

INTERIM JOINT COMMITTEE ON HEALTH AND WELFARE AND FAMILY SERVICES

Minutes of the Fifth Meeting of the 2018 Interim

October 17, 2018

Call to Order and Roll Call

The fifth meeting of the Interim Joint Committee on Health and Welfare and Family Services was held on Wednesday, October 17, 2018, at 10:00 a.m., at the Northern Kentucky University Health Innovation Center, Highland Heights, Kentucky. Representative Addia Wuchner, Co-Chair, called the meeting to order at 10:07 a.m., and the secretary called the roll.

Present were:

Members: Representative Addia Wuchner, Co-Chair; Senators Ralph Alvarado, Tom Buford, Julian M. Carroll, and Reginald Thomas; Representatives Danny Bentley, George Brown Jr, Joni L. Jenkins, Mary Lou Marzian, Chad McCoy, Kimberly Poore Moser, Steve Riley, and Russell Webber.

Guests: Ashish Vaidya, President, Northern Kentucky University; Valerie Hardcastle, Vice President for Health Innovation, and St. Elizabeth Executive Director of the Institute for Health Innovation, Northern Kentucky University; Sarah Giolando, Chief Strategy Officer, St. Elizabeth Healthcare; Ray Takigiku, PhD, President and CEO, Bexion Pharmaceuticals; John L. Villano, MD, PhD, Director of Clinical Neuro-Oncology, and Professor, Departments of Medicine, Neurosurgery, and Neurology, University of Kentucky; Roseanne Nields, Vice President, Planning and Government Relations, St. Elizabeth Healthcare; Teresa Koeller, MD, St. Elizabeth Physicians Journey Recover Center; Ellee Humphrey, DNP, Director, Women's and Children's Services, St. Elizabeth Healthcare; Sara Hamilton, Director, Planning and Program Development, St. Elizabeth Healthcare; Dawn Radcliffe, Northern Kentucky University Student/Graduate MSN; Lynne Saddler, Northern Kentucky Health Department; Shauna Kitts, Lloyd Memorial High School; Katie Bentley, Commonwealth Council on Developmental Disabilities; Robin Osborne; Chuck Scheper, Bexion Pharmaceuticals; Anne Wildman, Northern Kentucky Area Development District; Heather Bailey, Carespring; Louis Kelly, Kentucky Board of Physical Therapy; Tammy Gunnon, The Point; Julie Lehmann, Highlandspring of Ft. Thomas; Adam Lewandowski, Coldspring Transitional Care; Sandra George, Noah Key Community Care; Donna Turner, Tri-Generations; Amanda Newton, Recovery Concierge; Kara Daniel, Cabinet for Health and Family Services; Kristen Bender, The Point Arc; Jo Lewton, Boonespring Rehabilitation Center; Lisa Anglin and Angie Scroggins, St. Elizabeth Healthcare; and Mike Hammons, Children, Inc.

LRC Staff: DeeAnn Wenk, Ben Payne, Chris Joffrion, Dana Simmons, Gina Rigsby, and Becky Lancaster.

Welcome

Ashish Vaidya, President, Northern Kentucky University (NKU), stated that University would dedicate the Health Innovation Center (HIC) later in the day. He met earlier with the Liaison Committee for Medical Education, the accrediting body for the medical school, regarding the first class of students for the four-year medical program that will enroll in 2019 at NKU, in partnership with the University of Kentucky and St. Elizabeth Healthcare. In 2014, the General Assembly appropriated \$97 million for the HIC, and St. Elizabeth Healthcare invested another \$8 million. The HIC is going to be at the forefront of solving the challenges of healthcare by preparing more individuals for the healthcare professions.

Overview of the Institute for Health Innovation

Sarah Giolando, Chief Strategy Officer, St. Elizabeth Healthcare, stated that St. Elizabeth Healthcare is proud to have a public-private partnership with NKU and UK in many different aspects that will greatly impact the delivery of healthcare and innovation of healthcare across the Commonwealth. St. Elizabeth Healthcare has partnered with the UK Markey Cancer Center, and is in the process of building a \$140 million comprehensive cancer center in Kenton County on the Edgewood campus because of the high need for the treatment of cancer. St. Elizabeth Healthcare is also an investor in Bexion Pharmaceutical's cancer research. NKU's medical school will help train professionals to the highest level of capability to provide care for individuals in Northern Kentucky and beyond.

