

Ms, Melanie Hill, Director
Andrew Jackson State Office Building
502 Deaderick St,
Nashville, TN 37243

Dear Ms. Hill:

This is in reference to the proposed location of a Suboxone-methadone clinic in the Gray Commons area of Gray, Tennessee. As a citizen of Gray for 49 years, I would like to submit reasons why this could be detrimental to nearby businesses, other modest communities, the nearby schools, and the continued peaceful existence of the community of Gray.

- * Johnson City should locate the clinic within the city proper. It would be difficult to maintain an adequate police force to control the activities and movement of 600 to 1,000 individuals, over time, drawn from a likely area of 50 to 100 miles away. It is acknowledged that most of the participants in the program will be sincere in seeking help. However, some of these individuals, in spite of all precautions taken, will have ulterior motives. Sociopaths have been able to convince the most wary of their "sincerity".
- * It has been stated that some patients of the clinic obtain the Suboxone or methadone medications to subsequently sell them for personal gain. This would have to be closely monitored to insure that no illegal activity transpired. The police force would have to be on duty during all hours the clinic is in operation to insure that the condition would be properly met. Let us imagine crises that would require all officers to be at another location for contracted periods of time. The neighboring population and businesses would be vulnerable to any undesirable activity that could result.
- * Gray is located far from the nearest hospital (about 15 miles or more, depending on which hospital could receive patients at the time). In a recent family experience, Johnson City Medical Center had to direct a relative to the Bristol hospital because they did not have sufficient staff to treat his life-threatening condition. Should quick emergency treatment be required for a patient who experienced a critical reaction to the drug being administered, the ideal treatment situation delivered by a hospital's expertise and equipment would not be available for a considerable period of time. That could be crucial for the individual requiring it.
- *The stated hours coincide closely with the opening and closing hours of four nearby schools within close proximity to the proposed clinic. Patients traveling to and from the clinic could impede or interrupt the safe transportation of 3,000 children ranging in age from kindergarten through high school.
- *Traffic congestion is a problem, especially on Suncrest Drive, which is the thoroughfare heavily used to transport these children to school. And with the increase in traffic that the clinic would impose, the children and other residents of Gray would be seriously deprived of a quick and timely route to the nearest hospital should emergencies occur (a delay that could perhaps endanger lives).
- *This area is fondly and commonly referred to as the Tri-Cities. Is it possible that one of the other cities in the Tri-Cities area could accommodate the clinic with the complete availability of a police force, a hospital, and other necessary and useful facilities for safe and successful operation of an endeavor of this magnitude? Have the cities of Bristol and Kingsport been approached concerning this matter?

Most citizens in the Gray area would support the idea of addicted individuals being able to receive treatment for their affliction. However, they feel that such a treatment facility should be in tandem with other supportive institutions that could intervene quickly and successfully in the case of a critical situation. Given time, such a crisis will inevitably happen.

As a former teacher for 29 years, I especially do not want to see young children forced to live in an environment which could negatively impact any one of their lives or futures. This is perhaps one of the gravest reasons that the clinic should be located in an area where business and medical facilities comprise the population and not in a community that is ill-equipped to supply the clinic's ancillary needs.

The citizens of Gray have carefully and thoughtfully reviewed the history of the proposed clinic and strongly believe that it could be situated in a far better location to achieve its intended purpose. We will be extremely grateful to you for your attention to the stated problems inherent in the location of such a clinic in our small community. We will be very grateful for your attention to this matter. Thank you deeply for your time.

Respectfully yours,

Mary T. Winebarger

Cc: jim christoffersen @tn.gov

August 19, 2016

James Christoffersen
Andrew Jackson State Office Building
502 Deaderick Street
9th Floor
Nashville, TN 37243

Re: CN 1605-021, Application of East Tennessee Healthcare Holdings, Inc.

To Whom It May Concern:

I am writing to you as a resident of the of the community in which Mountain States Health Alliance and East Tennessee State University have proposed an addiction clinic. I, along with many of my neighbors, are very concerned about this proposal for many reasons. I am aware that you are considering this proposal in relation to the certificate of need, and therefore I will limit opposition in this letter to matters that are scope your scope of consideration. My opposition is based around three areas: the location, the future of the organization, and the operational structure of the proposed facility. I would welcome your consideration of these concerns and ask that you reject the proposal for this clinic.

