Industry roundtable: Medical Research

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On left of table: Jane Bellow Burke, left, and Dr. Ira Zackon.

Can regulations keep up with technology in health care? What role does big data play? What resources do you wish we had in the Capital Region to attract talent? Law firm Hodgson Russ and the *Albany Business Review* hosted a discussion to answer these questions and more. Mike Hendricks and Liz Young, of the *Albany Business Review*, moderated the discussion.

Can you please take a moment to introduce yourselves and tell us what you do?

Dr. Ira Zackon, president, New York Oncology Hematology: I'm a hematologist oncologist with New York Oncology Hematology with 30 years in the oncology field. My personal specialty is in the hematology side of blood diseases and blood cancers, leukemias, lymphomas and a disease called myeloma, primarily.

I'm from Canada originally, Montreal, and did medical school at Magill, but we found our way here to the Capital Region. We've been here 20 years now, so this is home. We raised our children here. I used to do more general cancer care and then became increasingly involved in the subspecialty of hematology. I direct a patient-centered stem cell transplant therapy program that treats the blood cancers.

Jane Bello Burke, partner, Hodgson Russ: I am a health care attorney representing health care providers, hospitals, nursing homes, assisted living, home care, and individual practitioners.

The health care laws and regulations are complex and ever changing, and I assist providers by providing and offering regulatory guidance.

When they find themselves in a situation where they are being challenged on some aspect of care, billing or other types of issues, they turn to us for assistance in understanding their obligations, and ensuring that they are doing what they need to do to protect their patients, or residents, as the case may be. Where necessary, we defend their actions in appropriate proceedings or pursue their rights in court.

What attracted you from Montreal to the Albany market and what are the resources here for health care, cancer treatment and research?

Zackon: Even though I grew up not so far away, I did not know the Capital Region and what it had to offer. It was a time for me of looking for a position in oncology and starting a young family. There was a decision to

locate close enough to family to have access for them to be a part of our lives, and for us to get up to them, but still have a strong career opportunity.

The medical community in the Capital District is very strong across the spectrum, from primary care to specialties. Living in the Northeast, patients who may spend their winters away in Florida are desperate to come home if they are sick because they know the qualitative difference in care. The health care sector is very robust here. It's a very significant part of the economy and the location is superb from a professional standpoint.

The challenge is letting others know that. It's critically important to attract high quality professionals or researchers to the area. If they're not from the area — and historically I think of my older colleagues — they went to medical school at Albany Medical College or did their training, clinical training, at Albany Medical Center, or they went to college here, so they had some familiarity or they were from upstate New York. Increasingly, we need to recruit physicians or researchers who don't have that path. That's where I think it's critically important to show that the Capital District, even outside the health care sector, is an attractive place.

When we interview, we take extra time to drive them around and let them appreciate the area and the breadth of what goes on from an economic, as well as cultural, standpoint. It's been challenging at times. There are a lot of choices because you could live in another climate. You could live in an area that has a lower tax base. Your net income could be significantly higher elsewhere.

We have had success. We are recruiting. We renewed our practice over the last five years in many ways, and have three new physicians coming this summer. I think we're also seeing more physicians who are foreign medical graduates. Some of them like being in New York. Some of them have connections in New York City through family. We see a little bit more in the last two years than we had five years ago in attracting high quality people to come, but it's a bit of salesmanship.

Where are the three physicians coming from?

Zackon: Two of them are doing their hematology oncology training at the University of Arkansas in Little Rock. It's actually a very large program and very well known in the field of blood cancers. One of them came through word of mouth, and we had a third applicant from that same program. We're developing a long-distance pipeline relationship. The other one is at the University of Pennsylvania. It's a bit more proximal to the Northeast and upstate was somewhat familiar because he's in western Pennsylvania. They're all coming from different backgrounds and different geographies. These are all immigrants to the United States and it's good that they're choosing us.

Jane, what's the biggest challenge that you work with in health care law?

Burke: The biggest challenge currently in health care law — and there are many of them — is the pace at which the regulatory framework changes. It has been a number of years now that the policy toward health care has started to move from a fee-for-service methodology to a more value-based structure. It's a big change that requires different ways of thinking about concepts that, under fee-for-service reimbursement, were accepted and settled.

Over the years, those kinds of changes have accelerated and they're occurring at both the federal and state level, and not necessarily in exactly the same way. It requires keeping up with a lot of the constant new information, some of which is not easily accessible.

As lawyers, we find out what's going on by looking at the statutes, by looking at regulations, by looking at guidance. Increasingly, many of the sources of this guidance are in informal writings from various regulatory entities, or sometimes not in writing at all. It's information that you learn along the way.

