

BUILDING A HIGH-TECH, 21ST CENTURY ECONOMY*

Panel 2 – Biotech and Healthcare

REMARKS OF JAMES LYTLE, ESQ.**

So I had prepared one set of remarks and then Dr. Reider suggested I speak to all sorts of other topics, so I'll try to meld the two. And I know that he . . . that the reference that David just made to federal bureaucrats was not intended to be a criticism of you, so I'm just keeping peace here at the panel. So my perspective is much more at the state level, and I actually . . . it is relevant I suppose to emphasize that here in the State capital, Albany Law School has always played a very important role in the government and the governance of this State . . . so I'm happy to give that perspective. I came to Albany in 1983 to work for another governor named Cuomo in his first term and was the Assistant Counsel for healthcare issues, among other things, and it was a tremendous learning experience, a great post-graduate education in public policy and in law, for which I am eternally grateful. And I've spent the last thirty years or so representing clients who try to navigate through this complicated enterprise called New York State government, primarily from the healthcare perspective, but a few other things as well. We represent academic medical centers, biomedical

* On March 19, 2015, the *Albany Law Journal of Science and Technology* presented a symposium on law and policy at the intersection of innovation and economic development. These remarks have been annotated and edited by the *Journal* staff.

** Managing Partner of the Albany office of Manatt, Phelps & Phillips LLP, a firm that provides legal and consulting services to clients from its offices in California, New York, and Washington, D.C. Mr. Lytle's practice focuses primarily on the highly regulated area of health care law and involves the representation of clients before the legislature, the executive branch and the courts. Mr. Lytle graduated from Princeton University and received his J.D. from Harvard Law School.

research entities, a few pharmaceutical companies, as well as advocacy groups, disease oriented organizations, and a lot of different kinds service providers. I had the pleasure when I first came here of working with a giant in public health named David Axelrod who was the long time Commissioner of Health. And I recall . . . one of the greatest things about being in the governor's office is you, once in a while, could kind of decide something that you're really interested in and try to get the powers that be to try and embrace that interest.

And my mother was suffering from Alzheimer's disease, . . . and it was sort of a new thing, at least it was not something that was quite as much in the public conversation in the early 1980's as it is today. I spent some time trying to see what state government might be able to do in that arena, and Dr. Axelrod, to his credit, felt that there was some limitations of what New York State government could really do in the era. We did have some enormous dispositive research activities underway in New York State in that field. But he felt, and others did generally at the time, that it wasn't the state government's role to really be the organizer of research activities, and that's something that falls better to the federal government where they both have the resources, have the sustained capacity to do something along those lines, might be a little less political in terms, and really be more based on the science than on politics. But as time went on, that debate changed, and I think New York State recognized that the economic development element of being involved in the biotech arena and biosciences was sufficient to cause the State to get more involved in it.

During my time in the governor's office, AIDS became the number one public health issue in this State. New York was obviously one of the epicenters of a national epidemic,¹ and that led also to the State recognizing that there probably was a more significant proactive role that we could play, creating the AIDS institute along the way, and beginning to play more of a role on that side. Over time, the State's role improved and increased in this arena.

During the governor Pataki era, there was quite a bit of

¹ See John Tierney, *The Big City; In 80's, Fear Spread Faster Than Aids*, N.Y. TIMES, June 15, 2001, <http://www.nytimes.com/2001/06/15/nyregion/the-big-city-in-80-s-fear-spread-faster-than-aids.html> (discussing the severity of the 1980's AIDS epidemic in New York City).

2015]

REMARKS OF JAMES LYTLE

479

activity. There was creation of a new agency, the New York Science Technology and Academic Research or “NYSTAR.”² Senator Bruno launched something called the “Gen*NY*sis Initiative,” which provided capital funding to promote research activities around the State.³ Speaker Silver . . . speaking of two former leaders both of whom faced legal issues following their retirement—or not retired yet. In any event, I’ll just get myself in trouble if I stay on that topic. In any event, Speaker Silver promoted stem cell research at a time when that was actually a highly controversial topic nationally. I remember I spoke at an event at which Christopher Reeve, following his accident,⁴ and Speaker Silver spoke about the need for stem cell research. And then when Governor Spitzer was elected, he launched a very robust stem cell research program—a commitment of six hundred million dollars over eleven years.⁵ I think it was initially over ten years—a recession got in the way and the State’s level of spending diminished for a period of time, but we are more or less back on track.

