



JALBCA

JUDGES AND LAWYERS BREAST CANCER ALERT

Vol. 14 No. 3

Editor: Martha L. Golar, Esq.

May 2010

JALBCA's ANNUAL DINNER

Monday, May 10, 2010

**The Water's Edge
Long Island City, NY**

Honoring Clifford A. Hudis, MD

Chief, Breast Cancer Medicine Service Memorial Sloan Kettering Cancer Center

Leadership Achievement Award

and

Ellen's Run

Hon. William C. Thompson Family Award

and installing Co-Presidents Hon. Ellen M. Spodek and Cynthia B. Rubin, Esq.

Silent Auction

6:00 pm Cocktails

7:00 pm Dinner

**NOTE: FERRY TRANSPORTATION, FREE OF CHARGE
FROM 23rd STREET (not 34th St.) & EAST SIDE DRIVE**

JALBCA FEBRUARY PROGRAM – NATIONAL HEALTH CARE REFORM



Edward Kornreich, Esq.

On February 2, 2010, Edward Kornreich, a Partner at Proskauer Rose LLP and a recognized authority on the legal, regulatory and business issues related to health care services, presented a comprehensive outline on the proposed healthcare bill during a JALBCA program entitled “The Implications of Health Care Reform.” Mr. Kornreich identified key points within the Senate bill and their potential impact on the health care industry and on cancer care.

Addressing breast cancer specifically, Mr. Kornreich explained that health plans would be required to pay in full for mammographies, as well as for all preventive screening studies. Moreover, an Office on Women’s Health in the Department of Health and Human Services would be created.

Passage of the Health Care Reform Bill followed. Mr. Kornreich addresses the new legislation in this article.

The recent Health Care Reform Bill is expected to alter fundamentally the mechanisms of health insurance coverage in the United States, with numerous collateral implications. Virtually every person in the country will be affected. Medicaid will be expanded for the poorest Americans. The wealthiest Americans will pay more in taxes. Retiree drug subsidy payments will

now be taxable. Employers will be required to provide insurance coverage or pay a per employee tax (“play or pay”), and small businesses and individuals will have access to an insurance exchange that will allow for the pooling of purchasing power, which should lead to lower prices.

But, what will happen to the many middle class Americans who do not have health insurance? In 2014, Americans will be required to purchase health insurance. Affordability will be addressed primarily through premium subsidies and limits on out of pocket expenses. For the first time, tens of millions of Americans who do not have insurance (whether out of economic necessity or personal cost benefit analysis) will be required to buy health insurance coverage. Those who do not purchase health insurance will pay a fine. By 2016, the fine will be the greater of: (1) \$695 per covered individual up to a maximum of three per family (*i.e.*, \$2,085 per family) or (ii) 2.5% of gross income. Some will be exempted from the mandate to purchase health insurance, particularly those for whom health insurance is deemed “unaffordable.” Unaffordability is defined as those for whom insurance premiums, after applicable subsidies, cost in excess of a certain percentage (up to 12%) of annual income. Those that are exempt from the mandate because they are deemed unable to afford health insurance, will not face the fine but will remain uninsured.

Will the large part of the U.S. population with income up to 400% of the Federal Poverty Level (approximately \$80,000) be thankful that they have highly subsidized insurance and agree that, like car insurance, mandatory health insurance is reasonable and necessary? Or, will they see the choice of either making subsidized, but not insubstantial, health insurance payments or paying a tax, as a taking from their already battered small piece of our huge national pie?

Similarly, how will employers respond to the new legislation? It is estimated that 35-40% of employer-sponsored health insurance will be subject to a new 40% excise tax on higher cost, so-called “Cadillac Plans” (*i.e.*, the tax gener-

ally will be imposed on costs in excess of \$23,000 for a family policy) in 2018. Will employers restructure or eliminate plans to avoid this tax and pay penalties for failing to provide insurance? Will employers provide increased compensation for the amount saved (as Congress anticipates)? Average insurance costs are expected to be lower post-reform, because broader coverage (prompted by the mandate) should reduce rates for commercial plans. Will this pan out? It should in part, because the law will adopt requirements for insurance companies to spend a minimum amount (80 - 85%) of premiums on health care services as opposed to profit or administrative costs. Nevertheless, younger and healthier workers will pay more in many cases, as insurance pools narrow the premium advantages of their health and age. Larger employers who do not currently provide insurance will be required either to provide insurance for their employees or pay a fine. The potential impact on workplace health insurance is uncertain and much debated.

In addition, insurance reform will limit certain problematic insurance company practices like pre-existing condition limitations and dollar caps on coverage. Also, some health care providers should benefit from the extension of insurance and the increase in insured patients. Recognizing this, Congress is imposing broad cuts in payments for existing public programs such as Medicare. Hospitals, however, are concerned since the cuts will be immediate and real while the benefits from expanded insurance coverage may be chimerical and, at the very least, take time to catch up with the cuts.

While the foregoing is far from complete, it is clear that this legislation will affect every American and the entire economy in significant ways. By historical anomaly, the current system of health care – the tax-preferred, employment-based system – is broken. There is much debate about whether these first steps toward a government managed (albeit not government run) system will be successful at expanding coverage and reducing costs. Only the future can answer this question.

NEWS BRIEFS

Comparative Effectiveness Research: Implications for Health Care

Clinicians and patients often have a plethora of choices available for diagnosis or treatment of a condition, but it is often unclear which therapeutic choice works best for the specific person involved. Comparative effectiveness research (CER) is the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat and monitor a clinical condition, or to improve the delivery of care. The purpose of CER is to assist consumers, clinicians, purchasers, and policy makers to make informed decisions that will improve health care at both the individual and population levels. CER is intended to improve health outcomes and reduce health care spending by providing evidence-based data on the benefits and harms of various medical procedures and therapies.

