# The Immuno-Oncology Network for Patient Organizations Event Report: Patient Leader Education Summit

Note: As of April 2017, the Immuno-Oncology Network for Patient Organization has been rebranded as the Collective Oncology Network for Exchange, Cancer Care Innovation, Treatment Access, and Education (CONECTed). Henceforth, CONECTed is considered the title of this group.

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## Introduction

On Friday March 31 and Saturday April 1, 2017, the Immuno-Oncology Network for Patient Organizations (henceforth referred to as 'The Network') hosted the Patient Leader Education Summit. This was the inaugural meeting of The Network, and in attendance at the meeting were health technology assessment professionals, medical professionals, and patient advocacy leaders from several cancer indications. The goals of The Network are to unify the patient voice and empower patients and advocates to be fully engaged in healthcare decision-making, to work in tandem with all the stakeholders involved towards solutions for a sustainable system, and to ensure that cancer patients have access to cancer therapies. The Network will be devoted to ensuring that the system remains sustainable for cancer care, and is committed to increasing innovation and research in Canada, while expanding access to new therapies within a dynamic regulatory framework that is dedicated to improving cancer care across all therapies and tumour sites.

The opening remarks of the summit were delivered by Kathleen Barnard (Founder and President, Save Your Skin Foundation), the keynote speech by Ryan Peck (Executive Director, HIV & AIDS Legal Clinic Ontario), and the closing remarks by Barry D. Stein (President, Colorectal Cancer Association of Canada); the remainder of the summit program consisted of three panels of presentations and discussions, and three open forum discussions. Panel members and speakers at the event represented a variety of topics and interest groups, as will be demonstrated in the breakdown of each panel included in this report.

## Steering Committee

The steering committee of The Network consists of:

- Kathleen Barnard (Founder and President, Save Your Skin Foundation)
- Louise Binder (Health Policy Consultant, Save Your Skin Foundation)
- Heather Chappell (Executive Director, Kidney Cancer Canada)
- Annette Cyr, C. Dir., C.C.P., SHRP (Chair of the Board, Melanoma Network of Canada)
- Martine Elias (Director Access, Advocacy and Community Relations, Myeloma Canada)
- Elizabeth Lye (Scientific Advisor, Lymphoma Canada)
- Christina Sit (Program Manager, Lung Cancer Canada)
- Barry D. Stein B.Com., B.C.L., LL.B. (President, Colorectal Cancer Association of Canada)
- Sabrina Hanna (Executive Director, Save Your Skin Foundation)

## Opening Remarks

Kathleen Barnard (Founder and President, Save Your Skin Foundation)
Friday, March 31st, 8.55-9.05

The opening marks were delivered by the Save Your Skin Foundation President and Founder Kathleen Barnard, who is a melanoma survivor. Her talk described her journey with melanoma and experience with clinical trials, and how this experience led to the creation of The Network. Barnard was diagnosed with melanoma in 2003, and in 2004 was told that it had advanced to stage 4 malignant melanoma. She underwent local treatments, which were largely unsuccessful, until taking part in a clinical trial for an immuno-therapy drug at the Cross Cancer Institute. The treatment cost $40,000 and the side effects were severe, but within a week a tumour in Barnard's lung had shrunk by half. Barnard was the first Canadian to undergo an entire immuno-therapy trial, and since the founding of Save Your Skin in 2006 she has been helping Canadian melanoma patients access trials. Barnard believes that innovative medicine, especially immuno-oncology, has shifted the focus in the melanoma landscape from hope to survivorship, and has the potential to do so for other cancer indications. The changes that innovative medicine will bring in cancer treatments, while exciting, have increasing costs and more barriers associated with them, creating a need for an organization like The Network. Barnard hopes that through collaboration, The Network will be able to bring important immuno-oncology innovations to Canada, including combination and triple therapies, and further, that The Network will be able to expedite approval processes, increase patient access to appropriate and affordable care, and further engage patients in their medical decision-making.

## Panel One: "Landscape of Cancer Today and Tomorrow"

Friday, March 31 9.05-10.20
Moderated by Elizabeth Lye (Scientific Advisor, Lymphoma Canada)
Presentations by Dr. Marcus Butler (Medical Oncologist, Princess Margaret Cancer Centre), Dr. John C. Bell (Senior Scientist, Centre for Innovative Cancer Research, Ottawa Hospital Research Institute), and Monette Greenway (Principal and Co-Founder, Precision Rx Dx)

### Dr. Marcus Butler: "Immunotherapy for Cancer: Where are we Now?"

In the first presentation of this panel, Dr. Marcus Butler presented on the current state of immunotherapy treatments for cancer patients. Butler prefaced his talk by noting that immuno-oncology is a rapid shifting field, but hoped to suggest what may be accomplished with immunotherapy and other innovative cancer therapies.

Butler began by comparing standard treatments to immunotherapy drugs for patients with 'incurable' cancers. Standard treatments provide benefit to increase survival (measured in months or weeks), and alleviated pain so patients could live more productive lives during their treatments, while the introduction of checkpoint inhibitors (ex. ipilimumab) saw patients living slightly longer in less successful cases, and surviving their disease and having good quality of life in successful examples. Unlike with standard treatments, some patients receiving immunotherapy achieved significant benefit. The goal of immuno-oncology is, therefore, to increase the number of patients receiving long-term benefit from treatments.

Butler then suggested that immunotherapy is generally not a treatment for cancer, but a treatment for the immune system, based on the notion that a tumour is not created exclusively from tumour cells, but a variety of cell types. Therefore, cancerous tumours often include

immune cells that may be helping these tumours grow due to the existence of the tumour-promoting cells in the immune system (which also contains tumour-suppressant cells). The goal of immunotherapy is to shift the balance of the immune system to induce cancer cell killing by increasing the agents that fight cancer cells. This is performed by introducing professional antigen presenting cells which mock tumour cells, and educate the immune system in recognizing the cancer cells and the immune cells that encourage tumour growth. This may take more time than the standard chemotherapy or targeted therapy, which directly target the cancer cells.

The challenge with this method of treatment is that cancerous tumours contain many traits common to normal, healthy tissue; therefore, the immune system may initially recognize the abnormal aspects of the tumour, for this response to be shut down by regular immune system function. A method of avoiding this issue is via immune checkpoint molecules, which use activated T-cells to shut down the immune system's usual methods of preventing toxicity in normal tissues. This interference with the regulatory elements of the immune system induces potentially dramatic responses in patients, which may cause the cancer to appear worse before improving; this is likely due to the time it takes to build the cancer-fighting agents.