My first area of opposition centers around the location of the clinic. I believe that the Gray area proposed for the clinic is completely inappropriate for a facility such as this. First, while the opioid epidemic affects people of all backgrounds and economic situations, there is no doubt that a location such as this will disproportionately disadvantage users of these services that have less economic means to travel. Gray is a small community with a population of roughly 1,500 residents compared to the 500,000 population of the Tricities area, the area which the clinic would serve. In excess of 90% of the population served by the clinic would have to travel at least 10 miles to get to the clinic. In addition, the Gray area is accessible primarily by Interstate 26. Foot traffic is not advisable or feasible for this location. Gray is also not served by any means of public transportation, and there are most likely not plans in the future for expanded public transportation because of the distance to other urban areas. All of these factors would make access to the clinic for those with limited means of transportation very difficult, if not impossible. The certificate of need application filed even identifies this economic group as a significant portion of the potential users of the facility. I would ask you to consider, would a facility that is not easily accessible for a large majority of the population it is attempting to reach even be useful? Please reject this facility on the basis that a location in a more urbanized area would be much easier from much greater numbers of people to access the facility.

Additionally, the fact that this clinic would bring among other things, a medical treatment of opioid addiction is one of the central themes of the certificate of need application. Gray Tennessee is not located near any of the major medical facilities in the Tricities area. Of all of

the other methadone clinics in the state of Tennessee, all but one are within 2 miles of a major medical facilities with emergency room services. The one that is not is seven miles away. This facility would be 9 miles from the nearest hospital, the furthest in the state. Even the closest hospital has limited emergency room and ICU services. The next 3 closest hospitals would be 11, 16 and 25 miles from the facility. There is no doubt that the location of the facility is too far from other medical services, and with the high-powered drugs being dispensed at this facility, it would be much better for this facility to be located close to other medical services.

My second area of opposition centers around the fact that Mountain States Health Alliance is itself in a period of tremendous change and uncertainty. Mountain States Health Alliance currently has another issue before the State of Tennessee, and that is a merger with another major health provider in the region. Management of the organization has on several occasions over the past several years publically stated the difficulty they were experiencing operating in the current state of the healthcare industry. As a result they have announced a plan to merge with Wellmont Health System, the only other major medical services in this region. Currently their certificate of public advantage is under consideration by both the states of Tennessee and Virginia and if that merger is approved by both states, the organizations would become one, with different governance organizations, management teams and most likely different goals and strategies for future operations. It seems logical to me that such a big undertaking should not be made by an organization on the brink of such a major change. What assurances do the community have that this facility will still be run appropriately under the new leadership? Can it be said all of the promises made by the organization today will still be kept by the new organization? I would urge you to reject this certificate based on the fact that the organization is in a period of change and that it would be better to wait and have the new organization file a certificate based on their long-term operation strategies.

My third area of opposition to this addiction clinic surrounds the structure of the clinic. The two organizations have publically touted that this facility would not be like any ordinary methadone clinic. This facility would combine methadone treatment with counseling and academic research to create a whole new approach to treating opioid addiction. It should be noted however, that this partnership between Mountain States Health Alliance and East Tennessee State University is actually with the School of Public Health and not the Quillen College of Medicine. This means that even though they are advertising this medical research component, that those who are teaching our future doctors and those who will be our future doctors at this very reputable medical school are not actually involved in this "research." It seems that if we are talking about a medical treatment that the school of medicine should have been involved. Additionally I question whether either of these organizations have the expertise to run such a clinic. Since they are basing this application on a new approach for this epidemic, are either of these organizations and their top people in charge of this clinic qualified to run such a facility in accordance with their promises made on this application? After some research it has come to light that ETSU professor Dr. Robert Pack of the School of Public Health will be in charge of the clinic. I question his qualifications for this particular endeavor and what skills and experience he has that make him qualified to dispense methadone.

