HIDDEN CREEK
RETREAT
RECOVERY &
RENEWAL CENTER

Business Model & Concept for a Recovery Retreat

March 5, 2021

Forward

To understand the business concept and components of the model that ***Hidden Creek Recovery Retreat*** portends to operate, would be to grasp the overview and background of the entire recovery industry, as well as the newest advances in medications to treat opioid and alcohol addiction.

This business model is based on new opportunities presented by a paradigm shift in the alcohol & addiction treatment industry-- from the 1980's to 1990's concepts of psychological and behavioral treatment based on abstention and the 12 step principals and philosophies of AA, and "*just saying no...*" abstention by willpower and peer support... to the 21st century advances in medication technology called *Medication Assisted Therapy* (or "MAT"), have become viable and effective treatments to the physiological mechanisms that constitute addiction.

The emergence of Vivitrol (*later discussed*), was only approved by the FDA in 2006, and only then was aggressively marketed and promoted over the next several years-- catapulting its constituent active ingredient-- naltrexone-- to the spotlight (and acceptance) within the recovery industry.

Hidden Creek Recovery Retreat will develop a vital role in this transition to MAT based treatment, which to summarize our role, we will be redefining and implementing the recovery support program that will be tailored to accompany the administration of the medications-- a requirement of the FDA and the drug manufacturer that there be "*adjunctive psychosocial treatment*".

Although such drugs were developed in the late 80's and 90's, the medical industry, pharmaceutical industry, and the FDA are very slow and methodical to respond to new pharmaceutical developments. All the medical ramifications must be continually researched, studied and tested in numerous clinical trials, and must be by-and-large-- must be validated and accepted by the community-- the doctors, clinicians, academia, and the FDA... all-- a time consuming process that can take years. The arsenal of medications used in the treatment of primarily opioids, and some for alcohol abuse, are:

- Methadone
- Disulfiram (Antabuse®)
- Buprenorphine with naloxone (Ex. Suboxone®)
- Buprenorphine (extended-release, injectable, for example, Sublocade®)
- Buprenorphine sub-dermal implant (Probuphine®)
- Naltrexone oral pills
- Naltrexone (extended-release, injectable, for example, Vivitrol®)

Property & Facility

This concept model is presented by Hidden Creek Recovery & Retreat, LLC, a Georgia based company which owns a 70 acre property and 9,000 square foot commercial lodge was originally being renovated over the past couple years to serve as a ASAM Level 3.1 *Residential Care* for addiction treatment facility The principal, however, has shifted in scope and purpose to take advantage of the newest developments in addiction medications and treatments.

The original design of Hidden Creek Lodge & Retreat was as a commercial grade high-end seven bedroom B&B, that was opened in 2006 as a banquet and event facility and conference center, and operated as such for a couple of years. Since that time, it became the residence of the designer & builder, until he passed away in 2018. The building and property was acquired out of his estate by his brother, Reed Hatkoff, who recognized its' highest potential as a residential rehab, and embarked on a renovation and remodeling program to adapt the structure and floor plan to use as a modern and upscale Eurostyle retreat, with an entire floor devoted to treatment offices, meeting rooms, and other amenities, as well as expanding the number of bedroom from seven to nine. The bed capacity was increased to 16 (14 of which are semi-private rooms), and the commercial kitchen is a fully licensed by the county health department. The lodge, at this time, is still undergoing renovations.

The palatial grandeur of the lodge must be visited to experience and appreciate it, as well as the secluded, serene, and heavily wooded 70 acre estate, surrounded by another 2,600 acres of heavily forested natural woodlands.

Aside from the lodge as a secluded & modern- Eurostyle destination retreat, it must offer an exclusive, unique, and cutting edge program tailored for, and marketed to such demographic of professional, executive, and high-status individuals who would seek out the most innovative, advanced, and effective treatment available, as well as the creature comforts of a retreat location and setting.

Conceptually, ***Hidden Creek Recovery & Retreat*** intends to operate as a boutique, upscale, and exclusive recovery retreat catering to affluent, professional and executive clients who desire to undergo the newest upcoming state-of-the-art MAT treatment-- extended-release naltrexone, and will seek a short-term intensive recovery workshop and accelerated program incorporating the most advanced concepts and technology specifically tailored to integrate and synchronize with the newest medication-assisted therapy available-- naltrexone implants.

Legal Authority & Required Licensing

Hidden Creek Retreat will operate as a one to two week alcohol and addiction recovery intensive workshop "retreat" that would qualify and operate under the legal authority of a "Sober Living" facility exemption from licensure as stipulated by **OCGA § 26-5-5**, and ***Rules And Regulations For Drug Abuse Treatment And Education Programs*** Rule 111-8-19-.21-Residential Transitional Treatment Programs.

Hidden Creek Recovery has already has obtained a business license from Haralson County as an "*Residential Alcohol Recovery Facility*", as the State of Georgia Dept. of Community Health HFR[1] has no licensing requirement for alcohol treatment... only for drug treatment.

Description & Scope Hidden Creek's Recovery Support Program

Hidden Creek would offer NO therapeutic or medical services, and would only supply recovery peer-support workshops[2] to individuals who have undergone detox or prior therapy, or who are currently engaged in or undergoing some unaffiliated professional treatment program or individual services through virtual telemedicine platforms. Hidden Creek Recovery will provide a structured schedule and private terminals to provide for such concurrent online sessions.

With the explosive growth in a new treatment segment (*called Medication Assisted Treatment-or "MAT"*), there are many clinics and doctors that provide the medications, however do not have the facilities to provide the after treatment support or after-procedure adjunctive recovery program through what's called "psychosocial" support. '

This is a loosely defined term that can generally refer to peer support, which can apply to group sessions that can be led by non-professional moderators or facilitators -- however trained and certified by Smart Recovery, or similar organizations.

These forms of support are all meant or designed to reinforce the addict's or alcoholic's resolve for continuing abstinence-- professionally referred to as *compliance* or *adherence*-- which in layman's terms means the propensity of the sufferer to stick with the program, and stay the course. This is the biggest challenge in the entire recovery field.

This is especially important in the field of MAT-- because the greatest challenge to the physicians or clinics providing the medications-- is to keep the recovering OUD/AUD client or patient, engaged and involved-- so that they continue the medication on a long term basis. Unfortunately, without AA, Smart Recovery, or a variety of other recovery support groups-- there is an attrition rate which extrapolates into a high relapse rate.

[1] Georgia Dept of Community Health-- "Healthcare Facility Regulation"
[2] Smart Recovery

With modern technology such as a variety of smart phone apps promoting "compliance" with peer-support capabilities, and new legislation in telemedicine, as well as new technologies in teleconferencing and zoom meetings, so incorporating recovery with MAT and the modern technology--is a whole new era and landscape.

The medications work to combat the cravings-- especially naltrexone, however their long-term "outcome" is dependent on the addict's compliance and commitment to stay on their medications. This needs to be reinforced on a long-term basis-- to prevent the "drop-outs" from the medication program. Especially with BioCorRx®'s long term implant coming on the market... where the quarterly implants must be surgically performed (*as a minor procedure*), the term "out of sight-- out of mind would probably be applicable.

So, as part of our program, the question posed to the retreat attendees would be:
"what will it take in three to four months hence to insure that you all return for your next round or refresh?"

The program will endeavor to elicit a commitment from the attendee's... perhaps even a written pledge to reinforce their commitment. If they are to receive their implant during, or at the end of their stay from an independent corresponding physician, this commitment will be the most important element.

The attendees will be provided with an smart phone app to correspond with a virtual platform peer-support specialist provided by **BioCorRx®** (fee based).

See Appendix C for a "recast" (in layperson's terms) of the seminal professional epitome & presentation entitled *"Supporting individuals using medications for opioid use disorder in recovery residences: challenges and opportunities for addressing the opioid epidemic"*

This professional paper which specifically describes the need and validates this specific business model, core platform of the program.

Demographic

The program will be the agenda as an alternative upscale recovery-support facility-- with an accelerated and intensive program targeted for affluent, upper-status, executive, and professional demographic-- with chronic alcohol and addiction issues, however still able to function as CEO's, executives, professionals, and businessmen. They have responsibilities that control their lives, and can't afford the time and resolve to go through the proscribed treatment and recovery steps in the conventional addiction "*continuum of care*" highway. This demographic gets by-- because they can afford to, and they can't afford to, or will not relinquish control of their careers and their autocratic executive or board positions. They can afford the deluxe treatments, the short-cut, or the latest and greatest technology. They are the ones would opt for a retreat over a rehab-- even just in the difference of the characterization or presentation. This demographic also includes the affluent segment that has already been

through the system-- and relapsed. They know what to expect, what the drill is, what are the pitfalls, and are still searching for the answer.

It can be presumed that many in this demographic group have either heard of, or are familiar with naltrexone, which in the injectable form is called *Vivitrol®*, and perhaps have pursued this treatment avenue with a physician. We expect that the physician will be referring this patient to us for the augmentive program support that must accompany naltrexone injections-- or the latest and greatest next-gen version-- naltrexone implants-- the new wave in MAT technology.

Hidden Creek Recovery could be considered a short-term stay in a modern and residential recovery environment in which accelerated intensive recovery workshops are offered as an next-gen alternative to patients from a detox.

Prior to discharge and departure from detox's, patients are offered choices for their next-step continued treatment on the road to recovery, and usually are encouraged to enter a 30-day residential rehab. These levels of treatment-- are levels of intensity of care as proscribed by ASAM, and well known to everyone in the behavioral health industry as the "*continuum of care*" map as a standard. However, the choice is always up to the patient, and the detox's will generally provide pamphlets and brochures of the various facilities available for an upcoming discharge patient to select from. It then becomes a price, insurance and destination issue, but the biggest issue, would be the patient's goal, commitment, determination, and job, professional or business responsibilities. Many of those going through detox, have been there before. They have gone through the recovery system, and may have months or years of sobriety under their belts... only to relapse for whatever circumstances.

These people are in search of new answers, as the old paradigms of "being powerless over their addictions", is an old wives tale perpetuated by old concepts. There is new medical technology available, and new concepts that work in relation with this cutting edge pharmaceutical technology.

History of Medications for Addiction

Methadone and Antabuse have been around for the latter part of the 90's, however Buprenorphine and Naltrexone are the new drugs on the scene as effective agents to combat the actual addiction physiology, which have been approved by the FDA as safe and efficacious formulas and medications. Buprenorphine, however, is a controlled substance, whereas naltrexone is not, and has been readily available world-wide since the late 80's, as its stunning ability to regulate (or block) the dopamines and endorphins that provide the euphoria in the users brain, has been recognized.

In the past 15 years-- both drugs have been introduced into the behavioral clinical MAT regimen, which is now on the threshold of the next-generation in addiction treatment once the implants are approved.

This concept has literally taken years to gain acceptance in the community, and were it not for an Irish company-- *Alkermes*-- marketing naltrexone in the form of an extended-release injection formulation called Vivitrol®, and without their massive and multi-million dollar marketing and lobbying campaign, naltrexone would not have never caught on organically through it's grassroots followers, and would have been relegated to relative obscurity-- as is was after DuPont's relinquishment of their naltrexone patent in 1986.

This evolution is detailed in an entire section elsewhere in this paper, as it leads-up to where we are today with a drug proven to be effective against alcohol and opioid cravings *(as well as some protection from opioid overdoses)*, and how we got here.

So naltrexone has evolved from it's initial orally-administered pill form-- which depended on user's adherence (called "compliance"), to the second-generation delivery method of injection which propelled Vivitrol® into the treatment community's consciousness and on the radar screen, which propelled academic investigations into creating an extended-release implant that would be effective for 3 to 4 times longer than the Vivitrol® injection.

BioCorRx® Relationship

An American publically-traded company (OTC) based in Orange County California called **BioCorRx®** realized the potential of developing such a delivery system-- in connection with receiving grants from NIDA[3] for almost $10 million in connection with their IND[4] application to the FDA to manufacture naltrexone implants. Hidden Creek has cultivated a close working relationship with **BioCorRx®.**

As well other similar research has also being been funded by the FDA, and is being conducted in the development of the implant delivery system by an Australian doctor George O'Neill, as detailed in the NY Times article. There were certain original dealings and relationships early on between O'Neill and BioCorRx®, however no current relationship exists between the independent parties.

The **BioCorRx®** naltrexone implant might be considered an innovative, novel and disruptive medical technology, as it evolutionary. Naltrexone has been around since the 1970's, and heavily researched and tested early 1980's, however use as an alcohol/drug treatment-- was confronting a $35 billion dollar per year medical industry establishment that had it's methodologies set in place. The mere fact that the FDA has approved naltrexone as efficacious treatment for alcohol and opioid addiction, and has given it credibility as a quasi-preventative treatment, is miraculous. As everyone is aware, the long term abstinence rates is not very impressive, so the odds are high for a recovered drug or alcohol abuser, to eventually relapse.

[3] National Institute for Drug Abuse
[4] Investigational New Drug

Elsewhere in this discourse, the case has been stated for the drug-- naltrexone-- to have the properties that interfere with the brain's endorphin receptors[5], and thereby effectively blocking the high. We have documented the evolution of the early pioneering research by Doctors David Sinclair, Joseph Volpicelli, and more recently Dr. George Woody[6], Dr. Adam Bisaga[7], and a host of others-- that realized the potential of this drug, comes close or is the nearest thing to being a cure-- as an effective preventative.

There are thousands of highly motivated self-administering users that are organic grass-roots disciples and sycophants of naltrexone, who use the pill in conjunction with a formerly-patented regimen called "*The Sinclair Method*". Such grass-roots followers are those who are able purchase their pills from online Indian or Mexican Internet pharmacies without doctors prescriptions, or now the 5 or 6 U.S. web-based Internet purveyors and preachers of naltrexone in combination with the Sinclair Method. This grass-roots movement are following the principals and protocols of Dr. Sinclair's as detailed in the book "*The Cure for Alcoholism*" by Dr. Roy Eskapa-- who worked as an associate of Dr. Sinclair. They consider the book to be as fundamental authority, and they all self-adhere to the protocols as if it were gospel, and their Facebook Group page-- "*The Sinclair Method Warriors*" has 3.8 thousand members. While this concept of taking a naltrexone pill before they drink most likely works-- many of such followers, if not most-- report that they have lost their enthusiasm for alcohol, and they will occasionally drink a few drinks (usually socially)-- without consuming the entire bottle. This is only if they remember to take their pill prior. This is still the original technology of the 1990's, and the oral form of Naltrexone. This is also proof that there are many self-motivated AUD sufferers who will bypass the rigors of a medically proscribed conventional course of treatment, for a self-administered program that they adhere to and believe in. And they are supported by a peer-group of almost four thousand fellow adherents on their Facebook group page, and to be a member, is quite enlightening. To call them "engaged", would be an understatement.

As a side note-- this would be a research opportunity to have this home-grown group of almost four thousand self-motivated AUD sufferers, participate in a questionnaire-style study of their

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[5] From Wikipedia: "Naltrexone and its active metabolite 6β-naltrexol are competitive antagonists at the μ-opioid receptor (MOR), the κ-opioid receptor (KOR) to a lesser extent, and, to a far lesser extent, at the δ-opioid receptor (DOR). **The blockade of opioid receptors is the basis behind naltrexone's action in the management of opioid dependence—it reversibly blocks or attenuates the effects of opioids**. **Its mechanism of action in alcohol dependence is generated via** κ-opioid receptor antagonism, which blocks the actions of the endogenous opioid peptide dynorphin. Dynorphin typically instates drug-seeking behavior when it binds to the κ-opioid receptor, as well as decreasing dopaminergic signalling in the nucleus accumbens."

[6] Dr. Woody is a professor ermitus at the University of Pennsylvania Perelmen School of Medicine Department of Psychiatry serves on the Board of Technical Advisors of BioCorRx. Dr. Woody studied naltrexone for heroin dependence treatment in Russia in addition to opioid relapse and HIV risk associated with ER injectable naltrexone. Dr. Woody is BioCorRx's Chief Medical Advisor.

[7] Dr. Adam Bisaga- Current Project Leader of NIDA Grant 5UG3DA047720-02 to study the O'Neill Long Acting Naltrexone Implant ("OLANI")

reported efficacy and experience of using oral naltrexone in conjunction with, or attenuating alcohol consumption.

So the evolution of naltrexone has taken us from the early days of the oral form (pills) to the period of obscurity when DuPont relinquished their patent, and naltrexone became an unloved orphan... until *Alkermes* had an epiphany that they could patent the delivery method, and thereby have an exclusive and highly efficacious product called Vivitrol-- that is simply time-release naltrexone.

As naltrexone ("NTX") has been recognized as the most effective mediations in blocking and treating the addictive euphoric effects of opioids and alcohol, the National Institute on Drug Abuse ("NIDA") has dedicated hundreds of millions to fund research to develop potential and known medication treatments, and has awarded multiple grants to various valid researchers with promising technology to develop long-acting extended release delivery systems.

BioCorRx® has been funded with almost $10 million in grants[8] from NIDA, has developed an implantable naltrexone pellet-- that provides a longer term release than the Vivitrol monthly shot.

[8] NIDA Grant #UG3DA047925

NIDA has also funded trials of the ***O'Neill Long-Acting Naltrexone Implant*** ("OLANI"). owned by Australian company-- **Go Medical Industries Pty Ltd.** and its' principal, inventor Dr. George O'Neill. Trials are being conducted by Dr. Adam Basaga of New York State Psychiatric Institute and Columbia University Department of Psychiatry.

The effectiveness of OLANI is anticipated to last from a quarter year, to potentially a year or more based on the current applications and delivery systems, which has been established in Australia, and used successfully over the past ten years or so.

It is only the technology of the polysaccharide coatings and other polymer coatings and materials that encapsulate the active therapeutic drugs that control the extended release rates, that determine the longevity of the effects of the naltrexone. Long-term extended-release efficacy is achievable, and already has been demonstrated by *O'Neill* in Australia, however there are other considerations in producing an ER implant or injection that lasts a year or more... such as-- do the polymer coatings totally resorb into the body, or do they leave tell-tale lumpy residue? Are there any side-effects to the materials?