Butler then elaborated on the example of ipilimumab (anti-CTLA-4). Ipilimumab was approved because 10-15% of patients saw increased life spans. Butler suggests that this treatment may change the behavior of tumours, and patients that do not respond well to the drug see the tumours grow less quickly while a small percentage of patients have a complete regression of their disease without recurrence. This is especially true in the case of melanoma patients, who have seen an improvement/survival increase of 15% in the last five years.

Butler then moved to anti-PD-1 drugs, which are showing special promise in lung, melanoma, and oral cancer tumours. Anti-PD-1 drugs, according to Butler, have created opportunities for more cancer indications to benefit from immunotherapy drugs, with patients often having significant responses. However, these benefits are often not as long-term as they are in melanoma patients. Butler suggests that the lack of response in some patients may be due to patients not having a strong enough anti-tumour response to induce clinical benefit. Patients who do not have immunogenic tumours, for example, will likely require additional combination therapies. Here, Butler gives the example of CAR therapy in leukemia patients with weak immune response, wherein blood is drawn and T-cells are engineered to recognize cancer cells in the laboratory before being infused back into the patient's blood.

Butler concludes by stating that while immuno-oncology has benefitted many patients, there is room for further long-term improvement for a greater percentage of patients. This improvement would include the development of new combinations of chemotherapy, targeted therapy, vaccines, and immunotherapies. A further challenge is developing ways to identify a patient's likelihood to respond to a specific therapy, or which patients are unlikely to respond to immunotherapy at all. This goal may be possible through further collaboration with patients, HTAs, the government, and healthcare systems. While these drugs are expensive, it is important that patients have access to them for the value they possess, from shrinking a tumour and allowing a patient more time, to complete response.

Dr. John Bell: “Oncolytic Viruses: Programmable Cancer Killing Machines”

Dr. John Bell presented on the creation of oncolytic viruses, which were created to treat cancers. The current challenge with standard cancer treatments is that many metastatic cancers are incurable because chemotherapy attacks normal tissues and suppresses the immune system while fighting cancer. Cancer-targeted therapies (such as immunotherapies) are therefore beneficial, as they do not affect normal tissues and rouse the immune system to fight cancer, rather than suppressing it.

Oncolytic viruses are designed to be parasites of cancer cells. As a virus only has 5 genes, it can only replicate by moving inside a cell and using that cell’s genetic information to copy itself, sometimes killing the cell in the process. Therefore, oncolytic virus parasites can only replicate in mutated cancer cells, often killing these cancer cells in the process. Oncolytic virus therapy does not create the same side effects as chemotherapy, and has been used effectively to treat patients.

Oncolytic virus treatment was initially tested in mice that had been injected with cancer cells that mimicked metastatic melanoma (this is different from treating metastatic cancer in humans, as the mice get sick very quickly and are often near death within two weeks). The mice were then treated with the oncolytic virus intravenously; in this case, the virus was coded with a gene from a jellyfish, so it would turn green when it infected a cell and the scientists could see where the virus was growing. While humans are genetically different from mice, and the mice were genetically identical, the oncolytic virus therapy was successful in affecting only the cancer and leaving the normal tissue unscathed.

Bell then discussed vaccinia, a virus currently in late stage testing. Vaccinia is selectively engineered to grow in cancer cells and not normal tissues. So far, testing has seen some great responses, which have been labelled ‘elite responders’. Bell notes that these viruses could still be improved by making them engage with the immune system more frequently and effectively. He gives an example of oncolytic virus’ engagement with the immune system by citing Dr. Kelley Parato’s experiment wherein she implanted a colon tumour in mice, then cured them with oncolytic therapy treatment. Seven months later, Parato attempted to infect the mice with cancer again, but the mice rejected the tumour; the virus had educated their immune system to recognize the cancer, and eliminated it upon return. These results have also been seen in humans; Bell cites a case of a 32-year-old woman with melanoma whose immune system responded well to oncolytic therapy, eradicating the cancer where the virus was injected and in the surrounding areas.

Bell then moves into the benefits of combination treatment strategies. He states that while cancer is often too complex to be cured with one treatment, there are better chances of eliminating cancer with strategic combinations. Virus therapy could effectively be combined with checkpoint inhibitors, both engaging the immune system and educating T-cells to attack cancer. The introduction of virus therapy could further increase the effectiveness of checkpoint inhibitor treatments, by thwarting the cancer’s use of a PD-1 molecule to camouflage the cancer in the body. The development of antibodies via virus therapy stimulates immune response, allowing the body to continue attacking these cancer cells. Trials combining virus therapy with checkpoint inhibitor therapy are currently available for lung cancer, which BioCanRx are promoting in hopes of better outcomes for patients.

Bell concludes by discussing biotherapies, which can use various methods to attack cancer, providing benefit to patients and potential for a cure. He suggests that by collaborating, the industry can accelerate the development of therapies and deliver them to patients faster, noting the effectiveness of his program in Ottawa and Toronto, wherein they develop the virus in the lab, and manufacture and deliver the virus to patients in the same building.

Monette Greenway: "Precision Medicine: Today and Tomorrow"

Monette Greenway presented on the rapidly changing and high-impact area of precision medicine and companion diagnostics. She discussed the clinical value of precision medicine with real world evidence, and gave an overview of what may come in the future and potential barriers for patients.

Precision medicine is the use of biomarker information obtained through companion diagnostic tests (CDx), which identifies and stratifies patients to determine which will be more likely to benefit from particular drugs called targeted therapies. The companion diagnostic tests guide the healthcare provider in making appropriate treatment choices for their patients. While in standard treatments such as chemotherapy, one treatment is presumed to work for all patients and often does not, targeted therapies tailor treatments to patients based on their biomarker type. Targeted therapies focus on specific mechanisms within targeted cells, and are used across many cancer indications and even outside of oncology.

Precision medicine and companion diagnostics are an exciting area in the medical community, as standard treatments for cancer have been shown to be ineffective in up to 75% of cases (Spear Brian B. et al Trend in Molecular Medicine volume 7, Issue 5, 1 May 2001 pp.

