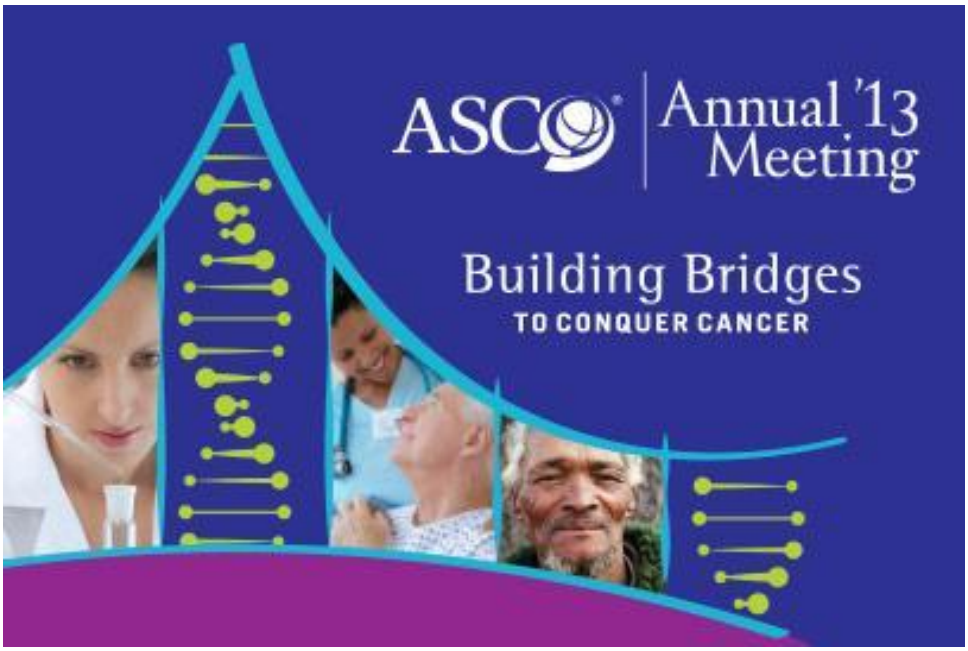
An Advocate's View of the

# 2013 ASCO Annual Meeting

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**Acknowledgments and Introduction:**

I would like to thank the Research Advocacy Network for the opportunity to attend the 2013 Annual Meeting of the American Society for Clinical Oncology (ASCO) as a Focus on Research Scholar. I would also like to thank my disseminating organization and mentor, the Kidney Cancer Association and its CEO William P. Bro. Mr. Bro and the KCA gave me the freedom and encouragement to attend and participate in presentations and sessions of my choosing instead of restricting me to topics dealing primarily with kidney and other genitourinary cancers; Mr. Bro and the KCA have recognized the subtle and yet important fact that information and material in other tracks can often be more enlightening and empowering for an advocate during these scientific assemblies. I am honored to submit this report for your consideration.

As a sixteen-year survivor of active kidney cancer which is still being treated, I have witnessed the ushering in of targeted-therapy drugs, more active roles that patients and caregivers are taking in their treatments, innovations in surgical and diagnostic procedures, and yet I continue to mourn the passing of those stricken with cancers that fail to respond to treatment. This summary report does not focus on breakthroughs in scientific innovations; it focuses instead on what appears to this observer to be a rising groundswell, a call for change in the way cancer research will be conducted in the future. It would seem that many of the presentations given in Chicago this year contained reflections of past cancer research and clinical trial design that somehow resembles a remark made to Mutt by Indiana Jones as the enemy approaches in *The Kingdom of the Crystal Skull:* "Nice try, kid, but I think you just brought a knife... to a gun fight."


**Behind the Scenes**

Like it or hate it, healthcare is in fact a business; the fortunes of publicly traded pharmaceutical and other companies in the industry often rise and fall depending on the outcomes or preliminary reports of clinical trials. The Patient Protection and Affordable Care Act (ACA or Obamacare) is greatly influencing the way medicine and healthcare will be practiced in this country; regulations in place by the FDA, the EPA, and a host of other agencies further dictate how the business of healthcare is practiced. In a summary of events at ASCO the following quote appeared June 8 in *The Motley Fool* concerning a company's trial of a product that increased median overall survival to 9.8 months from 7.4 months when used in combination with the standard of care drug: "the worry among investors is that this data may not be significant enough to merit an approval by the FDA." http://www.fool.com/investing/general/2013/06/08/all-about-asco-2013-highlights.aspx

**The Changing Face**

As Dr. Derek Raghavan, President of the Levine Cancer Institute shared some of his experiences with the Focus on Research Scholars and other patient advocates he informed them that when he started in oncology 35 years ago the elusive goal was to cure people; he recalled that as a first-year fellow the death rate of his testicular patients hovered somewhere at 80 to 90%. Today as 5-year survival rates approach 95% (99% for localized cancers) Dr. Raghavan notes that the focus for 90% of the cases are primarily on dealing with after-effects of therapy and how to make the treatments less intense while remaining effective.