² NYSTAR is a division of Empire State Development, New York State’s “chief economic development agency.” *About Us*, N.Y. STATE EMPIRE STATE DEV., <http://esd.ny.gov/AboutUs.html> (last visited May 22, 2015). NYSTAR is independently responsible for enabling “new and existing businesses to become more competitive through the use of innovative technologies” and emphasizing “the importance of working with industry to leverage the state’s technology strengths to produce new products and, therein, new and expanded jobs in the state.” *Division of Science, Technology and Innovation (NYSTAR)*, N.Y. STATE EMPIRE STATE DEV., <http://esd.ny.gov/nystar/> (last visited May 22, 2015).

³ See Stephanie Hankin, *U. to Receive State Funds for Life Sciences*, CORNELL DAILY SUN (Nov. 2, 2002, 7:00 PM), <http://cornellsun.com/blog/2002/11/03/u-to-receive-state-funds-for-life-sciences/> (explaining that “[t]he Gen*NY*sis program, which was initiated by [New York State Senate Majority Leader Joseph L.] Bruno and New York Gov. George Pataki, provides \$225 million to various institutions to stimulate the development of the state’s biotechnology industry.”).

⁴ See Lois Romano, *Riding Accident Paralyzes Actor Christopher Reeve*, WASH. POST, June 1, 1995, <http://www.washingtonpost.com/wp-dyn/articles/A99660-1995Jun1.html> (providing initial coverage that “[a]ctor Christopher Reeve, best known for his role as Superman, is paralyzed and cannot breathe without the help of a respirator after breaking his neck in riding accident in Culpeper, Va.”).

⁵ See Press Release, N.Y. State Dep’t of Health, *New York’s Stem Cell Research Strategic Plan Available for Public Comment* (May 28, 2008), https://www.health.ny.gov/press/releases/2008/2008-05-28_stem_cell_strategic_plan.htm (inviting the public to “review and comment on a strategic framework to guide New York State’s \$600 million, 11-year investment in stem cell research”).

There are other initiatives—the spinal chord injury program that was initiated,⁶ but it's a good example of Dr. Axelrod's fears. This was an initiative which was started by a surcharge on speeding tickets⁷ under the logical theory that a surcharge on the people who speed, among other things, cause spinal chord injuries. This created so much money, much more than every was spent on spinal chord research, that although there was a sort of lock box and notion that these funds would be designated for this purpose, the State in its usual tendency decided that "well we don't really need to spend it on its intended purpose, we'll use it to deal with general fund problems," and not as much money was spent on spinal chord research as had been promised. The State is getting back to that level of commitment now. And some very significant developments have occurred as a result of that research across the State and New York has become a much more of a leader in that science.

In the START-UP NY program⁸ you've heard a little bit about—this is a program that unites the academic world especially the SUNY institutions and startup business—a number of private institutions, including Albany Med was mentioned. But we work with the University of Rochester and New York University, both of which are now also participating in this program.⁹ Of the initial forty-one startup businesses that were part of this START-UP NY initiative where they were relieved of certain tax obligations for a period of time if they were located in one of these incubators, nineteen of the forty-one were in the bioscience arena.¹⁰

So with all of that activity, the State has begun to play a larger

⁶ See Act of Jan. 1, 1999, ch. 338, § 5, 1998 N.Y. Laws (S. 7287–C) (codified as amended at N.Y. STATE FIN. LAW § 99-f (McKinney 2015)) (creating the "Spinal cord injury research trust fund").

⁷ See *id.* § 4 (codified as amended at N.Y. STATE PUB. OFF. LAW § 17 (McKinney 2015)) ("[A]n amount not to exceed \$ 8,500,000 shall be annually transferred . . . out of surcharges collected pursuant to . . . the vehicle and traffic law to the spinal cord injury research trust fund . . .").

⁸ START-UP NY helps owners to "start, expand, or relocate [their] qualified business to a tax-free zone in New York State." *What is START-UP NY?*, START-UP NY, <http://www.startup-ny.com/business-growth> (last visited May 22, 2015). See also N.Y. ECON. DEV. LAW §§ 430–40 (McKinney 2015) (codifying the START-UP NY program).