2001-2004). Precision medicine promises great benefits for patients, healthcare stakeholders, and physicians, and is an efficient use of healthcare resources. Additionally, drug and clinical trial approval rates are accelerating; while in chemotherapy the standard drug approval rate is 8%, precision medicine sees an approval rate of 25% (qtd. in Greenway slide 6). Approvals of precision medicine in Canada are generally oncology focussed. The first approved precision medicine treatment in Canada was herceptin in 1999, and approvals continue to accelerate across cancer types. However, the volume of targeted therapies currently in pharmaceutical pipelines (50-70%) presents clinical and reimbursement challenges for precision medicines.

Greenway proceeded to give some examples of precision medicine demonstrating value for patients, beginning with herceptin as a treatment for HER2 positive breast cancers. HER2 positive cancers create too much HER2 protein, which receives signals to allow cancers to grow and spread. Approximately 25% of breast cancers are HER2 positive, and tend to be more aggressive and difficult to treat than HER2 negative cancers. In treatment of HER2 positive breast cancer with herceptin in addition to standard chemotherapy, 10-year survival increased by 40% and overall survival by 37%. Generally, the use of targeted therapies to treat breast cancer has improved the overall survival from 1.5 years in 2001 to 4.5 years in 2015 (breastcancer.org/herceptin long-lasting benefits 28.10.14). In cases of melanoma, targeted therapy treatments have seen tumour size decreases of 50% and progression-free survival increase by 40-60% relative to standard therapies (Butts et al *Curr Oncol*, Vol. 20, pp. 475-483).

The clinical process for precision medicine is multidisciplinary due to the specificity of the drug selection. After the Pathologist confirms the presence of cancer in a patient, he orders a biomarker test, which is then performed in the laboratory to confirm mutation status. This report

is returned to the pathologist who then makes a treatment decision. Test technologies in companion diagnostics are evolving, more biomarkers mutations are being identified and linked to treatments, and more precision medicine options are becoming available. Liquid biopsies are in development, allowing access to circulating tumour DNA and blood cells without the need for invasive tissue biopsies.

Challenges for precision medicine assessment include regulations existing at both the national and provincial levels, as opposed to concurrent approvals of drugs, testing methods, and reimbursements. This split in regulations manifests itself in independent and variable review processes for drugs and testing, decentralized CD diagnostic access and decision making for testing, and no national laboratory standard. Potential solutions include the new assessment, review, and recommendation process for biomarker tests by province proposed by CADTH. Additionally, Health Canada is working with provinces to determine a national quality standard for laboratories. Other issues include the adoption-reimbursement process of new companion diagnostics tests and their coordination with drug development, as laboratories are generally funded to deliver tests but not to develop new ones. Currently, pharmaceutical companies sponsor the development and validation of new tests and collect real world evidence of the value of precision medicine. The usual review time for reimbursement of these tests is currently 8-18 months. However, the lack of alignment between funding for biomarker tests and drug approval is slowing access for patients to new therapies. CADTH and provincial bodies are working to coordinate these processes.

As precision medicine is a new field, there is still work to be done to streamline the testing and drug approval processes. Greenway concluded by noting that precision medicine is a

valuable and exciting new form of therapy, and encouraged medical professionals and advocacy groups to increase the limited educational resources for patients about this area of treatment.

Panel One: Question and Answer Period

In terms of real world evidence, can we develop a randomized control that is the perfect gold standard for a real evidence trial? It would require all shares of databases and stratifying information, but if we don't understand who does well with drug in the real world we don't know how it'll work in the real world.

- The regulators are faced with real world patients getting access to drugs and using phase III trials with many exclusions, whereas in real world evidence they exclude some patients and sometimes they don't. It is not practical to withhold a drug that works in double-blind trials.
- We need registries where patients with preconditions can go on to receive treatments that demonstrate real world evidence. Much of the data is retrospective, and might not be realistic. Funding decisions are based on excluding certain populations so they can make the bottom line; however, this isn't a legitimate reason if patients can benefit from the medication.

How do we deal with a lack of drug reimbursement? What can we do in terms of basket trails? How can we do our best to not waste people?

- Different diseases behave differently, and there have been basket trials where pharmaceuticals are trying to do signal assessments by treating many patients with the

same agent in order to see what the specific signal is. To understand the value of the drug in certain populations, you need to dedicate studies to those patient populations. It is more expensive to collect more information for patients and samples, but more valuable because if some are better through a treatment than getting everyone treated with the same treatment

What percentage of immunotherapy drugs in the pipeline are being developed with CDx? How do patients and oncologists make decisions about which treatments to undergo?

- Different antibodies are used to develop PD-1 tests, so it may be found that one antibody is sufficient to treat a broad group of patients, but other types of patients require specific antibodies; this is precision medicine.
- As PD-1 drugs require PDL-1 testing, all drugs being developed have a requirement for PDL-1. For example, in lung cancer companion diagnostics have shown increases in survival and approval of drugs; however, there is not enough in the budget to pay for companion diagnostics tests and drugs. The ‘best’ treatment is picked by which seems to be the most consistent antibody, so we be using the most consistent antibodies instead of those suggested by companion diagnostics.

Why was the combination of immunotherapy and viruses further combined with adaptive therapies?

- Some of the therapies being developed right now initiate immune response, so antibodies will attack cancer tumours.
- Combination therapies in melanoma show a response rate of 55%, and it's difficult to determine why some patients respond well and some do not at all.
- These therapies (antibodies) allow the immune system to attack cancer and mature in that area (epitope spreading), so if they see cancer spreading, they will generate more cells in your body that illicit response to cancer.

## Panel 2: "Building an Ideal World for Improving Patient Outcomes in Oncology"

Friday, March 31 10.30-12.00
Moderated by Louise Binder (Health Policy Consultant, Save Your Skin Foundation)
Presentations by Dr. Reiner Banken (Senior Fellow, Institute for Clinical and Economic Review (ICER)), Joanne Castonguay (Research Director, Institute for Research on Public Policy (IRPP)), Dr. Femida Gwadry-Sridhar (Founder and CEO, Pulse InfoFrame), Martine Elias (Director Access, Advocacy, and Community Relations, Myeloma Canada)

### Dr. Reiner Banken: "Building an Ideal World for Improving Patient Outcomes in Oncology"

Dr. Reiner Banken presented on health technology assessments, and methods of improving access to treatments for patients and medical professionals. He suggests that there are three elements to increasing access: innovation, market access, and coverage (reimbursement), which he further breaks down into the categories of evidence and safety, evidence and effectiveness, and price.