Since there are so many different kinds of providers, you must assimilate the differences in the context of a particular provider type. For example, are you dealing with a hospital, are you dealing with home care, are you dealing with an individual physician or a nurse practitioner? It may not be immediately apparent how to relate the changes to a particular provider type.

Can regulations keep up with the technology advancements in health care?

Burke: Technology in health care comes into play in a number of different ways. Much of the regulations we're seeing are around how to deliver care faster, more efficiently, less expensively and in a way that increases patient satisfaction. Technology can be a tool to achieve those goals.

One kind of technology we see coming into play is telehealth. This is the use of electronic communication to deliver health care. Telehealth can take many forms, and there are different modalities. But it has the ability to connect with your physician via an audio-video link.

The potential of telehealth can be huge. For example, it can enable physicians to deliver care across long distances without requiring the patient to travel, and that can be enormously helpful, say, in a rural area, where there are not as many physicians, particularly in specialties, to care for the population.

In New York, telehealth is right now starting to gain traction. In the executive budget enacted for 2018-2019, the governor included an expansion of telehealth. We're now waiting to see how the agencies expand that to deliver faster, more efficient care to the people of New York.

Are you treating patients with the work you do around stem cells?

Zackon: Yes. Working with stem cells, we are at the forefront of this whole field of cellular therapy, which is not really using stem cells. It's a whole new world of treating cancers that is derived from patients and donors. We're really involved in translating science into therapy or into applied therapies, and learning that when you're doing that, you need to learn about safety: what are the toxicities, the risks, as well as the efficacy?

Molecular engineering scientists insert genes into a cell to allow it to behave in a certain way. We are doing that with immune therapy now. We are going to open the first trial in our region, hopefully within the next few months, using what's called CAR T-cell therapy. We had the first approvals of therapies for children with acute leukemia that currently have lymphoma, and would die with their disease otherwise. The concept is that our immune system has a lot of strong potential, including suppressing or attacking our own disease, like a cancer, but there are a lot of things that inhibit it from doing so.

This therapy would take what are called T-lymphocytes, or the white blood cells that are part of the immune system, and remove them. Just like you donate blood or platelets, you can take white cells and isolate the T-lymphocytes. We can identify certain subtypes and get the right subtypes.

Then, in a scientific laboratory, a gene is what's called transfected, or inserted, into the cells. That gene is going to express a protein that would be placed in the cell that targets the disease. If there's a particular target that is abundant on that form of cancer, then this T-cell will recognize that target. It also has an activating gene with a protein. Once it engages, the whole cell gets activated to attack mode and it also

replicates, making an army of these cells. You end up with a population of cells within your immune system that is specifically focused on suppressing disease.

The vast majority of children with a form of acute leukemia are, thankfully, cured with chemotherapy. But children who relapse if they don't get a successful bone marrow transplant, will die. And in those children, or if they relapsed after stem cell transplant, which can happen, we're now having children that are now four, five years hopefully cured in some of the early trials. There is a realistic vision that one day chemotherapy will be an anachronism and we will be treating things in different ways.

Advances in cancer research now allow a lot of patients to work while they're being treated. To what extent is that a part of your process?

Zackon: Having started out in oncology back in the late 1980s, I lived through the transformation of cancer care. The vast majority of what we do, including chemotherapies, is delivered outpatient in the office setting and integrated into patients' lives. What's changed is the ability to prevent certain side effects. The drugs have improved, so the quality of life in going through therapy is better. I've never been a cancer patient, so I can't speak to it directly, other than observation of patients. But over time, more people are living their lives while being treated, whether it's work life or whether it's their retired life.

There's no question that having cancer also changes the way you think about life and the things that you do with your time. This is increasingly reality.

Even if we're not curing them, we're increasingly changing some cancers from being more like a chronic disease and living with it over many, many years, compared to dying within a year or two, depending on the cancer. We've seen that transformation ongoing. We have new therapies that are achieving that, whether targeted or immune therapies.

Now, some cancers are cured. Many more are cured than they used to be. But the challenge is more in patients who maybe have a chronic cancer they're now living with. From a care delivery standpoint, we have to be thinking ahead and preparing to adapt, to manage people for whom it is not so convenient or easy to get to an appointment, and that may be good from a business economic standpoint to keep them in the workplace. This is where the use of technology interconnects, whether remotely for those with rural access, and the generations that are used to living with these social media tools as a means of communication.

I think the challenge is going to be — and we're mindful of this — how to preserve the doctor-patient relationship because it's an important personal relationship. That's part of the therapy if it's done well. Many patients do like to come into the office.

Can you talk about the alternative payment model used in oncology?