An important component of CER is pragmatic or practical clinical trials (PCTs). These are clinical trials for which the hypothesis and study design are developed specifically to answer the questions faced by decision makers. The characteristic features of PCTs are that they: (1) select clinically relevant alternative interventions to compare, (2) include diverse population of study participants, (3) recruit participants from heterogeneous practice settings, and (4) collect data on a broad range of health outcomes. PCTs have not traditionally been the focus of the primary funders of clinical research, the National Institutes of Health and the medical products industry. The distinction between a regular clinical trial and a PCT is that the former measures efficacy (whether or not a treatment works under optimal circumstances) while a PCT measures effectiveness (the benefit that the treatment produces in routine clinical practice or usual care). An efficacy trial is

undertaken to meet regulatory approval – its design will maximize the potential for detecting efficacy in a population where toxicity is minimized. An effectiveness trial is designed to convince formularies and payers of the actual usefulness of the drug in current practice. (C. Bombardier and A. Maetzel, *Ann Rheum Dis*, 1999; 58:182-185)

There is apparently a pressing need for PCTs because they have not been the focus of the major funders of clinical research. (Tunis et al, *JAMA*, 2003; 290:1624-1632) The American Recovery and Reinvestment Act of 2009 – part of President Obama's stimulus package - allocated \$1.1 billion for CER. The legislation created a federal council on CER and asked the Institute of Medicine to elicit input from a broad array of stakeholders on which research topics should have the highest priority for funding through the ARRA and to then develop a list of the highest priority topics for the Secretary of Health and Human Services to consider.

Proposed New Guidelines for Multi-Drug Regimens

The *Wall Street Journal* reported on March 18, 2010 that the Food and Drug Administration plans to devise guidelines that could accelerate testing and approval of multi-drug regimens. Traditionally, new drugs were tested and approved individually; however, it is believed that drug combinations, and not single agents, are necessary to treat certain illness. The draft guidelines may be published as early as Summer 2010. It is expected that these would set forth what research would be required in the test tube, animals and humans to determine side effects, proper dosage and each drug's contribution to any therapeutic benefit from a multi-drug cocktail. It is not clear how competing companies (*i.e.*, where a drug combination involves drugs manufactured by different

companies) would share data, decide which drugs to combine into regimens, and market their drugs. The article cited several illnesses where multi-drug companies may be needed – cancer, AIDS and tuberculosis – and reported that Merck & Co. and AstraZeneca PLC are jointly testing two anticancer agents.

The collaboration between Merck and AstraZeneca had previously been announced in June 2009. Their arrangement is to test a potential new cancer treatment composed of two investigational compounds that are still in early human trials. It was then reported as the first time that two large pharmaceutical companies had established a collaborative effort at such an early stage of development – a Phase 1 clinical trial for the treatment of solid cancer tumors – rather than doing so when the drugs enter late-stage development or when marketing approval has been received. Reportedly, all development costs will be shared jointly.

SHARE – REMINDER - TELEPHONE SUPPORT FOR WOMEN WITH METASTATIC DISEASE

During 2009, SHARE (Self-Help for Women with Breast or Ovarian Cancer) initiated a pilot telephone support program for metastatic women funded by JALBCA, on Mondays, from 4:00-5:00 PM. The facilitator is a breast cancer survivor who is also a licensed social worker. If you are interested in participating in this program, please call the SHARE Hotline at 866.891.2392. SHARE has nationwide hotlines in English and Spanish for breast and ovarian cancer – early stage, recurrent, and metastatic. While SHARE speaks with women from all over the U.S. on its hotlines, educational and support programs are held only in the New York City area. SHARE's hotline volunteers, however, can help you find support groups where you live.

ELLEN'S RUN – SAVE THE DATE

Fifteenth Annual Ellen's Run

Sunday, August 22, 2010 • 9:00 a.m. rain or shine • Southhampton, NY

Pre-registration will become available on line at www.active.com or telephone 212.840.0916 or 631.907.1952 to request an application.

CALENDAR/CONTACTS

ADELPHI NY STATEWIDE BREAST CANCER

Hotline & Support Program

Adelphi University School of Social Work
Garden City, NY 11530

www.breastcancerhotline@adelphi.edu

CancerCare

275 Seventh Avenue
New York, NY 10001

www.cancercares.org

1.800.813.HOPE (4673)

ELLEN'S RUN

130 W. 42nd St., 22nd Fl.
New York, NY 10036

www.ellensrun.org

212.840.0916

MEMORIAL SLOAN KETTERING CANCER CENTER

Post-Treatment Resource Program

Educational Forums

215 E. 68th St., Ground Fl.

New York, NY 10021

www.mskcc.org/mskcc/html/59513.cfm

212.717.3527

Bendheim Integrative Medicine Center

1429 First Avenue (at 74th Street)

SHARE (*Self-Help for Women with
Breast or Ovarian Cancer*)

1501 Broadway, Ste. 704A

New York, NY

www.sharecancersupport.org

212.719.0364

Speak to a survivor toll-free:

1.866.891.2392

TO LIFE!

410 Kenwood Avenue

Delmar, NY 12054

518.439.5975

518.475.9141 (fax)

www.tolife.org

YOUNG SURVIVAL COALITION

61 Broadway, Suite 2235

New York, NY 10006

646.257.3022

www.youngsurvival.org

JALBCA

c/o Jennifer Fiorentino

Executive Director

1324 Lexington Avenue, PMB 324

New York, New York 10128

www.jalbca.org

Address Service Requested