Valerie Hardcastle, Vice President for Health Innovation, Northern Kentucky University, and St. Elizabeth Executive Director of the Institute for Health Innovation, stated that NKU and the HIC is centered on developing talent, nurturing place, and fostering innovation. The College of Health Professions works to enhance human health and preserve a good quality of life. The College is able to take advantage of the simulation center. NKU has the only simulation center in the state and it is comparable to any cutting edge, state-of-the-art simulation centers across the country. The simulation center will allow NKU to expand its clinical programs and interprofessional training.

The Institute for Health Innovation develops pioneering solutions to health challenges facing Northern Kentucky and drives change that directly addresses urgent unmet health needs. The primary partnerships areas are chronic illness, social determinants of health, and developing the health innovation sector. NKU received a grant from Health Resources and Services Administration (HRSA) to develop a comprehensive workforce plan with a special focus on substance use disorder. The grants are given to help rural areas and NKU's primary focus is Owen County which encompasses the entire Northern Kentucky region. Setting up additional clinical sites in Owen County and the surrounding

rural areas will provide no cost or low cost care to people who desperately need it. Currently there are only three full-time primary care providers in Owen County, if someone needs substance use disorder treatment, that person is referred to another provider outside of the county which presents a problem with transportation to get to the provider. If students work with providers in Owen County and surrounding rural areas, it would provide an easy and inexpensive way to increase NKU's capacity to produce more healthcare workers and provide better care in rural areas. Hopefully the students would come from the region and would want to return there upon graduation. The second part of the comprehensive plan would focus on individuals who are early substance users who are not fully addicted, addicted but have not shown up in a treatment center, or have overdosed and been taken to an emergency room. If there is intervention for someone who can be caught early in their addiction, it would reduce the need for expensive treatment in the future. The goal is to train the school nurses, the counselors, the resource officers, and the teachers in an early intervention and recognition program for substance use. Often the first line of defense for middle and high schoolers is what happens in the schools.

NKU, St. Elizabeth Healthcare, and St. Elizabeth Physicians has collaborated in a project in health informatics. Most physicians prescribe drugs they learned about while in medical school or the drugs they are comfortable with. There is data in the Medicaid and Medicare systems about what drugs are being prescribed to what patients. The aim is to take this deidentified information and add in cost factors to produce an algorithm that would help physicians know if a patient would benefit more if a particular drug is assigned to help manage symptoms in order to help provide less expensive care.

If a baby is exposed to opiates while in utero, it affects brain development, but the challenge is to figure out how the brain is affected. School systems are unable to manage children born with neonatal abstinence syndrome (NAS), because no one knows the full extent of all the symptoms. NKU has partnered with St. Elizabeth Healthcare to get medical data to perform an analysis of children born with NAS versus children who were not born with NAS, matching birth weight and diagnoses to see if there are any trends. A support group of parents whose children were diagnosed with NAS has been organized to talk about their experiences and help healthcare professionals that attend the meeting organize better care and support for families that are trying to manage this population.

Large determinants of health are food and housing security. Approximately 10 percent of all college students are housing insecure. If a student does not have a place to live and a real means of support, it will impact how the student performs in college. Achieving a college degree can be very important in lifting a student out of poverty and into a better life. NKU is conducting a study to look at the actual incidence of homelessness on campus. The university is engaged in a fundraising effort to dedicate part of the dormitory space to provide a place for students in need to live without cost and to provide wraparound services for them to help with the transition from a life of lower socioeconomic status to becoming a productive member of society.

In response to questions by Representative Bentley, Dr. Hardcastle stated that because the objective of federal funding is to study the opioid addiction problem, it is difficult to get funding to study the effects of methamphetamines in combination with opiates and alcohol. She stated that she does not have any data on the co-occurrence of marijuana abuse with respect to opiate addiction, but would research the problem. NAS is a combination of some symptoms of autism, ADHD, and vision problems. The symptoms resemble what is seen with autism spectrum disorder.

In response to questions by Representative Wuchner, Dr. Hardcastle stated that the symptoms of bi-polar disorder, schizophrenia, and other types of psychosis begin to show up in the college attending age range. It is very important to have comprehensive mental health services on campus that students can access. One of the challenges is that the mental health services are overwhelmed because there are so many students in need of those services. The strategy is to lift some of the burden from the healthcare professionals by being able to embed some mental health counselors in the dormitories to deal with students who have less of a comprehensive need and allow the mental health services on campus to deal with students who have more comprehensive needs.

