Interview: Michael Rudnicki – Chair, Regenerative Medicine Alliance of Canada (RMAC)

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Michael Rudnicki, chair of the Regenerative Medicine Alliance of Canada (RMAC) discusses the mandate of the newly established organization, the exciting potential of regenerative medicine, and Canada's competitive edge in this cutting-edge field.

Michael, could you share the mandate and mission of the newly established Regenerative Medicine Alliance of Canada (RMAC)?

The idea for Regenerative Medicine Alliance of Canada (RMAC) really came about in a workshop on the state of regenerative medicine in Canada organized by the Council of Canadian Academies in 2016.

RMAC is a voluntary organization comprised of national, provincial and regional organizations, from the Center for Commercialization of Regenerative Medicine (CCRM); Center for Drug Research and Development (CDRD); CellCAN; Medicine by Design; the Ontario Institute for Regenerative Medicine (OIRM); TheCell; BCRegMed; the Canadian Stem Cell Foundation; and the Stem Cell Network (SCN).

Of course, I lead the SCN as Scientific Director. SCN was the first network for stem cell research internationally and we have led the formation of other stem cell networks globally as well as supported the creation of a number of organizations over the years, including CCRM, CellCan, OIRM and Medicine by Design. SCN is proud to have played a longstanding leadership role in developing the regenerative medicine field in Canada.

While RMAC organizations have different missions and address different aspects of the field, there is a long history of close collaboration from annual meetings to training and policy workshops. For instance, we have convened workshops based on different topics like technical approaches, entrepreneurship, science communication, regulatory practices, clinical trials and unproven stem cell treatments.

During the 2016 Council of Canadian Academies (CCA) workshop, the idea of formalizing the existing network of cooperation and partnerships materialized, so we decided to do it. Our goal is that RMAC will provide the mechanism to further develop joint activities in the areas of training, policy and communications. I believe that we all feel it is important to speak with one united voice in support of building a vibrant regenerative medicine sector in Canada.

I am thrilled to have been appointed Chair of RMAC for a two-year term. Over my term we will work to identify areas of common interests and potential partnerships. The idea is to maximize our impact by uniting our voices. We would also like to establish proper governance and operational practices to lay the foundation for successful future collaboration. Furthermore, to grow in the longer term, we need to think seriously about resourcing RMAC and developing a pan-Canadian strategy. This will require a sustainable funding environment and support from all those who wish to realize the health and economic benefits from the sector.

The field of regenerative medicine is a hot topic globally. What are some of the most exciting developments in this area?

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Canadian stem cell researchers have paved the road for regenerative medicine and today we are seeing stem cell-based therapies and technologies entering the clinic. Our field is bringing forward disruptive technologies that will change the practice of medicine – and already have.

For example, Dr. Harold Atkins from the Ottawa Hospital is using bone marrow transplants to essentially cure auto-immune diseases like multiple sclerosis. Dr. Timothy Kieffer from University of British Columbia is focused on diabetes. His work follows on the heels of the Edmonton protocol – a procedure for implanting pancreatic islets to treat patients with type I diabetes – with a new cell-culture method that has allowed for the faster generation of reliable, insulin-producing cells in a far shorter amount of time. SCN and OIRM are currently supporting a clinical trial on the use of mesenchymal stromal/stem cells to modify the immune response for treating sepsis. There is also important work going on in synthetic biology, 3D printing and organoids. All of this will lead to innovative next generation therapies that ultimately will change the face of health care.

Globally, the market for regenerative medicine is expected to exceed USD 53.7 billion by 2021. Since the discovery of stem cells by Canadian scientists Drs. James Till and Ernest McCulloch in 1961, Canada has established a world-class presence in regenerative medicine. Countries around the world like the US, Japan and the UK are already taking bold steps to invest and modernize their life sciences ecosystem to promote a vibrant regenerative medicine ecosystem, and Canada certainly can have a share of this pie.

The common issue with Canadian science and R&D is commercialization. What stage is the regenerative medicine field at within Canada?

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Currently, there are approximately 43 regenerative medicine biotech companies in Canada, including new ventures like BlueRock Therapeutics, which saw a USD 225 million investment by Bayer and Versant Ventures. This company is founded on cardiovascular research and IP developed by two Canadians: Drs. Gordon Keller and Michael Laflamme from the University of Toronto. We are seeing more and more investment in this area and it is very exciting.

What used to happen is that technology tended to be licensed in Canada and then it left our country. But I think the biotech ecosystem has now reached a tipping point that can promote sustainable commercialization. Certainly, as a Canadian myself, I see no reason why these technologies should not feed a homegrown industry. If other countries can do it, Canada certainly can. Innovation is in our DNA, we are a highly-educated country and Canadians are also very entrepreneurial.

Canadians also tend to not slap ourselves on the back for a job well-done, so to speak. The Canadian scientists that discovered stem cells, Dr. James Till and Dr. Ernest McCulloch, would probably have received the Nobel Prize if they came from the US or the UK! If Canada is to build a robust industry, then we need to start speaking more loudly and globally about Canada’s strengths in regenerative medicine. Attracting investment, angel funding and supporting small biotechs and researchers who wish to commercialize must be a focus in the years to come.