I appreciate your time in considering my opposition to this clinic. My opposition to this facility spans many more areas than are listed here, but I have tried to keep my reasoning relevant to your area of focus. The bottom line of my argument is that this facility is completely inappropriate for the location being proposed and that this application seems to be rushed and only an attempt to get a license to run a facility such as this before any competition could get one.

Thank you for your time and I would ask you to please reject this application.

Sincerely,

A handwritten signature in black ink, appearing to read "Eric Nauman". The signature is fluid and cursive, with a long horizontal stroke at the end.

Eric Nauman
Concerned Citizen of Gray, Tennessee

Wendy Gayle Fleenor, PharmD

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August 23, 2016

Tennessee Health Services and Development Agency
Attention: Mark Farber
502 Deaderick Street
Andrew Jackson Bldg., 9th Floor
Nashville, TN 37643

RE: East Tennessee Healthcare Holdings, Inc. Application CN1605-021

Dear Mr. Farber,

Thank you for time and consideration to review **my letter in opposition** for the Certificate of Need (CON) application regarding a Methadone Clinic located at the proposed site, 203 Gray Commons Circle, Johnson City, TN 37615. I had made plans to attend the meeting tomorrow, on August 24, 2016, in Nashville, Tennessee to give my expert opinion in person, but my schedule has changed. I am sending this letter be added to the opposition letters for planned the meeting, and am very passionate about my patients in this region receiving the safest best treatment and outcome regarding their quality of life.

My name is Wendy Fleenor, and I am a mother, Gray citizen, clinical pharmacist, and patient advocate. **My pharmacy and health care expertise are focused in patient and medication hospital safety practices, toxicology, adverse drug reactions, and medication errors.** I have family members struggling with opiate addiction.

I have treated some of the local area and surrounding regional patients from most of the methadone and buprenorphine treatment clinics, patients in the overdose and death statistics in East Tennessee and Southwest Virginia, and worked and educated some of the health professionals for MSHA and ETSU in the application. I felt proud to have proactively addressed the issues, complications, medication errors, adverse drug reactions, and inappropriate dosages or medications to prevented or stop further harm in the patient's care with the goal of continuing or improving their quality of life.

I treated and interviewed patients that had been to the local urgent care clinics for immediate treatment that should have went straight to the emergency department, but the patient was so resistant to being treated at MSHA they first tried the urgent clinic (numerous patients seen from State of Franklin Healthcare Associates and Medical Care in Johnson, City, Tennessee). **My question for my patients has been, "Is there a lack of patient support for the Gray Substitution-Based Treatment Center or lack of patient support of a MSHA and Frontier Health Substitution-Based Treatment Center?"** Recently, the few patients I have seen have been the lack of support for a MSHA Substitution-Based Treatment Center, because they have experienced issues with treatment within their facilities.

As I read the CON application, the purposed application for the need, economical feasibility, and contribution to the orderly development of healthcare may appear complete by individuals unfamiliar with research standards, substance abuse treatment, and federal guidelines for treatment centers.

The argument supporting the area's need for the treatment center has poorly represented all patient populations receiving opioids, enrolled in substance abuse treatment, or abusing drugs.

Data and Statistical Flawed

- Inconsistent and avoid answering the questions appropriately in regards to the statistical data referenced by the CDC, **included methadone as a prescription opioid in the data.**
- Failure to notate **methadone was notated as the highest opioid in the noted overdoses and deaths** by the CDC when referenced the prescription opioids.
- Failure to note the referenced statistical data, **methadone accounts for 1/3 of the incidents per the CDC.**