Patient No. 1 and the Cancer Trial that Just Might Change Everything

Ray Takigiku, PhD, President and CEO, Bexion Pharmaceuticals, stated that patient 1, began the treatment of the experimental drug BXQ-350 made from a human protein that destroys cancer cells without destroying healthy cells. Phase I of the clinical trials began in late 2016. Approximately \$40 million was invested in Series A and Series B, and \$6 million in non-dilutive grants mostly funded by Small Business Innovation Research (SBIR) program. Phase I does not have anything to do with clinical trials. Bexion received a \$3 million Phase II Bridge Award. Bexion's Phase II Bridge Award had to be vetted by Dr. Harold Varmus, MD, NCI Director, because the award is not given annually. Bexion has orphan drug status for glioblastoma multiforme (GBM) for brain cancer. In 2019, Bexion is planning a Phase I pediatric trial and a Phase II trial for adult GBM. The University of Kentucky, University of Cincinnati, Ohio State University, and New Mexico University recruit and refer patients to Bexion for its clinical trial.

Bexion started the company by licensing technology at Cincinnati Children's Hospital. The NCI \$5 million funding was matched for \$1.1 million by Kentucky. The Kentucky Enterprise Fund invested \$400,000 in 2009 and \$350,000 in 2018. Bexion located in Kentucky because of the reasonable cost of living. The company built a life sciences incubator where offices and laboratories are located. More available capital access is needed to bring more companies to Kentucky.

John L. Villano, MD, PhD, Director of Clinical Neuro-Oncology, and Professor, Departments of Medicine, Neurosurgery, and Neurology, University of Kentucky, stated that Markey Cancer Center's (MMC) mission is to reduce cancer mortality in our state

through a comprehensive program of cancer research, treatment, education, and community engagement with a particular focus on the underserved population of Appalachian Kentucky. Markey has 36 sites statewide it is recruiting and research networks led by Dr. Tim Mullett. Approximately 59 percent of all new cancer cases in Kentucky are directly or indirectly cared for by MCC. MCC has \$41.9 million in cancer research funding, and have trained 5,700 health care professionals since 2013. MCC's clinical protocol and data management's goal is to maintain high quality clinical cancer research.

In response to questions by Representative Bentley, Dr. Takigiku stated that there is definitely some activity in the mitochondria in cell cultures. One of the mechanisms of cell death that has been published for this compound is on apoptosis, the death of cells that occurs as a normal and controlled part of an organism's growth or development. Consistent with this mechanism, there are changes in mitochondrial membrane potential that has been found in tissue culture. Dr. Villano stated that based on the pathology of GBM, the trial drug causes cell death.

In response to questions by Senator Thomas, Dr. Villano stated that there are a lot of clinical trials for men's health issues and there are a lot of studies conducted on gynecological and breast cancer. MCC has a precision medicine unit that incorporates more innovative agents, and some of the agents include immunotherapy.

In response to questions by Senator Alvarado, Dr. Villano stated that part 2 of Phase I study has been for solid tumors and not focusing on the lymphatic and hemolymphases. Dr. Takigiku stated that Bexion has enrolled five different types of tumors in the Phase I program. In a world of precise medicine which is geared to specific genome types and specific tumors, Bexion has targeted therapy that are unique to tumor cells but are ubiquitous in tumor cells. The goal is to try to impact more tumor types.

In response to questions by Senator Julian Carroll, Dr. Villano stated that for clinical trials it is very important to restrict agents such as CBD oil. A lot of herbal and other types of medicine available for sale on the internet do not list all the ingredients and some of them contain steroids. People in clinical trials who choose to take these drugs need to be aware of the ingredients and the high cost to purchase the drug. There are other medical options to available to treat patients for conditions than to treat them with medical marijuana.

In response to questions by Representative Marzian, Dr. Villano stated that educating people about the negative effects of smoking will have the best impact on Kentucky's health. There needs to be more studies on the impact of exposure of environmental conditions that cause cancer. MCC has a financial counselor to help patients deal with costs related to treatment and clinical trials. Dr. Takigiku stated that in rural communities, healthcare is often provided by federally qualified health centers (FQHCs)

who provide excellent care. Each FQHC has different quality measures, but usually include preventive care.

In response to a question by Representative Wuchner, Dr. Takigiku stated that the Federal Drug Administration (FDA) in conjunction with Congress does have multiple incentive programs for large pharmaceutical companies to devote efforts to study less prevalent cancers such as GBM. There are approximately 10,000 new GBM cases per year nationwide, and because it is not considered a rare tumor type it falls under the orphan category. It is significant to have the orphan drug designation for GBM as a financial incentive and for research purposes. Bexion is hoping to collaborate with St. Elizabeth for recruiting patients for the Phase II study.

