INSIDE: Balancing Treatment & Punishment • Lawyers At Risk • Medical Marijuana • "Orphan Disease" Challenges

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DRUGS

Crime
Addiction
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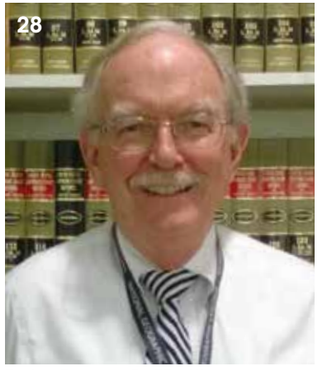

Judge Jerome O. Herlihy

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EDITORS' NOTE

Gregory A. Inskip & Gregory W. Werkheiser

When it comes to the role of drugs (both legal and illegal) in our society, Delawareans can be forgiven for believing that this tumultuous era is unlike nothing the First State has ever seen. The exceptional collection of articles in this issue certainly reinforces such a notion:

• Our first article, co-authored by Kathleen Jennings and Brian Robertson of the Delaware Department of Justice, is a hard-hitting look at Delaware's current drug crisis, emphasizing changes being been made to Delaware's criminal justice system to more effectively deploy the State's resources to address this ongoing problem.

• This issue's second article, authored by Catherine Devaney McKay, Steven T. Davis and Adam Taylor of the Connections Community Support Program, Inc., enlightens us as to, among other things, the extraordinary steps that one leading alcohol and drug treatment provider is taking to help Delawareans who are among those most at risk of the scourge of opioid addiction.

• Our third article, authored by R. Judson Scaggs, Jr., Chair of the Lawyers Assistance Committee of the Delaware Lawyers Assistance Program, delves into the toxic brew of stress and competition that makes lawyers particularly vulnerable to addiction and provides an overview of the resources and support the organization provides.

• Next, Mark Lally, the man at the helm of Delaware's first medical marijuana dispensary, discusses the special challenges associated with getting such an enterprise up and running.

• Our fifth feature, authored by Christopher Moen, M.D., explores the hurdles to research and development of new pharmaceutical treatments for "orphan diseases" – conditions with a patient population too small to garner attention and investment by big pharma. Dr. Moen speaks with unique resonance, as both a person afflicted with an orphan disease and a physician on the frontline of efforts to develop treatments for it.

• Finally, we close with a profile of the Honorable Jerome O. Herlihy, who, after serving two full terms as a Judge on Delaware's Superior Court, has taken on the challenge of presiding over the New Castle County Drug Diversion Court.

These are indeed unsettled times for Delaware. Yet, it occurs to us that we have been through such upheaval before and have emerged stronger for it. For example, some digging through newspaper archives led us an article declaring that the "universal problem" of narcotic drug addiction "has become acute in America through the spread of heroin addiction." Another article warns ominously that "[t]he world traffic in narcotics is a grave menace to civilization …." A third article laments: "The United States is in the grips of one of the worst heroin epidemics in its history …." Two of these statements were published in 1924 and 1931, respectively; the third appeared in a Delaware newspaper in 2014.

We take reassurance from these quotes. These may be trying times for drug policy. But drugs did not bring us to an end in 1924 or 1931, and we expect that Delaware and the nation will successfully navigate its current challenges.

Gregory A. Inskip

Gregory W. Werkheiser

Steven T. Davis

has served as General Counsel of Connections Community Support Programs, Inc., since January 2009, handling all legal affairs for the organization. Prior to joining Connections, he was in private practice for 20 years, most recently with the firm of Obermayer Rebmann Maxwell & Hippel, LLP. Mr. Davis' areas of responsibility include human resources, contract negotiation and review, real estate transactions, litigation and insurance. He also serves as Connections' Privacy Officer. Mr. Davis received his J.D. from The Delaware Law School and his B.A. in International Relations from Ursinus College.

Kathleen M. Jennings

is the State Prosecutor for the Delaware Department of Justice, responsible for overseeing all criminal prosecutions throughout the State. She received her B.A. from the University of Delaware and her J.D. from Villanova University School of Law. After law school, Ms. Jennings worked as a Deputy Attorney General for 16 years in the Criminal Division of the Delaware Department of Justice. During that time, she prosecuted a full range of cases, from misdemeanors to homicides, and she supervised the Rape, Felony Screening and Trial Units. Among her more than 100 jury trials, Ms. Jennings successfully prosecuted serial killer Steven Pennell, introducing DNA evidence for the first time in a criminal trial in the State of Delaware. She also served as Chief Deputy Attorney General under Attorney General Charles Oberly. In 1995, Ms. Jennings and Mr. Oberly established a private legal practice in Wilmington, where she handled criminal defense, white collar, regulatory and civil litigation. In November 2011, Ms. Jennings was appointed State Prosecutor for the Delaware Department of Justice by Attorney General Beau Biden. Ms. Jennings is a member of the American College of Trial Lawyers.