- Eliminated the CDC has commented on the impossible task of identifying the drug that caused a patient death when multiple drugs were present (for example, heroin or a prescription opioid—including methadone).⁵
- **Eliminated references to CDC reanalyzing the prescription opioid data** to exclude tramadol and illegally made fentanyl.
- Eliminated the fact that the methadone patients receiving treatment doesn't reflect patients starting or leaving treatment **inaccurately reflecting positive results from treatment, overdoses, death, and many other reasons for patient number fluctuations.**
- Provided list of buprenorphine and pain clinic physicians without notation or recommendation of PMP database information to determine which of the **areas' physicians prescribed methadone for chronic pain, hospice or cancer.**
- Eliminated a factor in the increase of opioid related deaths and overdoses were **impacted the opioid shortages that started in 2009, still an issue.**
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- Eliminated the inclusion of the Tennessee Appalachian High-Intensity Drug Trafficking Areas (HIDTAs) and Gulf Coast HIDTAs statistics about the heroin problem increasing in Tennessee were noted referencing the **increase in heroin deaths and overdoses were in Shelby County, Tennessee,** on the other end of the state.
- **Failure to notate/research how many drug offenders where listed for the proposed TN counties in The Tennessee Bureau of Investigation (TBI) Drug Offender Registry Database,** only had 2 offenders listed for position of heroin for the last 5 years.
- **Failure to notate/research the public Johnson City Police Annual Report regarding the number of heroin doses seized;** 3 dose of heroin in 2013, 36 doses in 2014, and 0.5 doses in 2015.
- **Excluded the unsafe drug information in treatment with methadone,** proposed methadone was as safe as buprenorphine.
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The economical feasibility of a treatment center may close before the doors opens with concern regarding unethical financial gain impacting research on vulnerable patient populations, the sustainability of decreasing physician and team member turnover to reduce impact of required licensing and accreditation requirements for the center, and shunting the patients away from beneficial services that aide in compliance with treatment.

- **Removed the treatment center from the proximity of ETSU medical, pharmacy, and nursing schools.**
- **Promoted unethical practices in relation to the Institutional Review Boards (IRB) research criteria for vulnerable patients and financial gain.**
- **MSHA has a high turnover with their physicians and team members,** physicians in an outpatient physician clinic has been a contracted physician.
- Lack of documentation on **cost associated with obtaining appropriate DEA requirements, licensing, training, and certifications for providers.**
- Lack of documentation on **cost associated with provider and team member turnover.**
- If a provider resigned, **lack of documentation on the patient's right not to start over in their treatment when switching providers or transferring clinics.**
- **Misrepresented patient's compliance** with regards to the proposed location and transportation.
- **Eliminated the benefit of public transportation for methadone patients living in Johnson City, TN** with the proposed location.
- **Lack of compassion, acceptability, and unprofessional conduct toward the patients in regards to the warm greeting for treatment decision in our area with a treatment center located out in the middle of pasture fields.**

- **Misrepresented the driving distance as further distance from the I-26 exit to the clinic if located in Johnson City, TN vs the proposed site in Gray, TN.**
- **Lack of the City of Johnson City Law Enforcement office in Gray.** The Johnson City zip code 37615 represents the Gray community with a small little section of the City of Johnson on Bobby Hicks Highway about as wide a needle laying in a paper clip box. The jurisdiction would belong to the county expect for the needle size area belonging to the City of Johnson City, and leaving patients and residents without assistance from law enforcement if there was a problem.
- **Only one ambulance in Gray** for the whole community.
- **Elevated risk for increase crime in the "vacant" surrounding area**, otherwise known as farms with pasture fields.
- **Unprofessional conduct and misrepresenting the literature to the community and governing officials that methadone clinics don't increase crimes.** The literature misrepresented and eliminated demographic details later revealed to be bias and based on with a saturated area, mainly methadone patients, with 15 methadone clinics and the research funded by an interested new methadone clinic owner partnering with a university to open another clinic.

The CON implicated a **disorderly** development of health care by supporting unethical, unsafe culture of patient safety, and potential for malpractice resulting in a poorly planned clinic at high risk of closing and turning away promised services to the area's methadone patients.

