Dr. Barry Mennen MD, Strategist and Advisor to ROI[2], comments on his recent trip to a cancer conference held in June 2012 at the Grand Hyatt Hotel, Washington DC. The conference was sponsored by Personalized Medicine Coalition (PMC), American Association for Cancer Research (AACR) and Feinstein Kean Healthcare (an Ogilvy company.) www.turningthetideagainstcancer.org

"Turning the Tide Against Cancer Through Sustained Medical Innovation"

"A national conference on cancer science and policy'

Background: The development of new cancer therapies targeted to an individual's tumor based on its genomic profile is a complex issue. The purpose of this conference was to look at the scientific data and policy issues in oncology, and discuss the issues from the viewpoints of multiple stakeholders. Those who took part in the panel discussions represented physicians, the FDA, PhRMA, big pharma, academic clinical and bench-science researchers, payers, think-tank policy individuals, the NCI, venture capitalists, patients, and advocacy groups (perhaps an IT healthcare whiz might have been added to the mix). All of these groups need each other, and the purpose of this conference was to see how they might all improve methodologies for achieving this in order to ease the development and deployment of effective, targeted therapies in a cost-efficient and rapid manner.

Takeaways

Ed Abrahams, PhD, the Executive Director of the Personalized Medicine Coalition (PMC) led off the session. This was paid for by pharma, and to a lesser extent diagnostic companies as they are the major players in the PMC.

- Interesting comment from an executive with Covance, that 'precision' medicine is a better term than 'personalized' medicine. Although it sounds like an overpromise, he pointed out that it does not give the outcome, only the methodology. Evidently Novartis and some other companies are beginning to use the term. **John Mendelsohn**, MD, Past President of the Khalifa Institute for Personalized Cancer Therapy at the University of Texas MD Anderson Cancer Center gave the keynote and covered the history of cancer innovation. He pointed out that much of it *was* actually personalized. He outlined the challenges for personalized cancer therapy:
    - Heterogeneity and plasticity of cancer cells
    - In the genetic abnormalities that are found in the cancer cell: how can we tell the drivers from the passengers?
    - Molecular and genetic influences can modify the tumor's response to therapy
    - Molecular and genetic profile of patient can also influence response to therapy, e.g., patient's individual inflammatory response to tumor and therapy

The first panel was chaired by **Ramsey Baghdadi**, Editor, *The RPM Report* on how innovative models might address the challenges in cancer research and care. Terrific set of panel members, including **Laura Esserman**, MD. MBA, Prof. of Surgery and Radiology, UCSF, who runs both the comprehensive cancer center and the breast cancer center. She is developing a network that combines clinical results and patient information that allows personalized therapy to get to the individual in a faster manner.

Another excellent panelist was a most impressive woman named **Kathy Giusti**, **MBA** who was a pharma exec with Merck and Searle (head of global arthritis franchise at the latter). In 2004, she was diagnosed with (the inevitably fatal) multiple myeloma, and started the Multiple Myeloma Research Foundation. Partly due to her energy, smarts and experience she has changed the landscape of this disease--including therapeutic choices based on genetic analysis of the tumor. As an example, she has the 414 translocation, and that's how people often friend her on Facebook; and, as she put it, "…I'm really only interested in what's going on with patients with this translocation" [for her own care, that is]. There was much talk about this 'myeloma model' and it undoubtedly will be more important in the next few years.

Leonard Lichtenfeld, MD, Deputy Chief Medical Officer of the American Cancer Society had a few interesting things to add, such as '…*pharmageddon* is coming…' meaning that the price of drug development is unsustainable. For pharma, there is actually a named law about this, called *Eroom's Law* which states that the number of new drugs developed per billion dollars is halved every nine years (this is, in a way, the opposite of technology's *Moore's Law*). Therefore, we must be much more efficient in drug development to begin to sustain the industry—some chilling doses of reality here.