The health technology assessment process began in 1974 by the request of the United States Congress Centre on Human Resources to the Office of Technology Assessment. Prior to

this, decisions were based on needs assessments created by physicians. Now, formal and transparent assessment of evidence is used to make decisions, making it difficult to discern what is a reasonable amount of justification for releasing a drug. The health technology assessment process begins with research to determine if the proposed treatment will work, then considers theoretical safety and efficacy, which is often difficult to translate into real-world settings. Next, appropriateness is considered; this is also difficult to evaluate, as different treatments are appropriate in different settings, and price is considered an element of appropriateness. If a drug successfully passes these assessments, implementation is considered.

Dr. Banken concluded by describing some challenges to the health technology assessment process, which include the possible lack of primary studies for a specific treatment, and the general uncertainty of the decisions being made. Other challenges include the trade-off between the time taken to collect real-world evidence and uncertainty, bridging the gap between research and practical patient care, and affordability; the goal being to limit the price of experimental drugs with conditional approvals. Requirements for this conditional approval include a strong vision, transparency, patient participation, evidence, clear methods and infrastructure, and patient organizations acting as catalysts for economic, scientific, administrative, and political perspectives.

Joanne Castonguay: “Barriers and Enablers for Innovative Medicine”

Joanne Castonguay presented on the search for a solution to expand access to innovative care, largely in cancer. She began by citing the adoptive cells transfer method of immunotherapy, which involves engineering a patient’s own cells to recognize and attack cancer tumours. While

this method has been restricted to small clinical trials, it has seen remarkable results in advanced cancers, and pressure exists to extend this treatment to all patients. These innovative treatments can be beneficial to both the patient and the medical system; Castonguay cites current T-cell therapies for blood cancers, which often result in less hospitalization, or treatments in specialized environments.

Castonguay continues by describing resistance to medical innovation, which she terms ‘a great divide between the demand for innovation in health and health innovation policies’. In order to provide evidence of value, innovators need to demonstrate value applicable to the entire clinical system. Policies surrounding innovation often fail to sustain the innovative trial to completion; therefore, it is important to identify the factors that enable and inhibit innovation in health. Traditional innovation policies do not address the current obstacles facing innovation, as innovation has been traditionally understood as a linear process from research, to production, to commercialization. Where innovation is supported, it is supported in all stages through funds, knowledge transfer, commercialization, production support, etc.. Therefore, the changes in the healthcare system required to further innovation are in the realm of public administration toward the government, or public services. Truly benefiting from innovative medicine will require major changes in our healthcare system, including high-level government leadership, collaboration between health sectors and levels of government, transparent information systems, and a reform of the culture of accountability in healthcare. Failure in these changes will continue to inhibit innovation and implementation of innovative medicines.

Castonguay closed by suggesting some solutions to these issues. She claims that the first step is to foster a system where accountability considers the value of a treatment for patients

further than the one-year period that budgets are allocated, followed by the collection of timely, secure, and accessible data. While there is currently effort being placed into the development of new technologies, the problem is that not enough attention is being given to how to integrate these innovations into our healthcare system.

Dr. Femida Gwadry-Sridhar: “Pulse InfoFrame”

Dr. Gwadry-Sridhar presented on real world evidence and the collaboration of Pulse InfoFrame Inc. with the Global Melanoma Research Network (GMRN). Pulse InfoFrame allows physicians in speciality or outpatient clinics a secure method for capturing and sharing data with patients and healthcare stakeholders. She was inspired to create this system after continually having difficulty finding patients for clinical trials before her grants would expire, as she was unable to access medical records to find eligible patients. The technology of Pulse InfoFrame allows scientists a means of organizing information to enable collaborative research. As researchers, pharmaceutical companies, and device manufacturers require data to make decisions, it is imperative that data be moved out of silos and into accessible space. An issue with consolidating data is that different forms of data are stored in different devices in different places in the current data ecosystem. For this data to be valuable, it must be accessible for providers to use it to improve patient outcomes. Patients would also benefit from access to this data, as it would encourage participation in their own care.

A proven solution that Gwadry-Sridhar suggests is the creation of a pipeline for data that allows researchers, patients, and other stakeholders access to reports on quality of care, outcomes, etc.. One challenge in the creation of this pipeline is the potential lack of real-world

evidence associated with drugs, which may require forms of adaptation to create data. Real-world evidence is imperative to decision-making regarding drugs outside of clinical trials, as clinical trials generally contain a homogeneous population and the real world does not.

Gwadry-Sridhar then discussed the Global Melanoma Research Network (GMRN), cofounded in 2010 with Dr. Scott Ernst. The goal of the GMRN was to encourage data contribution from cancer centres and use this data to enhance collaboration in the industry. It began with one cancer centre in Canada and has expanded to eleven, and is in the process of moving into the United States. The establishment of the GMRN has resulted in 200% yearly increases in industry collaboration through clinical trials, changing how treatment is being delivered. This availability of real-world evidence is changing outcomes; for example, real-life data can now demonstrate potential toxicity profile changes if drugs are given in a certain sequence.

This data can also demonstrate the value of a treatment in the face of its cost. Giving the example of treatment for unreceptive metastatic melanoma, Gwadry-Sridhar states that by connecting real-world data, outcome data, and administrative data, you can have a powerful case for how a treatment can save lives. This is also true of rare and orphan diseases with common data elements, which could be used to inform treatment of multiple orphan and rare diseases.

Gwadry-Sridhar concluded by reiterating that the data trapped in silos isn't useful to anyone, and that communication between medical professionals, patients, and other stakeholders is vital to analysing trends in diseases, measuring real-world evidence, and improving outcomes.

Martine Elias: "Building an Ideal World for Improving Patient Outcomes in Oncology: Myeloma Canada's Experience"

Martine Elias presented on Myeloma Canada's Research Network (MCRN), and how patient organizations can be a catalyst for generating data, working with government, and changing policy. By working together as patient groups, government, pharmaceutical companies, and researchers, we can improve outcomes not only in terms of survival rates or disease-free progression, but also the patient's quality of life.