Mark S. Lally

is the president and chief executive officer of The First State Compassion Center. Mr. Lally had a distinguished 24-year career in law enforcement with the Delaware State Police, retiring as a decorated Trooper with a Medal of Valor and a Superintendent Citation for Acts of Heroism. During his law enforcement career, Mr. Lally received DEA training in drug detection and investigative measures, served as an instructor at the Delaware State Police Academy and acted as an undercover detective in the Special Investigations Unit. After retiring, he served more than six years as the Sussex County Regional Director for U.S. Senator Thomas R. Carper and founded M.S. Lally & Associates, a governmental affairs and consulting business.

Catherine Devaney McKay

is the chief executive officer of Connections Community Support Programs, Inc. With approximately 1,300 employees, Connections serves more than 30,000 Delawareans annually, providing healthcare, employment and housing opportunities. Before founding Connections in 1986, Ms. McKay worked as a substance abuse counselor, as the director of program development for Big Brothers/Big Sisters of America and as the executive director of CONTACT Delaware. She has a Master's in counseling and a certificate in nonprofit management from the University of Delaware. Ms. McKay was president of the Delaware Homeless Planning Council, the Delaware Association of Rehabilitation Facilities and the Delaware Mental Health Counselors Association. She was appointed by Delaware Governor Ruth Ann Minner as chair of the Delaware Interagency Council on Homelessness, serving from 2005 until 2010. She is the recipient of the Agenda for Delaware Women's Trailblazer Award, and was inducted into the Hall of Fame of Delaware Women in 2014.

Christopher Moen, MD

is an Emergency Medicine board-certified physician in the Christiana Care Health System in Newark, Delaware. Following his graduation from the Pennsylvania State University College of Medicine in 2002, Dr. Moen received his residency training in emergency medicine at Christiana Care. Throughout his career, Dr. Moen has been involved with Choroideremia research. He has worked with the Choroideremia Research Foundation (CRF) since 2007, serving on its board of directors and science advisory board. Dr. Moen is currently president of the CRF.

Brian J. Robertson

is a Deputy Attorney General with the Criminal Division of the Delaware Department of Justice, presently assigned to the Homicide Unit. A former Unit Head for the Drug Unit and the Wilmington Felony Trial Unit, Mr. Robertson was part of the advisory committee to craft the 2011 revisions to Delaware's drug statutes. Mr. Robertson is a graduate of the Pennsylvania State University and Widener University School of Law.

R. Judson (R.J.) Scaggs, Jr.

is a partner at Morris, Nichols, Arsht & Tunnell LLP, where he is a member of the Corporate and Business Litigation Group. During his 25 years at the firm, he has concentrated on the litigation of corporate law issues and business disputes. Mr. Scaggs is chairman of the Delaware State Bar Association's Lawyer Assistance Committee, which assists Delaware lawyers affected by substance abuse, mental illness or other life issues. He earned a B.A. from Washington and Lee University and law degree from the College of William and Mary. He has been married over 30 years to his loving wife, Colette, and has three daughters.

Adam Taylor

is the public information officer at Connections Community Support Programs, Inc. Before that, he was an award-winning newspaper reporter for 28 years — from 1987 to 2000 at the *Delaware County Daily Times* in suburban Philadelphia and from 2000 to 2014 at *The News Journal*. While mostly a government-watchdog reporter, he spent much of last year writing stories about heroin's resurgence in Delaware. At the Delco Times, he wrote about young people in recovery and called on local rehabilitation centers to broaden their treatment curriculums. Mr. Taylor is a 1985 graduate of Boston University, earning a Bachelor of Science degree in mass communication. He is also a person in long-term recovery from addiction to heroin and prescription opiates.

Kathleen M. Jennings,
State Prosecutor
Brian J. Robertson,
Deputy Attorney General

Crime and Drugs: A Path Forward

Photo by Bob Craig

With drug abuse still pervasive, shifting approaches to enforcement, penalties, incarceration and treatment give hope for safer communities.

The illegal distribution of controlled substances is one of the most pervasive and persistent problems our State is facing. Drug dealers ensure a steady supply of dangerous drugs, frequently arming themselves and employing violence to further their trade. At the other end of the spectrum, drug consumers often point to a seminal hit of heroin, cocaine or pain medication as a choice that led to a lifelong struggle with addiction. Addicts report having started on pain medication only to end up on the cheaper but deadly drug, heroin, spawning an epidemic that has spiraled out of control.[1]

Heroin addiction crosses all geographic, racial and economic lines. Caught in the middle are residents in the poorest neighborhoods in Delaware, who face the challenge of raising families in an environment where addicts, dealers and their accompanying violence are everyday features. Also caught in the middle are grief-stricken family members of people who have lost their lives to this disease.