Zackon: This alternative payment model, or APM, is part of federal legislation that led to an innovation arm of CMS, or Medicare, to develop alternative teams of paying for health care with the idea of reducing cost but also being value-based. On our end, we have to choose the right therapy for the right patient at the right time in their disease. It may be costly, but it's value and we must ultimately deliver cost effectiveness.

When you look at what drives cost in health care, it's hospitalizations, emergency room visits leading to hospitalizations, and it's drugs. Managing those are the real cost centers. Medicare is trying to find a way to solvency and sustainability in a federal program, or for a state dealing with Medicaid.

What role does big data play in bridging the gap between cost and value?

Burke: With more technology and more ability to gather, store and analyze data, we have the advantage of potentially being able to evaluate the data and to see trends. One way to bridge the gap between the need to reduce cost and the need to increase value and improve outcomes, could be to use data. The concept would be the development of a continuous learning health care system in which favorable outcomes, like the ones that we've been talking about, can drive improvements in the delivery of care to individuals. It's more and more possible with the electronic health records and other algorithms to access the information that is within the medical record.

What is the role of HIPAA in all that? Is that a hindrance? Does it affect the positive use of data in any way?

Burke: HIPAA, which is the federal structure for protecting the privacy and security of health care information, is essentially important, but also presents challenges in handling the information. It's important because people need to know that their personal health information is both private and not to be used for matters that they don't expect it to be used for, and also secure. That becomes more important as we hear about breaches of security systems accessing any number of data bits about each of us.

HIPAA serves the important role of creating a framework for the protection of privacy and security in that area. However, it presents challenges to the sharing of data, especially when there are large amounts of data. There are also challenges coming about from the sheer magnitude of the data. Storage becomes an issue. And that, too, has ramifications under HIPAA because we need to be mindful of the obligations to protect privacy and security, not only in the use of data, but also in its storage.

Zackon: Some of the challenges are interconnectivity to different systems. It's not there. But it also opens up the vulnerability. The more you're on the platform, the more vulnerable you are to criminal activity into your systems, or HIPAA violations, which happen unintentionally.

There's human error constantly that happens with disclosure and some health care information. We certainly receive regularly phishing emails into our email. If you click on the wrong link, it could open up your systems. It could devastate a health care delivery system that's dependent on the technology for course of delivery.

But it's the nature of being an open system that can deliver on the positives. It's like being an open society. You have vulnerabilities.

There are private practices that are simply disappearing from the landscape because they cannot manage that cost or the regulatory reporting requirements that go along with that. If you're a physician in a small practice and near your age of retirement, you may go in five years rather than 10, depending on demands of the practice. You are seeing either acquisitions of practices by hospital systems or networks, or the consolidation of practices into either large specialty groups or multi-specialty groups.

Do you see many HIPAA violations in your practice?

Burke: Simple answer is no. We are not really seeing significant breaches on an ongoing, frequent basis. If, as and when they occur, we work with the client to mitigate the impact, make sure that they are reported as required by law, and improve their systems, so that in the future they've minimized their vulnerabilities.

In your practice, what is the bulk of your activity? Who are your biggest clients and in what fields are they?

Burke: I have a provider-based practice in which I represent primarily, but not exclusively, institutional clients that operate out of institutions, buildings. For example, hospitals or nursing homes or assisted living providers.

The primary thing we do for our clients is assisting them when they are confronting regulatory requirements to help them comply. When they find themselves charged with a potential violation of the regulatory requirements, we help them to understand their obligations and, where appropriate, to defend themselves against allegations.

With the idea that the snowbirds come back here to be treated, what areas are you seeing growth in?

Burke: There is a push to keep people in their homes and to keep them out of hospitals, because hospitals are more expensive for a variety of reasons. We are seeing growth in the assisted living area, in the home care area, in particular.

What specific regulations do you find yourself coming up against?

Burke: As an example, nursing homes are regulated under both federal and state law. The federal government has recently implemented new requirements in participation for nursing homes. They regulate everything from the admission of a resident into the nursing home, to the frequency with which they need to be evaluated, to resident rights, to any number of things regarding the care of a resident in a nursing home. We frequently deal with those requirements.

In the event that a nursing home is found to have violated those requirements, it can have enormous ramifications for the facility. Centers for Medicare & Medicaid Services (CMS) has implemented a five-star rating system that takes into account several factors, and results of inspections and surveys are among those. If a nursing home has an adverse survey, it can push the five-star rating down. Five stars is the best rating a nursing home can get. Lower than five stars is not the direction the nursing home wants to be going in.

The reality is that the surveyors are not always, necessarily, correct in their evaluation. There is an opportunity for nursing homes to challenge survey results. A five-star system can be very beneficial to consumers because it can give them information about the quality of a nursing home that they otherwise might not have access to, but it's crucially important that the considerations that go into that rating are accurate.