So what if they were able to develop an implant that the antagonist effect were to last a year or two... or maybe 5 years? At this point, it could be, and perhaps already is technologically achievable-- like dropping the rover on Mars. This new technology is here, in use, emerging, and disruptive.

However there is a trade-off between what is technologically feasible, and what the drivers are behind supporting a use-duration efficacy design... it is not driven by the end-user market, who would all naturally desire the longest duration, and the least amount of time intervals between refresher doses, or even driven by technology-- it will be driven by the doctors (especially ASAM doctors) who want to see their patients ever four months. That's probably a good starting place, however as this takes-off and becomes accepted by the clinicians as main-stream, consumer demand for an extended-release formulation will ultimately determine the product marketplace. The obvious question is why would anyone want to undergo even a minor surgical implant procedure every four months, if they only have to get it once a year. And ultimately, some manufacturer will step in to fill that demand.

Hidden Creek Recovery's Intensive Workshop Retreat

This demonstration program is designed as an innovative and alternative structure to dispense with the professional care component (psychiatrists and therapists) that are essential to licensed recovery treatment programs, and to focus on the essential support component in a conducive and healing environment to reinforce the efficacy of the primary effective therapy-- the naltrexone implant medication.

But what happens to the $35 billion a year treatment industry with the emerging medication technologies? Well, the word "disruptive" is certainly applicable. The conventional rehabs will ultimately find ways to adapt themselves to the reality of the effectiveness of the naltrexone

implants, by integrated MAT into their business models or programs, and will continue to fill their hospitals and 30-day rehabs wherever they can, as long as there will always be new patients, however they will become the metaphorical Blockbuster Video stores in the age of Amazon and Netflix, as it is anticipated that afflicted persons will ultimately choose a long-term extended-release implants or injections-- over a 1 to 6 month regimen of rehabs and outpatient "abstinence" program every time. Although Vivitrol® has proven to be successful to be mainstream in the addiction community, is also has its drawbacks-- being expensive, and unwieldy and inconvenient to patients have to schedule monthly re-injection refreshers with ones doctor or clinic-- and therefore-- adherence becomes an attendant issue.

There are many manifestations of addiction, as it is very destructive to the human psyche, to interpersonal relationships, and to the damage that one has done to their self-esteem, as well as a host of other casualties and suffering. Many clients feel they would consciously be prepared to deal with those collateral issues-- if the root cause of such aberrant behavior was caused by the addiction itself.

This defines our target market demographic-- the high functioning affluent, intelligent, individuals successful in their careers, professions, or industries, who are tired of the recovery industry merry-go-round that has not worked for them, and who realize that the "*just-say-no*" abstinence model of the conventional and traditional treatment-- is a route that hasn't worked for them, or will ultimately fail due to the uncontrollable cravings of the addiction. The want to get off the merry-go-round, and regain balance and control in their lives. They are knowledgeable about medications, and are awaiting next-gen solutions in medications to climb on the band wagon.

The Growth of Medication Assisted Treatment ("MAT") Industry

The treatment industry is now adjusting to the emerging technology of MAT, and incorporating MAT into their services and syllabus, and the database of certified clinics registered with SAMHSA, totals 7,449 listings around the U.S. (of a total of 14,167 registered providers in the Opioid Treatment Program (OTP)

With *Alkermes'* launch of ***Vivitrol*** in 2006, as well as other effective medications, we are now on the threshold of a new era in medications to treat addiction, although medical technologies advance at a glacial pace in the United States due to the rigors of testing and FDA regulations.

Naltrexone implants are already in use successfully in Russia, India, Australia, and other parts of the world, however are only being validated by clinical studies here in the United States, and will ultimately be at odds with the well-entrenched behavioral health industry that has invested in, and enjoys enormous corporate profits generated by the conventional treatment protocols.

While there are admittedly co-occurring disorders along with addiction and alcoholism which must be evaluated and treated, and for which there will still be a need for residential programs, MAT is very much the answer for many high functioning alcohol and drug afflicted

persons. Many going on naltrexone, report that they've simply lost their taste for alcohol or opioids.

Here are the specific drug datapoints administered by those certified MAT programs listed in the SAMHSA database:

- Buprenorphine maintenance
- Buprenorphine maintenance for predetermined time
- Buprenorphine detoxification
- Buprenorphine used in Treatment
- Naltrexone (oral)
- Naltrexone (extended-release, injectable naltrexone (Vivitrol®))
- Methadone
- Methadone and buprenorphine clients only
- Buprenorphine sub-dermal implant (Probuphine®)
- Naltrexone used in Treatment
- Buprenorphine maintenance
- Buprenorphine with naloxone (Ex. Suboxone®)
- Disulfiram (Antabuse®)
- Buprenorphine (extended-release, injectable, for example, Sublocade®)

So the implants are now on the immediate horizon as the ***next-gen*** latest and greatest treatment, and the industry is only now responding to the recent popularity and growth of Naltrexone/ Vivitrol®, and its general safety and lack of controlled substance regulation and supervision... whereas Buprenorphine, Suboxone®, and Methadone-- are all **Schedule III controlled substances,** and must be administered and supervised in a more restrictive and controlled environment.

Treatment centers and clinics engaging in MAT using these above listed addiction-treatment drugs-- is the fastest growing sector in the treatment community. And all of these clinics that administer the are mandated by law to refer their patients to a recovery rehab or program.

The implant is evolutionary in its development as the next iteration of naltrexone delivery, and revolutionary as to its potential to develop a sizable market share. MAT will be the hottest industry segment, however the traditional "*continuum of care*" treatment model that is the blueprint or recovery road-map, does not incorporate a *recovery support program* specific to apply to patients who receive the naltrexone implant.

They have undergone a medically implanted pharmacologic procedure to shortcut, or replace the *abstinence* and 12-step treatment model, with a medication that removes the addictive effects of opioids or alcohol, and will diminish or eliminate their desire for drugs/alcohol, and simply need a modified support program-- not a treatment program that costs the patient weeks, if not months undergoing "treatments". The naltrexone implant has replaced the need

to teach the patients to "*just say no*" and accept a life of abstinence with acquired techniques-- when the addiction (the cravings) itself is still a clear and present danger.

Hidden Creek Recovery has assembled a unique developmental program concept and structure to provide such a short-term recovery curriculum specific to application with naltrexone implants, and will address behavior from an educational and psychosocial perspective -- rather than traditional psychiatric and psychological treatments as the mainstay of rehabs, IOP's and PHP's.

Hidden Creek Recovery will utilize and integrate components of ***BioCorRx's*** proprietary *Beat Addiction*® recovery program, with *Smart Recovery* curriculum and facilitators to the syllabus.

As well, those higher functioning OUD and AUD sufferers, who have all [unsuccessfully] navigated through the recovery industry's "continuum of care", are searching for real medical answers to their "disease". After all, diseases can be cured or controlled (like diabetes). They are in search of something that makes scientific sense as to why they are the way they are.

These segment will constitute a large segment of functioning society that are of high intellect, high status, and are afflicted by the predisposition to addiction, and the ravages of their cravings.

Hidden Creek Recovery is also disruptive in its strategy. While one of the potential manufacturers of the naltrexone implants, **BioCorRx**® is anticipating near-future FDA approvals of their IND application to be able to manufacture the implants-- currently, the implant pellets are available in the U.S. by compounding pharmacies creating the pellets to specs, as naltrexone is readily available, and a known and FDA approved drug.

Here is Hidden Creek Recovery's core program model... which has been well received by many of the professional researchers previously mentioned. It is left in the context of the professional paper by Dr. Adam Bisaga:

Extracted text from Abstract entitled:

*"**EVALUATION OF SAFETY AND PHARMACOKINETICS OF NALTREXONE IMPLANT**"*

New medication treatment approaches are needed to help address the severe epidemic of opioid use disorder (OUD) and opioid overdose deaths in the US.

Currently available medications, methadone, buprenorphine, and extended release injection naltrexone (XR-NTX; trade name: Vivitrol), ***are highly efficacious, but their effectiveness in practice is limited by poor adherence, with many patients stopping treatment prematurely and relapsing*.**

The goal of this proposal is to develop an innovative long acting subcutaneous implanted formulation of naltrexone, the O'Neil Long-Acting Naltrexone Implant (OLANI), towards FDA approval. Expected to produce naltrexone blood levels sufficient to block the effects of opioids for 6 months after implant, OLANI circumvents the need for adherence to monthly injections with XR-NTX, and could represent an important new addition to the medical armamentarium for treatment of OUD

The foregoing statement, that spells out the challenge of "***poor adherance***" is a common disclaimer and caveat in many, if not most professional papers and studies. This is the **existential reason** for **Hidden Creek Recovery's** business model and concept of ***recovery support***, and why is has been so well received by clinicians and researchers: as medical technology advances in the very near future, and these treatments are expected to be FDA approved and becoming available and popular, there will be an absolute necessity for specially tailored program that augments the benefits of long-term extended-release naltrexone implant (or injection), and supports long-term adherence.

Once sufferers undergo naltrexone implants or injections --because of the its extraordinary effect to block the euphoric high resulting in the mitigation or attenuation of the cravings for alcohol or drugs, those on the ER naltrexone will come to accept or believe this as their being normal, or relegating their addiction as being defeated or extinguished. While the need to feed the cravings may be in remission, and some neural pathways perhaps atrophied or "decommissioned"-- once the life of the naltrexone depot is depleted, there is the ability for whatever reason-- either intentional or inadvertent ingestion-- for relapse into a full-blown episode. This is why long-term support and any technological devices or platforms to promote adherence to refresh/replenish the naltrexone, is crucial.

Scope of the Hidden Creek "*Recovery Retreat*" Concept

The conceptual scope and content of the "recovery retreat" and intensive workshop, is designed to entertain, enlighten, educate, and engage the client:

A) specifically adapted curriculum to a naltrexone-specific preventative or suppressant to alcohol or opioid cravings;

B) effecting behavioral and cognitive adjustment and using CBT and peer-support groups to deal years of aberrant alcohol and drug related dysfunctional behavior,

C) to provide a pro-active telehealth app and platform to continue to reinforce sobriety;

D) to provide an educational program to understand the history, the pharmacology and physiological effects derived from the ER naltrexone implant/injection, and create a more informed and knowledgeable pre-active patient.
Specifically that the dangers of relapse will be at some point in the future at the end of

the ER efficacy life, which poses the greatest danger of relapse-- when the naltrexone no longer has any endorphin/dopamine blocking properties, and the user self-deceptively believes that they are no longer susceptible to alcohol or drug "addiction", and discontinues or fails to refresh the implant/injection which is the typical reason why long-term outcome rates are not higher-- "adherence" to the reload/refresher protocols.

The Hidden Creek Recovery program will reinforcement the concept that adherence to the refresh/reload implant or injection, even if it is months to potentially a year or more in the future-- is essential to the recipient's survival, and that without such, a relapse will only be a matter of time-- and unavoidably triggered by an inadvertent and unconscious drink, event, or even some type of medical or dental surgery that requires opioids for pain. Those familiar warm and fuzzy feelings can certainly be reactivated without naltrexone-- even long term.

E) **Hidden Creek Recovery** will seek to elicit some form of binding commitment or pledge from the client/ patient, which will have the effect of reinforcing their pledge to maintain adherence at some distant point in the future-- which could involve a future auto-text or email to themselves reminding themselves of their sacred and solemn pledge.

As a precursor to such treatment, a potential client may choose to enroll in the **Hidden Creek Recovery Retreat** workshop prior to making such decision to undergo the implant procedure.

Arrangements will be able to be made with the corresponding participating doctors to accommodate the client onsite with the minor procedure at the end of the workshop. The doctors will bill the clients separately, whether a cash transaction, or a covered healthcare insurer reimbursement. Such doctors specialized in such procedure, will make onsite visits to our location utilizing an exam and treatment room to perform the procedure. The issue of detox will obviously have to be dealt with in some way, and drug and alcohol testing will be administered before admission.

BioCorRx® which will presumably be the manufacturer of the NTX implants predicated on the success of their IND application, acknowledges the need for the adjunctive recovery support to allow the patient a smooth and well-informed transition back to a life devoid of alcohol or opioids... and to be able to deal with the dysfunctional damage that they need to leave behind. **BioCorRx®** has developed a curriculum specific to recovery support in conjunction with their naltrexone implant-- incorporating modern technology into the recovery formula-- that doesn't require a person "in recovery" to devote months spent in abstinence-based recovery rehabs.

At this writing, to our knowledge there are no other ***recovery residence*** operators offering anything similar to what we are intending to do-- establish a "***recovery retreat***" (*an adaptation of the term or designation "recovery residence"*) that would be a appealing and tempting

solution to the many anticipated implant candidates seeking an expedited short-term solution in the form of an intensive workshop.

Such workshop program will have continuity beyond the term of the physical workshop attendance using the state-of-the-art teleconferencing platform capabilities, and a peer-support smart phone app after their return to normalcy. The workshop curriculum will engage the participants in the use of the platform as a "check-in" to track or chart their progress, and provide virtual peer-support if and when necessary, as well as providing periodic positive affirmations and maybe even a text-messaging news feed on new technological advances in addiction medications. Our goal, would be to keep those persons choosing the implant, engaged and involved in their own recovery-- and to persuade or promote their follow-up with the next scheduled implant. The objective, is to make the "retreat" so enjoyable or pleasurable a stay (*as in a "staycation"*), that is possible that they might want to attend refresher courses during the course of their naltrexone treatment or procedure.

Our strategy is unique, cutting-edge content and structure, reinforces, and supports **BioCorRx®**'s next gen MAT technology. Our success will be directly related to the advances and success of the **BioCorRx®** naltrexone implant. We will be a component of that marketing, offering the recovery support services to dispensing doctors and clinics under the form and format of a "recovery retreat", for their clientele.

Financial Forecast & Proforma

While the f*inancial forecast & pro forma's* are provided in the accompanying spreadsheet form as an attachment, there are certain variables both in projected operating costs, and some, in a greater extent- revenues.

Part of the inherent business model is operating as a retreat, which is in it's essence, a hospitality operation, and as such, will require specific staffing: a facility manager, a chef, an assistant cook, housekeepers, security, maintenance, transportation, landscaping & groundskeeper, and a part-time IT person.

Then there will be the concierges (*usually referred to in the recovery-space vernacular as 'BHT's' or 'behavioral health technicians'*) that are the go-fers for the guests. These are minimum-wage employees who cater to the guests, and do all the running around errands etc. These "BHT's" will initially total 2, and could grow as necessary, maybe to 4 or 5.

With 9 bedrooms and 16 available beds, would in essence operate as a bed & breakfast, a lodge or a country inn (*obviously without any alcohol*). The costs associated with such an operation would remain static and predictable, as will the staffing be (*with the variations in the number of "BHT's as noted above*) , and the costs such as lease, insurance, utilities, fees relatively static. Propane prices get higher in the winter, as does the weather getting colder, so the propane

prices, as will the electricity vary several thousand dollars. As well, maintenance items are difficult to predict without a crystal ball.

Additionally, one input factor, would be an advertising and marketing budget, which we have allotted a $10,000/month budget-- probably higher than we might need. So, suffice to say, that the low and high of the monthly operating costs, could be between $85,000 and $95,000.

The cost of the guest meals, is imputed into net revenue variables-- because of only 16 beds total to offer. Meals are expected to be $35/pp daily, and are deducted from the individual gross revenue per bed-- rendering a net amount.

At the end of the year, we will be able to accurately ascertain and state from real-world results, how many beds we are able to fill on what average basis-- after the business stabilizes-- eliminating the expected first six month start-up phase from the average.

Elsewhere in this paper, there is a matrix of the potential revenues from an average number of beds occupied-- from 16 beds (*a terribly optimistic number-- but not impossible*) to maybe 12-14 beds average, which might be considered our "*sweet-spot*" of achieving. Although we could be pleasantly surprised as was Jeff Bezos-- in the earliest start-up days of Amazon-- when they attached a bell to ring each time the received a new Internet order. That bell didn't stay attached for very long, and it's quite possible that we might wind-up with a waiting-list each month to get in.

So what can the revenue projections look like each month. This is a matter of math, and marketing, and because there are only 16 beds (or 16 slots).

This is where we could play with the algorithms:

Price the program for 1 week at $4,995 or 4 weeks totaling $20,000.

X 16 beds = $320,000 (100% occupancy) monthly gross revenue
X 10 beds = $200,000 (62% occupancy) monthly gross revenue
X 8 beds = $160,000 (50% occupancy) monthly gross revenue

or $3,995/week for 4 weeks totals $16,000

X 16 beds = $256,000 (100% occupancy) monthly gross revenue
X 10 beds = $160,000 (62% occupancy) monthly gross revenue
X 8 beds = $128,000 (50% occupancy) monthly gross revenue

-or-

Perhaps we could structure a 10 day program (3 per month) at $4,995 totaling $15,000/month per bed:

X 16 beds = $240,000 (100% occupancy) monthly gross revenue
X 10 beds = $150,000 (62% occupancy) monthly gross revenue
X 8 beds = $120,000 (50% occupancy) monthly gross revenue

In any one of the forgoing hypothetical calculations, the business would still be profitable, and there would be ancillary revenues from the professional services through the virtual platform we will provide.

So, instead of prognosticating what profits would be made, the revenue matrix in the separate financial forecast pro forma incorporates many of the what-if pricing and occupancy variables to determine the more optimistic, the conservative centrist projection, and a pessimistic *"what's the worst we could do"* break-even scenario.

As we would be riding the wave created by BioCorRx's naltrexone implant's entry into the marketplace if and when their IND is granted by the FDA , we also would be pioneering an ancillary program to a newly approved drug-- as an enhanced short-term recovery program in the form of an intensive workshop retreat that can operate under the legal authority (or exemption) of a *Recovery Residence* as a cutting-edge program.

Conventional residential rehabs, and outpatient patient IOP's and PHP's are not yet adapted to support an addicted patient that undergoing the naltrexone implant procedure. Their abstinence model syllabus is based on resolve, willpower, and peer support. The resultant abstinence from NTX is not generated from conventional proscribed treatment protocols and therapies- moreover it is more likely related to a systemic loss of desire for alcohol or opioids due to the unique effectiveness of the naltrexone.