For Elias, the latter is an important indicator of success that clinicians don't always consider. One needs to consider the side effects of a drug they are administered to a patient, and if that drug will affect the patient's happiness and ability to continue living their regular life. To achieve these goals of increasing quality of life for patients, it is important that organizations use patient data to make medical decisions. The MCRN aims to improve the patient experience by attempting to offer their phase I and II clinical trials that are relevant and cost-effective, and by publishing their evidence-based and peer-reviewed consensus about the diagnostics and treatment of myeloma. The MCRN is currently comprised of 24 cancer centres across 9 provinces, but is looking to expand their clinical trials to more patients across the country. By accumulating patient-based data, the patient voice is heard in the clinical process, and real-world evidence exists to support decisions related to increasing patient outcomes.

Elias quotes Dr. Donna Reece's statement that "if we don't know how we're doing, then we don't know where we are going" to stress the importance of data collection and access (Reece qtd. in Elias slide 15). Having available data can help providers identify risk groups among

patients, assess consistency, and see where there can be improvement. Data can also help answer questions such as the efficacy of innovative medicine over standard treatments, the changes between clinical trials and the real world for a particular drug, and how to decide which innovations to prioritize.

Elias concluded by suggesting some difficulties with developing such a database. One challenge to creating a database like this is the expense of training and hiring data entry employees, and paying for research. Another question is the integrity of research and data, and assessing whether particular sets are valuable. Regardless, patients are dying, and it is important to be able to engage with data and learn to effectively utilize it to improve patient outcomes.

Panel Two: Question and Answer Period

Many exciting drugs are being developed in melanoma, myeloma, and HIV, but it is difficult to match these innovations with affordability. How do we find this ideal world, how do we work towards it, and is there anywhere in the world that this is being done?

- Stakeholders have to work together, and look at this differently. The research world is currently lightyears ahead of the operational world, and because of this there's a rigidity in the operational world that needs to be broken. The first step is making information available for all, which can’t be done in silos. The government should be acting as leader in providing a vision to unify information, and act as a support system in reaching this

vision, by managing information, making information available to all, and protecting patients.

- In regards to open data, this is more advanced in the United Kingdom and Australia. This is not so in Canada because research is not a part of patient records in hospitals. There is a separation between hospital records and research reports that must be addressed in the data organization of healthcare systems.
- The Melanoma Registry is an example of what can be done. It started as global registry, even though initially it was pan-Canadian. Legislation needs to be passed to create a common data standard, to see practices like the Melanoma Registry adopted in other sectors.
- Stakeholders, researchers, government, payers, and patients need to be able to look at situations from different perspectives than their own when we come to the table.

Shift in dialogue of value to affordability, and desire to create methodology for real world evidence in Canada. Could patient databases ever be used in health technology assessments in health data?

- Though it is essential that the patient voice is heard, we must be careful not to say "evidence from patients," as evidence must be science-based. In academic collaboration, the onus is not on the patients to provide evidence of disease, it is up to the researchers.
- While patient data could be valuable in health technology assessments, it needs to be structured differently first.

- There isn't a dichotomy between value and affordability, as value brings better outcomes, which result in more monetary investments. It needs to be determined what kind of budget we can allow for each patient to provide the best possible services for all of them.

Connection between value and affordability:

- Value and affordability are tied together, but should be considered separately. A lot of drugs don't have any value, as they do not provide the desired outcomes.

  Immuno-oncology drug have an extremely high value, as they allow for better patient outcomes.

## Panel 3: "Current State of Affairs"

Friday, March 31 13.00-14.30
Moderated by Christina Sit (Program Manager, Lung Cancer Canada)
Joint presentation by Marie Hotte (Scientific Coordinator, Drug Evaluation Directorate for Enrolment, Institut national d'excellene en santé et en services sociaux (INESSS)) via video, Alexandra Chambers (Director, pan-Canadian Oncology Drug Review (pCODR)), Heather Logan (Executive Director, Canadian Association of Provincial Cancer Agencies (CAPCA)), Imran Ali (Senior Manager, pan-Canadian Pharmaceutical Alliance (pCPA)), and Scott Gavura (Director, Provincial Drug Reimbursement Cancer Care Ontario (CCO))

### Marie Hotte: "A Look at the Organization and Evaluation of Drugs"

Marie Hotte's video presentation discussed the institut national d'excellene en santé et en services sociaux (INESSS), which was created in 2011 through the merger of the Conseil des Medicaments and the Agence d'évaluation des technologies et des modes d'interventions. The goal of INESSS is to promote clinical excellence and efficient resource utilization in the health

and social service sectors. Their values are excellence, independence, openness, scientific rigour, transparency, integrity, and fairness; their mandates include developing recommendations and clinical practice guides aimed at optimal use of products, and providing access to medications, technologies, and interventions used in healthcare and personal social services.

In Quebéc, health care responsibilities are divided amongst various services, and the health minister acts according to INESSS' recommendations. Drug evaluation legislation is based on the following aspects: therapeutic value, reasonableness of price, cost-effectiveness ratio, the impact that it will have on the health and social services system (based on three criteria: the extent of the benefits to the population, the system's financial ability to offer the drug, the availability of diagnostic tests and the system's organizational ability to offer the drug), and the advisability of listing a drug depending on the basic prescription drug insurance plan. The reasonableness of price and cost-effectiveness ratio have been merged into a single criteria: the efficiency of the drugs. There are two criteria for evaluating the therapeutic value: the health need extent, based on the state of health, current treatments, and patient focus groups, and the drugs ability to offer clinical benefit, efficacy, safety, and therapeutic features.

At the end of these evaluations, there are five options of recommendation to the health minister: a notice of refusal based on the therapeutic value, a notice of listing without any restrictions, a notice of listing with drug exceptions or to a specific population, a notice with conditions, or a notice of refusal based on all criteria.

There are several challenges to this evaluation process. These include the potential lack of clinical data, an obsolete or absent comparator treatment, surrogate endpoints, absence of quality of life data, and variance of biomarkers. There are also economic issues, including the

high price of drugs, drugs that are not cost-effective, a high budget impact, and the inability to estimate cost-effectiveness when the clinical data is based on non-comparative studies.

Alexandra Chambers: pan-Canadian Oncology Drug Review (pCODR)

Alexandra Chambers presented on the role of Health Technology Assessments (HTAs) in the Canadian Health Care System. Health Technology Assessments differ from standard review protocols, as instead of looking at the efficacy of a drug, HTAs consider how drugs compare to other current therapies in terms of benefits, risks, cost, patient perspective, and implementation consideration. Currently, the Canadian Agency for Drugs and Technologies in Health (CADTH) and the institut national d'excellene en santé et en services sociaux (INESSS) are responsible for assessing the value of drugs in Canada. CADTH has two drug review programs: the pan-Canadian Oncology Drug Review (pCODR) with assesses oncology drugs, and the Common Drug Review (CDR) which looks at non-oncology drugs.

