CEO Life Sciences Consortium UPDATE

Winter, 2010

Inside this issue:

START Clauses

are freely available from:

http://ceo-lsc.org/

and

http://cancercenters.cancer.gov/documents/StClauses.pdf

The
Life Sciences Consortium
Is an initiative of:

CEO ROUNDTABLE ON CANCER

A message from *CEO Roundtable on Cancer* chairman Bill Weldon

Dear Friends,

Many of you will recall from *CEO Roundtable-IX*, our annual meeting held last September in Philadelphia, hearing from Dr. David Dilts. Dr Dilts' research was a catalyst in prompting our Life Sciences Consortium (LSC) efforts to reduce time wastage during the contracting phase of cancer clinical trials. Dr. Dilts emphasized that time wastage remains a critical factor in the success or failure of a clinical trial, noting that, every day, there are ~3,800 new cancer diagnoses and ~1,500 cancer deaths. This is a business issue too, as an estimated average of $1M of sales is lost every day a drug is not in the market.

In this context, I would highlight the successful efforts of our LSC, working together with the National Cancer Institute and Hogan & Hartson, to create the Standard Terms of Agreement for Research Trial (START) Clauses. **I would urge you to adopt these contract templates not only in oncology research, but across all therapeutic areas.** I would also urge that you consider an ongoing assessment of the impact of the START Clauses on time-to-contract-completion. In this way, we can learn from our collective experiences and improve and expedite this process.

At our meeting, NCI Director, Dr. John Niederhuber and Dr. Richard Goldberg, physician-in-chief of the North Carolina Cancer Hospital, also urged the creation of "START-like" contract clauses that would apply to pre-clinical research. Currently, issues such as intellectual property and materials transfer agreements are not addressed through the START Clauses. To that end, **I am requesting that LSC Members designate an appropriate contact or contacts to participate in a "START-2" (preclinical standardized MTAs) initiative.** I am particularly excited about this endeavor as it has great potential for implications beyond oncology.

Lastly, we also heard from LSC Chairman, Dr. Gregory Curt, U.S. Medical Science Lead, Emerging Products, AstraZeneca and Dr. Jim Doroshow, Director of the NCI's Division of Cancer Treatment and Diagnosis, on the importance of identifying cancer "biomarkers" to hasten new drug development. Dr. Doroshow encouraged LSC companies to take advantage of both the research capabilities and the scientific objectivity of the NCI. He asked that companies consider presenting biomarker research under confidentiality to NCI so that they could help identify the most promising markers, eventually validating them and entering them into the public domain for additional research. **I encourage all LSC Members to assess your company's potential and willingness to present biomarker programs to NCI.** This collaboration would create a pool of pre-competitive IP in the area of standardized reagents and assays in the public domain which all investigators could utilize. In this regard, AstraZeneca is presenting to the NCI this month, and Johnson & Johnson and Pfizer have also agreed to participate.

Your participation in these initiatives will ensure that we will continue to be *"bold and venturesome"* in our work on behalf of cancer patients.
Thank you for your time and consideration.
Yours,

William C. Weldon
Chairman, *CEO Roundtable on Cancer*

Expanding Partnership

The Institute of Medicine

The *CEO Roundtable on Cancer* recently entered into a reciprocal membership agreement with the Institute of Medicine. Dr. Martin Murphy, our CEO, will represent the *CEO Roundtable on Cancer*, including its Life Sciences Consortium, on the IOM's National Cancer Policy Forum. Likewise, Drs. Harvey Fineberg and Roger Herdman of the Institute of Medicine were named Honorary Members of the *CEO Roundtable on Cancer* and will represent the IOM in our activities.

One early development of this promising new collaboration is that Life Sciences Consortium Chair, Greg Curt of Astra Zeneca, spoke at the recent National Policy Forum public workshop addressing the widening spectrum of precompetitive collaboration in oncology biomedical research and development. On February 10, 2010, Dr. Curt introduced those in attendance to the work of the *CEO Roundtable on Cancer's* Life Sciences Consortium in a session on precompetitive collaboration in oncology.