Any recovery support for MAT-- needs to be adapted to the unique needs of the patient's circumstances-- who have already committed to the anticipated abstinence resulting from the unique medication properties- not the conventional therapy concepts of reinforcing their conscious effort to use their own willpower and fortitude to *"just say no..."*. Long-term outcomes with this conventional model of treatment, are no better than 35%, and relapse is an ever-present potentiality.

The mission of **Hidden Creek Recovery**'s recovery support program in conjunction with the concomitant naltrexone implant, will be encouraging compliance and adherence to receiving the refresher-replacement implant periodically, and providing peer-support to redefining one's life characterized as ex-alcohol or drug dependent, and avoiding all the traps and triggers that were part and parcel of the addictive life-style-- and regaining the balance, control, and equanimity in their lives. With the absence of cravings, their affliction must be treated like a life threatening allergy, and the naltrexone to be viewed as life-saving injection of epinephrine.

Deal Structure

Hidden Creek Retreat, LLC, is a Georgia limited liability company-- which presently holds the business license under the operating name "*Hidden Creek Recovery & Retreat*". It is solely owned by Reed Hatkoff, and holds the title to the 9,000 SF lodge, and 70 acres.

Hidden Creek Retreat, LLC will act as the lessor of facility, and execute a triple-net lease to the operator.

The proposed operator of the R&R program, will be Next-Gen Recovery, Inc. , a domestic for-profit corporation which will own "Hidden Creek Recovery Programs, LLC". Next-Gen Recovery, Inc. could possibly be filed as a Wyoming corporation-- is it is the only state that doesn't impose any state taxes whatsoever. This could potentially avoid the 11% in Georgia State taxes

Part II

Medication Assisted Therapy ("MAT") [i]

This section is added for uninformed and unfamiliar laypersons reading this document, to understand the specific areas, complexities and methods used in the addiction industry, which is important to this overall business model as on the cutting-edge of the pre-eminent growth sector within the industry.

There are three primary medications used in MAT:

Alcohol Use Disorder Medications - Acamprosate, disulfiram (*Antabuse*®), and naltrexone are the most common drugs used to treat alcohol use disorder. They do not provide a cure for the disorder, but are most effective in people who participate in a MAT program.

The only cure for addiction-- is "extinction" of the underlying brain functions that cause both the cravings, and the subsequent reward of the high, the buzz, the euphoria, or the warm and fuzzy feelings-- due to the physiological effect and neuroscience of the alcohol or drugs interaction with the brain. Such extinction [process], is the cause and effect, or the cause and reward: the intake of alcohol or drugs-- will produce the desired effect. If the stimulus (alcohol or drugs) ceases to provide the desired effects (the high), then over time as side-effect or consequence of reverse conditioning, the brain's neural pathways linking the cause to the resulting effect-- will diminish or atrophy.[9] This is only a function of one single drug: naltrexone (or the similar molecularly-structured clone-- "*nalmefene*"-- in Europe).

Medications used in the MAT include:

- ***Acamprosate*** - is for people in recovery, who are no longer drinking alcohol and want to avoid drinking. It works to prevent people from drinking alcohol, but it does not prevent withdrawal symptoms after people drink alcohol. It has not been shown to work in people who continue drinking alcohol, consume illicit drugs, and/or engage in prescription drug misuse and abuse.

- **Opioid Dependency Medications** - Buprenorphine, methadone, and naltrexone are used to treat opioid use disorders to short-acting opioids such as heroin, morphine, and codeine, as well as semi-synthetic opioids like oxycodone and hydrocodone.

- ***Buprenorphine*** - suppresses and reduces cravings for opioids. Unlike methadone treatment, which must be performed in a highly structured clinic, buprenorphine is the first medication to treat opioid dependency that is permitted to be prescribed or dispensed in physician offices, significantly increasing treatment access.

[9] Sinclair, J.D. Method for Treating Alcohol-Drinking Response. USA patent 4,882,335 Nov. 21, 1989.

- ***Methadone*** - reduces opioid cravings and withdrawal and blunts or blocks the effects of opioids. Methadone works by changing how the brain and nervous system respond to pain. It lessens the painful symptoms of opiate withdrawal and blocks the euphoric effects of opiate drugs such as heroin, morphine, and codeine, as well as semi-synthetic opioids like oxycodone and hydrocodone.

- ***Naltrexone*** - blocks the euphoric and sedative effects of opioids and prevents feelings of euphoria. Naltrexone blocks the euphoric and sedative effects of drugs such as heroin, morphine, and codeine. It works differently in the body than buprenorphine and methadone, which activate opioid receptors in the body that suppress cravings. Naltrexone binds and blocks opioid receptors, and is reported to reduce opioid cravings. There is no abuse and diversion potential with naltrexone.

- ***Opioid Overdose Prevention Medication*** – Naloxone saves lives by reversing the toxic effects of overdose. Naloxone reverses the toxic effects of the overdose.

- **Naltrexone**[ii]-- The most effective "anti-craving" medication on the market.

What is Naltrexone?

Naltrexone once in the system, has a profound and beneficial effects in helping to mitigate the cravings for alcohol or opiates that constitute the actual addiction. With the plethora of well documented clinical studies and research documenting the attenuation or mitigation of the euphoric effects or alcohol/opiates with naltrexone.

Naltrexone was a drug first developed in the 1970's, and acquired by DuPont who attempted to market it under the brand names of Trexan® and Revia, and ultimately abandoned their patent in 1986 due to poor marketing and resulting sales. This abandonment led to the FDA awarding the drug as a recognized, safe orphan drug status, which then became "open source" and could be manufactured anywhere by anyone (in pill form).

Such lack of exclusivity and financial incentive resulted in inadequate incentive to be of interest to big Pharma-- which relegated the drug to languish because of the total lack of marketing budgets to promote the specific benefits and suppression of cravings for alcohol or opioids. The drug was subsequently produced at a low cost in China, India, and from a number of other sources. It is sold over-the-counter in pill form in many countries-- including Spain.

In the book "*The Cure for Addiction*" by Dr. Roy Eskapa first published in 2008, and updated in 2012, it details exactly what millions of alcoholics and families of alcoholics had been hoping for: a painless, dignified, and medically proven cure for their addiction. At the time of publication, it was backed by 82 clinical trials and research that extends back to 1964, It details

the research of Dr. John David Sinclair funded by the Finnish Ministry of Health into the unique properties of a drug called **naltrexone**, that blocks the endorphins created by opiate and alcohol-- from reaching the receptors in the brain-- thereby depriving the subject of the "buzz", "high", or euphoria-- the primary element of the addiction is the cravings for the endorphins-- and therefore, the substance that provides the endorphins that create the euphoria. It their book, they detailed a success rate of more than 78 percent of patients in the clinics in Finland using the naltrexone oral tablet.

While DuPont's sales of Trexan® and ReVia® languished in the 1980's, the drug did not escape the attention of the researchers. Dr. David Sinclair, performing all the laboratory government-funded research in Finland, proffered his Pavlonian[10] model of combining naltrexone with drinking to elicit the "extinction" (or "reverse-conditioning") of the cravings-- such as in Pavlov's dogs deprived of receiving food when the dinner bell was rung-- and therefore, after time, the dogs would no longer salivate without the stimulus-reward cycle.

Dr. Sinlair received a U.S. Patent on this "proven" method (using his extensive laboratory research on alcoholic rats). However in 1986, when DuPont relinquished its patent protection on naltrexone and there was no longer any big pharma marketing budgets to promote naltrexone, Dr. Sinclair also abandoned his patent. Clinics in Finland, and elsewhere around Europe-- continued to successfully operate on this business model and methodology, and are still operating today-- such as ContrAL[11] (*"control alcohol"*) in Helsinki-- as well as a few others. Naltrexone to this day, is still sold over the counter in a few countries-- without any restrictions about having to detox first-- an FDA mandated restriction promulgated on the theory that if there was alcohol or opioids in one's system, the naltrexone could bring about withdraw if they were to immediately deprive themselves of the alcohol/drugs-- which is not really how it works.

With the widespread availability of naltrexone as an FDA assigned status as an "orphan drug", interest in the benefits of naltrexone (*and a sister drug in Europe--"nalmefene"*) continued grow organically, as it was used extensively throughout Europe and Russia, and continued to be researched and clinically tested by noted pioneers and researchers-- most notably Dr. Sinclair, and Dr. Joseph Volpecelli[12], who has authored over 120 research papers on addiction and pharmacologicals, many of which on Naltrexone, and one peer-reviewed paper- which is the now standard-discipline BRENDA integration model[13] (see Section "*Naltrexone Compliance*").

Naltrexone simply hadn't caught on in the U.S., however, until the early 2000's when an Ireland based drug manufacturer-- ***Alkermes,*** investigated the potential of an exclusive delivery system-- as an injectable "depot" deposit of naltrexone *(a timed-release injection inside the body that would last a month)* that gained FDA approval, and was marketed as Vivitrol®. The formula for the naltrexone for them was free-- there was no new formula development costs-- only clinical trials of the efficacy of injecting it as a time-release deposit *in vivo.*

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[10]

[11] https://contral.com/?lang=en

[12] https://volpicellicenter.com/about-us

[13] The BRENDA Model: Integrating Psychosocial Treatment and Pharmacotherapy for the Treatment of Alcohol Use Disorders

Since 2006, however, was a second generation medication wave in MAT[14] *Vivitrol*® (injectible naltrexone), penetrated the market and made it a recognized name and treatment medication.

Most recently, a brand-new next-generation iteration- of a naltrexone delivery system-- a long-lasting pellet implant that will last 3-4 months. Naltrexone will be later discussed, but suffice to say that it has been around since the 80's, it is safe, with numerous clinical studies and research, to validate that naltrexone blocks the action in the brain receptors that are responsible for the buzz or euphoric effect in the brain-- that creates the constant cravings that constitutes the addiction. If the endorphins are blocked from the brain receptors, and there is no "buzz" in the brain-- then the brain no longer craves the stimulus (alcohol or opioids). It is the mitigation of craving that breaks the addiction (or relapse) cycle. And those with profound addiction disorder-- who have already been through the system and relapsed-- are forced to start over again.

Many are anticipating the widespread availability of the naltrexone implants, as its competition-- Vivitrol®, is very expensive, and inconvenient (*to see a doctor for an injection each month*). The naltrexone implant is now on the cutting edge of medication-assisted treatment, and can short-cut the quitting process of sheer- will power and determination methodology.

Vivitrol® however, has its' drawbacks-- it is expensive, and it requires the patient to return to a doctor every month to receive a new injection, and it has been documented that there is a high attrition rate to "compliance" (or "adherence") by patients sticking with the monthly schedule. So the high price was simply the issue and was the result of the function of the monopoly of Alkermes. The story of ***Alkermes'*** unusual marketing program to introduce and mandate Vivitrol® to the U.S. market through lobbying and legislation is available as a report on NPR.

Alkermes had spent the millions on the marketing of its' product that was necessary to get the attention of the professional clinicians and academia in the United States to gain recognition of the drug, and its miraculous properties to block the high resulting from drug and alcohol consumption, and even blocking the residual effect of getting buzzed just anticipating or thinking about the abuser's next drink or fix. Prior to their marketing campaign in the U.S. -- naltrexone had simply been relegated to obscurity, although still very much of interest to researchers-- such as Joseph R. Volpicelli-- who continued his research on nalrexone through the late 80-'s, through the 90's, and into the early 2000's-- co-authoring numerous papers and co-opting numerous studies, even serving as a consultant to Alkermes on Vivitrol.

A milestone research paper was published in 2006, in the the *Journal of Psychiatric Practice* 2006 March; 12(2): 80–89 (of which Dr. Volpicelli was a co-author):

[14] Medication Assisted Therapy

The BRENDA Model: Integrating Psychosocial Treatment and Pharmacotherapy for the Treatment of Alcohol Use Disorders

Aron N. Starosta, PhD,, Robert F. Leeman, PhD,, and Joseph R. Volpicelli, MD
University of Pennsylvania, Department of Psychiatry
University of Pennsylvania, Department of Psychology

*"[T]he preponderance of evidence suggests that **naltrexone**, acamprosate, and disulfiram, the only three medications approved by the FDA for the treatment of alcohol use disorders (AUDs), **are all efficacious**.*

For instance, in a recent meta-analysis, Srisurapanont and Jarusuraisin assessed findings from more than two dozen trials of naltrexone for alcohol dependence.

They found that naltrexone use was associated with a significantly lower likelihood of relapse (38%) than placebo (60%) in short-term (12-week) trials.

However, these findings are not reflected in clinical practice, with low rates of prescriptions for these drugs to treat AUDs as noted above.

*When asked why naltrexone prescribing rates were not higher, one physician focus group cited **concerns about low compliance**.*

***Patient compliance has been a concern in the pharmacological treatment** of many chronic illnesses, including diabetes mellitus (less than 60% full compliance) as well as hypertension and asthma (less than 40% compliance for both).*

Adherence to behavioral regimens for these three conditions is even worse, averaging less than 30%. Compliance with alcohol addiction treatment is equally poor. "

This entire article was authored on the basis of clinical trial results of **oral** naltrexone (a 1 X per day pill regimen), the only delivery method of naltrexone at that time in 2005. The issues and concerns then regarding compliance (and adherence) as the same issues and concerns as today.

Studies and trials of outcomes have improved significantly with the introduction of *Vivitrol*® to the market in 2006, however the challenge of compliance and adherence to a schedule of injections each 30 days-- still exists, with an attrition rate of those that for what-ever reason, fail to pursue refilling their monthly injections.

The "next-gen" version of naltrexone that everyone has been waiting for, is ***BioCorRx®***'s Extended Release pellet implant, at a fraction of the price of Vivitrol®. ***BioCorRx®*** has applied to the FDA for "*Investigational New Drug*" ("IND") approval to manufacture the naltrexone pellets, although the product is allowed to be compounded by pharmacies as naltrexone is a known and approved drug, as well as being uncontrolled by Schedule II [15], and being available for prescription outside of a MAT licensed and certified clinical environment.

The *BioCorRx®* implant will have the same patient "*compliance*" and "*adherence*" challenge and issues, however, at a refresh rate of several months, it will be somewhat to easier to manage compliant and pro-active subjects-- especially with smart phone apps and other platform technology. Hidden Creek is one of the qualified providers of BioCorRx®'s proprietary *Beat Addiction Program*.

BioCorRx® recognizes the complexity of addiction, and the underlying psychosocial and behavioral issues that are the constituents of alcohol and drug abuse, and strongly recommend and promote adjunctive treatment and support to use of its naltrexone implants. While the naltrexone may mitigate the cravings, it does nothing to modify or alter the dysfunctional behavioral patterns contributing to the use disorder. However, the attenuation of the cravings is only half the battle, and a necessary component of the recovery process-- even with naltrexone-- is the behavioral aspect of the addictive personality, and bad habits that have become deeply embedded as part-and-parcel of the addiction.

And so, those who want to go on naltrexone, and receive the implant, must first undergo detox before qualifying for the surgical implant procedure, or even the injection form. And so, they must sacrifice a week in detox before they can receive the naltrexone treatment, and after such implant procedure, will most likely have no appetite or desire to endure a 30-day rehab. They will want to get on with their busy lives and careers.

Once they are being discharged from detox, they are presented with options, which are generally presented or recommended in accordance with the ASAM levels of care, -- usually an in-patient rehab for starters. Some of those being discharged, will opt to return home, and attend a day-treatment center-- either an IOP[16] program or a PHP[17] program. Sometimes these are attended in combination or conjunction with living in a sober-living halfway house.

If a recovery course is given as a treatment-- it must be administered or rendered by a licensed practitioner and therefore considered a medical treatment, and is presumed to by psychological or psychiatric, in that the patient has other issues called "co-occuring disorders". Licensed counselors and therapists are trained to deal with these disorders-- like someone who in an alcoholic and bipolar. However, recovery coaches and courses deal with the manifestation of the addict's behavior. There are a number of recovery programs-- the most

[15] §1308.12 Schedule II (b)(1) ...[e]xcluding apomorphine, thebaine-derived butorphanol, dextrorphan, nalbuphine, naldemedine, nalmefene, naloxegol, naloxone, 6β-naltrexol and naltrexone, and their respective salts.
[16] Intensive Outpatient Program ("IOP") [Generally 3 hours a day, 3 days per week]
[17] Partial Hospitalization Program ("PHP") [Generally 5 hours a day, 5 days a week]

well known is the AA 12-step, followed by a popular and more modern and in touch-- *Smart Recovery®* , followed by a number of recovery support programs-- which are all in their essence-- peer-support groups.

So once those patients are being discharged from a detox, they will also be presented with the option of attending a week-long intensive workshop, and pursuing a naltrexone implant-- which would be expected to ameliorate the likelihood of relapse.

Hidden Creek Retreat will neither prescribe, nor be involved with the minor surgical procedure implant procedure. It will work in conjunction with a physician specializing in this procedure in the adjunctive and companion recovery offering courses, and recovery support groups, and has a internet telemedicine platform for the program attendees to have time to teleconference with licensed professionals trained with specialties in addiction and MAT-- especially naltrexone.

Our target demographic is affluent professionals who have battled addiction on and off, and been through the recovery system-- and know the drill well. And they have already relapsed, and have lost faith in the ability to "cure" them, and are looking for the answers of what will remove the pervasive and ever-present cravings. Many are cognizant of the ability of naltrexone to accomplish this, but as yet, have not pulled the trigger because of the lack of specific recovery support consistent with naltrexone.

MAT is now the cutting edge of the addiction industry

Hidden Creek Recovery, a retreat-style intensive recovery workshop will be featured, with an alcohol and addiction recovery support curriculum under the umbrella of *Smart Recovery* syllabus and accreditation.

Additionally, the program will incorporate some elements gleaned from AA's 12 steps, and updated in scope, and a proprietary CBT[18] program designed by BioCorRx® to work in conjunction with, and as an augmentation to their newly developed *naltrexone* implant. Such program has been made available as a teleconference presentation through the proprietary independent telemedicine Internet platform.