Baby Steps and Beyond: A Regional Plan for Pregnant Moms and Babies with Substance Use Disorder

Roseanne Niels, Vice President, Planning and Government Relations, St. Elizabeth Healthcare, stated that in 2017, there were over 2,000 overdoses and 220 deaths in Northern Kentucky. The Hepatitis C rates in Northern Kentucky are 11 times higher than the nation and 3 times higher than the rest of Kentucky. St. Elizabeth Healthcare assembled a regional planning group to develop a process to improve the outcomes for mothers that suffer from addiction and their babies.

Sara Hamilton, Director, Planning and Program Development, St. Elizabeth Healthcare, Ellee Humphrey, DNP, Director, Women's and Children's Services, St. Elizabeth Healthcare, Teresa Koeller, MD, St Elizabeth Physicians Journey Recover Center, stated that the Annual Report on Neonatal Abstinence Syndrome in Kentucky reports over 86 percent of Kentucky mothers of babies with NAS are between the ages of 20 and 34. St. Elizabeth reports that from 2015 to 2017, the average length of stay for a NAS baby was 14 days, 650 babies were born exposed to opiates, 290 babies were born with NAS, and 57 percent of NAS babies were born to mothers who tested positive for Hepatitis C. When a NAS baby goes home, 42 percent went with a mom and no required supervision, 33 percent with another relative or into foster care, and 25 percent with mom with required supervision. St. Elizabeth was awarded a Kentucky Opioid Response Effort (KORE) grant to fund the Baby Steps program. In 2017, there were 525 referrals to the program. While moms are in recovery, moms and babies stay together. Eighty percent of moms that go through recovery with their children use the Comprehensive Opioid Response with Twelve Steps (COR-12).

St. Elizabeth and its collaborative network's mission is to create an evidence-based continuum of care for pregnant women with substance use disorder (SUD) that promotes better health and well-being for both mom and their newborn, up to 2 years. The vision is to promote healthier outcomes for pregnant women with addiction, particularly to opiates, and their children. Treatment for moms and babies does not stop at birth, but should expand to two years postnatal to help study the effects of NAS has on the babies. The four

collaborative goals are to facilitate early induction on buprenorphine/Subutex for pregnant women with SUD, increase post-birth collaboration and coordination of care among facilities providing post-partum services and parenting to women with SUD to improve the developmental trajectory of NAS babies born at St. Elizabeth Family Birth Place, enhance the recovery of mothers who deliver at St. Elizabeth Healthcare by providing recovery support and quality medical care up to two 2 years post-partum, and track and monitor relevant data on birth outcomes for women with SUD and the impact of recovery support up to 2 years post-partum. Housing, transportation, and child care are huge barriers to treatment.

In response to questions by Senator Buford, Dr. Koeller stated that currently Transitions has a residential addiction program available. In November, Transitions will open a 60 bed residential treatment center. Brighton Recovery Center is a 100-bed abstinence-based housing that does not allow medications where a woman can stay for up to 12 months. St. Elizabeth sees residents from Northern Kentucky, Cincinnati, and Indiana. She was unaware of any residential treatment centers in outlying areas, but would love to partner with other residential centers that are available.

In response to a question by Representative Jenkins, Dr. Koeller stated that St. Elizabeth Healthcare does not provide long acting reversible contraception (LARC) treatment and does discuss other options with women. Representative Wuchner stated that St. Elizabeth Healthcare is a Catholic facility which takes care of everyone without challenging its own faith as an institution.

In response to questions by Representative Wuchner, Dr. Koeller stated that when Oxford House opens in Northern Kentucky, the moms will be allowed to stay with their children unlike the one in Louisville that does not allow children to stay with their moms.

Representative Wuchner stated that Senate Bill 250 from the 2018 Regular Session had language that stated if a pregnant woman tested positive for Hepatitis C, the results would become part of the permanent medical record of the woman and the permanent medical record of the child or children she was pregnant with at the time of the testing after the child or children are born. Children will be tested again at the 24-month well-baby check. Dr. Koeller stated that St. Elizabeth Healthcare is considering partnering with Children's Hospital to monitor developmental delays in babies with NAS. St. Elizabeth is partnering with The Christ Hospital in Cincinnati to send eligible women to be a part of its research program on the transmission of Hepatitis C as long as the pregnant woman does not have Hepatitis B. At the end of the study, The Christ Hospital will pay the \$80,000 to \$115,000 treatment cost for each woman.

Adjournment

There being no further business, the meeting was adjourned at 11:48 a.m.