The CADTH/pCODR health technology assessment accepts submissions from drug manufacturers and provincial tumour groups, which are then reviewed by key stakeholders such as ministries of health and cancer, patient advocacy groups, and registered clinicians. The package then moves through the pCODR expert review committee (pERC), who suggests a recommendation which is open to feedback from key stakeholders, after which a final recommendation is made. This is the process for every pCODR drug recommendation. In 2016, pCODR issued 80 notifications to implement; 22% of these recommendations were negative, 11% were positive without conditions, and 67% were positive with conditions (often improvement of the cost-effectiveness ratio). pCODR surveys drug manufacturing pipelines

every year to gauge what is incoming. Nearly 200 drugs will enter the system this year, while pCODR has the capacity to survey between 20 and 25, making submission volume management an issue in the review process. Other difficulties include a lack of comparative trials, which make it difficult to determine the effectiveness of a treatment.

Heather Logan: Canadian Association of Provincial Cancer Agencies (CAPCA)

Heather Logan describes the Canadian Association of Provincial Cancer Agencies as "a snowflake on an iceberg," as the organization is centrally tiny but represents members across the country and oversees the delivery of cancer care in the province. The goal is to encourage collaboration between the provinces, with the priorities of: quality and safety in the delivery of cancer care, operational efficiency, risk management (drug shortages), and drug funding sustainability.

As the bottom line is to ensure that cancer patients have access to effective treatments, provincial cancer programs across Canada are concerned about the sustainability of cancer funding programs, as in most provinces drug budgets are increasing by 12-15% annually. The integral goals are to optimize how cancer drugs are selected and used, to harmonize how new cancer drugs are being implemented into clinical pathways, affordability, and creation and utilization of real-world evidence. If provinces collaborated more effectively in cancer care, this would diminish issues such as difficult budget choices, and possibly unsustainable increasing cancer drug budgets.

Imran Ali: pan-Canadian Pharmaceutical Alliance (pCPA)

Irman Ali presented on the pan-Canadian Pharmaceutical Alliance (pCPA), which aims to increase access to clinically effective and cost effective drug treatment options, improve consistency of decisions among participating organizations, achieve consistent and lower drug costs for participating organizations, and reduce duplication of effort and improve use of resources. pCPA receives recommendations from Cancer Drug Implementation Advisory Committee (CDIAC), the pCODR Expert Review Committee (pERC), drug manufacturers, provincial cancer agencies, and federal, provincial, and municipal drug programs.

The pCPA process is as follows: the health technology assessment (HTA) review contains clinical and patient group input, manufacturer feedback, and a final recommendation for a drug. pCPA picks up this recommendation and tables it with jurisdictions, which continue to work with HTA bodies and manufacturers to further develop recommendations. This dialogue has also recently begun to be extended to patient groups. The pCPA consideration phase begins with a a decision whether to open negotiations or not, if it is decided to open negotiations the manufacturer will get an engagement letter from the office,  identifying the lead jurisdiction that will act on behalf of the pCPA and identifying the participating jurisdictions. Once the engagement letter is out, it becomes an active negotiation and the lead jurisdiction has ownership of that file. If terms are reached then a letter of intent to list by the jurisdictions is submitted and becomes the responsibility of each jurisdiction to take the Letter of Intent (LOI) and translate that into a product listing agreement (PLA). If terms are not reached the manufacturer also receives a letter informing them of the latter.

Some challenges the pCPA face include reaching a common objective for 14 public drug programs, managing the volume of submissions, as 2015-16 saw a 50% increase in product recommendations at the CADTH level, financial tensions when working with multiple jurisdictions in differing fiscal positions, and the needs for therapeutic treatments are constantly changing.

Scott Gavura: Provincial Drug Reimbursement Cancer Care Ontario (CCO)

Scott Gavura of Cancer Care Ontario (CCO) discussed the process of drug investment for his organization. CCO manages a budget of around 2 million dollars per day, which creates uncertainty in making decisions for the future. Their goal is to deliver the best possible population-level outcomes by covering clinical standard of care and considering patient-specific circumstances and eligibility. Their concern is how to best allocate funds, relative to all other treatments on the market.

CCO engages clinicians in their allocation process, as they inform CCO of what the current priorities are. The price negotiation process is negotiated by pCPA and other agencies with implementation issues before treatments are implemented, so patient access is consistent across Canada. Health Canada heads the process of market authorization, funding submissions are managed by manufacturers and CCO's drug advisory committee, price negotiations are generally conducted by pCPA, and implementation recommendations made collaboratively with other organizations to ensure patient reach is equal across Canada.

Budget sustainability has been a concern of CCO; in 2010/2011, it was predicted that the growth of drug costs would be 11.4%, while the provincial budget was projected to increase by

1.8% (increase in drug costs calculated using ODB data sourced from ICES (Aug 2016) and NDFP data sourced from CCO (Nov 2016); projected growth rate for the health sector over the medium term as reported in the 2016 Ontario Budget). Due to the success of bodies such as pCODR and pCPA, new therapies have been continually implemented. Part of this sustainability has been achieved through a commitment to evaluate new drugs that are going to be better funded through provincial reimbursement programs and ensuring that these investments in cancer therapies are delivering the projected benefits. Challenging these aims are the uncertainty associated with drug-specific funding decisions, especially when there is a lack of real-world evidence and multiple drugs are coming through the pipeline simultaneously.

Panel Three: Question and Answer Period

How do we judge cost effectiveness for reimbursement? What is the threshold for quality of life or mortality?

- Health technology assessments rely heavily on outcomes of people and processes. pCODR process is multifactorial, as for majority of submissions they would not be conducting secondary analysis.

In the future, might there be one body or agency to review, make recommendations, and deliver the drugs in parallel?

- Not as long as health is a provincial responsibility, as there is too much variation among agencies.
- The system we currently have relies on people, and we are trying to push these discussions upstream so issues aren't being debated long after a recommendation.

Pick one thing that is highly leveraged by helping people be efficient in public money, that would accomplish restructure from these points of view.

- Pulling money from provincial governments, so the federal government would be a central body that creates drug plans, which are then implemented provincially.
- You could achieve further efficiency if a drug were to be developed as cost effective before pCODR makes their recommendations.