Delaware's Vulnerability to Illegal Drugs and Drug Crime

Delaware's location in the Mid-Atlantic region leaves the state particularly susceptible to the drug trade. Personal vehicles, passenger trains and commercial ships have all contributed to the illegal drug market in the First State. Although heroin is a statewide crisis, the hub of Delaware's drug trade lies in the poorer neighborhoods in the City of Wilmington. Interstate 95 bisects City neighborhoods. Open-air drug markets thrive in close proximity to I-95 exit ramps.

Easy accessibility and steady supply provided by these markets have made Wilmington a "source city" for smaller communities, with drug buyers traveling from downstate Delaware, southeastern Pennsylvania and the eastern shore of Maryland.

Drug markets — where the competition for customers dictates the possession of and, all too frequently, the use of firearms — are often the situs for violence. On a hot early summer evening in July of 2013, a five-year-old girl walked outside her house to retrieve her scooter. She was shot near a drug corner, when a drug dealer opened fire on another dealer following an argument.

This relationship between the drug trade and violence is profoundly disturbing. Drug dealers often carry firearms.[2] They carry them for many reasons. They carry either to protect themselves against rival drug gangs or to take over territory. They carry to protect themselves against other criminals who rob them for their drugs and money.

Exacerbating this problem is the reality that often those individuals carrying firearms report having been under the influence of illicit drugs at the time of their arrest, creating an even greater chance that violence will erupt.

The Statutory Basis for Delaware Law Enforcement Against Dangerous Drugs

It is against these formidable challenges that Delaware police and prosecutors employ the tools available under the Delaware Uniform Controlled Substances Act.[3] Frequently referenced by practitioners as "Title 16," on account of its location in Chapter 47 of the Delaware Code, the Delaware Uniform Controlled Substances Act was adopted from the federal Controlled Substances Act.

The federal law and its myriad state law doppelgangers designate a ranking system for controlled substances. Classified as Schedules I, II, III, IV and V, the rankings consider a controlled substance's relative potential for abuse, whether the substance has an accepted medical use in the United States, and the potential that abuse could lead to physical or psychological dependence.

Designations vary from those that represent a reduced concern, such as Alprazolam (commonly traded as Xanax) at Schedule IV, to the highest level at Schedule I, which includes heroin. Substances may be added, deleted or rescheduled as their exposure and effects become more widely known.

One of the recent additions to Delaware's list of banned Schedule 1 substances is synthetic cathinone. Prompted by alarming reports from emergency rooms and, in particular, tragic confrontations involving those having ingested the drug, a 2011 amendment prohibits the possession of certain synthetic cathinones, which are more commonly referred to by the street name of "bath salts."

Title 16 designates schedule classifications for hundreds of substances, isomers, salts and derivatives; however, the vast majority of the drugs distributed through the illicit markets involve a fraction of these controlled substances. Opiates (including heroin), cocaine base and crack cocaine, marijuana and, to a lesser extent, methamphetamine, constitute the bulk of the street drug trade.

The statute scales offenses, depending on whether the prohibited conduct reflects an intent to distribute the drug to others or whether the conduct suggests that individual consumption of the drug is the intended result. Distribution of the drug is treated differently from personal use.

Statutory Amendments in 2011 Reduce Harsh Sentences

In response to concerns about lengthy prison sentences for individuals convicted of certain drug offenses, in 2011 the Delaware General Assembly enacted sweeping changes to the state's drug laws The new Title 16 adopted a matrix-style system to replace the former system, which would often yield multiple drug charges for one possessory act. The changes also either reduced or eliminated minimum mandatory sentences for drug crimes committed without a weapon.

Delaware's drug law prior to the 2011 amendments included a hodgepodge of criminal offenses that had been added to Title 16 in the previous decades. Protected zones were established for proximity to schools, churches and parks. The use of a vehicle or building for keeping or delivering controlled substances constituted a separate offense. The charge of Trafficking was also enacted for possessing a threshold weight for several of the frequently distributed controlled substances.

The collection of offenses resulted in scenarios in which a person could be charged with as many as four drug felonies for a single possessory offense: an offender arrested in a car, in a park in possession of half an ounce of cocaine could expect felony charges for Trafficking in Cocaine, Possession with Intent to Deliver Cocaine, Maintaining a Vehicle for Delivering Controlled Substances and Possession of a Controlled Substance within 300 feet of a Park. Moreover, the numerous options often created felony-level offenses out of what would otherwise be misdemeanor conduct: while a person with a gram of cocaine might reasonably expect to be charged with mere possession, that same gram of cocaine would become a felony offense if the person came within 300 feet of parkland. Clearly, reform was needed.

The amendments to Delaware's Title 16 eliminated the former charging system in favor of charging one of three main drug crimes: Drug Dealing, Aggravated Possession or Possession. Drug Dealing addresses delivery or possession with intent to deliver a controlled substance. Aggravated Possession recognizes that possession of larger amounts of heroin, cocaine, marijuana and other drugs is, at a high threshold, no longer consistent with personal use. Possession of a Controlled Substance, or, *simple possession* as it is commonly described, covers smaller amounts of controlled substances without an intent to distribute and is a misdemeanor-level offense.