⁹ See EMPIRE STATE DEV., START-UP NY: 2014 ANNUAL REPORT app. B (2015), available at http://esd.ny.gov/Reports/2014_STARTUPNY_REPORT.pdf (listing the approved college and university sponsors).

¹⁰ See *id.* app. C (listing the approved businesses).

2015]

REMARKS OF JAMES LYTLE

481

role in the development of a high-tech infrastructure here in New York, specifically in the biomedical research area. New York continues as a result of that, and by its own just long history, to have some enormous strength in continuing to be a leader in biomedical research. We're the number one state in training physicians, with I think thirteen medical schools.¹¹ I've lost track, but there is quite a number of medical schools. We are sometimes criticized for the fact that we export many of the graduates of those medical schools. We are number two in the country in clinical trials in this State.¹² We are number three in receiving funding from the National Institute of Health.¹³ All of which are very positive signs.

But there is another side to the New York State kind of environment in the high-tech and biotech arena. We are number thirteen among the fifty states in venture capital investment in New York. Venture capitalists, despite all the activity that takes place in New York, do not see this as the place in which they seem to think is a good place for investments of their resources. We are number thirty-eight in employment growth in biomedical research, and we are number fifty in conversion of all of that basic research funding that we receive. Being the third largest recipient of NIH grants, we are the fiftieth in converting that into private sector investment and translating that basic research into high-tech jobs. And that's worrisome, and I think there's a number of challenges that New York faces that continue to be addressed.

You're going to hear from Andrew Kennedy I think later today, who is one the leaders in the governor's office on dealing with these economic development strategies. But figuring out a way in which the business community and the investor community sees New York as truly open for business, especially in the biomedical arena, seems to be a challenge. Again I think in some ways Dr. Axelrod wasn't wrong. It's difficult for this State on a sustained

¹¹ See *Medical School Directory*, LIAISON COMMITTEE ON MED. EDUC., <http://www.lcme.org/directory.htm> (providing a list of medical schools by state).

¹² See *Studies on Map*, CLINICALTRIALS.GOV, <https://clinicaltrials.gov/ct2/search/map/click?map.x=179&map.y=170> (last visited May 22, 2015) (noting that New York has performed 18,651 clinical studies, second behind California).

¹³ See *NIH Awards by Location & Organization*, NAT'L INST. HEALTH, <http://report.nih.gov/award/index.cfm#tab1> (last visited May 22, 2015) (indicating that New York has received over \$741 million from NIH, third behind California and Massachusetts).

basis to be the generator of the research dollars. Sometimes those dollars have been driven more by political influence than by science, as he feared.

Mr. Silvers current predicament in fact is in part related to the fact that he had enough authority to allocate funds to an asbestos disease researcher in New York City (that was at least alleged by the U.S. Attorney's Office) in return for referrals of cases to his . . . the law firm with which he was affiliated.¹⁴ When you have a system, and it definitely occurred, it is very much less the case today in which large pools of money are available to the Senate, the Assembly, and the governor's office to allocate for these purposes with little if any real public debate or oversight. There have definitely been problems as a result and there is inevitably . . . the degree to which New Yorker's bang for the buck can be questioned.

We've had growing competition in this field. We've always been sort of nipping at the heels of Massachusetts and California, but now Texas and Alabama and a whole bunch of other states have entered into the biomedical research sweepstakes. New York has some very heaving competition from those other places, and that may be part of why venture capitalists have seen their dollars go elsewhere. We have, speaking of regulation, a regulatory environment in New York, which keeps me hopefully occupied, for which I suppose I should be grateful. But it is a regulatory environment that really knows no peer. Massachusetts sometimes runs, I think, a close second to the level of regulation as New York. You know, there are several state agencies that would give the federal Department of Transportation a run for its money.

I represent, for example, Memorial Sloan-Kettering Cancer Center, which is recruiting or has already recruited a physician trained at the institute that sponsors the Nobel Prize in medicine to come and head their Melanoma practice in New York City. They cannot get a license for him from the State Education Department after months, and months, and months of review because of the process by which physicians are subject to a very prolonged review for licensure.¹⁵ That's not helpful.