- Unclear business proposal involving patient care meeting all of the **federal regulations for opioid (§42 CFR 8.11) and federal (§42 CFR 8.12) treatment standards**
- Lack of **diversion control plan**
- Lack of notations on plans to address concerns related to **safe packing per the Poison Prevention Packaging Act, Public Law 91-601 (15 U.S.C. 1471 et seq.)**
- Lack of plans to **bridge the continuity of care of transferring patients to the proposed clinic**
- **Lack of education plan to preventing exposure to, and the transmission of, human immunodeficiency virus (HIV) disease for each patient admitted or readmitted to maintenance or detoxification treatment.**
- **Failed to prove the improvement the health of Tennesseans noted under Principle 1** of The 5 Principles for achieving better health.
- **Eliminated the reason why methadone was removed from formulary** by Centers of Medicare and Medicaid Services (CMS).
- **Excluded President Barack Obama's plan on prescription opioid addiction** from his immediate press release on October 21, 2015.
- **Excluded CMS press release** to the public on January 28, 2016.
- **Excluded the increase risk of death and overdose with methadone** when compared to other substitution-based treatment options.
- **Promoted a lifelong chemical restraint as a safe option without regards of noting it has been the deadliest opioid** in the proposal, which maybe the treatment outcome for a patient from an overdose, decreased quality of life, lifelong treatment of methadone, or death.

I apologize for the length of this letter for your review, and hope this brings awareness to the issues I wasn't able to address well in the public meeting.

Thank you for your time,



Wendy Fleenor, PharmD

The following information was more detailed information condensed for the bulleted points in my letter.

As a clinical pharmacist, the application hasn't clearly and concisely defined the business and treatment model, culture of patient safety with the highest opioid, methadone, associated deaths, and proposed to obtain the certificate of need. On page 2 of the CON application the letter to Ms. Hill refers to certificate of need application **"for the establishment of non-residential substitution-based treatment center for opiate addiction,"** and the letter has no reference to methadone. On page 4 of the CON, the applicants checked **Non-Residential Methadone Facility.**

- Methadone was classified as a prescription class II narcotic by the FDA. The application discussed focused heavily about prescription opioid abuse, which included methadone abuse.
- The CON doesn't address methadone as part of the prescription opioid dependency and addiction issues.
- Methadone has been associated with disproportionate numbers of overdose deaths relative to the frequency with which it is prescribed for pain. Methadone has been found to account for as much as a third of opioid-related overdose deaths involving single or multiple drugs in states that participated in the Drug Abuse Warning Network, which was more than any opioid other than oxycodone, despite representing <2% of opioid prescriptions outside of opioid treatment programs in the United States; further, methadone was involved in twice as many single-drug deaths as any other prescription opioid (123).⁶
- In the Federal Regulations for Opioid (§42 CFR 8.11) and federal (§42 CFR 8.12) treatment standards were not clearly addressed throughout the CON.
 - *Diversion Control Plan wasn't included in the CON and defined related to patients in therapy, public, and team members.*
 - *Poison Prevention Packaging Act, Public Law 91-601 (15 U.S.C. 1471 et seq.) regarding the take-home dose and accidental ingestions.*
 - *The CON doesn't address the plan to bridge the continuity of care regarding patient's current treatment history when initiating treatment in the proposed clinic.*
 - *The CON excluded the required education regarding preventing exposure to, and the transmission of, human immunodeficiency virus (HIV) disease for each patient admitted or readmitted to maintenance or detoxification treatment.*

The CON has been inconsistent and avoided answering the precise clarification of each statement by mispresenting data and statistics, providing redundant answers, and ignoring the sole purpose of substance abuse treatment regardless of the "drug of choice" or methadone patients, even if methadone was the "drug of choice" for patient seeking treatment.

Principle 1: "The purpose of the State Health Plan is to improve the health of Tennesseans," in the 5 Principles for achieving better health doesn't included the goals set forth by **President Barack Obama in the immediate press release on October 21, 2015 and Governor Bill Haslam's Prescription for Success. The press release from President Obama affected the decision from the Centers of Medicare and Medicaid Services in their press release on January 28, 2016 giving MSHA and ETSU appropriate time to address and include these important points in their CON application.**

- Heroin, methadone, and opioid addiction has a significant clinical correlation with excessive prescribing practices for acute pain. The CON doesn't address the issues with the over prescribing of opioids in the area, especially since MSHA who owns 13 hospitals, 6 urgent clinics, and over 90 physicians' offices write the most narcotic prescriptions in the mentioned counties.
- The "Take Back" programs were obsolete in the application never discuss removing unused, excess, or expired narcotics off the streets decreasing accessibility and potential for abuse.
- Regardless of location, the CON doesn't address increasing education and awareness of the consequences of substance abuse to the regional children, especially the 12-18 year old population.
- What about patient safety, patient quality of life outcomes, resources for the region, and indigent programs?