The new matrix also incorporates some of the considerations from the former Title 16, such as offenses occurring in proximity to a school. One significant difference is that these violations are no longer stand-alone felony offenses but instead constitute aggravators that enhance the main drug charge. For the earlier example of the offender with a half an ounce of cocaine, the same conduct that prior to 2011 resulted in four felony charges would now constitute a single felony offense, with the aggravators serving to elevate the single felony classification.

Significantly, the revisions to Delaware's drug law dramatically curbed minimum mandatory sentences. Under the former law, all Trafficking convictions resulted in minimum mandatory incarceration. In addition, for persons having been convicted of distribution

crimes, a subsequent conviction for Possession with Intent to Deliver also required a minimum mandatory sentence. For a repeat offender in possession of trafficking-volume drugs, conviction on those two offenses often brought the prospect of a decade or more of minimum mandatory incarceration.

Presently, the highest minimum mandatory provision under Title 16 is two years. While the judge may order the offender to serve in excess of the minimum mandatory provision, gone are the provisions that mandate lengthy sentences based exclusively on the amount of drugs, without regard to the surrounding circumstances or the offender's history.

At the other end of the spectrum, simple possession of marijuana is the lowest level offense, an unclassified misdemeanor, carrying the potential of imprisonment of not more than three months and a fine not to exceed $575. The General Assembly is considering a bill to "decriminalize the possession or private use of a personal quantity of marijuana."[4]

Less Incarceration, More Treatment for Personal-Use Possessors

One of the most persistent of the myths regarding the criminal justice system is the belief that a significant portion of the incarcerated population is there for simple possession of marijuana. A recent analysis of 2013 misdemeanor marijuana possession cases by the Statistical Analysis Center of the Criminal Justice Council ("SAC") determined that out of more than 2,000 marijuana cases, only nine resulted in the Court ordering that the defendant be incarcerated; further, seven of the nine cases involved accompanying more serious offenses, while the remaining two defendants had additional reasons for their detention and were released after a day of time-served.[5] The SAC concluded that none of the 2,334 cases reviewed could be legitimately said to have resulted in incarceration for "simple possession."

For personal-use possessors of controlled substances, Delaware criminal courts and practitioners increasingly look toward treatment as the preferred course rather than criminal sanctions. Drug Diversion Courts have been in place for years in both Delaware Superior Court and the Court of Common Pleas. For defendants with pronounced addiction, these programs defer adjudication of the underlying drug offense while the defendant undergoes treatment.

> Police and prosecutors must focus resources on the network of larger-scale dealers and those in the drug trade who resort to violence.

The treatment regimen typically lasts several months and is supervised by the Court, with regular in-court sessions requiring the appearance of the defendant. New criminal offenses or a violation of the conditions of treatment can result in termination; however, a successful participant will avoid a criminal conviction.

In the new legislative session, Attorney General Matt Denn, among other initiatives, will be offering a bill to remove lower-level drug crimes from the designation of violent felonies for which habitual offender status attaches.

Meanwhile, Governor Jack Markell has proposed that additional resources be devoted to increasing the State's capacity for drug treatment. The Attorney General has proposed that $3 million be allocated from bank settlement funds over three years for drug treatment. These treatment dollars are essential to provide the means for addicts to pull themselves out of the depths of addiction. They are also essential to lowering the crime rate because addicts often resort to theft, burglary and other property crimes to acquire funds to feed their addiction.

Law Enforcement Focuses on the Worst Offenders

Police and prosecutors must focus resources on the network of larger-scale dealers and those in the drug trade who resort to violence. To this end, Delaware was recently added to a regional designation as a High-Intensity Drug Trafficking Area, by the federal government. This designation brings much-needed federal resources and a unified law enforcement concentration on large-scale drug investigations.

United States Attorney Charles Oberly and others in his office worked hard to obtain this designation. Also, thanks in large measure to the efforts of United States Senator Chris Coons, Wilmington has been designated as one of five cities in the country to receive federal assistance through the Violence Reduction Network.

Our office works closely with all of law enforcement on these two important initiatives. These efforts have led to the creation of programs aimed directly at crime reduction, such as GUNSTAT, as well as others.

In summary, the criminal justice system must strike the appropriate balance between incarceration and treatment. Simply put, we must be smarter at helping those who strive to pull themselves out of addiction and crime and focus our resources on identifying and incarcerating those who destroy lives and the communities in which we live. ◆

FOOTNOTES

1. Adam Taylor, *Heroin in Delaware: Cheap, pure, plentiful*, The News Journal (June 14, 2014), http://www.delawareonline.com/longform/news/local/heroindelaware/2014/06/14/delaware-heroin-problems/10468289/.