Read more here:

http://www.iom.edu/Activities/Disease/NCPF/2010-FEB-09.aspx

PhRMA

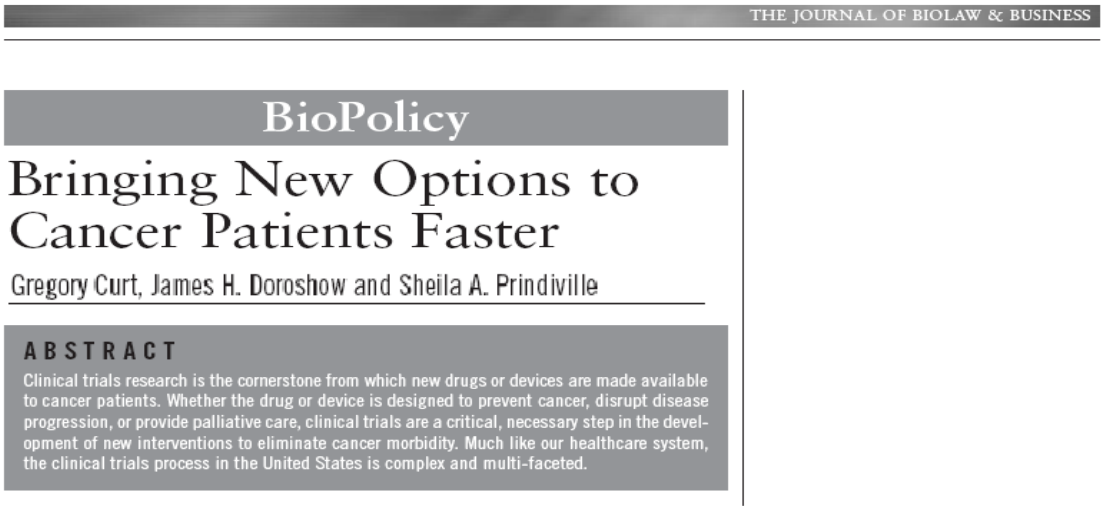
David Brennan, Chief Executive Officer of AstraZeneca, board chairman of the Pharmaceutical Research and Manufacturers of America (PhRMA) and Honorary *CEO Roundtable on Cancer* Member, invited the *CEO Roundtable on Cancer's* Dr. Martin Murphy, to address PhRMA's annual meeting on March 18th to discuss the *CEO Roundtable on Cancer* and its Life Sciences Consortium. Dr. Murphy is hopeful that those attending the annual meeting, many of whom are already represented on our LSC, will leave with a greater sense of urgency about the challenges and opportunities ahead as outlined by *CEO Roundtable on Cancer* Chairman Bill Weldon of Johnson & Johnson on Page 1.

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for new cures. PhRMA members alone invested an estimated $50.3 billion in 2008 in discovering and developing new medicines. Industry-wide research and investment reached a record $65.2 billion in 2008.

START Clauses in the News

Watch for the upcoming issue of The Journal of Biolaw & Business. Drs. Jim Doroshow and Sheila Prindiville of the NCI, together with LSC Chairman, Dr. Greg Curt of AstraZeneca and Hogan & Hartson's Phil Porter, have written of the unique process that created the START Clauses and the transformational opportunity they represent to help speed the delivery of new drugs to patients who need them.

http://www.biolawbusiness.com/



THE JOURNAL OF BIOLAW & BUSINESS

BioPolicy

Bringing New Options to Cancer Patients Faster

Gregory Curt, James H. Doroshow and Sheila A. Prindiville

ABSTRACT

Clinical trials research is the cornerstone from which new drugs or devices are made available to cancer patients. Whether the drug or device is designed to prevent cancer, disrupt disease progression, or provide palliative care, clinical trials are a critical, necessary step in the development of new interventions to eliminate cancer morbidity. Much like our healthcare system, the clinical trials process in the United States is complex and multi-faceted.

The START Clauses were featured in the September 9, 2009 edition of ACCConnect, the newsletter of the Association of Community Cancer Centers. Nearly 17,000 cancer care professionals from approximately 900 hospitals and more than 1,200 private practices are affiliated with ACCC. It is estimated that 60 percent of cancer patients nationwide are treated by a member of ACCC.

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ACCC

ASSOCIATION OF COMMUNITY CANCER CENTERS

ACCConnect

A bi-monthly e-newsletter from the Association of Community Cancer Centers

New Toolkit Helps Expedite Clinical Trial Contract Negotiations

http://www.accc-cancer.org/mediaroom/newsletters/2009/media_ACCConnect_9-9-2009.html

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