The application referenced heroin numerous times in various sections, but the 13 counties doesn't have a significant heroin problem. Per the Tennessee Appalachia High-Intensity Drug Trafficking Areas (HIDTAs) and Gulf Cost HIDTAs presented statistics about the heroin problem increasing in Tennessee were noted referencing the **heroin deaths and overdoses were in Shelby County**, the other end of the state.

- Prior to the submission date on the CON application, the CDC commented on how the heroin overdose or death data has been hard to specifically only reporting heroin, but the illegally-made fentanyl has been used to intensify the high related in heroin.⁵
- The illegally made Fentanyl data was extracted from 2014 after the prescription opioid overdose data only wanted to included methadone; the data included all the synthetic opioid drugs, included methadone, tramadol, and illegally made fentanyl.

- The Tennessee Bureau of Investigation (TBI) Drug Offender Registry Database only had 2 offenders listed for position of heroin for the last 5 years;
 - 1 resident in Greene County (9/19/2014)
 - 1 resident in Washington County (7/8/2015)
- The public Johnson City Police Annual Report noted only seizing 3 dose of heroin in 2013, 36 doses in 2014, and 0.5 doses in 2015. There were noted **only 1200 residents in Gray**, per the US Census, out of 66,027 Johnson City Residents (out of 122,929 Washington County Residents).

Buprenorphine (Suboxone) providers continued to increase in the area over the last few years, which was the appropriate treatment option for our need regarding the "establishment of non-residential substitution-based treatment center for opioid addiction." They provided a long list of buprenorphine providers **without notation separating the regional pain clinic physicians prescribing methadone for chronic pain, hospice, or cancer patients.** The CON application contained this patient population in the data and statistics providing a skewed perception of the problem was only with opioid addiction, methadone, or heroin patients.

The data and statistics also included patients **involved in opioid related deaths and overdoses seen during the enormous opioid drug shortages over the last 7 years with FDA warnings sent to healthcare professionals, misadventures when converting the current opioid to a different opioid to treat pain, and provider's unfamiliarity with the opioid's pharmacokinetics, and drug-drug/disease interactions.**

- The Tennessee Hospital Discharge Data System noted an increase in the ED admissions for drug overdose from 457 in 2003 to 678 in 2012, also included some of my patient cases regarding the drug shortages, confusion, geriatrics, drug-drug/disease interactions, and misunderstanding on how to take opioid.
- The TDMHSAS reported the accidental drug poisoning mortality increased from 2002 to 2011. In 2009 – 2013, the drug shortages were the highest, and should be considered as one of the significant indicating factors in the increase of overdose deaths. During this time, the opioid overdose rate was high in MSHA, and they developed a hydromorphone protocol at Franklin Woods Community Hospital (FWCH). MSHA Risk Management participated in the patient cases I reported, and FWCH administration was aware of the issues. Unclear, why the notation of these patient cases was considered a weakness in their CON on the statistics provided.

Therefore, the counties noted in the CON have met the need with buprenorphine providers, and the application didn't reference how MSHA and ETSU would meet the federal guidelines for both methadone and buprenorphine regarding the cost of training to obtain appropriate DEA requirements, licensing, and certifications for providers. If a provider resigned, what would be the patient's right to not having to starting over in their treatment when switching providers or transferring clinics.

What would be the plan for a patient that refuses to participate in the research, inappropriate candidate for methadone, or chose a drug-free treatment option? Would the patient be denied any further treatment?

The prescription opioid addiction and prescribing problems have increased awareness for oxycodone, hydrocodone, and methadone for overdose potential. There have been a very limited patient population qualified for methadone treat when considering other drugs or options for addiction therapy. Current practice has started shaping the future practice of taking patients off the lifelong chemical restraint, methadone, to provide better patient quality of life outcomes with safer evidence-based treatment options.