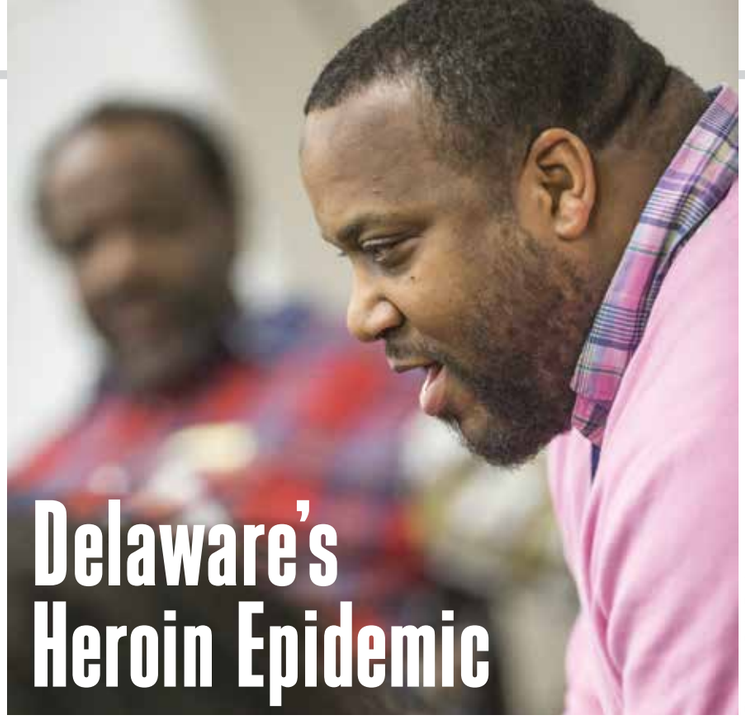
2. Paula Wulff, *Drug-Linked Firearms Cases: A Primer for Prosecution*, American Prosecutors Research Institute (May 2005), http://www.ndaa.org/pdf/drug_linked_firearms_cases_05.pdf

3. Del. Code Ann. tit. 16. §§4701 – 4798.

4. H.B. 39 148th General Assembly (2015).

5. *Delaware Criminal Justice System: Myths or Realities?*, Statistical Analysis Center (Nov. 2014) (copy on file with authors).

Catherine Devaney McKay,
Steven T. Davis and Adam Taylor
Connections Community Support Programs, Inc.



Grandville Brown (foreground), a re-entry services specialist, and Doug Hamilton, a peer support specialist at the Hope Commission.

Photo by Bob Craig

Confronting Delaware's Heroin Epidemic

In-prison treatment, methadone maintenance and providing post-release support and counseling can reduce recidivism and discourage a return to addiction.

The U.S. Center for Disease Control has called the current explosion in heroin use the worst drug addiction epidemic in United States history. Delaware is being hit hard. Overdose deaths in Delaware from all drugs, including alcohol, have jumped from 12 to 15 a month – a 25 percent increase – in the last two years. That's a death every other day. State officials say the driving force behind the spike in fatalities is the increased use of pure and inexpensive heroin that has flooded communities in every corner of the state.

While the tragic deaths have been well chronicled, less has been written about what happens to the addicts who survive.

As one of the largest outpatient drug and alcohol treatment providers in Delaware, as well as the agency that provides all of the substance abuse treatment in Delaware's statewide unified correctional system, Connections Community Support Programs, Inc., is at the forefront of dealing with Delaware's addiction crisis. We're doing that in both traditional and progressive ways. We're doing it in our programs behind the prison walls and in our community clinics in all three counties. And we're beginning to connect the two.

Epidemic Abuse of Prescription Opioids and Heroin

The latest heroin resurgence was born of the prescription drug epidemic of the 2000s.

Last fall, a busload of Delawareans — some of them parents whose children had died from heroin overdoses in the last few years — traveled to Washington, D.C., for a rally at the Washington Monument and a march to the White House, where they called for more access to treatment and a moratorium on new prescription opioid drugs.

When they got there, they were told by top addictions-treatment physicians from Johns Hopkins University that the United States uses 80 percent of the world's prescription opioids, despite having only 5 percent of the world's population. And Delaware has had one of the highest rates of high-dose prescribing of such drugs in the country. In 2010, only Florida, Nevada, Oregon and Tennessee sold more opioids such as Vicodin, Percocet and Oxycontin per 10,000 people, according to the CDC.

When accidents, addiction rates and death counts started to climb from this problem several years ago, Delaware and other states began cracking down on doctors who were operating pill mills. Pharmaceutical companies, which just a few years prior supplied their sales representatives with Oxycontin pens and other feel-good merchandise to help market the drug to physicians, began to alter the makeup of the pills to make them harder for addicts to break up to snort or inject.

These reforms drove the black market prices for prescription opioids sky high. Soon, a single 30-milligram Percocet tablet was sold for $30 on the street. The Mexican drug lords saw a business opportunity and flooded American communities with inexpensive heroin that sells for as little as $3 a bag and does the trick for an addict just as well as a 30-milligram Percocet, at one-tenth of the price.