The major takeaways from this panel were:

- Cancer patients are being balkanized by mutation type
- The key is data management for all patients
- Getting all patients access to advanced care
- Computer-based networks are the logical means of achieving patient-care goals

The next panel was on defining *value*, and was a tough one (Patient value? Societal value?). Standout panelists here were **Al Benson** III, MD, Assoc. Director for Clinical Investigations at Northwestern Univ. Comp. Cancer Center and **Lee Newcomer**, MD, MHA, Senior VP, Oncology, UnitedHealthcare. Benson made one interesting sidebar comment about the electronic health record (EHR) : [paraphrasing]"Since we have gone completely digital, our costs have gone up. Although I certainly recognize its contributions…but, I now walk into the office and constantly see new people. 'Who are they?" I ask…well, it turns out that they're data management people. There are now so many requests for data of different types that we need full-time people to get the reports out…it's crazy. How will small practices manage this?" Although he didn't specifically say this, I imagine he was alluding to the demand for data reports from the feds, the state, insurance companies, pharma, etc.

Newcomer said that they might now say to a doctor: "We know that we spend about $120,000 on a prostate cancer patient over his lifetime, here's $120K: you and the patient decide how you want to use it."

The luncheon speaker was Columbia University's **Siddhartha Mukherjee,** MD, author of *The Emperor of All Maladies: A Biography of Cancer;* incredible speaker—brilliant and entertaining. The eye-opening fact he

dropped on us was an example of the heterogeneity of tumors. He gave an example of one of his patients who had two separate areas on the same breast with cancer; each tumor had *different* genetic signatures, and each called for its own therapy. They had to put her through one cycle of therapy and then through another that had its own menu of drugs. After listening to him I thought: "Math is easy; *cancer* is hard."

The afternoon panel was "Policies to Sustain Innovation in Cancer," and there were some very interesting comments. For me, the best was that of **Ken Anderson**, MD, Chief of the Multiple Myeloma Section, Dana-Farber, and Prof of Medicine, Harvard. At Harvard they are now in the process of changing the reward system for their staff MDs and PhDs. Their question to the staff: "Have you or have you not changed outcomes?" That is, they will not merely count papers published in *Nature*, but look for real-world effects. They will also change their structure to that of "team science" which will reduce the silos that their doctors now work in; there will now be more shared data and experience. Their goal is to remove (or reduce, at least) competition between individuals. Good luck with this, I thought, but perhaps some barriers will come down with this kind of innovative thinking.

When asked for a sentence at the end of the session from each panelist (**Anna Barker**, PhD, Director, Transformative Healthcare Networks at AZ State; she is a forceful and excellent moderator and would recommend her if a chair is needed for a meeting related to this subject) that would best represent their innovation-sparking recommendation, here's what they said:

- **Richard Pazdur**, MD, Director, Office of Hem-Onc Products, CDER, FDA: When he was asked during the panel discussion what five things he wanted to see for innovation in oncology he said: 1) good data; 2) good data; 3) good data; 4) good data and 5) good data. Yes…he said it five times to emphasize that with all the talk, the FDA still needs to see clinical benefit. For his summary sentence, he said that there was a continuing need for coordinated private and government efforts against cancer, but offered no specifics.
- **Ken Anderson:** change the initiatives in academia. But how? (see above for more specifics). He also said: "How to incentivize innovation? We have a crisis in research—who will fund it?"
- **David Parkinson**, MD, Venture Partner, New Enterprise Associates: Reward systems that link regulatory and economics to clinical utility/evidence.
- **Ira Klein,** MD, MBA, Chief of Staff, Office of Chief Medical Officer, Aetna: Government must lead the way in policy debate; and, they must change Medicare reimbursement.

Amy Abernathy, MD, an oncologist from Duke and an adviser to the PMC summed the day up well. We now have a Rubik's Cube of information that we must figure out how to use; because, **DATA ≠ KNOWLEDGE.** We need organizational efficiency in trial design, and drug companies (as **Christi Shaw** from Novartis mentioned) need to bring the complete package (drug, biomarkers, access programs) to the patient. We must embrace the complexity of cancer and apply some of the creative solutions discussed: *that* is innovation.