NY 11714, phone 516-803-2304, fax 516-803-2303.

SWOG RFA Available For Use Of Tissues

The Southwest Oncology Group's Translational Medicine Committee has issued a Request for Applications for a new grant program that will support translational research that makes use of SWOG tissues or other patient resources.

Any NIH-eligible cancer researcher may apply (SWOG membership is not required).

The RFA is at https://swog.org/Members/Download/BulletinBoard/Article181.pdf.

NIH Annoucements

Recovery Act Limited Competition: Biomedical Research, Development, and Growth to Spur the Acceleration of New Technologies (BRDG-SPAN) Pilot Program (RC3) (RFA-OD-09-008). Application Receipt Date: Sept. 1. http://grants.nih.gov/grants/guide/rfa-files/RFA-OD-09-008.html

Recovery Act Limited Competition: Small Business Catalyst Awards for Accelerating Innovative Research (R43) (RFA-OD-09-009). Application Receipt Date: Sept. 1. http://grants.nih.gov/grants/guide/rfa-files/RFA-OD-09-009.html

Biomarkers for Early Detection of Hematopoietic Malignancies (R01) (PA-09-197). http://grants.nih.gov/grants/guide/pa-files/PA-09-197.html

Biomarkers for Early Detection of Hematopoietic Malignancies (R21) (PA-09-198). http://grants.nih.gov/grants/guide/pa-files/PA-09-198.html

Identifying Non-coding RNA Targets for Cancer Early Detection and Prevention (R01) (PA-09-199). http://grants.nih.gov/grants/guide/pa-files/PA-09-199.html

Identifying Non-coding RNA Targets for Cancer Early Detection and Prevention (R21) (PA-09-200). http://grants.nih.gov/grants/guide/pa-files/PA-09-200.html

Distribution Policy for The Cancer Letter

Thank you for your purchase of this issue of The Cancer Letter! Because issue and subscription sales are our major source of revenue, we wouldn't be able to provide you with the information contained in this newsletter without your support. If you have any questions or comments about the articles, please contact the editors (see page 2 of your issue for contact information).

We welcome your use of the newsletter and encourage you to send articles once in a while to colleagues. But please don't engage in routine distribution of The Cancer Letter to the same people week after week, unless your organization has purchased a site license or group subscription. If you aren't sure, ask the person who is paying for this subscription. If you are sending the newsletter to an unauthorized list, please stop; your actions are against Federal law. If you received this newsletter under an unauthorized arrangement, know that you are in receipt of stolen goods. Please do the right thing and purchase your own subscription.

If you would like to report illegal distribution within your company or institution, please collect specific evidence from emails or photocopies and contact us. Your identity will be protected. Our goal would be to seek a fair arrangement with your organization to prevent future illegal distribution.

Please review the following guidelines on distribution of the material in The Cancer Letter to remain in compliance with the U.S. Copyright Act:

What you can do:

- Route a print subscription of the newsletter (original only) or one printout of the PDF version around the office.
- Copy, on an occasional basis, a single article and send it to a colleague.
- Consider purchasing multiple subscriptions. We offer group rates on email subscriptions for two to 20 people.
- For institution-wide distribution or for groups larger than 20, consider purchasing a site license. Contact your librarian or information specialist who can work with us to establish a site license agreement.

What you can't do without prior permission from us:

- Routinely copy and distribute the entire newsletter or even a few pages.
- Republish or repackage the contents of the newsletter in any form.

If you have any questions regarding distribution, please contact us. We welcome the opportunity to speak with you regarding your information needs.

The Cancer Letter
PO Box 9905
Washington DC 20016
Tel: 202-362-1809
www.cancerletter.com