Meanwhile the U.S. Food and Drug Administration continues to approve new prescription opioids such as Opana, Zohydro and Targiniq. Agencies such as Connections are serving more and more individuals who have become addicted to these legal prescription drugs, using medications that treat addictions in a regulated environment. Our Newark facility recently expanded. We entered into a lease that will double the size of our Millsboro facility and we are looking for a new sites in Dover as well. The only reason we can't serve more people is because we need more space to do so.

Lamont Baker, the manager of Connections' Newark clinic, said many of the clients are young and white, part of the wave of new "opiate naïve" people who didn't know there was very little chemical difference between Percocet, which they viewed as safe, and heroin. They underestimated the former and, to their surprise, became addicted to the latter when their legal supply of Percocet ran out and they became vulnerable to heroin dealers.

Untreated opioid dependence often leads to criminal activity, continued illicit drug use, increased mortality and increased health risks, including hepatitis B and C and HIV/AIDS.

Intake-to-Release Treatment for Opioid Addicts

A Vera Institute of Justice report, issued in February of this year, states that 68 percent of people in America's jails have histories of abusing drugs, alcohol or both.[1] Only a small portion of offenders receive drug abuse treatment while incarcerated or immediately upon release. Research has shown that these offenders, once released from incarceration, are at high risk of relapse to heroin use, criminal behavior, HIV infection and death from overdose.

Comprehensive drug treatment for opioid addicts is particularly important for criminal offenders in Delaware, where there are no local or county jails. On any given day, about 20 percent of the 5,600 people in Delaware's correctional system are pre-trial detainees. These detainees often enter the system addicted and will be in need of a discharge plan quickly upon their release. Many of them will not be sentenced when they are discharged, but will be released on bail, or for time served, or because their charges are dropped.

Those who came into the correctional system with an addiction to opioids are very likely to seek drugs immediately upon release, and their outcomes are almost always poor. Some will overdose because they use heroin or another opioid drug at the same level that they were using before incarceration. Because they no longer have the tolerance for the drug that they had pre-arrest, they take too much. Some of the overdoses will be fatal. Others will almost immediately re-offend in a drug-related crime.

A solution used in some states, which Connections supports, is to start the offenders on a medication that treats addiction while they are incarcerated, and then assist with transportation and a warm handoff to a community provider on the day of discharge.

Connections is one such community provider in Delaware, having offered the synthetic opioid methadone since 2010. In all, the agency treats 4,093 clients at its seven outpatient facilities – three in New Castle County, two in Kent County and two in Sussex County. Most of the clients receive Medicaid, or have no health insurance. About 30 percent of those clients are on Methadone or Suboxone, another synthetic opioid. Demand is soaring for both medications, however.

A 1997 National Institutes of Health Panel concluded that the safety and efficacy of methadone maintenance treatment has been "unequivocally established."[2] Research shows that longer-term methadone maintenance treatment, combined with counseling, is far more effective to treat opioid dependence than short-term detoxification, and it remains the most widely used and demonstrated-effective treatment option.[3] "Methadone maintenance treatment (MMT) has been shown to improve life functioning and decrease heroin use; criminal behavior; drug use practices, such as needle sharing, that increase human immunodeficiency virus (HIV) risk; and HIV infection."[4]

On Rikers Island in New York City, participants in the Key Extended Entry Program (KEEP) are treated with methadone within the prison walls. In 1998, 4,431 inmates, serving time for either a misdemeanor or low-grade felony, received treatment. The average length of stay for KEEP patients was 39 days, and 79% of KEEP patients reported to their assigned programs after release from jail for continued treatment.

After release, criminal recidivism was reduced among 62% of program participants. Among released participants who receive Medicaid, recidivism was reduced by 100%.[5] The success of that program has led other prison and jail systems to adopt this approach with positive results for recidivism and health.

Lamont Baker said he's seen success stories at the Connections Newark clinic among clients who are seeking to arrest their addictions. "Most people come in not because they want to stop getting high, but because they want to stop feeling sick," he said. "It's our job to offer them an integrated treatment approach to start the actual recovery

process. Today, we have dozens of clients who have a better life, developing coping skills and maintaining jobs and healthy relationships."

Although there is strong evidence supporting the effectiveness of medications in reducing drug use and criminal activity, many people in the general population and among law enforcement personnel are philosophically opposed to using medications for addiction treatment. However, recent research clearly shows the efficacy of medication-assisted treatment for addiction in terms of helping the offender, reducing turmoil in the correctional facility itself and reducing addiction-driven crime in the wider society.

Photo by Bob Craig

Two members of a support group hug after a recent session.

It has been argued that MMT is essential healthcare for addicted offenders, access to which is a constitutional right. Opioid dependence is a serious medical condition with immediate and future risks. To deny previously prescribed methadone, whether by imposing detoxification or abrupt withdrawal, could be construed as constituting deliberate indifference to serious medical needs, in violation of the Eighth Amendment's prohibition of cruel and unusual punishment.[6] In March a nurse who is addicted to opioids filed a federal action to compel Kentucky's court system to permit her to undergo MMT while she is released on bond.[7]

Community Support for Prisoners After Release

Connections has been the provider for behavioral health care — mental health and addictions treatment services — in Delaware's jails and prisons for nearly three years. The agency has also been the provider for primary medical care since last July.