Raghavan recounts how a long-time friend and colleague, Dr. Ron Bukowski, a specialist in kidney cancer with the Cleveland Clinic would come to ASCO year after year and report on study after study that did not work. Since the development and approval of Tyrosine-kinase inhibitors (TKI's) which restrict the ability of tumor cells to attract blood supplies and nutrients in 2005 Bukowski finally had something to talk about. Today, there are seven targeted-therapy drugs that have been approved for kidney cancer.

"…here's the thing that's hard to understand – we don't have enough money in America to pay for everything… so what we have to do is to spend our money on things that actually provide benefits to the community."

Derek Raghavan,
MD, PhD, FACP, FRACP
President, Levine Cancer Institute
Carolinas Healthcare System


**Dr. Bukowski's Suggestion**

Despite the availability of these seven drugs, Dr. Bukowski continues to come to ASCO and talk about kidney cancer. In his presentation *New Targets and Strategies in Renal Cell Carcinoma: What Will the Future Hold?* Bukowski expresses his concern about "trying to continue to develop drugs for some small gains in the therapeutic index… In terms of efficacy there are not a lot of differences, they are quite similar."

"…we have reached a plateau. We need to think about how we can move on."

Ronald M Bukowski, MD
Cleveland Clinic
Taussig Cancer Institute

He maintains that patients would be better served by clinicians gaining a better understanding of the disease and developing novel forms of therapy instead of trying to develop another first line TKI that is marginally better. He suggests using different dosing strategies similar to those used in administering antibiotics and anticonvulsants based on better therapeutic monitoring for existing drugs. "We need to move towards genomic and personalized medicine" Bukowski states, "we need to focus on development of molecular profiles for these tumors and incorporate these findings into future therapeutic strategies." He also included a cautionary note about clinical trial design mentioning that while there are several studies underway involving novel targets and investigational agents the development of one particular agent with potential that clearly worked in kidney cancer in an interesting pathway has stopped and may be abandoned because of poor clinical trial design especially in the pivotal arm phase of the study.

In the general poster session for genitourinary (non-prostate) cancers, Dr. Georg A. Bjarnason of the University of Toronto presented information that illustrates the value of using different dosing strategies. His study (abstract number: TPS4594) measured the blood flow in tumors through Microbubble contrast-enhanced ultrasound (DCE-US) of patients receiving the standard first-line TKI therapy for kidney cancer (sunitinib). The study revealed that the maximum reduction of tumor blood flow occurred in the first 14 days of a dosing cycle with an increase in flow in the final 14 days of the labeled dosing regimen; toxicity was lowest during the first 14 days and then began to increase. By changing the dosing regimen from 28 days on/14 days off to a 14/7 cycle, tumor control was maintained with less overall toxicity. This study also observed high inter-patient variability rates in pharmacokinetics (drug action in the body) of 40 to 60%.


## Concluding Quotes and Remarks


"…I believe the advocate's role is to educate themselves independently as much as possible to understand the issues. Our role is to collaborate with the scientific community to achieve the mission; but it is also to challenge the scientific community and to bring a different perspective to the conversation."

Fran Visco, PhD, MPH
President,
National Breast Cancer Coalition

As a survivor and advocate I am grateful for the dedication and hard work the scientific and medical community exerts in pursuit of increasing the quality of life and easing the burden of cancer for those afflicted by this condition. I would also suggest that my comments in this report are akin to the 8-second sound bites that are so common in the general media today; that they perhaps are biased and present a distorted view of the real situation. Despite that disclaimer, the following are quotes that were heard in presentations.

"Drugs are tested in mouse models which do not adequately predict human response."

"We have had decades of investments, billions on drug development with a minimal impact on mortality."

"Maybe we need to step back, look at the entire system, question all of it, and together design a brand-new approach."

Fran Visco: *The Appearance of Progress: Resisting the Siren Song of Modest Benefits*

"Less than one in five studies that are registered in clinicaltrials.gov are published in peer-reviewed journals."

"The Institute of Medicine estimates that less than 50% of treatments delivered today [by physicians] are supported by evidence."

"Of 2 trillion spent in healthcare in the United States annually less than 0.1% is invested in assessing the comparative effectiveness of available interventions."

Dr. Scott David Ramsey: *Pragmatic Trials in Oncology: Methodology and Application*


# The Meeting in a Nutshell

Dr. Lee M. Ellis of The University of Texas, M.D. Anderson Cancer Center made the following statements to his peers during his presentation on *The ASCO Cancer Research Committee's Efforts to Set Guidelines on Clinically Meaningful Benefit*

"We only have so much money in the bank.
We can do a few large trials or we can do many small trials.
Small trials have to be smaller and smarter."

"Let's not forget why we are here;
We are not here for Academic Accolades.
We are not here for promotion to tenure;
We are not here for money.

*We are here to help our patients* –
We can never, ever forget that."