- The Division of Health Statistics from the TN Department of Health collected data on the number of accidental drug poisonings with methadone mentioned on the death certificate between 1999-2006, note the cause of death in 8 patients.
- The state had 10 methadone clinics, and the Division of Health Statistics collected data on the number of accidental drug poisonings with methadone mentioned on the death certificates for 2007 had increased from the prior 8 deaths to 138 deaths.
- CDC calculated their prescription opioid deaths by including natural, semi-synthetic, and synthetic (methadone, tramadol, and the illegally made fentanyl) opioids. The increase of opioid related deaths in 2014 was 19,000 (52 deaths per day) and 16,000 in 2013 included methadone in the prescription opioid data.
- The CDC analyzed the samples from 2014 to excluding tramadol and illegally-made fentanyl, the only synthetic opioid included in the data was methadone. After the new analysis, the prescription opioids deaths were 14, 000 (40 deaths per day), which includes methadone.

The applicant submitted a drug comparison chart for buprenorphine and methadone noting there were no differences in their side effect profiles, safe outcomes, monitoring, etc. The reader of the CON has been provided information that inaccurately represents the drugs would have the same outcomes. The statistics provided in the CON would not contain overdoses and death from buprenorphine, because it has a unique opioid agonist/antagonist

feature, unlike methadone being on an opioid agonist. Therefore, the drug safety profiles would be incomparable in relation to patients receiving substitution-based therapy.

The applicant failed to mention the leading causes of death with methadone have been related to respiratory depression (risk at every planned dose), cardiovascular (QTC prolongation), significant drug-drug interactions and adjunctive therapy to treat other withdrawal symptoms (also noted in the CMS press release), and overdoses related to the "wear off affect with methadone" (patient assumed it was safe to take another opioid or dose). Methadone has never and will never be a safe option for any patient, and it has been the very last option in all substance abuse, cancer, and chronic pain patients.

The proposed site only has one ambulance in Gray potential to delay quick, emergent, access to a higher level of care, compromised culture of safety, increased liability for the patient/providers/community, and increase of morbidity/mortality risk factors.

- Respiratory depression is the most common side effect with methadone treatment, and the risk increases with addition adjunctive therapy medications with the same side effect or known drug-drug interaction. Buprenorphine (Suboxone) has less risk for respiratory depression, which has become the reason for provider seeking an increase daily max dose transiting patients off methadone.
- Hypoxia, lack of oxygen, happens any time the respiratory drive decreased requiring immediate treatment.
- Cardiac complications related to QTC prolongation increase with methadone dosage changes, drug-drug interaction, adjunctive therapies, and patient non-compliance issues.
- Methadone has a long half life (duration of action) of 3-5 days after an established dose, meaning their baseline has always been mental fatigue, slow responses, decreased quality of life, and increase risk of morbidity/mortality with treatment. The peak onset (starts working) has been around 30-60 minutes after a dose for most patients, and any of the above side effects would be significant after the 60 minutes, not 30 minutes based on patient's genetics and metabolism.

MSHA and ETSU has submitted a CON application to increase their access, but they have chosen a poor location. Med Tech Parkway was much closer to the prior CON from New Path and Crossroads with sincere efforts to find the appropriate locations for a methadone clinic on Susanna Street and Princeton Road in Johnson City, Tennessee. Their targeted patient population were the patients traveling to Asheville, NC that were residents in Johnson City, Jonesborough, or Elizabethton, Tennessee.