¹⁴ Dionne Searcey et al., *In Silver Case, U.S. Cites Link to Litigation Tied to Asbestos*, N.Y. TIMES, Jan. 24, 2015, http://www.nytimes.com/2015/01/25/nyregion/sheldon-silvers-link-to-a-bonanza-and-a-cancer.html?_r=0.

¹⁵ See N.Y. EDUC. LAW § 6524 (McKinney 2015) (providing the requirements

2015]

REMARKS OF JAMES LYTLE

483

We have a genetic research statute that actually I have a colleague in our Washington office whose doing a survey of—for a company who was interested in doing some innovative research in the genetic arena—that makes it more difficult to use samples and do genetic research in New York than any other state in the country.¹⁶ All well intentioned, I had to confess, in fact, that I had something to do with the initial original statute when I was in my regulatory frame. I also had something to do with a few of the amendments to make it a little bit more user friendly and while there is enormous and valid, and hugely significant reasons to protect the privacy genetic information, it was impeding the ability for researchers to actually undertake very important research.

HIT¹⁷ issues have been mentioned. New York, together with the federal government, has made significant investments in health information technology. We are still not at a point where we should be in terms of inter-operability, meaningful use, etc. An interesting example, when the State, a couple of years ago, given the huge crisis in prescription drug abuse came up with a new approach towards trying to regulate prescription drug dispensing and to monitor abuse in that arena. Part of the provisions included a mandate that no prescriptions should be issued from about a week from now, March 27th, on any basis other than electronic.¹⁸

A very sound public policy, as has been mentioned. It is the only way in which we can be sure that the information is communicated correctly. It provides for instant ability to identify drug interactions and all sorts of other benefits. The problem is that about . . . that close to 98 percent of the pharmacies in this State are ready to receive electronic prescriptions, a very small percentage maybe only in the twenties or thirties of physicians were prepared to order electronic prescriptions—and that wasn't their fault is the worst of it all. The vendors with which they

for medical licensure).

¹⁶ N.Y. CIV. RIGHTS LAW § 79-I (McKinney 2015).

¹⁷ The term “HIT” refers to “health information technology,” which includes “the use of electronic health records (EHRs) instead of paper medical records to maintain people’s health information.” HEALTHIT.GOV, <http://www.healthit.gov> (last visited May 22, 2015).

¹⁸ Act of Aug. 27, 2012, ch. 447, pt. B, §§ 2–3, 2012 N.Y. Laws (S. 7637) (codified as amended at N.Y. PUB. HEALTH LAW § 281(3), N.Y. EDUC. LAW § 6801(10) (McKinney 2015)).

contract for the electronic systems needed to get their, particularly to satisfy the New York law, to get their software or whatever it is—this is where I totally cannot carry on a conversation that deals with information technology—but there were some measure of technological components that needed to be satisfied for that electronic prescribing to take place, and their vendors were unable to provide that, at least by a week from now. And just a few days ago, the governor signed a law that extends that deadline another year.¹⁹ So, and it's a good example as well of well-intended regulation, appropriate direction by State policy leaders but needs to be informed as much as possible by what is in fact taking place in the field so that we weren't in a position where people would not have access to medications that they needed.

We have land use issues, and Albany Med can speak to this, I think, in terms of some of their recent expansion. I represented, again in Sloan Kettering's case, they were building a research building around the corner from the main campus—very important to develop more space to do the clinical trials, to do the work that they are engaged in—and the neighborhood was very concerned about the height of the building, its intrusion on sunlight that some high price condominiums on the upper east side had come to depend upon. One of the – I swear to you we did not plant this person – but one person had testified that the land use hearing on this was a resident of the community, who pointed out that nobody in his community wants anything to be built anywhere, number one. And number two, pointed out that if he were God, I think he said, “in my opinion, maybe the cancer researchers should get some of that sunlight” that was being blocked by . . . from the other residents of the community. And ultimately, the building was built. But building, especially around the biomedical hub on the what's referred to as “bedpan alley” on the east side of Manhattan is not easy. And doing so even in other urban areas has proven to be a challenge.

And we have outdated regulatory requirements that I could spend another hour speaking about. I'll just mention one. Again, relating to my favorite comprehensive cancer center in New York City—they have a treatment center two blocks from the hospital

¹⁹ Act of Mar. 13, 2015, ch. 13, §§ 1–2, 2015 N.Y. Laws (S. 2486) (codified as amended at N.Y. PUB. HEALTH LAW § 281(3), N.Y. EDUC. LAW § 6801(10) (McKinney 2015)).