Coordinating those two was important. The next step has been to begin to provide comprehensive discharge plans for people after they leave jail or prison. The comprehensive discharge plans are taking place now. There is no better example of how they can work than the case of a 35-year-old inmate who was first released from prison in 2013, after serving 13 years for an attempted murder charge.

The former inmate didn't do well in a community program for high-needs former offenders. He was evicted from an apartment, began to abuse alcohol and drugs – including heroin – and was eventually homeless.

He missed meetings with his probation officer and wound up back in jail. In February, however, a judge crafted a detailed discharge plan that will allow him to return to the community with more services provided to him.

The court order requires the man to live in housing provided by Connections. He also must receive medical and psychiatric evaluations, receive a drug and alcohol assessment and receive job-training services from the agency.

Dr. Robin Timme, Connections' Vice President for Correctional Healthcare, said the man has a far better chance for success with his current aftercare plan than he did the last time.

"The ball is in his court to make the right decisions," Timme said. "It's difficult to make the right decisions when you have little support. You're going to make different decisions if you don't have a roof over your head than if you do."

Grandville Brown, a re-entry services specialist and a former offender himself, has been working with the recently released inmate. He says he's doing well so far.

"He's really optimistic right now and grateful that a lot of these services have been put in place," Brown said. "He's really sees the difference in this transition from the first time, when they were not available."

Intervention For Pregnant Addicted Women

Four recently released inmates that we treated while they were serving their sentences are now entering our community treatment programs after they leave. They are residents at New Expectations, a program at a house in Newark for justice-involved pregnant women who are addicted to opioid drugs, which include not only heroin but also prescription painkillers.

Before New Expectations opened, Delaware judges were in a difficult position. They would see pregnant women in their courtrooms who had committed relatively petty crimes, such as violations of probation. Many of these crimes were related to continued drug use, an offense that worried some judges because of the risk such use posed to the offenders' unborn children.

Judges often found themselves committing pregnant women to the highest level of incarceration at the Baylor Women's Correctional Institution because there was no other way to protect the baby. Women are taken from prison to go to a local hospital to deliver their babies. Sometimes the babies go to relatives, other times they go a foster home. In extreme cases, a mother's parental rights can be terminated by the state.

New Expectations tries to avoid these outcomes, which studies have showed harm the mother and the child. Judges can now place women at New Expectations while they are pregnant, and they can stay there for as long as six months after their babies are born. The women attend Connections' outpatient clinic on Polly Drummond Hill Road for four hours each day during the week, so they are in an intensive outpatient rehabilitation setting. Residing at the home is like being in a sober living house, where people in early recovery support each other.

The house is staffed around the clock. The women get medical and dental care, job training, parenting education, financial literacy education, breast-feeding and nutrition classes, as well as yoga and other wellness-oriented sessions. The staff also makes sure the women are signed up for any public assistance programs the women are eligible for before they leave the house. A case manager dedicated to the program helps women identify the financial and other resources they need to establish a permanent home for themselves, their new baby and any other children they have.

"This is a vulnerable population. In the traditional community setting, it's hard to give them comprehensive services because of transportation issues," New Expectations' Director of Re-entry Services Jill Walters said. "Here, we either have the services come to the house or we provide the transportation they need."

New Castle County Police Chief Elmer Setting says he is happy about the series of changes within the Department of Correction and in community treatment. Setting, who became chief in November 2012, in many ways began Delaware's public conversation about heroin. He changed his police operations to target traffickers and successfully lobbied his boss for $500,000 for an opioid awareness and prevention campaign.

Setting said he soon realized after becoming chief that most of the shootings and property crimes his department was dealing with were related to the heroin epidemic.

"Yet the prisons and the evidence lockers are full," he said. "Why? Because we deal with this crisis as if it's only criminal in nature. And we spend all our time and money following that failed model.

"I'm glad to hear that other systems are changing as well. We need to get rid of the stigma, get people into recovery and educate the next generation about how heroin is simply not a recreational drug." ◆

FOOTNOTES

1. Vera Institute of Justice, *Incarceration's Front Door: The Misuse of Jails in America* (Feb. 2015).
2. NIH Nat'l Consensus Dev. Panel on Effective Med. Treatment of Opiate Addition, *Effective Medical Treatment of Opiate Addiction*, 280 JAMA 1936, 1937 (1998).
3. Rebecca Boucher, The Case for Methadone Maintenance Treatment in Prisons, 27 Vt. L. Rev. 453, 456 (2003).
4. Karen L. Sees, *et al.*, *Methadone Maintenance vs. 180-Day Psychosocially Enriched Detoxification for Treatment of Opioid Dependence: A Randomized Controlled Trial*, 283 JAMA 1303 (2000).
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FEATURE

R. Judson Scaggs, Jr.,
Chair of the Lawyers Assistance Committee of the Delaware Lawyers Assistance Program

Drugs and Lawyers: A Match Made in Hell

A toxic mix of high-stakes responsibilities, long hours and pressure to perform makes attorneys prime candidates for alcohol and drug abuse.