- The application noted the Gray location would improve patient compliance with closer access to treatment from all the proposed counties, but I don't understand how a clinic located in the middle of fields would be the best location for the patients.
 - The location at 203 Gray Commons Circle was 8.4 miles from 300 Med Tech Parkway (Franklin Woods Community Hospital (FWCH)), Johnson City, Tennessee.
 - Med Tech Parkway area would provide better accessibility, safer commercial site for patients, and better economical feasibility for surrounding businesses located about 1.7 miles off I-26 (Gray location about 1 mile off I-26)
 - Med Tech Parkway was a plan area to establish medical services not available for patients in the region, and it was the site where Wellmont Health System proposed to build a hospital in Johnson City, Tennessee.
 - There was land available to develop without any parking issues to build a treatment clinic next door for both an urgent care and hospital.
 - The FWCH pharmacy department would be available to review, replace, and assist with expired medication in the crash carts, appropriate storage, and unit inspections.
 - The FWCH pharmacy team covered Woodridge Hospital 24 hours a day, and the methadone clinical pharmacist may be considered part of the FWCH, which also directly reports to Lindy White, Vice President of Strategic Planning and FWCH CEO.
 - However, MSHA built their corporate office beside of State of Franklin Health Care across from FWCH, and the plan advertised to FWCH team members apparently only provided unavailable services to certain type of patients.

- My low to moderate income patients struggled to find transportation to the clinic and found a reason to be admitted to the hospital.
 - The Gray location has no public transportation, but patients without a private vehicle would have public transportation to Med Tech Parkway or other locations in the immediate area between FWCH and Johnson City Medical Center eliminating some patient compliance issues.
- The Gray location only has one ambulance to serve the whole area.
- The Johnson City Police Department has no office in Gray and has jurisdiction of about 5 miles starting at the proposed location to HWY 36 about 10-40 acres wide. The tiny chunk of the "City of Johnson," noted under zip 37615 for the proposed site in Gray, Tennessee, looks like a horizontal needle in a paper clip box on the map.
- Substitution-based treatment for opioid addiction in the middle of fields has a significant risk of business suicides. Non-complaint patients would quickly figure out the lack of law enforcement in the county, and arguments regarding who would respond to calls if there was a problem, city vs county jurisdiction.
- The non-complaint patients would increase risk for diversion and crime in the "vacant" fields, per the applicant's reference to the surrounding "vacant" land.

The article *Not in My Back Yard: A Comparative Analysis of Crime Around Publicly Funded Drug Treatment Centers, Liquor Stores, Convenience Stores, and Corner Stores in One Mid-Atlantic City*, has been referenced as the literature that methadone suggested don't increase crimes.

- The background information to the above article was submitted after the Saturation of Metropolitan Service Agencies (SMSA) Task Force was convened in 2014 to confirm or refute the claim in the original article, *Use of a "microecological technique" to study crime incidents around methadone maintenance treatment centers*.
- The residents surrounding the methadone clinics were known as "saturation," which means the methadone patients outnumber the non-substance abuse patients.
 - The research was determined to be bias among the medical community when it was published noting the research was completed by the University of Maryland and the owners of the new proposed clinic wanting to establish a clinic with the other 15 clinics in the immediate area.
 - Non-compliant methadone patients don't plan to let the clinic staff, providers, or surrounding business witness their crimes, which would prevent them from receiving the next dose of methadone.
 - The crimes would be located a few blocks or miles away avoiding identification as the offender. The crimes would be increased around liquor stores, convenience stores, and corners stores due to low customer volumes and purchasing alcohol.
- The healthcare practitioners treating substance abuse were with the flawed data in the article suggesting methadone clinic doesn't increase crimes, because the federal regulations for opioid and substance abuse treatment centers require a diversion control plan to proactively address and deal with these problems. Again, the main reason why most patients only receive a daily dose of methadone.

Physician and nurse practitioner education was removed from the proximity of ETSU medical, pharmacy, and nursing programs to the farthest end where the City of Johnson touched the county line.

- If the site accepted a medical student every month for rotation, then one physician with one medical student would only average about 12 students a year in the worst case scenario. The proactive approach to training future prescribers was obsolete, and potentially reduced the interested students taking an elective rotation outside the proximity of the other rotations sites in Johnson City, TN. This would be a problem with all the healthcare professionals.
- ETSU Research Foundation has unethically agreed to establish a practice of intimidating and bullying a vulnerable Institutional Review Board research population into a lifetime treatment with a chemical restraint, methadone. As a result, the partnership between MSHA and ETSU has planned to inappropriately educate our future healthcare professionals that these unethical and immoral guidelines would be accepted among this patient population and medical community-at-large.

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