We will only accept persons who have either already underwent a detox program, and available to persons accepting such elective naltrexone implant therapy, or those who anticipate undergoing the minor implant procedure from an independent physician while attending our intensive workshop retreats. Additionally, there are those who alternatively, who would desire to receive an Vivitrol® injection to determine the benefits before committing to an implant. This would be discussed with their physician.

[18] Cognitive Behavioral Therapy

This curriculum is strictly a recovery educational enhancement and augmentation support to be employed with the use of naltrexone implants or injections to understand the benefits of physiological actions, bio-mechanics and advantages of the properties of naltrexone's active potential to mitigate and attenuate the pervasive cravings of alcohol and opioids.

Admissions

- Assessment webform (on-line)
- Referrals from detox operators
- Referrals from participating doctors administering BICX implants
- Admissions office maintained

Pricing Considerations

- This is a self-pay model, as insurance does not normally reimburse for sober-living homes.
- Any "ancillary revenues" from the add-on professional services provided through the mechanisms of the on-line platform, cannot be derived from, or be of benefit to **Hidden Creek Recovery** from the professional service providers as a commission, or in any way to be construed as a "kick-back". A doctor rendering an on-site service such as a minor 15-minute surgical implant procedure, since he is being paid directly by the patient, could conceivably rent an monthly office space to be used for such purpose, and the rent of such office would or could be legitimized and officiated by an official month-to-month rental agreement.

  While to other professional "on-line providers" may not in any way compensate Hidden Creek for any referrals, such professionals must compensate the platform for use of the built-in technology and credit card clearing, or for the insurance billing if such option is chosen. These fiduciary arrangements are between the professional providers, and the platform fee schedule.

Cost Considerations for the all-inclusive retreat package.

The retail cost for the all-inclusive retreat package, is at this point, under discussion. The Financial Pro Forma & Forecast uses four (4) different price point revenue scenarios:

Scenario (Price Point)	Monthly Price per Bed - Single Occupancy	Monthly Price per Bed - Double Occupancy
1	$12,000	$10,000
2	$13,000	$11,000
3	$14,000	$12,000
4	$15,000	$13,000

There are 16 beds available, however it cannot be expected that the occupancy will normally run 100%. At the end of the year, there will be an average number that will account for the variations in sales and occupancy.

The above are four (4) hypothetical scenarios of per room gross revenues, that are adjustable and variable figures. The varying spread between the price points is a function of what the best marketing price is, and what the market will bear.

Within the spreadsheet, it also provides for "what-if" scenarios (or calculations) of differing occupancy rates-- 90%, 80%, 70%, and 60% to determine where the "sweet spot" is between profitability, break-even, and loss, and what the potential profit could look like if our optimistic goals are met.

Price Points

The above spreadsheet matrix contained in the *Pro- Forma Forecast*, computes the room revenues over the span of a month-- not the pricing of the individual packages. The matrix is the average revenue of the presumed total packages sold. If two (2) $5K packages sold would total the $10K amount in scenario # 1.

If the 10 day packages were priced at $6,500, this would equate to the revenue in scenario # 4. If all conditions are ideal, and we are able to sell 4 weekly packages at $4,995, the revenues would be $20,000, an amount not entered into the spread sheet, as even with the less aggressive projections appear to be extremely profitable.

If the reader were provided an **Excel** spreadsheet forecast & proforma, such scenario can be modified by clicking in the cells (C-21 thru C-24) for dbl occupancy rooms, or for changes in the two single room rates click in the cells (B-21 - B24) to modify the pricing variable amounts.

As an "all-inclusive retreat", with 3 meals per day, snacks, beverages, housekeeping, and

intensive workshop seminars and sessions, there will be 2 private, and 14 semi-private accommodations.

We need to conduct further marketing studies to determine the optimal pricing and retreat duration and composition and efficacy of the program.

In the formulation and structuring of a program, we could structure the package in the following ways:

(a) 1 Week Program (8 days- 7 nites) (x 4 per month)

Price Points: $3,995 - $4,995

We could fit 4 of these sessions into a month, however, would need time in between for a complete turn-over including a deep cleaning of rooms, as well as the entire lodge.

(b) 2 Week Program (14 days- 13 nites) (x 2 per month)

Price Points: $7,995 - $9,995

We could fit 2 of these sessions into a month, however, would need time (perhaps a day in-between for a complete turn-over including a deep cleaning of rooms, as well as any repairs required.

(c) 10 Day Program (8 days- 7 nites) (x 3 per month)

Price Points: $4,995 - $7,995

We could fit 3 of these sessions into a month, however, would need time in between for a complete turn-over including a deep cleaning of rooms, as well as the entire lodge. The additional two days, might be the "additional buffer time" needed for client adjustment, and to allow them to "settle in". This writer is inclined to believe that the little extra time might yield the maximum effectiveness inasmuch as the days or arrival and departure are basically wasted days in terms of accomplishing certain goals.

One Week Intensive Workshop & Recovery Support Course Syllabus

Program Components & Curriculum

(a) An integrated ***Online Internet-based Platform*** with teleconferencing capabilities will provide independent professional therapeutic services provided through a partner telemedicine licensed providers (billed directly by those providers) for:

- Adjunctive Psychotherapy
- Cognitive Behavioral Therapy
- Psychiatric evaluation

(b) Workshop: Group discussions (Smart Recovery)

- Two - 1½ Hour ***Smart Recovery*** sessions per day
  (We will be a *Smart Recovery*- program based workshop & platform, and will also integrate BioCorRx®'s *Beat Addiction®* proprietary 35-module CBT program into the curriculum) as the main components of the workshop content.
- Speaker Presentations: 1 hour per day
- Check-Up & Choices (Smart Recovery Self-Assessment App) for self-study periods.

(c) **Shrin Yoku** (Forest Bathing Therapy). As a respite to the intensive workshop sessions, these outdoor sessions could be sequenced-in several days a week on the nicer days that would support hiking into our 70 acre wooded estate with an ANFT (Association of Nature and Forest Therapy) Certified instructor. This form of "nature therapy" is a scientifically-proven method of decompressing from the hustle and bustle and pressures of life, and getting back to the essence of nature that is within ourselves. This would be an ideal afternoon opportunity to absorb the lessons of the day, as a as prelude to dinner.

(d) Reel Recovery (Film Festival) screenings (in the evenings following dinner)

These evening screenings will follow dinner, and be followed by discussion groups to examine the various implications of the movie. (see Appendix C List of the feature movie line-up)

Curriculum Content

- There is a plethora of content on YouTube to craft a program schedule of relevant recovery presentations.

- We could retain luminary presenters to either produce our own presentations to run, or schedule actual live teleconferences with such luminaries. See list in Chapter___.

- Russell Brand "*Freedom From Our Addictions*" Podcasts would be presented in the theater presentation room as a late evening distraction or wind-down before bedtime. It would also be accompanied by a late-nite buffet snack table of pastries,

fruit, coffee/tea smoothies, etc. Also, could be an optional alternative to other outdoor activities that would be precluded by inclement weather.

Virtual Platform subscription.

Hidden Creek Retreat will incorporate the services if an independent platform (website) designed specifically for the delivery of virtual counseling and other telemedicine services. This platform is comparable to that of the relationship of Uber to the landscape of the taxi and transportation industry.

The specialized telemedicine platform integrates:

(a) Standardized Intake Assessment web forms (HIPAA Compliant)

(b) the services of licensed professional counselors and therapists who offer independent counseling specific to the areas of alcohol and drug addiction, co-existing disorders, and psychiatry where deemed advisable or necessary;

(c) Medical evaluation for potential medication assisted treatment by licensed medical doctors. There are specific medical doctors on the website who have contracted with BioCorRx® to provide on-site visits to perform the surgical procedures to implant BICX 102.

Each service provider will have an "*About*" page that will display the particulars of his/her practice, their specific areas of practice, their licenses and accreditations, their office location (if the maintain such location), and their fee schedule. It will also be noted if they accept insurance, and what insurance companies they are in network with. If it is an "out of network" situation, if they would accept the deductable portion. The professional service provider would work on a "net remittance" arrangement, paying the platform a percentage for marketing, teleconferencing, credit card clearing, and submitting claims to the healthcare insurors.

If a service provider is so disposed to accept insurance under this condition, there is a behavioral health billing company which would submit and facilitate such claim management. This is a function of the platform available to the subscriber service providers, is called Claims Management System, whereby the patient provides all their health insurance information in their client registration, and such information can be pre-screened for coverage limitations, and coded as such. We will be in discussions with Prosperity Behavioral Health or Cherry Hill N.J. to provide such back-end financial and billing services.

Ascertaining what the client's health policy coverage will be for anticipated specific behavioral telehealth billing codes, will be assigned to a client's account as a credit limit, so that what will be reimbursable, will be a certain specific.

The client will have their own account page containing all their personal information and insurance particulars, as well as certain "Medical & Psychological Assessments" that are HIPAA protected, and once a relationship with a professional service provider is chosen, the client can go into their account panel and check the uploaded or webform documents that are authorized to be released to the provider for access.

The active features embedded into the platform, is:

1. An appointment scheduler for a "zoom" type teleconference session;
2. An app for Android, iPad, iPhone, or a desktop that facilitates the sessions;
3. An fee-in-advance for an appointment for a consultations or a medical procedure (such as the naltrexone implant surgical procedure), which could either be billed to the client's credit card, to their insurance carrier, or both-- depending on the deductable, and if the procedure was pre-approved.
4. This platform can be privately labeled with Hidden Creek Recovery branding, however the web-platform is a separate and distinct entity, and each provider signed with the web-platform is an independent licensed professional providing counseling, therapeutic, or medical services using the specialized technical capabilities of the web platform for the intermediary virtual marketing, billing, and teleconferencing facilities.

Chapter III
Georgia State Licensing & Authority

Hidden Creek would operate under the exemption from any licensure requirements as stipulated by: **O.C.G.A. §§ 26-5-5, 26-5-6.**

Hidden Creek already has been issued a business license from Haralson County to operate as an Alcohol Recovery operation. Hidden Creek would offer NO therapeutic or medical services, and would only supply recovery peer-support workshops[19] to individuals who have undergone prior therapy, or who are currently engaged in or undergoing some unaffiliated professional treatment program or individual services through virtual telemedicine platforms. Hidden Creek Recovery will allot a structured schedule and private terminals to provide for such concurrent online sessions.

RULES AND REGULATIONS FOR DRUG ABUSE TREATMENT AND EDUCATION PROGRAMS
111-8-19-.21 Residential Transitional Treatment Programs.

Such residences provide services on an intermediate basis for clients characterized as chronic substance abusers[20] who are transitioning to the community or to other treatment modalities, and who, typically, lack a stable living situation and require variable levels of therapeutic services. ***Facilities that only provide housing for persons, such as half-way houses or temporary shelters, are not subject to licensure as residential transitional treatment programs, unless the residence offers treatment services or is a supportive service owned and/or controlled by a licensed program*.** In addition to the general rules set forth, programs offering residential transitional treatment programs shall meet the requirements of this subsection (.21).

> (a) Client intake, assessment, and admission; individual treatment planning; and discharge and aftercare shall be done in accordance with rules .13, .14 and .17. Additional admissions requirements, including laboratory tests, may be required by facility policy and/or determination of the medical/clinical director. The program has the discretion to use physical and psycho-social assessment information from another licensed program, licensed hospital, or a state or federal agency, if the client is transitioning directly from another program.
>
> (b) The program shall provide at least five or more hours per week of therapeutic services designed to enable the client to function without substance abuse. Such services shall be rendered by persons who have been determined qualified by training, education, experience, and who are licensed/certified if required by state practice acts to render such services.

(c) There shall be sufficient types and numbers of staff members on duty in the residence to provide for safe supervision of clients whenever clients are present.

[19] Smart Recovery
[20] By Georgia Statute, "alcohol" is specifically exempted by definition of "substance abuse", and any treatment of "alcohol use disorder" (AUD) or abuse, is exempted from this rule.

Professional Affiliations & Certifications

Hidden Creek Retreat shall endeavor to obtain membership or certification with the following professional industry organizations:

- Smart Recovery Smart Recovery is the modern alternative to AA 12-step programs. Self-Management And Recovery Training (SMART) is a global community of mutual-support groups. At meetings, participants help one another resolve problems with any addiction (to drugs or alcohol or to activities such as gambling or over-eating). Participants find and develop the power within themselves to change and lead fulfilling and balanced lives guided by our science-based and sensible 4-Point Program®.

- The National Association of Addiction Treatment Providers (NAATP) is a nonprofit professional society designed to offer support to organizations across the continuum of care. Since 1978, it has extended resources, advocacy and thought leadership to its members.

- The Joint Commission for the Accreditation of Healthcare Organizations (JCAHCO) evaluates quality of care provided by healthcare organizations. Footprints has the Gold Seal of Approval, which means we possess the highest standard of safety and quality of care.

- LegitScript is a third-party certification that confirms that Footprints follows all applicable laws and regulations. It shows that our company has been vetted and that we demonstrate an ongoing commitment to integrity and transparency.

- NAADAC, the Association for Addiction Professionals, represents the professional interests of more than 100,000 addiction counselors, educators and other addiction-focused health care professionals in the United States, Canada and abroad.

- National Alliance for Recovery Residences (NARR)

  The National Alliance for Recovery Residences (NARR) is a 501-c3 nonprofit organization dedicated to expanding the availability of well-operated, ethical and supportive recovery housing. We have developed the most widely referenced national standard for the operation of recovery residences. We work with and support 30 state affiliate organizations. NARR and these organizations collectively support over 25,000 persons in addiction recovery who are living in over 2,500 certified recovery residences throughout the United States.
  We envision all persons in recovery from addiction having access to the recovery support they need to live happier, healthier lives. NARR values hope, compassion, respect, honesty, responsibility, and fairness.

NARR was founded in 2011 by a group of organizations and individuals with deep recovery housing expertise, and a goal of developing and promoting best practices in the operation of recovery residences.
NARR works with federal government agencies, national addiction and recovery organizations,with our state-level recovery housing organizations, and with state addiction services agencies in pursuit of better and more accessible recovery housing opportunities.

- Georgia Association of Recovery Residences
  8343 Roswell Road #267
  Atlanta, GA 30350
  470-296-3435
  info@thegarrnetwork.org

  The Georgia Association of Recovery Residences (GARR) is a founding member of the National Alliance for Recovery Residences (NARR) and is one of the oldest recovery residence organizations. GARR was founded in 1987 out of the need to evaluate and monitor quality of care in the rapidly growing field of addiction recovery related services in the state of Georgia. It was the first association to develop and maintain a standards system for recovery residence programs in the state.

  GARR is an affiliate of NARR, and therefore, a company acquiring membership in GARR, automatically becomes a member of NARR.

Chapter IV
Sober Living Houses & Recovery Residences

What is a recovery residence?

"Recovery residence" (RR) is a broad term describing a sober, safe, and healthy living environment that promotes recovery from alcohol and other drug use and associated problems. Many thousands exist in the United States that vary in size, organization, and target population. (The exact number of recovery residences is unknown since many RRs are not regulated by government or independent organizations.) At a minimum, RRs offer peer-to-peer recovery support with some providing professionally delivered clinical services all aimed at promoting abstinence-based, long-term recovery. Recovery residences are sober living environments, meaning that residents are expected to abstain from alcohol and illegal drug use. Each credentialed recovery residence publishes policies on relapse sanctions and readmission criteria and other rules governing group living. Recovery residences may require abstinence from particular types of medications according to individual policy.

Recovery residences have spread rapidly in the United States in recent decades. In 2011, the National Association of Recovery Residences (NARR) was founded to promote a recovery-oriented continuum of support for those with substance use disorders by credentialing recovery residences that implement empirically based recovery principles and practice standards. NARR currently represents more than 1,900 recovery residences in the United States

Congressional Authority & NARR

In 2018 U.S. Congress enacted H. R. 4684 *''Ensuring Access to Quality Sober Living Act of 2011"* which defined directed the Secretary of Health and Human Services to identify or facilitate the development of best practices for operating recovery housing, Such act defined "sober living residences" and deemed the National Alliance for Recovery Residences, to identify or facilitate the development of best practices, which may include model laws for implementing suggested minimum standards, for operating recovery housing.

NARR attempted to standardize rules through their seminal document: https://narronline.org/wp-content/uploads/2014/06/Primer-on-Recovery-Residences-09-20-2012a.pdf However, what this document constitutes a conceptual guide *(a "primer" as noted in the name)* as opposed to any steadfast rules that must be followed.

Recovery Residence (RR) vs. Retreat model & format

While concepts incorporated into the RR model are leaning towards the meaning and definition of the word residence, and the difference between a residential home and a retreat, for a short-term stay to be construed as a residence, would be a stretch.

However, the NARR rules do contain other precepts that are applicable, and therefore the proposed business model would be a short-term stay in a "residence" (a lodge) for the purpose as stated in NARR's primer:

> *"The purpose of a recovery residence is to provide a safe and healthy living environment to initiate and sustain recovery—defined as abstinence from alcohol and other non-prescribed drug use and improvement in one's physical, mental, spiritual, and social wellbeing. Individuals build resources while living in a recovery residence that will continue to support their recovery as they transition to living independently and productively in the community."*

A short-term intensive retreat could also meet this mission. When it comes to the next section [3] as to the services provided, it states:

> *"Recovery residences are divided into Levels of Support based on the type as well as the intensity and **duration of support** that they offer. Services provided span from peer-to-peer recovery support (all recovery residences) to medical and counseling services (recovery residences offering higher levels of support). The NARR Standards define minimum services for each Level of Support, but additional services may be provided at each level. Section 5 of the NARR Standards included in the Appendix details the minimum required service elements for each Level of Support."*

This passage in their ***Primer*** Chap 21 defines the element of the length of stay:

> *"Length of stay varies depending on the residents' needs, progress, and willingness to abide by residence guidelines as well as on the payment structure of the residence. Many residences encourage a minimum length of stay or, for Level 3 and 4 residences...*"

Therefore, setting any length of stay, is undefined, and optional-- qualifying a one or two week stay following a detox completion, would be a viable alternative for certain demographic individuals who would seek medication-assisted treatment-- and especially naltrexone medication. These individuals most likely have history going through the *"continuum-of-care"* system, who have relapsed, and are looking for a more expedited and efficacious treatment course to deal with their addiction. Abstinence achieved by "*just saying no*"... is not a viable option... especially to those who can afford premium treatment. Others in the same demographic group-- who are high level/high status

individuals, who under normal circumstances would avoid and dismiss recovery at all because of the stigma, might be encouraged by a retreat complexion of recovery if cast as the hallmark of an executive retreat and/or intensive workshop.