2015]

REMARKS OF JAMES LYTLE

485

that provides chemotherapy to patients in a much more attractive, comfortable setting than would be on the inpatient side. There are medications that have to be provided to these patients, sometimes controlled substances to deal with pain and other issues, and with the Department of Health's complete consent and review they have an automated dispensing machine that has all sorts of security attached to it that allows for them to dispense controlled substances there. They've had this in place for four years. The Department of Health, taking a closer look at its regulations has said, "I'm sorry your authority to operate one of these things is only valid if you were two blocks away at the main campus in the hospital proper, not at this outpatient center or if you're a nursing home." And in lieu thereof, theoretically, the thirty-four prescribers who are in charge of prescribing medications for these people have to themselves receive the medications directly from the wholesaler and dispense them, you know, from their large packing case that they carry in their backpack. That will be . . . that's one of the solutions that they have recommended. Or you build a full-fledged pharmacy in the place at a cost of close to a million dollars and hire pharmacists that will cost several hundred thousands of dollars to staff when you really need a little machine on the wall that allows people to access the drugs that they need when they need them.

There's a lot more examples of that, but it is definitely part of the problem at least from where I see the world—that we have a regulatory environment, let alone a potentially tax environment, as well as a climate perhaps, that may not be everyone's favorite place to invest their dollars in biotech development. But New York State still has some work to do. You know, as a result of this, there is about thirty billion dollars in venture capital invested nationally in bioscience. Forty-seven percent of which ends up in California, again it could be climate related, but it could also be because Californians, a few years ago, voted at the polls for a three billion dollar loan program—a three million dollar bond issue to fund bioscience in that state.²⁰ There was a signal sent to the rest of the country that California was going to be very serious about it. So they get about half. Massachusetts gets about 12 percent, 37 percent is scattered everywhere else.

²⁰ See 2004 Cal. Legis. Serv. Prop. 71 (codified as amended in scattered sections of CAL. HEALTH & SAFETY CODE) (providing \$3 billion in bonds to fund stem cell research in California).

New York gets about 4 percent of that venture capital investment in biotech.

So I thought I'd end with a comment about medical marijuana, which is obviously a logical topic to switch to. But I was on a panel yesterday—it's my week for panels on that topic—and the sponsor of the legislation in New York, which may seem odd except for if one understood the legislative dynamics, he was sort of forced to agree to a compromised approach to his proposal by the Governor in order to get the bill passed. He spent his entire time talking about what a complete disgrace the legislation that he sponsored was because it was so wildly overly regulatory. This is someone who, from the State Assembly, has never thought there was ever adequate regulation in any other area I might add. So I thought—as I said with one of the many of the puns of the day when we talk about marijuana—I thought that Mr. Gottfried had “turned over a new leaf” or that it was a “half baked” solution or that “what were they smoking.” But with all those having been said, the reality is that New York ended up with the only state law that requires a pharmacist to be present when medical marijuana is dispensed.²¹ The only of several, a couple of states that have very rigid requirements about how you advertise and what the signs can say outside the dispensaries.²² They have a very limited number—a grand total of twenty sites—that will be available in New York at least in the short term,²³ while there are seventy of them in the city of Los Angeles, for example.²⁴

On every other . . . on every conceivable level, New York leads the league in taking the most restrictive and most highly regulatory approach. As a result, an industry that tilts towards the pharmaceutical arena, I suppose, and is certainly involved in bioscience is going to have a very difficult time getting started in this State. So with that, I'll conclude my remarks. Thank you.

²¹ N.Y. COMP. CODES R. & REG. tit. 10, § 1004.12(a) (2015).

²² *Id.* § 1004.16.

²³ Kristina Sgueglia & Greg Botelho, *New York Governor Announces Plan for Medical Marijuana at Hospitals*, CNN (Jan. 9, 2014, 10:41 PM), <http://www.cnn.com/2014/01/08/health/new-york-state-medical-marijuana/>.

²⁴ John Hoeffel, *L.A. Acts to Cap Medical Marijuana Dispensaries*, L.A. TIMES, Dec. 9, 2009, <http://articles.latimes.com/2009/dec/09/local/la-me-medical-marijuana9-2009dec09>.