In those circumstances, it's crucially important for the facility to push back and to defend itself. There are processes through which we can do that. We spend a lot of time helping facilities pursue that process.

Are there specific regulations that you come up against particularly?

Zackon: Certainly, HIPAA changes the culture within the practice. How you call on a patient to be seen, you can't say their name. Sometimes you get more than one person with the first name and they're all coming up. You have to be very mindful of where you have conversations, and then of moving yourself off to a location where you're not overheard.

Instructing our staff to be very careful with handling paper, to know what they're taking off that copier, and that it's a violation if someone shouldn't be in there, or faxing out to another provider.

Oncology is a complex delivery. We have a pharmacy with five dedicated pharmacists. A lot of pharmacy regulations apply. We are going through some renovations to meet new regulatory definitions and requirements that are requiring us to reconfigure our space and how we operate. It was working well before, but you have to meet the requirements.

Moving forward, what would you like to see us accomplish in health care?

Burke: Back almost a decade now, when the concept of the Triple Aim was first suggested, I remember thinking, how can it be that we're going to improve outcome, reduce costs and improve the patient experience of care? What's happened has been that a lot of people put a lot of thought into how can that happen, and a number of demonstration projects and experimental programs were started. Many of them have been in the area of reimbursement.

Medical research has continued. There have been developments in technology. Technology has continued to improve. We've expanded the things that worked into more settings. If we think about how things were 10 years ago, and we look at how they are today, we can see progress toward the Triple Aim, progress that we could not have imagined 10 years ago. I think, moving forward into the next 10 years, we're going to see some of the same kind of changes. And we have the potential to accelerate on those changes because of the foundation that has been building, because of the improvements in technology, because of an increase in our understanding about the challenges of managing data. In the next decade, we're going to see even greater improvements in the delivery of care.

Zackon: I'm on a national task force, within the U.S. Oncology Network, looking at physician wellbeing and how to mitigate burnout. It is very real. It is significantly technology driven in terms of how that affects the labor time of the physician. It's regulatory, in terms of things that you have to do. You spend, as a physician, much more time on the process of care and documentation and accurate billing, and all of the things that you do face-to-face with patients, and of course, you have a computer in the room that you have to learn how to navigate without losing your connectivity with the patient, and that's a skill.

We are moving to things like scribes who will be in the room and doing the dictation. There are a lot of innovative models on how to do that, having assistance to do a lot of the process work to unburden. We're looking at workflow and how to nurture resiliency in providers, but burnout is very real.

We looked at statistics, and in the oncology field there's a more than 50 percent burnout rate. More women than men. I think women face other challenges. Medicine is a field in which women are the majority in medical school, and many women are therefore in the workforce, but there are challenges of raising a family and work and work/life balance.

There's an 8 percent suicide rate annually in physicians. Burnout impacts our health care system in terms of early retirements, and being able to replace those losses. If you have a fatiguing, burning-out provider, they are less attentive to what they do. They become disconnected from the physician/patient relationship. They affect the environment in which you work, and the patient satisfaction survey and the quality of care go down.

We are trying to be very proactive in adding that fourth aim, that we need a sustainable labor force or workforce in health care. It's true of nursing. Nurses work very long hours, compensated less for the value they provide, and there's a lot of flux in there. At the same time, health care is a vital part of our economy. Job opportunities, especially in a global world, are still very local. We need much more attention paid to those that provide care.

How is the Capital Region situated for a provider in terms of quality of life and not having to, say, deal with stress and burnout when you don't have an hour commute like in Manhattan?

Zackon: I think the largest driver is in the effects of electronic records and internal workflow, but there's no doubt there's advantages to living in a small city. This is a good region. There are good people, good communities, good schools. There's sanity to raising your kids in this environment. It's ideally geographically located. That certainly, from our perspective, adds value, that we see ourselves as a hub amongst being blessed in our region with major other academic centers. There's Sloan Kettering in New York City and Dana Farber and others in Boston and even Upstate, University of Rochester has a strong program, and Roswell Park.

We developed relationships across these institutions so we can function as that hub. Physicians need to know the quality that's provided here so that we can collaborate not only on patient care, but also on research projects or trials.

Are there resources you wish the area had to make it easier to recruit people?

Zackon: Maybe a more coordinated recruitment strategy. I know it happens in sectors, and some of this is largely a government supported tax base, but how do we sell the area for an individual to practice or a hospital? We all have an interest in certain sectors of industry, and health care is one of those large industries and employment base. The more that we make ourselves an attractive place across the board, maybe we can help each other by bringing specifically good people to the area.