Hidden Creek Recovery will operate as a *Level 2 is defined as Monitored Recovery Residence* environment as defined by NARR:

This level offers a minimal amount of support and structure, with access to affordable services over a longer period of time.

- House manager or senior resident
- Policy and Procedures (contained in welcome packet)
- House rules provide structure (highly structured intensive workshop)
- Peer run groups (Smart Recovery curriculum)
- Drug Screening (dependent on detox release interval)
- House meetings (will coincide with presentations and programs)
- Involvement in self-help and/or treatment services
- Primarily single family residences
- Possibly apartments or other dwelling types (lodge)
- At least 1 compensated position (will be 12 employees)

Under this structure, Hidden Creek Recovery proposes to operate its' unique next-gen program and regimen.

Part III

Scope & Validation Of Hidden Creek's Recovery Support Program

The following is an important article, because it describes and validates the treatment or recovery support niche that is the essence and backbone of the proposed ***Hidden Creek Recovery*** program. This validates the existence or operation of a recovery support program under an unlicensed and flexible structure as a "Recovery Residence", as provided for as a legal exemption in **O.C.G.A. §§ 26-5-5, 26-5-6.**

From the professional paper:

THE AMERICAN JOURNAL OF DRUG AND ALCOHOL ABUSE-2020, VOL. 46, NO. 3, 266–272

Note to the reader: This professional discourse is recast and rewritten with all common word replacements for medical acronyms, and all references & cites removed for enhanced legibility, readability and comprehension by laypersons not trained with interpreting medical terminology--instead substituting common vernacular.

Note to Professionals: Please forgive the "artistic" liberties taken in doing so.

DEFINITIONS

• **OUD** (Opioid Use Disorder):	"Addiction"
• **MOUD** (Medication for Opioid Use Disorder):	*"Addiction medication*" or *"Medicated opioid use disorder"*
• **RR**	"Recovery Residences"
• **Psychosocial**	Characteristically is a term used to describe the influences of social factors on an individual's mental health and behavior.
• **Psychosocial support**:	Group meetings or sessions with peers
• **Agonist**	Agonist, is a replacement drug for the original more addictive one, where the user experiences the same effects;
• **Antagonist**	Antagonist is where the receptors are blocked, and the user experiences no effects.

THE AMERICAN JOURNAL OF DRUG AND ALCOHOL ABUSE-2020, VOL. 46, NO. 3, 266–272

"Supporting individuals using medications for opioid use disorder in recovery residences: challenges and opportunities for addressing the opioid epidemic"

By Jennifer Milesa, Jason Howellb, Dave Sheridanb, George Braucht, and Amy Mericleca

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Abstract

Full and partial opioid agonists and opioid antagonist medications play an important role in containing the opioid epidemic. However, these medications have not been used to their full extent. Recovery support services, such as recovery residences (RRs), also play a key role. RRs may increase an individual's recovery capital, facilitate social support for abstinence, and foster a sense of community among residents. These processes may be critical for individuals with opioid use disorder (*addiction*). In combination these two recovery pathways have the potential to enhance one another and improve outcomes among residents with *addiction*. Barriers to doing so have resulted in a limited supply of residences that can support residents using opioid agonist and antagonist medications.

This perspective describes key interpersonal and structural barriers to medication use among individuals with an *addiction* seeking support from a recovery residence and discusses measures for reducing these barriers. These measures include workforce development to address stigma and attitudinal barriers and enhancing residence capability to ensure resident safety and reduce potential diversion. The perspective also highlights the need for additional research to facilitate the identification of best practices to improve outcomes among residents treated with medications living in recovery residence.

Introduction

Opioid use disorder (*addiction*) is a significant driver of the opioid epidemic. Both the National Institute on Drug Abuse and the Substance Abuse and Mental Health Services Administration (SAMHSA) are encouraging states to expand access to medications for *addiction* (*addiction medication*) and associated treatment services to contain the effects of this crisis, including the use of medications. The *American Society of Addiction Medicine* recommends that *addiction medication*s be used in conjunction with psychosocial interventions including recovery support services. However, little is known about how *addiction medication*s may best be used in conjunction with recovery support services. This article describes one type of recovery support service, the recovery residence(a continuum of residential, substance-free living environments for individuals in recovery from a substance use disorder, and discusses the unique opportunity for addressing the opioid epidemic in these settings.

Background Medications for opioid use disorder (*addiction medication*s)

Three types of *addiction medication*s are FDA-approved: full agonist(methadone), partial agonist

(*buprenorphine*), and antagonist (*naltrexone*). Both methadone and *buprenorphine* activate opioid receptors to reduce opioid withdrawal and craving, and can result in a similar physiological response as experienced with other illicit and commonly misused opioids.

Naltrexone does not activate opioid receptors but instead prohibits opioids from binding to and activating them, preventing a physiological response.

While oral formulations of naltrexone have poor medication adherence, the extended-release injectable formulation has been found to be as effective as *buprenorphine* in multiple medication trials. Overall, the evidence base for the effectiveness for all three *addiction medication*s is robust, as evidenced by the significantly lower odds of mortality while receiving *addiction medication*s. Despite this evidence, significant gaps in access to treatment remain. Due to their risk of diversion, both full and partial agonists are classified as Schedule II and Schedule III narcotics, respectively, under the *Controlled Substances Act*. These medications must be dispensed in either a specialty clinic setting (methadone) or in an office-based outpatient medical setting (*buprenorphine*) by a physician with a waiver from the Drug Enforcement Agency.

Other barriers to access include inadequate physician staffing in specialty treatment settings, medication cost, patient factors that affect medication adherence (e.g., smoker status, co-occurring psychiatric disorders), and negative perceptions toward full and partial agonist medications. Additional research is needed to better understand for whom these medications are most effective and how best to deploy *addiction medication*s across different settings.

Discussion: Recovery Residences - Recovery Support Services (RSS)

Psychosocial factors such as employment, peer support, and co-morbid health conditions play a key role in the course and management of *addiction*. Therefore, additional supports are needed to increase an individual's psychosocial recovery capital, or the social, financial, cultural, and human capital needed to achieve and maintain recovery long-term. These resources are commonly referred to as recovery support services (RSS), and *"provide emotional and practical support for continuing remission as well as daily structure and rewarding alternatives to substance use"*.

Examples of RSS include mutual aid groups (e.g.- Alcoholics Anonymous, Narcotics Anonymous), peer recovery coaches, and recovery community centers.

Another type of RSS is the recovery residence (RR),commonly referred to as sober homes, therapeutic communities, or Oxford Houses (OH). RRs may increase an individual's recovery capital. Importantly, RRs promote peer support for abstinence by fostering a sense of community among residents which may be critical for individuals with *addiction* struggling with cravings and relapse triggers on their own. While the total number of RRs in the United States is unknown, there are an estimated 4,500 residences supporting approximately 45,000 individuals in a given year among residences that can be identified, i.e., those that are affiliated with the National Alliance for Recovery Residences (NARR) or are chartered by Oxford House. NARR developed a typology of RRs that identifies four distinct levels of support (see Figure 1), varying by the staffing, governance, and intensity of clinical services or supports offered on-site, and the stage of recovery for which each level is appropriate.

- The **first level** of support refers to settings that are wholly peer-run and have no staff or clinical supports and services offered on-site.
- The **second level**, such as sober homes or sober living homes in California, may have a house manager that oversees the daily operation of the residence, and often require residents to attend mutual aid meetings in the community as a condition of their stay.
- The **third level**, such as those that have been studied in Philadelphia, Figure 1 also have a house manager, and may require residents to attend community-based mutual aid meetings and/or outpatient treatment.
- The **fourth level**, such as therapeutic communities or the Minnesota Model (i.e.,28-day residential treatment), are typically licensed and have trained clinicians that deliver clinical services on-site in addition to peer-supports.

The evidence base for these models is growing. A systematic review of the literature on resident outcomes by Reif, George found moderate evidence of reduced substance use and criminal justice involvement and higher rates of employment and higher income levels. However, this evidence is limited by small sample sizes, few randomized trials and a lack of control or comparison groups, and little focus on organizational characteristics. Empirical evidence of RR effectiveness for individuals with *addiction* is emerging. Preliminary evidence indicates abstinence rates are higher following opioid detoxification and during psychosocial substance use treatment among individuals residing in RRs compared to those who do not. However, negative attitudes toward *addiction medication*s among RR residents may present a barrier for those utilizing *addiction medication*s who may concurrently benefit from a stay in a RR. While research comparing outcomes for those in *addiction medication*-specific RR's with those in general population RRs has not yet been conducted, some evidence suggests that population-specific RRs may be beneficial. No research has been conducted that examines the effects of RRs on *addiction medication* adherence or prescriber attitudes toward or perceptions of RRs.

Combining recovery pathways

Supporting individuals utilizing *addiction medication*s in RRs could have a significant impact on the opioid epidemic, particularly in rural areas. Individuals with *addiction* are more likely to relapse if they received short-term inpatient care only, during the period immediately following *addiction medication* initiation, and upon *addiction medication* discontinuation, and relapse too often results in premature mortality. RRs extend the continuum of care beyond detoxification and medication initiation to assist with longer-term symptom management in the community. While a number of barriers work to under-mine the support of individuals on *addiction medication* in recovery housing, these barriers may be overcome with adequate infrastructure and guidance from the empirical literature.

Barriers to *addiction medication*s in RRs

Disparate belief systems and stigma

*Addiction medication*s and recovery housing evolved out of separate communities and disparate belief systems. The use of medication emerged from the medical model, wherein a trained clinician offers expert advice and treatments primarily targeting underlying biological processes of a disease. In contrast, RRs emerged from a social model approach, wherein non-clinician peers play a central role in the provision of experiential psychosocial support. These residences are largely 12-step oriented, and may espouse an abstinence-based approach which would prohibit resident use of any psychoactive substances, including

*addiction medication*s. These disparate philosophies may lead to mistrust between the two communities, potentially worsening stigma against people treated with *addiction medication*s. Indeed, stigmas may not only come from the general public, medical providers, or the criminal justice system, but may also come from substance use treatment counselors, participants of mutual aid groups (63), or RR operators and residents. Additionally, anti-medication stigma varies by type and in some cases has resulted in an overemphasis on antagonist medication despite its limitations for some individuals.

Residence safety

RR operators may not consider an applicant who is utilizing a full or partial opioid agonist due to their risk of diversion. Factors that increase the risk for diversion include their potential for abuse, the difficulty of legally accessing these medications, and their potential as a source of income. When misuse of these medications occurs in a RR the entire community's safety is at risk, given the increased risk of relapse caused by drug-seeking environmental cues that can trigger relapse. A primary tool for reducing the risk of diversion is direct monitoring of medication use. However, monitored administration in RRs presents several challenges. RRs may lack tools that support medication safety such as lockboxes or safes which require upfront capital investment. Staffing is also a concern in some RRs. While higher-intensity settings (e.g., Level III and Level IV residences)may have credentialed staff and closer supervision of residents, staff-to-resident ratios in lower-intensity settings are usually lower, and staff may have little or no training in medication management. Long-acting injectable or implantable *buprenorphine* with *naloxone* also show promise in reducing overdose, as does maintaining a supply of naloxone on-site. However, access to these medications is often cost-prohibitive and varies widely by state.

Facilitators of medication use in RRs

Workforce development

Over time the definition of recovery has evolved from one that is abstinence-based to one that is recovery-oriented. SAMHSA describes recovery as occurring across "multiple pathways". While abstinence-based approaches are still dominant, the concept "medication-assisted recovery", i.e.-- *the use of medications in combination with abstinence-based recovery to support individuals for whom both pathways are appropriate*, is gaining acceptance.

Educating RR operators on *addiction medication*s and how best to support residents using these medications could reduce stigma, particularly by including the voices of individuals who have had success using *addiction medication*s. At the same time, building collaborations between RR operators and *addiction medication* prescribers requires increasing prescribers' understanding of RRs' and the need to establish resident information exchange protocols.

Preventing diversion and overdose

Even when an operator is supportive of *addiction medication*s the setting must be properly equipped to monitor medication adherence. Some low-cost protocols are already being implemented by RR operators. These include screening protocols that ensure that a prospective resident's needs can be addressed. For example, a prospective resident who needs to be closely monitored while initial dosage levels are established may be more appropriate for a higher level of support with the accompanying staff who can conduct this monitoring. Regular and random drug testing for all residents–regardless of medication status–is another strategy that is already commonplace in many RRs. Other low-cost strategies include conducting pill counts, keeping medication logs, having staff accompany residents when picking up medications from

the pharmacy, and behavioral monitoring by staff and/or fellow residents. Injectable medication formulations also reduce the risk of diversion, although they may not be appropriate for, or available to, everyone.

Conclusions and implications for future research

In response to the ongoing opioid epidemic, states are exploring opportunities to increase the availability of *addiction medications* and the supply of RRs for individuals using *addiction medication*s. A variety of approaches, as discussed above, may address the challenges of doing so. However, mandating changes without providing financial incentives and operational support limits the ability of key stake-holders to meet these goals. Therefore, we suggest that policymakers and operators work together to create a comprehensive set of policies that account that for local contextual factors that may affect implementation. Many of the above suggestions are primarily based on anecdotal evidence and practice-based experience. Research is urgently needed to examine the effects of various interventions on rates of medication initiation and maintenance, and the effects of these interventions on proximal and distal recovery outcomes. These research gaps are indicative of the limited research infrastructure needed to conduct rigorous research on recovery residences more broadly. Specifically, there are too few researchers knowledgeable about RRs, there is no central registry of RRs, and few incentives for RR operators to participate in research. More training and funding opportunities are needed to address these challenges, and to stimulate new research on RRs, including studies focused on outcomes of individuals with *addiction* residing in RRs.

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Editors Note

The foregoing professional paper is on-point, and summarizes and validates the science behind the business operating model scope & concept proffered by Hidden Creek Recovery.

Hidden Creek's recovery support program is highly adapted to this structural framework, and excludes the support of all the medications available as discussed herein, with the exception of naltrexone, wherein, to reiterate, it states:

> *"Three types of addiction medications are FDA-approved: full agonist (**methadone**), partial agonist (**buprenorphine**), and antagonist (**naltrexone**).*
>
> *Both methadone and buprenorphine activate opioid receptors to reduce opioid withdrawal and*

craving, and can result in a similar physiological response as experienced with other illicit and commonly misused opioids.

Naltrexone does not activate opioid receptors but instead prohibits opioids from binding to and activating them, preventing a physiological response.

While oral formulations of naltrexone have poor medication adherence, the extended-release injectable formulation has been found to be as effective as buprenorphine in multiple medication trials.

We believe that implantable long-acting naltrexone is the wave of the future, and for that reason plus the potential for the misuse of the other two above-identified drugs, we will only support and endorse naltrexone as the treatment medication of choice.

CHAPTER IX

POTENTIAL PRESENTERS & LUMINARIES

1. **Joseph R. Volpicelli**- Researcher, Author, Professor, & Doctor
   - https://volpicellicenter.com/about-us
   - https://youtu.be/R2ILKLTh9tM

2. **Judith Grisel**- Addiction Neuroscientist- Bucknell University
   - https://www.youtube.com/results?search_query=dr.+judith+grisel
   - https://www.bucknell.edu/meet-bucknell/bucknell-stories/faculty-stories/judith-grisel-psychology

3. **Tom Welch**- BioCorRx, V.P.
   - What is the BioCorRx® Recovery Program - BioCorRx® - Naltrexone Implant: https://vimeo.com/214547116
   - BioCorRx® offers medical professionals free use of its recovery mobile platform: https://youtu.be/2XckqLAEmlw
   - BioCorRx® seeks FDA approval on its anti-opioid and alcoholism naltrexone implant: https://youtu.be/Pof2DDDjaBc
   - BioCorRx® CEO discusses uses for recent $6 million capital raise https://youtu.be/R4HNEronFt0

4. **Claudia Christian**- Three C Foundation
   - https://cthreefoundation.org/about
   - https://youtu.be/6EghiY_s2ts

5. **Kevin Fleming**- Grey Matters Int'l - Coaching
   - https://greymattersintl.com/about/dr-kevin-fleming/
   - https://vimeo.com/170035924
   - https://youtu.be/u2QZxs_pCBs

6. **Katie Lain**- Embody Daily - Coaching
   - You tube channel: https://www.youtube.com/channel/UCdeh0LP6kuSQ9GsorQpVnUw

Chapter X
Professional Affiliations & Certifications

Hidden Creek Recovery shall endeavor to obtain membership or certification with the following professional industry organizations:

- Smart Recovery Smart Recovery is the modern alternative to AA 12-step programs. Self-Management And Recovery Training (SMART) is a global community of mutual-support groups. At meetings, participants help one another resolve problems with any addiction (to drugs or alcohol or to activities such as gambling or over-eating). Participants find and develop the power within themselves to change and lead fulfilling and balanced lives guided by our science-based and sensible 4-Point Program®.

- The National Association of Addiction Treatment Providers (NAATP) is a nonprofit professional society designed to offer support to organizations across the continuum of care. Since 1978, it has extended resources, advocacy and thought leadership to its members.

- The Joint Commission for the Accreditation of Healthcare Organizations (JCAHCO) evaluates quality of care provided by healthcare organizations. Footprints has the Gold Seal of Approval, which means we possess the highest standard of safety and quality of care.

- LegitScript is a third-party certification that confirms that Footprints follows all applicable laws and regulations. It shows that our company has been vetted and that we demonstrate an ongoing commitment to integrity and transparency.