How are we going to work together so that nothing is done without patient groups? Processing is about mutual trust and respect, and patient groups should be included in the approval process from start to finish.

- There are scarce resources that health technology assessments have to allocate to a number of different therapies. Health technology assessments must be transparent and accountable for the decisions made concerning public health.
- pCODR and CADTH have been receiving patient input for years, but there always room for improvement and growth.

Challenges of evaluating a drug when there are other drugs in the pipeline for that indication:

- Decisions are guided by evidence, therefore health technology assessments have to make a decision based on the total population that received the therapy, depending on what the clinical evidence is. Embedding new therapies in existing treatments takes a lot of time and imposes a great challenge.
- A fundamental challenge is that public drug plans take a few months to negotiate a deal that will be implemented for years, therefore there is great pressure to get it right the first time.

## Keynote Speech: "Charting a Course: How HIV Paved the Way for Advocacy in Cancer"

Ryan Peck (Executive Director, HIV and AIDS Legal Clinic Ontario (HALCO)
Friday, March 31 14.45-15.00

Keynote speaker Ryan Peck discussed HIV and AIDS advocacy, and the impact it has had on modern cancer advocacy. Peck begins by noting that in HIV advocacy the term 'patient' is rarely used, as those with HIV are not patients full-time, and 'patient' has connotations of passivity. They were generally referred to as 'people with HIV'. In HIV advocacy, user input is integral; it is seen as both sensible and ethical. This is especially true of HIV as it is prevalent in marginalized communities, making it both a health and human rights issue and bringing people with HIV to the forefront of advocacy.

Peck then discussed "The Denver Principles" (1983) and how they continue to reflect and affect HIV advocacy. Three especially applicable recommendations for people with AIDS in the document are as follows: to "form caucuses to choose their own representatives, to deal with the

media, to choose their own agenda and to plan their own strategies," to "be involved at every level of decision-making and specifically serve on the boards of directors of provider organizations," and to "be included in all AIDS forums with equal credibility as other participants, to share their own experiences and knowledge" ("The Denver Principles" 1983). The message of community put forward by "The Denver Principles" inspired those with HIV to fight together and participate in research ethics boards, and make demands for treatments and care centres.

Quickly after the discovery of the AIDS virus in the 1980s, organizations became publicly funded which allowed them to spread and focus on care, treatment, support, prevention, and involvement in advocacy. The largest centre was AIDS Action Now, a non-funded group of activists that demanded access to medication, including experimental medicine, and a conference for the standards of AIDS care. Their efforts at knowledge transfer eventually formed into an organization called KATIE, which became the source for HIV and Hep C information. Furthermore, AIDS Action Now inspired the Health Minister to make a range of experimental treatments available, and eventually pharmaceutical companies were releasing medication on a compassionate basis. In 1994 came the government announcement of the trillium drug problem, which further assisted with the costs of medicine though the deductible was often too expensive even for working people with decent insurance coverage.

Integrally important to HIV advocacy work was the combination of front line work, systemic work, and emotionally impacting people. At HALCO, they work in the concept known as 'greater and meaningful involvement of people living with HIV'; the majority of the board has to be people living with HIV, and they continually get feedback from the community by

providing legal services and running public legal workshops. They also attempt to be supportive of day-to-day issues that the demographics most affected by HIV experience, without focussing on them so much as to become complicit in maintaining the status quo.

# Day Two: Saturday, April 1, 2017.

## Open Forum: Environmental Scan

Moderated by Sabrina Hanna (Executive Director, Save Your Skin Foundation)
Saturday, April 1, 2017 8.30-10.00

The environmental scan that opened the second day of the Patient Leader Education Summit largely consisted of the attendees introducing themselves and the organizations they represent, to establish the current activities they are undertaking in terms of patient advocacy and what steps will need to be taken in the future. The information given about each organization is as follows:

Colorectal Cancer Association of Canada (Barry D. Stein)

- Patient Values and health technology assessment: an ongoing project based in Montreal, Toronto, and the University of Calgary. This is a quantitative and qualitative evaluation of defining and determining what weight should be applied to patient value in health technology assessments. This will soon be opened up to Global Action for Cancer Patients.

- June 13th: Patient Group Pathways to Clinical Trials meeting. Will bring together all stakeholders in clinical trials to determine that patient groups should be included in the model.

Rethink Breast Cancer (MJ DeCoteau)

- Running a workshop with metastatic patients to explore patient values
- Intending to attend IMC meetings, stakeholder consultation meetings, and perhaps bringing patient advocates to these meetings
- Considering their campaign for Metastatic Breast Cancer Day on October 13th
- Is hoping to bring American drugs to the Canadian market

Myeloma Canada (Martine Elias)

- Is in the early stages of creating a national patient information database
- Another ongoing project is the 'five-for-five' program to educate general practitioners about the early symptoms of Myeloma so it is not confused with other diseases
- Currently launching a general Myeloma advocacy program called "Math"
- Currently has three treatment drugs in different stages of negotiations-- however, there is likely to be a shortage of drugs as there is only going to be one supplier in North America of the Bacillus Calmette-Guerin vaccine

Lymphoma Canada (Elizabeth Lye)

- Is part of a Coalition of 40 international patient groups, which collect data and share it across jurisdictions
- There is no national clinical treatment for lymphoma in Canada, provincial guidelines are based on reimbursement policies
- Has concerns about the lack of transparency about non-approval and reimbursement of drugs

Brain Tumour Foundation of Canada (Tracey Jones)

- Connected to groups internationally
- Access to oral chemotherapy is an issue across Canada, so advocating for equal access to treatment is important
- The Canada Brain Tumour Registry is important because there is a lack of accurate statistics in Canada, despite having one of the highest brain cancer incidence rates in the world
- Analyzing the research landscape and trying to determine how to advocate for more research dollars for brain tumours
- Educating patients as to why it's important to participate in clinical trials, and have their voice in trial design

Chronic Myelogenous Leukemia (CML) Society (Cheryl Simoneau)

- Patient Advocacy encouraged Doctors working in CML to create an international CML foundation, and transparently share key opinions of researchers and available information about biomarkers (relevant to other hematological malignancies)
- Pharmaceuticals are beginning to allow patients to be on the scientific advisory board for clinical trials, so patients can understand goals of treatment and not be irresponsible with their drug use in lifelong treatment cases
- Published a paper with patient perspectives on CML treatment
- Current problem in Canada with access to oral treatments