The government is a significant source of science and R&D funding. With innovation at the core of the Liberal government’s agenda, how do you expect the funding environment to improve over the next few years?

Science funding in Canada has generally flat-lined since 2009. Frankly speaking, it has not been a priority area for past governments and in terms of R&D expenditures as a proportion of GDP, we

have slipped in the rankings from 7th to 17th in the past decade.

However, with recent initiatives like the appointment of Dr. Mona Nemer as the Chief Science Adviser for Canada, and Dr. Molly Shoichet as Chief Science Advisor for Ontario, we certainly hope that science will once again be at the top of federal and provincial government agendas. We know that the federal government recognizes the important benefits that will come from the field, and are optimistic that this will translate into a stable and predictable funding environment that will allow us to bring forward the best therapies and technologies possible. We would encourage provincial governments in places like B.C. and Alberta to also consider how they can strategically invest. In both these provinces, there is considerable strength in regenerative medicine.

How important is the involvement of industry in this field?

In Canada, we look to industry to partner with us on research activities. In addition, we also try to assist in building the right conditions (a sticky environment) so industry will want to remain in Canada.

RMAC members network extensively with industry players, both formally and informally. In spring 2017, some RMAC members came together to host a summit to look at what needs to be done to grow Canada's regenerative medicine sector. It was an important initiative as it brought together key players from across the sector for the first time. They represented policy, academia, biotech companies and life science investors. Over the course of the day, we heard some important observations about the current investment and regulatory climate and what it will take for Canada to move forward. I think that everyone in that room learned something, and I know that it seeded a number of important follow on activities. I hope that we will be able to capitalize on the growth summit in years to come.

Industry is also supported by member organizations such as SCN and CCRM. SCN funds the research of academic investigators who are connected to Canadian biotechs. Thereby, helping to further research goals and move therapies closer to the clinic and market. SCN also helps to protect IP and provide tools to assist both tech transfer offices and researchers with the licensing of IP.

Organizations such as CCRM and CCRD work very closely with both international and national pharma companies. In addition, they offer support to researchers to validate their work and provide business development support. They have also had success in bringing academics and industry together to solve challenging problems. Currently, CCRM is focused on addressing technology scale up issues associated with cell manufacturing and are working in partnership with GE Healthcare in

this space. Overall, industry collaboration is an important priority for all of us.

Regenerative medicine is an extremely niche and technically complex area. How important is it that the public understands and engages with the work of RMAC and other stakeholders?

It is our responsibilities as scientists to clearly communicate about our work to the public. Members of RMAC have always been active in this space because we know it is important for the public to be able to access credible and accurate information about stem cell therapies. The emergence of clinics that offer unproven stem cell treatments is of considerable concern for us, as it is for many around the world.

Up to recently, public education was a key area of interest for the Canadian Stem Cell Foundation. For organizations like SCN, a mandate exists to ensure public education and awareness is undertaken. As such, SCN has a partnership with Let's Talk Science to offer a tailored program for high school students called Stem Cell Talks, where students come together and spend the day discussing issues relating to stem cell research, on both the technical as well as ethical sides.

We strongly believe that RMAC can further build on what has already been done and I am confident that we can put forward a strategy around the opportunities and challenges that come from stem cells.

What best practices can Canada share with other centers of excellence in regenerative medicine?

I think what is really key is the culture of close collaboration. This is an aspect that often shocks our American colleagues because collaboration often means giving up sovereignty over your project and in particular, funding. But the idea of simply dividing funding by the number of participants is overly simplistic. In Canada, the SCN has pioneered the approach where funding is allocated based on work flow and project needs. At the end of the day, we are all working towards the same goal.

In addition, multi-disciplinary teams are certainly more productive and there are good metrics highlighting the effectiveness of this type of work. If you can bring together a group of investigators, engineers and scientists on a project, you will make faster progress – and it is more fun!

An example of this collaboration is SCN's work with ExCellThera, a Canadian start-up led by Dr. Guy Sauvageau, who found a molecule, UM-171, that could expand blood stem cells over tenfold compared to conventional expansion protocols. This meant that more units of life-saving cord blood

could be utilized for therapeutic purposes, which would be more cost-effective. SCN provided over CAD 3 million to Dr. Sauvageau to conduct a multi-year research project based on this, during which Dr. Sauvageau met Dr. Peter Zandstra, a bioengineer and professor at the University of Toronto, who was keen to engineer a solution to the challenge of cell expansion. Dr. Zandstra developed a bioreactor to allow for the scale-up necessary for clinical use. SCN went on to fund successive rounds of this research and today, it has been commercialized, with the support of CCRM, into the company, ExCellThera.

Even more so in regenerative medicine than in other specialty areas, scientists and researchers cannot do it by themselves. Without a strong research network, the work is extremely difficult. Canada needs to build this ecosystem involving all players from basic to translational so that everyone can collaborate closely. I am confident that RMAC will serve as a useful tool in this regard. The future is bright for regenerative medicine, and especially so, thanks to Canada’s spirit of collaboration.

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