- NAADAC, the Association for Addiction Professionals, represents the professional interests of more than 100,000 addiction counselors, educators and other addiction-focused health care professionals in the United States, Canada and abroad.

- National Alliance for Recovery Residences (NARR)

  The National Alliance for Recovery Residences (NARR) is a 501-c3 nonprofit organization dedicated to expanding the availability of well-operated, ethical and supportive recovery housing. We have developed the most widely referenced national standard for the operation of recovery residences. We work with and support 30 state affiliate organizations. NARR and these organizations collectively support over 25,000 persons in addiction recovery who are living in over 2,500 certified recovery residences throughout the United States.

We envision all persons in recovery from addiction having access to the recovery support they need to live happier, healthier lives. NARR values hope, compassion, respect, honesty, responsibility, and fairness.

NARR was founded in 2011 by a group of organizations and individuals with deep recovery housing expertise, and a goal of developing and promoting best practices in the operation of recovery residences.
NARR works with federal government agencies, national addiction and recovery organizations,with our state-level recovery housing organizations, and with state addiction services agencies in pursuit of better and more accessible recovery housing opportunities.

- Georgia Association of Recovery Residences
  8343 Roswell Road #267
  Atlanta, GA 30350
  470-296-3435
  info@thegarrnetwork.org

  The Georgia Association of Recovery Residences (GARR) is a founding member of the National Alliance for Recovery Residences (NARR) and is one of the oldest recovery residence organizations. GARR was founded in 1987 out of the need to evaluate and monitor quality of care in the rapidly growing field of addiction recovery related services in the state of Georgia. It was the first association to develop and maintain a standards system for recovery residence programs in the state.

- SAMHSA Is the official website for The Substance Abuse and Mental Health Services Administration ("SAMHSA"), the agency within the U.S. Department of Health and Human Services (HHS) that leads public health efforts to advance the behavioral health of the nation and to improve the lives of individuals living with mental and substance use disorders, and their families. It is the "go-to" on-line reference and resource for understanding addiction and treatment. Below are the links to the specific pages as discussed in this paper.

  - https://www.samhsa.gov/medication-assisted-treatment
  - https://www.samhsa.gov/medication-assisted-treatment/medications-counseling-related-conditions#medications-used-in-mat
  - https://www.samhsa.gov/medication-assisted-treatment/medications-counseling-related-conditions/naltrexone

Chapter 11
BioCorRx® Naltrexone Implant &
Beat Addiction ® Recovery Program

Forward

The above-titled program as presented and detailed herein, is based on proprietary products, systems and strategies developed, patented, and trademarked by BioCorRx, Inc. a publicly traded company operating in Fullerton California. BioCorRx, Inc. has received substantial funding from the National Institute of Health (NIH), to develop the next generation comprehensive multi-phase outpatient “non-narcotic, non-addictive” Medication-Assisted-Treatment (MAT) for alcohol and opioid addictions, using a well-established and researched drug-- "naltrexone".

The story of naltrexone as an effective treatment is compelling, and as an powerful treatment product, it has suffered being relegated to relative obscurity for the past 30-35 years because of economic circumstances of the absence of any initiative or marketing efforts and support by big pharma because it was declared by the FDA to be an "orphan drug" and therefore "open source" (*which would render it to be unprofitable in terms of potential corporate revenues*). Quite simply, being ignored (*except by researchers*), it's reputation has grown organically without corporate sponsorship, until after the new millennium when a company [21] recognizing it's economic potential, was able to cash in on the development of an exclusive and patented second generation delivery method with a time-release formula. It succeeded in establishing and promoting and popularizing the beneficial effect of naltrexone as a drug that blocks (or removes) the alcohol or drug cravings- which is the core causation of addiction.

With the proprietary development of the next-generation evolution of naltrexone as an implantable long-acting form and formulation, BioCorRx® is positioned for exclusive and unlimited growth once the formulation and delivery system becomes FDA approved. There is a substantial ongoing focus by SAMHSA and the NIH to promote and encourage the development such next-gen medication treatment for alcohol and drug abuse. Which is why BioCorRx® received substantial funding to not only develop the medication, but also to develop an adjunctive (and proprietary) program to address and treat the addiction from three avenues: (1) physical; (2) psychological; and (3) social.

While BioCorRx® is the manufacturer and developer of the treatment technology and the integrated program, it is not a treatment provider, and must ultimately rely on providers to offer such product and services. Currently, BioCorRx® has 12 licensed providers around the United States, all providing the treatment plan and the naltrexone implants under a regime of compounding the injectable pellets. In conjunct with the administration of the pellets, BioCorRx® also has developed a cellphone/ tablet app, and provides inbound 800 "peer-

[21] *Alkermes* based in Dublin Ireland

support" coaching and follow-on phone support. Such "telehealth" or "telemed" capability is the new paradigm in the Covid-19 era, and could potentially be integrated with a physical residential treatment program, as the State of Georgia recognizes

The adaptation and integration of such product and associated proprietary program system into Hidden Creek Recovery's residential alcohol and substance abuse treatment program, is proposed as a proof-of-concept demonstration project, and licensing or permissions are under discussion with BioCorRx® principals. While such support programs would be applicable to daytime IOP and/or PHP programs, it has yet been developed or adapted to an innovating "residential recovery" course syllabus and intensive workshop type presentation-- incorporating elements of Smart Recovery's 4-Point Program® protocols.

BioCorRx® has provided the *Policy & Procedures Manual* that is the operations manual for their proprietary program, as well as the curriculum and syllabus that comprises 35 module course which can be integrated in concert with their implant procedure provided by independent collaborative physicians.

Details

Within the context of integrating the BioCorRx® *"Beat Addiction ®"* Recovery Program, into Hidden Creek's proposed *Recovery Retreat* "Intensive Workshop" recovery support program, the following components would be integrated:

1. A comprehensive 35-Point Cognitive Behavioral Therapy (CBT) based, solution-oriented recovery program with a credentialed Counselor (LADC)

2. Followed by an on-going PHP [22] or IOP program if recommended or advised, with behavioral health industry's "*continuum of care*" model that coincides with the CBT and other therapies that correspond and conform with the patients' recovery and establishment of coping mechanisms with a new lifestyle without the need for alcohol or drugs;

3. Optional: A Naltrexone pellet implant in the third week of program residency. This is an elective alternative, and is addressed in one of the later program modules regarding the brain's technical interactions with endorphins created alcohol, opioids as well as a variety of other habitual activities such as over-eating, gambling, sex-addictions, etc.

4. Up to 12 months telemed coaching with a certified coach who has overcome addiction with a certified Peer Recovery Support Specialist (PRSS) [23]

[22] PHP-"*Partial Hospitalization Program*", IOP- "*Intensive Outpatient Program*" (see difference)
[23] This is a service provided by BioCorRx, which would require quarterly BICX 102 pellet implants.

By the time an AUD or SUD sufferer has reached the point of seeking treatment, their abusive relationship with alcohol or drugs is out-of-control, and either they themselves, or in conjunction with their immediate families who fall victim to this syndrome, or even jeopardy of their job or career, and generally, however begrudgingly, accept entry into a recovery program. This process usually begins with a requisite detox regimen... if the need of which is indicated or recommended by an interventionist of professional counselor.

While the out-of-control binges are the outward manifestation of the underlying causes, like anything else... a magic pill to remove this "*monkey-on-my back*" would be highly desirable, in some cases, some people-- especially during these times of Covid-related lock-downs, are ostensibly attributable to boredom and anxiety. AUD or SUD sufferers however, don't have the self-introspection to recognize the existence of underlying issues or trauma occurring right under the surface-- issues that trigger the over-consumption of alcohol or drugs. Those can be feelings of inadequacy, guilt, anxiety, and mostly repressed anger for long ago unresolved childhood family or adolescent issues that are tucked-away in the recesses of a sufferer's psyche, play an underlying role to trigger the use of alcohol or drugs as a coping mechanism.

The instantaneous "warm and fuzzy" or euphoric feeling that a sufferer expects to feel, that they consider a "relief" when he or she indulges themselves with alcohol or drugs, is alleviated or negated with naltrexone. Moreover, the cravings for the next hit of "fix" of alcohol or drugs, is highly attenuated or mitigated with the presence of naltrexone deposited [24] in the body and brain.

The CBT therapy program followed-on by an IOP or PHP program, is typically completed within 90 days, the program blends within the framework of one's everyday life, in conjunction with 12 months of discreet telemed *Peer Recovery Support* (PRSS) and Recovery Coaching after-care.

Medication-Assisted-Treatment (MAT)

According to the National Institute on Alcohol Abuse and Alcoholism (NIAAA) part of the U.S. Department of Health and Human Service (HHS) and their 2006 'COMBINE' study – (Combining Medications and Behavioral Interventions for Alcoholism) – the best outcomes in naltrexone therapy are a result of receiving naltrexone along with outpatient behavioral-modification counseling.

BioCorRx® Recovery Program, in compliance with NIAAA and HHS guidelines, has expanded significantly on this concept with our in-depth CBT counseling and 12-month support program.

[24] Naltrexone has a half life of less than 24 hours, and therefore has the best prognosis when using a time-release "depot" in the body, whether it be an injectable "depot"- good for only 30 days, or a tiny pellet implant "depot" for 90 days.

The Program

The comprehensive BioCorRx® Recovery Program blends aggressive medical management in the form of a simple procedure, involving the subcutaneous insertion of specially compounded implants (pellets) which contain the FDA approved medication naltrexone. This medication can be combined with customized, structured, and focused one-on-one Medication-Assisted-Treatment counseling sessions, specific to Naltrexone.

Naltrexone is an opioid antagonist that blocks the ***"pleasure feelings"*** and ***high*** in the brain receptors that respond to the endorphins released from opioids and alcohol when consumed. Once implanted just beneath the skin in the lower abdominal area, the completely bio-degradable naltrexone implant slowly releases the drug into the body over several months and ***eliminates or significantly reduces the cravings for drugs and alcohol*** in most people. It can also block the effects of other drugs. Program participants have reported minimal to no physical discomfort during the procedure. The procedure requires only local anesthetic and typically takes less than 20-30 minutes to perform. More importantly, within an hour or so of receiving the naltrexone implant, *participants have reported feeling complete freedom from drug and alcohol cravings*. Many have reported returning to work the same day.

Depending on the treating physician, participants may typically return periodically for follow-up well checks/incision inspection. Some patients may require longer term medical care depending on individual situations.

Next, BioCorRx® developed a multi-session counselling program identifying 35 key areas essential to early treatment in Substance Use Disorders. Delivered through comprehensive modules, these key concepts include specific instructions which address often unidentified key components essential to behavioral change in Substance Use Disorders. Written by addiction experts with decades of combined experience, the program is specifically for use with those being treating with sustained released naltrexone. Credentialed addiction counselors meet certain criteria before they are trained and certified in the BioCorRx® Counseling Program. Participants generally complete the counselling modules within 90 days of receiving the implant.

Additionally, BioCorRx® has expanded the support structure to include 12 months of a peer-support system utilizing trained recovery specialists usually matched to the consumer based on age, gender, etc. Typically, soon after the counseling modules begin, the patient is ready to enter the Recovery Support Specialist (RSS) portion of the program. This support segment, when implemented, includes very convenient weekly or bi-monthly interaction via telephone for over 12 months. In most cases, there is a period of overlap with counseling and RSS care occurring simultaneously.

This combined approach results in a comprehensive recovery program designed to pro-actively support the recovering individual's journey for around 12 months (assuming completion of aftercare program).

How is the BioCorRx® Recovery Program different?

- Unlike most traditional recovery programs which invest the first 30-90 treatment days in assisting a patient to deal with the physical cravings of addiction, BioCorRx® Program participants are typically absent the physical cravings on day one, and thus can focus clearly without distraction on the information, concepts, change, and education presented in the counseling program to learn and implement unrealized coping strategies and healthy behaviors.

- The implant used in the BioCorRx® Program tends to last longer than others available in the U.S. as evidenced by clinical outcomes (time lengths vary depending on the individual).

- Other naltrexone implant providers tend to simply perform the procedure and do not include a structured naltrexone early-recovery focused counseling program. Those that do include programs, tend to offer life coaching only referring patients to outside centers with no continuity of care or follow-up.
- No other recovery program of which we are aware provide MAT counseling modules specific to the naltrexone therapy and 12 months of peer support and tracking post-implant procedure.

What to expect after deciding to be a program participant:

- Screening for medical clearance, dual diagnosis, appropriateness
- History/physical/medical screening with one of our licensed physicians
- **Receive a medical Detox protocol, typically outpatient**
- Receive one pre-implant counseling session.
- Receive Naltrexone pellet implant, typically a 15-20 minute procedure
- Receive 16-20 One on One counseling sessions over course of next 90 days or less.
- Follow up with medical practitioner as directed for suture removal/wellness checks
- Begin PRSS (peer support and coaching) usually within the first week post-implant

The Case in Support of Adaptation of the BioCorRx® implant and Recovery Program Into a Recovery Retreat Model

In many aspects, the BioCorRx® program lends itself to an on-line virtual program taking advantage of the most recent state legislations regarding telemedicine, telehealth, and virtual delivery of therapy regimes, up to and including remote consultations with counselors, therapists, and doctors-- mostly as a result of Covid-19 concerns, as well as the advance of modern communications technology. Telemedicine can be very effective and popular.

In considering the various components to the BioCorRx® program-- certain elements cannot be performed virtually-- the most obvious being the surgical implantation procedure. The rest can be delivered virtually through online webinars or two-way zoom meetings-- which can be a viable substitute for in-person counseling sessions. What cannot be substituted however, would the preliminary necessity of the patient undergoing a detox process-- which is a serious treatment issue regarding withdraw, and requires the highest level of medical intensity.

In already having a facility specific to residential in-patient treatment, such infrastructure would lend itself towards having an abbreviated program of 1 to 2 weeks, that would provide detox services, and also the surgical implant of the naltrexone pellets by a doctor during this period.

It would also provide an opportunity to deliver the tailored CBT program, as part of the overall recovery curriculum-- which as well could be virtually delivered on-line through zoom or web-enabled counseling sessions by remotely-connected counselors or psychiatrists, and facilities set up for on-line patient conferences. This would obviate the necessity for some of the employment of on-site professionals in a remote location, and could in essence be a pilot program for new treatment protocols that have become the next-gen "treatment delivery system" correlating to the post Covid-19 economy customs.

At A Glance

The #1 indicator of a lasting, successful recovery is length of time in treatment. Period.

A second critical factor is *neutralizing the urges and cravings to use opiates or take pills in the early months of recovery*. This program excels at both.

The Naltrexone pellet not only stops those powerful desires for these drugs that keep us locked in active addiction, but blocks their 'pleasure effect' as well. What's more, traditional treatment lasts only 30 days while our Counseling, Coaching and Support extend to a full year…and within your everyday daily life.

The four constituents of the BioCorRx® *Beat Addiction* Recovery Program:

1. Participation in a specific intensive recovery program such as Hidden Creek Recovery proposes to launch in Georgia.
2. (20) ongoing Counseling/Therapy sessions for our 35-Point Recovery Program
3. The *Beat Addiction* CBT Recovery Program
4. Medically implanted our BICX-102 Naltrexone pellet
5. Follow-on *Certified Recovery Coaching* and *Certified Peer Support* via provider's telehealth facilities.

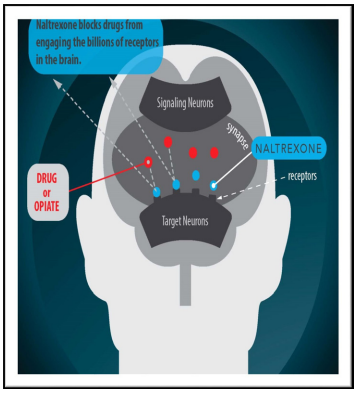
Highlights:

When used in conjunction with an in-patient residential program

- A comprehensive, proven 35-Point CBT Recovery Program
- That *naltrexone* blocks the 'pleasure effects' from all opiates and alcohol
- Bypassing the later recovery "sober living" stages in the continuum of recovery, and continue your life working, living at home during your recovery-- utilizing the cutting-edge telemedicine capabilities instead.
- Safe, near painless procedure, takes about 15 minutes
- FDA-approved Naltrexone: Non-narcotic, Non-addictive
- Recovery rates far superior to Inpatient/12 Step Programs
- Safely eliminates/reduces the powerful urges & cravings to use

- *Relapses nearly impossible with the Naltrexone implant*

Outpatient Opioid Rehab and Recovery



Recovery may well be the hardest work you ever undertake, but there is no other reward in life that comes close. If you have your sobriety, you can then have everything else…if you don't, you won't have anything, at least not for long.

The simple fact is, most people just don't make it beyond the first six months of attempted sobriety. Of those who go through conventional treatment programs, statistics show nearly 30% relapse within 30 days and roughly 80% relapse within the first year. Many can't even make it a day or a week.

Why?

The 'need' or 'drive' to use drugs or pop pills has been so deeply hard-wired into the brain (the "conditioning") for years, that we just have no defense when those urges and cravings strike. We simply cave. Usually it's the thought "I'll just take a couple to get me through, it will NEVER be like it was before when I lost control. I have changed, I'm different now, I got it this time."

This is delusional. It doesn't take long before we are swept back into the insanity of active addiction, and it only gets worse, never better. Those overpowering urges may win now or they may win later, but in the end they always win. And it's usually because we think we can manage our using well enough to get by, or it will somehow magically get better. Deep down we know we are just lying to ourselves yet again.

Before we know it, we have to keep using simply to avoid the withdrawals. A brutal cycle, and it's just no way to live. We offer a way out of this madness.

"Relapses with the implant are highly unlikely due to the medical blocking of the 'pleasure receptors' in the brain. Both the desire and craving for opiates, as well as any pleasure effect from them, are greatly reduced and usually eliminated. This lasts for months."

While this Medication Assisted Treatment (MAT) , specifically the pellet implant, is a highly effective tool in helping you stop using now, what helps you get drugs out of your life for good is working the Program with our Counselors and Recovery Support Team as you *meet life on life's terms*.