Louise Binder

- Need to advocate for a good quality of life on top of survival, especially as patients are beginning to survive longer
- Focuses on health policy, systemic treatment access, and knowledge transfer
- In health policy: Federal budget work and drug pricing, working with Health Canada regarding rolling reviews (allows efficacy data to be added to a Health Canada file after the file has been submitted)
- Systemic treatment: Working with Health Canada to create Phase II trial data, development of a real-world evidence trial with Health Canada and CIHR

Save Your Skin Foundation (Kathleen Barnard)

- Working to define what ‘survivorship’ means for melanoma patients: consensus is from diagnosis onwards

- I'm Living Proof Initiative: presents melanoma survivors as stars on a map with a biography and video of them, which allows other melanoma patients to connect with one another
- Coordinating Immuno-Oncology Network for Patient Organizations
- Determining how melanoma survivors transition into their new forms of medical care
- Global Inititaives

Ovaire Espoir (Josée Ann Mauris)

- Education and support group for gynecologic cancer
- Often faces surgical delays, and treatments are approved infrequently
- Advocates for patient rights regarding drugs, treatments, and attaining the quality of life they deserve

Bladder Cancer Canada (Tammy Northam)

- As there is no diagnostic screening for bladder cancer, women are often diagnosed late after blood in the urine is misdiagnosed as other things
- Currently running the popular 'See Red, See Your Doctor' campaign
- Canadian Bladder Cancer Information System (CBCIS) currently has four centres involved, and hopes to have ten more by the end of the year. Contains information about treatments, symptoms, follow up, recurrence, biopsies, and tumour size
- Expecting an immunotherapy treatment soon

- Has had success with the Bacillus Calmette-Guerin vaccine, but anticipates that shortages will be an issue as there will soon be only one supplier in North America
- Working on expanding research awareness, as the Canadian Cancer Research Alliance has indicated that while bladder cancer is the 5th most common cancer in Canada, it is ranked 20th in terms of research funding

Regroupement provincial des organismes et groupes d'entraide communautaire en oncologie (RPOGECO) (Tracey-Ann Curtis)

- Quebéc organization that regroups all other patient organizations in the province
- Looking to increase partnerships with all stakeholders

Chronic Lymphocytic Leukemia Advocacy Group (CLLPAG) (Deborah Baker)

- A working board of mainly patients
- CLL is the most common leukemia, but there are often not symptoms and General Practitioners often do not know how to treat it
- Educates patients in how to get proper care for their cancer
- Holds a patient conference every three years with an international audience, experts, and partners with blood cancer charities.

BioCanRx (Stephanie Michaud)

- Federally funded network of centres of excellence to accelerate new therapies to clinics--focussed on immunotherapy

- Holistic approach to bringing innovative medicine to Canada
- Has access to academic researchers, and engages with legal scholars and economists to carry out research
- Go Kart campaign to carry out analysis to improve the clinical trial process

Life-Saving Therapies Network (John-Peter Bradford)

- Focussing on precision medicines (immunotherapy, target therapies, molecular process)
- Mandate is to create a coalition of oncologists, researchers, payers, pharmaceutical companies, health care economists, and policy creators to change the approval frame for treatment and to change the accepted research protocols necessary to get drugs approved
- Has a clinical trial design they want to prove in the real world
- Interested in the reimbursement system at the systemic level

Lung Cancer Canada (Christina Sit)

- Accounts for 20-25% of cancer deaths in Canada, but only receives 7% of research funding
- Aims to amplify the voice of lung cancer and make a difference in the HTA process
- Increasing involvement in immunotherapy and survivorship initiatives
- All phase II data of pCODR submissions has been rejected- hopes to advocate for better access

Patrick Sullivan (Team Finn Foundation, Advocacy for Canadian Childhood Oncology Research Network (AC2ORN))

- Cancer is the number one disease killer in children
- From 2005-2014 there were 62 paediatric oncology drugs approved in the United States
- Precision medicine needs to be adopted in paediatric cancer to increase survivorship
- AC2ORN advocates for access to phase I and II clinical trials

Kidney Cancer Canada (Robert Bick)

- Encourages patients to make decisions about their treatments for kidney cancer
- About 1 in 5 treatments respond to immunotherapies, and there are no biomarkers for kidney cancer
- Working toward a universal method of funding oral drugs

## Open Forum: Road Mapping The Network and Next Steps

Moderated by Sabrina Hanna (Executive Director, Save Your Skin Foundation)
Saturday, April 1, 2017 10.15-11.50

The final segment of the Patient Leader Education Summit was an open forum in which the attendees discussed the appropriate next steps for The Network. Issues that need to be addressed include creating a mandate, knowledge exchange, cancer care innovation, treatment access, and education.

One suggestion was the creation of an information hub where information about all of the organizations that are part of The Network could be available for access. This would include

their reports, activities, resources, et cetera. This information could be additionally useful by providing it to patients and other stakeholders.

The group also determined that it would be useful for them to meet with relative frequency, and to encourage government stakeholders, CAPCA, and patient advocates to address this issue at conferences and other meetings. It was suggested that the patient voice in particular could be engaged to put pressure to make change in cancer care. The group was in agreement that collaboration with all stakeholders should produce results in encouraging the approval of cancer treatments and ensuring that patients have equal and timely access to these treatments.

## Closing Remarks

Delivered by Barry D. Stein (President, Colorectal Cancer Association of Canada)
Saturday, April 1, 2017 11.50-12.00

Barry Stein began his closing remarks by thanking the group for their attendance and contributions to the Summit. Stein suggested that improving patient outcomes will involve putting together national guidelines for economic and timely access to treatment. However, these standards are difficult to create across several cancer indications and it is difficult for patient organizations to have their voice heard within the system.

Stein cited the ‘Current State of Affairs’ panel as being particularly eye-opening, as there is interest in collaborating with HTA groups while these organizations have the difficult mandate of maintaining sustainability. Despite this, Stein encouraged patient groups to continue to fight for treatments for their patient groups, while being aware of the position of patient groups and of HTAs.

Stein continued by citing Ryan Peck's keynote speech 'Charting a Course: How HIV Paved the Way for Advocacy in Cancer,'and how inspirational it is that advocates in one disease site are able to achieve so much by staying focussed on their goals. He also noted that Peck echoed a general consensus of the meeting attendees, which is that the emotional impact of the patient voice can be harnessed to achieve better patient outcomes.