This is a real-life, real-time program where you continue working, living at home, and caring for your family and responsibilities. It's the only program of its kind, and fast becoming the new *gold standard* for state-of-the-art outpatient Recovery .

We believe in this approach because we've seen the amazing results. If you want to get drugs out of your life at the deepest level of your being, and you are honestly willing to do the work in the program, you can recover, really, you can! And without the obsessions, urges and constant battles with cravings that cause so many to relapse. Simply stated, put your recovery above all else and the reality of the life you truly want will slowly begin to appear…. and as close, as vital as your own beating heart.

What does Continuum of Care mean?

Continuum of Care is a concept involving guiding and tracking patients over a period of time through a comprehensive array of health services and spanning all levels and intensity of care. Depending on the need, Continuum of Care can be from birth to end of life for all levels and stages of care. It also includes both the services and the mechanisms of the integration of care.

Services can be broken down into the basic 7 categories which are:

1. Extended care
2. Hospital care
3. Ambulatory care
4. Home care
5. Outreach
6. Wellness
7. Housing

The mechanisms can be broken down into 4 basic categories:

1. Planning and management
2. Care coordination
3. Case-based financing
4. Integrated information systems

The term "*Continuum of Care*" can also be described as getting from illness to wellness. Continuum is defined as the gradual transition from condition to condition, without any abrupt changes. When clinicians use this term, they are recommending that the treatment should include a gradual transitioning of the physiological, psychological, and spiritual states from an unhealthy chemical dependency to a healthy state.

How is *Continuum of Care* used with treating addiction?

Addiction is not as simple as an acute illness or a broken bone. A chemical dependency is defined as a chronic and progressive disease. This means that it can be stopped or halted, but it can never be cured. It also means that if left untreated, it gets more serious and can eventually lead to death.

It can be a challenge to convince someone we love that they are a person with substance use disorder, or come to the realization ourselves, but it can be even harder to convince someone that the treatment can go on for a very long time. One of the more difficult tasks of a chemical dependency counselor is convincing a patient of their need for ongoing care once primary treatment is done.

The patient enters what is referred to as "a treatment system" at the level appropriate to their needs. This level of care step-up to be more intense or downgraded to less intense depending on the treatment needs. An effective Continuum of Care involves the philosophy that a patient can transfer across levels of care.

The American Society of Addiction Medicine (ASAM), has the levels of care are broken down into levels:

- **Level 4**: Is an intensive medically managed inpatient service (*detox, etc*)
- **Level 3**: Residential / Inpatient Services:
  (This level can be sub-divided into 3.1 , 3.3., 3.5, and 3.7)
- **Level 2**: Partial hospitalization / Intensive outpatient
  (This level can be broken down into 2.1 and 2.5)
- **Level 1**: Services for Outpatients
- **Level 0.5**: Early interventions services

It's important to keep in mind that every program varies in their philosophies, services, settings, and client characteristics as they can be tailored and personalized. For example: A rural setting treating females for alcohol addiction would be different than a major city treating males dependent on stimulants. It's important to decide what is right for you through an assessment and being placed with your specific needs.

Why is *Continuum of Care* important?

Addiction can be treated, but real recovery is a lifelong process. In the first year, as many as 85% (by some estimates) of patients will experience a relapse after they seek treatments for alcohol and drug addiction. This is a clear reason why Continuum of Care and long term aftercare programs are paramount in a life of sobriety.

These programs create a greater chance of success in the long term when it comes to preventing relapses. Continuum of Care can often be a the patient's best chance for their long term recovery. The main goal of relapse prevention is the teaching of how to manage triggers. These triggers can include very common things like the time of day, relationships, work, holidays, finances, favorite bars, or other things that may be stressful and remind a person of using. With successful prevention of relapse, the patient can learn these valuable life coaching skills like the identification and management of these triggers.

Inpatient programs are a very efficient path to sobriety when you have the struggles of addiction. The habitation of a trigger and temptation-free environment encourages sobriety. Not every individual after completing an inpatient program is ready to go back into regular life. Many will need a transitional environment, such as a temporary home for continued support and treatment. They have many rules and guidelines in place to keep people living there safe and sober.

Shortcutting the Addiction "Continuum of Care " Blueprint

The foregoing discussed "Continuum of Care" methodology is the "conventional wisdom" of treatment protocols which addresses the steps (or "step downs") of changing a person's lifestyle from "addiction", to "addiction free"-- a misnomer because the addiction is always there... waiting in the background to take over again, if an afflicted person for whatever reason-- loses their determination, conviction, or just simply self-control.

The "continuum of care" components are the tools to help an afflicted person find their way back to sobriety and abstinence, to combat the external factors that contributed to their addictions.

But the elephant in the room is simply this: not everyone has a predisposition to addiction. Some people with certain genetic compositions-- do not easily become addicted to endorphins, while others are more predisposed, and have more addictive "proclivities". Dr. David Sinclair in all his early day government research on naltrexone in Finland in the 1980's, identified two different lab rat types (the "AA", and the "AB") based on their addictiveness quotient to alcohol, and was able to breed these separately based on their pre-disposition to addiction-- to be able to research the action and effectiveness of naltrexone on the more addiction-prone rats.

While people aren't born as addicts or alcoholics, they train, or rather condition themselves for such affliction-- but share a common trait: their predisposition to addiction. And the addiction can simply be defined as uncontrollable urges or cravings.

Nothing within the conventional medical industry's paradigm of the "continuum of care" standards, addresses the mitigation, attenuation, or extinguishment of the insatiable cravings inherent in the addiction. This is why naltrexone has become the new "wonder drug"... albeit misunderstood and underestimated. Although not necessarily new, lacking any economic

incentive to be promoted and marketed, it has grown in popularity organically, until the Second Generation iteration of naltrexone as developed by Alkermes-- that focused a spotlight on naltrexone's ability to block the endorphins that provide the "buzz", "high", or the euphoric effects.

While the untreated alcohol and opioid addictions can escalate or evolve to self-destructive life-threatening behavior, habits, and events, even a magic-pill that removes or neutralizes the root cause of the addiction-- is simply not enough.

Reprogramming and modification of the addiction behavior is as important and necessary as the neutralization of the cravings that are fundamental to the addiction itself.

While naltrexone, which has been around and available in Europe[25] since the 1980's as a acceptable and effective weapon in the addiction treatment arsenal. it was initially relegated to obscurity and literally an orphan-- as it was abandoned by Dupont (relinquishing their patent), and therefore became a non-exclusive drug without any sponsorship, available for anyone to manufacture, and cheap enough that no drug company would commit any budget for marketing. This drug had to be grown organically, and by grass-roots adherents and advocates-- which is why it has taken so long to gain acceptance.

It is not for lack of clinical trials and research... there have been numerous peer-reviewed studies and professional papers on the safety and effectiveness of naltrexone. It is a function of capitalism and the profit motive. Any drug company spending any amounts to promote and market a non-exclusive drug that anyone can produce, is uneconomic, and a losing proposition.

What was required, was a unique and exclusive second generation formulation or an exclusive method of administration into the body.

The problem with the oral form, was that it would depend on the compliance of the subjects taking a daily pill, or conversely with The Sinclair Method, taking a pill prior to anticipated drinking and consumption activities.

Second-Gen

Along came Alkermes, a major biopharmaceutical company based in Dublin Ireland, which recognized the billion dollar potential of using naltrexone-- a well researched and established open-source drug, and developing an exclusive injectable time-release formulation for an *in vivo* "depot deposit", that would last for a month, and would retail for $1,500 to $1,800, a cost that would be covered by insurers. It is called Vivitrol®. This formula has been well received by the public, the addiction industry, and especially the insurers. It still ties the patients to an

[25] In Europe both naltrexone, and also a very similar drug-- Nalmefene are both available. Nalmefene, similar to naltrexone, an antagonist at the mu- and delta-opioid receptors, but, in contrast to naltrexone, acts also as a partial agonist at the kappa receptor (Bart et al., 2005).

injection every 30 days. It is a reasonable successful and profitable program, and having the monopoly on such, Alkermes employed lobbyists to propose and promote legislation in states to mandate Vivitrol® injections in court sentencing of alcohol and drug related case sentencing recommendations. *Alkermes*, has had free-reign with ER naltrexone since 2006, and has been the *force majeur* in promoting naltrexone as a safe and effective treatment for mostly opioid addiction, and to a minor extent-- for alcohol addiction treatment.

Next-Gen MAT Treatments

The next generation MAT (medication assisted treatment) in the naltrexone family is BioCorRx® implantable pellets, a longer lasting and cheaper alternative to Vivitrol®.

BioCorRx® has created a comprehensive adjunctive support recovery program called *Beat Addiction*® that works in conjunction with the time-release naltrexone, providing an afflicted client a opportunity to recover and heal in all the afflicted areas, physical, emotional, psychosocial, and most important-- relief from cravings.

Recovery Program Components

BioCorRx will offer a comprehensive and highly effective alcohol and opioid addiction recovery support program for it's implant clients. Our proprietary program is designed to offer treatment and healing to both the body and the mind of those suffering from addiction. Our alcoholism and opioid addiction treatment program is a two-part program that includes:

(i) the insertion of a naltrexone implant that is believed to reduce physical cravings of alcohol and opioids by a trained physician; and

(ii) peer support and CBT that focuses on the psycho-social aspect of addiction. The following is a detailed description of our treatment program.

Naltrexone Implant: Our unique program has reduced physical cravings for numerous patients suffering from alcoholism and opioid addiction. Our implant is believed to reduce cravings over the period of multiple months in most patients depending on their metabolism and other factors. During this time, the program focuses on addressing the mental dependence on alcohol and/or opioids. The implant is a naltrexone pellet(s) that is the size of a marble and inserted via an outpatient surgical procedure into the lower abdomen of the patient. The naltrexone pellets will be absorbed by the body over time and will automatically dissolve and not need to be removed unless otherwise required.

All procedures to place the naltrexone pellets into patients are performed at several independently owned and licensed provider locations. There are approximately 12 licensed providers throughout the United States that offer the BioCorRx® Recovery Program. The procedures are performed by a licensed medical professional.

The naltrexone implant is currently available and being produced by select compounding pharmacies contracted by BioCorRx® Inc.
The naltrexone implant is one or two small pellets that are inserted beneath the skin in the subcutaneous fat located in the lower abdomen. The implant procedure is an outpatient procedure that takes approximately 20-30 minutes. A local anesthetic is administered before the pellets are implanted and the patient is free to leave the clinic and return to normal activities within a few hours of the procedure in most cases. The pellets are biodegradable and will gradually dissolve in the human body. The pellets contain a medicine called naltrexone, which has been shown to block receptors in the brain that crave alcohol and opioids.

Naltrexone is an FDA approved medication and all patients are required to obtain a prescription for the medication from a medical doctor. The doctors employed by the licensed providers are responsible for evaluating the patients, determining if the patient is a candidate and, if so, writing the prescription. The prescription is then presented to compounding pharmacies contracted by BioCorRx® that produce the pellets using naltrexone as the core ingredient. BioCorRx® does not compound, manufacture or handle the naltrexone implants.

BioCorRx® Cognitive Behavioral Therapy (CBT) Program:

BioCorRx® has developed a CBT program to assist patients in addressing their dependence on alcohol and/or opioids, to be used in conjunction with the naltrexone implants.

Prior to, or upon receiving the naltrexone implant, each patient will typically speak with a counselor/therapist. This counselor/therapist will treat the patient for the next several weeks following the implant using the program modules in combination with their own skill sets to help them cope with and address their dependence on alcohol and/or opioids. It usually takes approximately 16 sessions to complete the program modules.

As part of the peer support and CBT program, peer support specialists/counselors focus on bringing family and friends into the recovery process.

This provides emotional support for patients and allows them to understand that they have people that care for them and want them to remain sober.

The program would begin with the medical detox treatment if required, and instead of the normal and usual release to a 30 day residential rehab, clients would opt for receiving a naltrexone implant in conjunction with attending a one week to 10 day Recovery Retreat Intensive Workshop. Alternatively, the implant may opt to received the implant upon completion of the intensive workshop.

The peer support portion of the program is introduced during the retreat, and typically lasts continues after the participant's conclusion of the recovery program, which will be facilitated by the phone app, and the platform. The newly formed friendships made in the retreat, can be

continued and updated by weekly scheduled "check-ins" with each other to discuss the groups progress, and would reinforce their commitment to the new lifestyle, and discuss the challenges of their transitions.

Competition to Naltrexone

As the "next-gen" of medication assisted treatment for the treatment of substance use disorder ("SUD"), alcoholism and opioid addiction, we believe this is the cutting edge of medical and medication technology that is just in its early stages.

The trail for MAT has already been blazed by *Alkermes* with their product-- Vivitrol injectable time-release naltrexone, having seized upon the exclusivity and uniqueness of their product, and their aggressive marketing and lobbying campaign, they have contributed to the exposure of, and acceptance by the clinicians and addiction industry as a whole. They have enjoyed and profited from their monopoly thus far. It must be remembered that Alkermes did not invent or invest in the research and development of naltrexone)... it was a fumbled ball, and lying there for them to grab (*at no development or research cost whatsoever for the primary ingredient-- naltrexone*), repackage it, test the efficacy of in-vivo time-release depot deposit delivery mechanism, and gain FDA approval for a patented and exclusive product.

They did the job that Dupont failed to do in the '80's, and contributed to (or should we say "propelled") industry recognition of naltrexone as the active ingredient that suppresses or attenuates cravings-- the essence of addiction.

What Alkermes also accomplished, was pursuing and negotiating the political hurdles via huge budgets for lobbying to mandate the use of Vivitrol in cases where the only alternative for a sufferer, would be jail or prison ordered by the courts.

While Vivitrol would be the primary competition with the lion's share of the marketplace, the consumers or clinicians would be offered an alternative product: a BioCorRx® implant that lasts , at a mere fraction of the price. This will be the end to Alkermes' sole dominance of the marketplace, however, BioCorRx's integrated MAT recovery program that is focused on substance abuse treatment in the United States is specific and tailored to naltrexone therapy.

Many treatment providers operate in a broader behavioral healthcare sector without focusing primarily on substance abuse with MAT. BioCorRx's core focus on creating a scalable MAT program gives us with an advantage over competitors in terms of building their brand and marketing the integrated program to potential customers. The hypothesis is simple: in the marketplace, would an implant with 90 day effectiveness at 10% of the price, be preferable or marketable to a Vivitrol injection with an effectiveness of 30 days, at 10 times the price?

The recovery program to be implemented by Hidden Creek Recovery shall incorporate the framework and all the elements of the BioCorRx® CBT program, and utilize BioCorRx®s *Policy & Proceedures Manual* , however, Hidden Creek shall have the latitude of participating in the design of a robust and effective program syllabus and curriculum which will incorporate the *Beat Addiction*® Program which has not yet adapted to a residential treatment & recovery program class-room environment.

A daily classroom schedule would need to be created, that would include the CBT psychosocial therapy (the *Beat Addiction* Program®), as well as individual counseling, group therapy, and perhaps films that are related to addiction manifestations and recovery (this evening class or feature would be called "*Reel Recovery*", and would be followed by a group discussion). There is a plethora of available content for viewing, and Hidden Creek lodge will feature a small "home theater" A/V capable room with theater-style seating, that would also be used for virtual presentations by remote professional presenters and luminaries.

While there will always be other competitive upscale rehabs in Florida, Texas, Arizona and California, each exclusive rehab develops it's own reputation and following. There will never be any shortage of addiction-afflicted individuals seeking help-- but there is a shortage of concierge-level facilities catering to the upscale demographic that is desirous of a higher and bespoke level of care and comfort.

Appendix A
Naltrexone
History & Background

The Beginnings

Naltrexone was originally synthesized in 1963 and patented in 1967 as "Endo 1639A" (US patent no. 3332950) by Endo Laboratories, a small pharmaceutical company in Long Island, NY, a company with extensive experience in narcotics.

In 1969, DuPont purchased Endo Labs. DuPont had been struggling to develop its drug business since the late 1950s, and the acquisition of Endo provided DuPont with valuable expertise in drug manufacturing and marketing.

In the purchase, DuPont acquired the rights to several successful Endo drugs, including: Coumadin (warfarin), an anticoagulant; Percodan, a prescription narcotic; and Naloxone, a drug used for narcotic overdose.

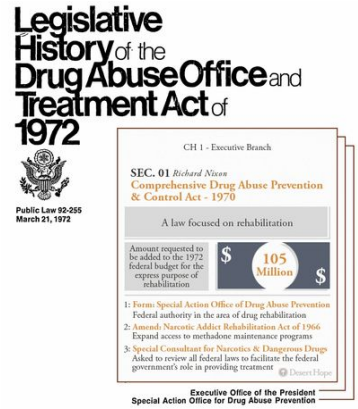
Naltrexone, still in its early development phase, came to DuPont as part of the overall purchase of Endo.

At the time it seemed unlikely that DuPont would develop naltrexone, because at the time, naltrexone seemed to have relatively low market potential, and its patent would probably expire before the completion of any clinical trials.

The Federal Government Steps In

In June 1971, President Nixon created the Special Action Office for Drug Abuse Prevention (SAODAP). The first director of SAODAP, Dr. Jerome Taffe, was determined to improve access to drug abuse treatment by shifting services from prisons and hospitals to community-based services. "I regarded the development of naltrexone as one of my high priorities," said Dr. Taffe.

SAODAP recognized that the development of naltrexone was of no burning interest to the private pharmaceutical industry, and that governmental funding would be necessary to bring it to market.



In March 1972, Congress passed the Drug Abuse Office and Treatment Act, calling for development of "long-lasting, non-addictive, blocking and antagonist drugs or other pharmacological substances for the treatment of heroin addiction." This Act provided substantial financial support for research.

By mid-1974, as SAODAP began to phase out of existence, the narcotic antagonist development project fell to the newly formed National Institute on Drug Abuse (NIDA). That same year, NIDA approached DuPont with the idea of developing naltrexone as a drug addiction therapy, and asked for DuPont's assistance in facilitating naltrexone's transit through the FDA approval process. DuPont agreed to assist NIDA with the development of naltrexone. In return, NIDA agreed to pay for the bulk of clinical development costs.

When asked later, DuPont representatives said that the primary reason for helping the government was Dupont's "public spirit", and that naltrexone would probably not have been developed without the government's clinical and financial support.
The clinical trials for naltrexone as a treatment for heroin addiction began in 1973 (Schecter 1974, O'Brien 1978).

Difficulties in Clinical Trials

Early trials of naltrexone in rats, rabbits, dogs and monkeys had determined that the drug was nontoxic at therapeutic levels, with very few side effects. The subsequent human trials confirmed that the drug was safe for humans, but the efficacy trials ran into some unexpected problems.

Dr. Arnold Schecter, who conducted many of the early studies, reported that many opiate-addicted patients feared a new drug, lacked a desire to become drug free, were unwilling to possibly receive a placebo, and disliked the rigid protocols associated with the clinical trials (Schecter 1980).

Patients had to remain opiate-free for a minimum of 5 to 10 days prior to treatment because naltrexone causes severe withdrawal symptoms in patients with opioids in their system (Schecter 1974). Many addicts were unable to comply, due to the physiological effects of withdrawal.

Taking naltrexone does not provide any drug reinforcement ("high"), and produces no negative consequences (withdrawal) when discontinued. Unlike methadone, which helps suppress cravings, naltrexone has no effect until the addict attempts to use

heroin. Some patients feared naltrexone would make them more vulnerable to these cravings, and felt that methadone was more effective in controlling them.
Because of these recruiting difficulties, researchers made no effort to screen out patients who might be difficult to manage in clinical trials -- e.g., patients who were poorly compliant -- and this may have compromised the results of the trials (Schecter 1980).

Since naltrexone is non-addictive and lacks the reinforcing effect of methadone, it requires more extensive psychosocial support services than methadone. Support services are expensive. Schecter estimated that total clinical treatment with naltrexone was almost twice as expensive as methadone -- not because of the medication itself, but because of the more intensive support services.

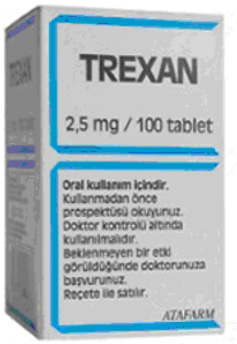
Early trial results showed that, compared with the methadone patients, the patients who were attracted to naltrexone therapy were relatively "more motivated and emotionally stable." Other studies showed that although naltrexone was an effective opiate block, clinical success (a reduction in heroin use), was limited to fully compliant patients.

As a result of these findings, the product labeling for naltrexone reads, "[Naltrexone]… does not reinforce medication compliance and is expected to have a therapeutic effect only when given under external conditions that support continued use of the medication". The final results of the clinical trials showed that naltrexone was modestly successful in the reduction of heroin use.

In 1984, the FDA approved naltrexone in a 50mg dose as a treatment for heroin addiction. Dupont brand-named the drug Trexan. The same year, DuPont's naltrexone patent expired.

On March 11, 1985, the FDA designated naltrexone a an orphan drug, which provided seven additional years of market exclusivity for naltrexone for DuPont.

Marketing Strategy for Trexan®



The DuPont sales force had trouble explaining the mechanism of naltrexone and its benefits to a lay audience. The consumer marketplace had many misunderstandings and negative perceptions about naltrexone. One former member of the DuPont sales force said these misunderstandings were a great barrier to the use of Trexan.

DuPont also had an extremely difficult time trying to convince

methadone clinic personnel to use Trexan. Most facilities could not afford to implement naltrexone therapy due to the combined price of the drug, the drug treatment program, and the additional time and staff necessary for psychosocial counseling.

Methadone clinics were also reluctant to refer patients for Trexan® because of their need to keep their own censuses high enough to receive funding (Schecter 1980).

Pro-methadone treatment providers argued that because methadone was dependence-producing, it was easier to maintain a patient on methadone, and thus more likely that treatment would be successful.

As a result of these problems, Trexan® failed to penetrate the highly regulated federal treatment market for opioid addiction.

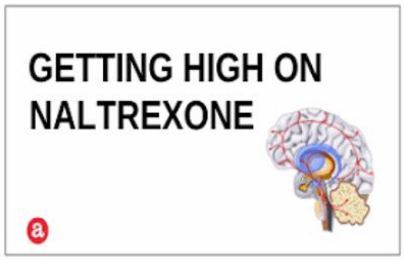
By 1995, Trexan® sales were approximately $5-8 million annually, which represented approximately 15-25,000 patients per year, or less than 5% of the estimated number of heroin addicts (Scrip 1993).

Naltexone as a Treatment for Alcoholism

Dr. Joseph Volpicelli first recognized naltrexone's potential to treat alcoholism while experimenting with rats as a graduate student in University of Pennsylvania. In 1981, he began to publish his findings.

In 1985, Volpicelli and Dr. Charles O'Brien, a professor at Penn and chief of psychiatry at Philadelphia's Veterans Administration Center, began a naltrexone study using volunteers at the Veterans Administration Hospital.

"We did it without any outside funding," says O'Brien. "We got it started against pretty great odds." According to O'Brien, the researchers had difficulty recruiting subjects because the idea of treating alcoholism with medication was not commonly accepted in the 1980's.



They tracked 70 men for 12 weeks in an outpatient detox program. Half received naltrexone, half a placebo. While 54% of the volunteers who received a placebo reverted to drinking, only 23% of those who took naltrexone experienced a relapse.

In 1991, researchers at Yale University School of Medicine tested the effects of

naltrexone in conjunction with psychological therapy in 104 alcohol-dependent men and women. Patients who took naltrexone were nearly twice as successful in their clinical outcomes as those who took a placebo.

After the Penn and Yale studies were published in the Archives of General Psychiatry in November 1992, DuPont showed interest in marketing naltrexone specifically as an alcoholism treatment.

Governmental funding for the development of naltrexone as a therapy for alcoholism was provided by the National Institute on Alcohol Abuse and Alcoholism.
The FDA modified existing regulatory requirements to encourage DuPont to develop naltrexone as an alcoholism therapy. They offered DuPont three additional years of post-approval market exclusivity for naltrexone as an alcohol therapy.

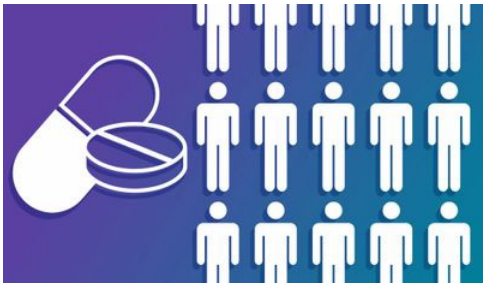
Marketing exclusivity allows a pharmaceutical company to sell its drug for a certain length of time free of competition from generic versions of the drug. This type of marketing exclusivity is often granted to encourage pharmaceutical companies to develop a use for a drug whose patent has expired or to encourage a company to develop an already approved drug for a new use. With market exclusivity, the expected returns are higher, thus improving the profitability of the drug.

The FDA also linked phase IV clinical trial requirements to annual sales. No phase IV trials would be required if naltrexone as an alcoholism therapy did not meet certain sales thresholds. If the drug did well in the alcohol-abuse market, DuPont would have to conduct phase IV trials based on the level of sales.

By allowing for flexible phase IV studies, the federal government lowered post-marketing costs, improved profitability projections, and made investment in naltrexone as an alcoholism therapy more attractive to DuPont.

Clinical Trials

Clinical trials for naltrexone as an alcoholism therapy encountered familiar problems -- difficulties with patient recruitment and compliance, high cost of clinical support services, and low funding of treatment centers.



Because researchers had difficulty recruiting patients, they accepted all patients who agreed to participate, and didn't reject any unsuitable patients. This may have negatively affected the results of the clinical trials by including a high proportion of high-risk patients, who may have been motivated more by payment for participating in the

trial than a desire for treatment, which led to poorer compliance and higher drop-out rates (Schecter 1980).

The study found that naltrexone as an alcoholism therapy did not perform significantly better than a placebo unless it was administered as part of a comprehensive, multidisciplinary treatment program (O'Malley 1995).

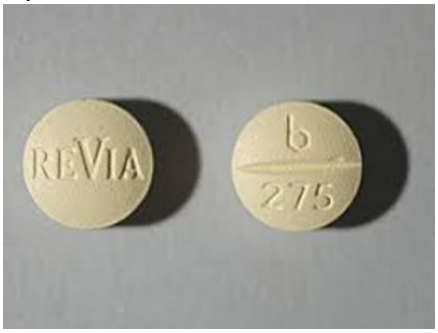
Although the government funded and supported the clinical trials, the funding fell short of the amount necessary to provide the necessary intensive psychosocial support. As a result, the labeling for ReVia® (the brand-name eventually chosen by DuPont) includes the following stipulation, "ReVia® should be considered as only one of many factors determining the success of treatment of alcoholism." Understandably, this labeling had a profoundly negative effect on marketing strategy and sales.
In 1995, the FDA approved naltrexone in a 50mg dose as a treatment for alcohol abuse.

The FDA surprised the researchers by authorizing naltrexone's use in alcoholism treatment in just six months. According to Volpicelli, the FDA was "pretty confident" that the drug was safe: It had been researched for 20 years and was on the market for 10 as a treatment for heroin addiction.

At this point, Dupont changed the brand name from Trexan® to ReVia.

Marketing Strategy for ReVia®

Because the alcohol treatment system is less regulated than the heroin treatment system, DuPont had more flexibility in marketing ReVia® directly to clinics and treatment providers. Despite ReVia's clinical effectiveness and less restrictive distribution channels, however, DuPont's sales force encountered marketing problems.



Like Trexan, ReVia® is most successful in highly motivated patients who have a strong psychosocial support and access to counseling services.

DuPont was not successful in selling ReVia, except in comprehensive alcohol treatment programs such as VA hospitals and "white collar" treatment centers. These patients tended to be more highly motivated and have a stronger support network. ReVia® became the treatment of choice for more upscale patients, such as physicians, nurses, pharmacists and attorneys (O'Brien).

Another roadblock to naltrexone's wider acceptance was insurance regulations. "Insurance companies often don't allow naltrexone to be prescribed by a primary care physician," said Tania Graves, spokeswoman for the Arizona Medical Association. "Their point of view is that drug or addiction problems should be sent to a specialist." Some insurance companies do not accept naltrexone at all. For example, a chain of California treatment centers using naltrexone as the primary treatment had to suspend operations after only six months, citing managed care companies' unwillingness to cover the treatment (Behavioral Health Treatment 1996).

Some physicians were reluctant to prescribe naltrexone due to the "black box" warning of liver toxicity in the package insert. The warning was included based on liver enzyme elevations reported with the100 - 300 mg/day dose (the recommended dose is 50mg) that was given during a study of naltrexone treatment for obesity.

A review of literature and adverse effect reports from Dupont demonstrates that a 50 mg/day dose poses no risk for liver damage, but the warning remains (Galloway).

From the American Council on Alcoholism website, 2005

"Many physicians and non-physicians in treatment programs are unaware of the usefulness of naltrexone or how to use it. In other areas of medicine, it is highly probable tht the development of such an efficacious medication would prompt physicians to use it readily. The biggest obstacle to using naltrexone for the treatment of alcoholism is the 'pharmacophobia' of many alcoholism-treatment professionals. This near-hysterical resistance to medication for treating alcoholism (or other substance-abuse disorders) has deep and tangled roots. Many recovering professionals learned in their recoveries that MDs and their prescription pads were evil purveyors of pharmacological lies and temptations. This attitude is often accompanied by a deeply rooted and strongly held belief that recovery has only one successful formula (usually the 12-step program) and that any modification to that approach is unethical."

Scientific evidence is irrelevant to these individuals. They believe they have the 'truth' about recovery and don't want to be bothered with other points of view.
[http://www.aca-usa.org/pharm2. htm]

Insufficient Sales for Big Pharma

Poor Sales Performance

DuPont never expected either Trexan® or ReVia® to become major revenue generators, but sales fell far short of even DuPont's modest expectations. In 1994, just prior to the launch of ReVia, Trexan® sales were approximately $5-8 million annually, which represented approximately 15-25,000 patients per year, or less than 5% of the estimated number of heroin addicts in the US (Scrip 1993).

When ReVia® was launched in January 1995, DuPont expected US sales of ReVia® to rise to $15-25 million annually. As of October 1996, however, ReVia® had not even reached the FDA's threshold of the 200,000 prescriptions required to trigger phase IV clinical trials (Pink Sheet 1996).

In 1997, ReVia's market exclusivity agreement lapsed. Other companies were now free to manufacture and market generic naltrexone. In May 1998, the first generic version of ReVia® was produced by Barr Laboratories in Pomona NY. At this time, ReVia® had annual sales of approximately $20 million.

In 2001, Bristol Myers Squibb acquired DuPont Pharmaceuticals. In April 2002, Bristol Myers Squibb sold the ReVia® brand-name rights in the U.S. and Canada to Barr Laboratories, which manufactures ReVia® in 50mg pills in the U.S and Canada. Bristol Myers Squibb continues to market ReVia® in countries outside of the U.S. and Canada.

Other versions of naltrexone are currently manufactured in the U.S. by Eon Labs and Amide Pharmaceutical; Mallinckrodt Pharmaceuticals manufactures 50mg and 100mg naltrexone pills in the U.S. under the trade name Depade.

Other 50mg versions of naltrexone are named Nalorex (manufactured by Bristol-Myers Squibb in the UK); Nodict (manufactured by Sun Pharma in India); Naltima (manufactured by INTAS in India), Narpan (by Duopharma in Malaysia), Antaxone (by Pharmazam in Spain), Celupan (by Lacer in Spain), Narcoral (by Siton in Italy), Nemexin (Bristol Myers Squibb in Germany), as well as Revez, Naltrexona, and Naltrexonum.

The Future of Naltrexone

Researchers continue to explore the potential of naltrexone as a drug and alcohol therapy.

Attempts to address compliance issues have resulted in the introduction of a ReVia® implant (2003). In 2005, Alkermes, Inc. developed Vivitrol, a naltrexone injection which lasts a month. It gained FDA approval and launched the product in 2006.

Over the years, researchers have tested naltrexone for a wide variety of medical conditions, including obesity, schizophrenia, and chronic obstructive pulmonary disease. In March 2005, Yale researchers began investigating the use of the naltrexone to help men and women quit smoking without gaining weight.

In 1986, the FDA awarded orphan drug status to naltrexone to treat symptoms of childhood autism. Another orphan grant has been issued to naltrexone as a therapy for self-injurious behaviors. (Naltrexone therapy for self-injurious behavior is already used extensively in veterinary medicine.)

In addition, researchers have used derivatives of naltrexone to treat other conditions. For example, the FDA granted orphan drug status to methyl-naltrexone as a drug that blocks the side effects of morphine without interfering with pain relief in cancer treatment. (Oncology 1996).

While *Alkermes* enjoyed their limelight and exclusivity from 2006 to the present as the second generation preparation of naltrexone, *BioCorRx*'s potentially now stands as the most effective and cost reasonable "next-gen" version of the evolution of naltrexone.

Appendix B

Georgia Telehealth Law

GA Dept. of Community Health, Physician Services Manual,(Jul. 1, 2019) .

Hidden Creek Recovery proposes to explore incorporating certain telehealth capabilities ancillary to BioCorRx's telemed support, as well as other providers that can operate remotely, in a two-way televised or broadcast Zoom meeting.

Georgia Medicaid reimburses for live video under some circumstances.

Telemedicine is the use of medical information exchange from one site to another via electronic communications to improve patient's health status. It is the use of two-way, real time interactive communication equipment to exchange the patient information from one site to another via an electronic communication system. This includes audio and video communications equipment. Closely associated with telemedicine is the term "telehealth," which is often used to encompass a broader definition of remote healthcare that does not always involve clinical services.

Telehealth is the use of telecommunications technologies for clinical care (telemedicine), patient teachings and home health, health professional education (distance learning), administrative and program planning, and other diverse aspects of a health care delivery system.

Telehealth is a broad definition of remote healthcare that does not always involve clinical services. Telehealth can be used in telecommunications technologies for patient education, home health, professional health education and training, administrative and program planning, and other diverse aspects of a health care delivery system.

Telemedicine Involves the use of two-way, real time interactive communication equipment to exchange medical/clinical information between a healthcare practitioner and the member from one site to another via a secure electronic communication system. This includes audio and video communications equipment designed to facilitate delivery of healthcare services in a face-to-face interactive, though distant, engagement.

TeleMental Health is a term defined by Ga. Comp. R. & Regs. R. 135-11-01. and is applicable only to Licensed Social Workers, Professional Counselors and Marriage & Family Therapists when either

1) practicing telemedicine as defined above, or

2) providing telephonic intervention when allowable via DCH/DBHDD guidelines). Per this rule and regulation, there are specific practice guidelines and mandatory training pertaining to what is identified as TeleMental Health. Providers shall adhere to these

rules and regulations when TeleMental Health is provided by one of these named practitioners.

An interactive telecommunications system is required as a condition of payment. The originating site's system, at a minimum, must have the capability of allowing the distant site provider to visually examine the patient's entire body including body orifices (such as ear canals, nose and throat). The distant site provider should also have the capability to hear heart tones and lung sounds clearly (using a stethoscope) if medically necessary and currently within the provider's scope of practice. The telecommunication system must be secure and adequate to protect the confidentiality and integrity of the information transmitted.

The service must be medically necessary and the procedure individualized, specific, and consistent with symptoms or confirmed diagnosis of an illness or injury under treatment, and not in excess of the member's needs.
See telemedicine manual for list of eligible telemedicine services and codes.

<u>Non-Covered Services:</u>

1. Telephone conversations.
2. Electronic mail messages.
3. Facsimile.
4. Services rendered via a webcam or internet based technologies (i.e., Skype, Tango, etc.) that are not part of a secured network and do not meet HIPAA encryption compliance.
5. Video cell phone interactions.
6. The cost of telemedicine equipment and transmission.
7. Store-and-forward transactions
8. Failed or unsuccessful transmissions.