"What good is it for someone to gain the whole world, and yet lose or forfeit their very self?" — *Luke 9:25 (NIV)*

The recreational use of alcohol and drugs promises relaxation and escape. We use a physical substance to relax our bodies and, more importantly, to change our mental state. We seek to improve our mood. We want relief from the pressures of our day. It is telling that we say "I *need* a drink" after a tough day. Under the influence, we become less inhibited. We feel better about ourselves. We obtain relief — even escape — from the stresses and pressures in our lives.

Lawyers specialize in stress. We live a parade of deadlines. We juggle our schedules. We are responsible for the rights, lifestyle, wealth, reputation and even freedom of other persons. We must navigate and manage multiple constituencies – judges, clients, opposing counsel, partners, supervising attorneys, assistants, paralegals and associates.

Add to the mix the general stresses of life, as well as the responsibilities and pressures of relationships and families, and our needles can easily spend too much time in the red zone.

There is yet another, really fatal, ingredient: If we lawyer successfully, we can be very highly compensated in money, in personal satisfaction for helping others and for an important job done well, and in high reputation and social standing. And to lawyer successfully, we must compete daily. We must compete to get clients, keep clients, win motions, settle cases favorably, win cases, close transactions, etc.

We, therefore, live in a toxic brew of stress and drugs. Our society in general, and our professional community, expect lawyers to perform without mistakes under highly stressful conditions, while tolerating — even encouraging — the use of alcohol (and other drugs) to allow us to be social, fun and relaxed. The overuse of alcohol and drugs to escape and relax, particularly when combined with the wrong genetics, can lead to abuse and addiction.

Addiction is not simply a bad habit. Any person who has not lived under a rock for the last 30 years knows that alcoholism and drug addiction cannot be cured by willpower. Addiction is not a weakness. It is not a moral failing. Addiction is "a chronic, relapsing brain disease that is characterized by compulsive drug seeking and use, despite harmful consequences."[1] Brain-imaging studies of addicted persons show physical changes in areas of the brain that are critical for judgment, decision making, learning, memory and behavior control.[2] Addiction changes fundamental aspects of our thinking and values.

Globally, harmful use of alcohol caused approximately 3.3 million deaths in 2013 (equal to approximately 5.9% of all deaths worldwide).[3] In the United States, excessive alcohol use led to approximately 88,000 deaths and 2.5 million years of potential life lost in 2013.[4] It contributes to social abuse and neglect, sexually risky behaviors, miscarriages, stillbirths and is linked to a higher risk of suicide.[5] Addiction is a serious disease with undeniably devastating consequences.

Satan no doubt is quite fond of addiction because it has one particularly despicable characteristic: denial. Denial is an unconscious defense mechanism. It reaches beyond the drug use and can include a refusal to acknowledge the destruction and loss of jobs, marriages and other essential parts of our lives. Addiction is the only disease that causes your brain to believe that you do not have it. How often do cancer patients die from refusing treatment because they simply would not believe they had cancer? *Happens all the time to addicts.*

Now The Really Bad News

If you combine the inherent stresses of our profession with the inherent characteristics of addiction, the result is ugly:

- A 1990 study by Johns Hopkins University found that among more than 100 occupations studied, lawyers were the most likely to suffer from depression and were 3.6 times more likely than average to do so.[6]
- In 1996, lawyers overtook dentists as the profession with the highest suicide rate.[7] More recent studies suggest lawyers now rank fifth.[8]
- Alcoholism impairs about 18% of lawyers who have practiced two to 20 years, which is twice the rate for the general public.[9]
- 25% of lawyers (yes, one in four!) who have practiced law for more than 20 years suffer from alcohol abuse problems.[10]
- Approximately 60% of attorney disciplinary prosecutions involve alcoholism.[11] A recent study suggests that 90% of serious disciplinary matters involve alcohol abuse.[12]

In maintaining our professional responsibility and competence, and in pursuing success, we are (as Luke 9:25 tells us) at risk of losing the most meaningful part of, indeed the essence of, ourselves. We, as lawyers, set and enforce the rules for almost everything — including lawyering. We have established and diligently maintain a system that is killing us, both literally and figuratively.

The respected leaders of the legal community speak of the need for balance and quality of life. We encourage, even demand, civility. But we continue to accept high levels of stress as unavoidable and accept overdrinking and drug use as simply a personal choice. We can expect the stress of lawyering to continue unabated and the use of alcohol and drugs to remain pervasive.

What C.S. Lewis wrote in 1944 about the coming post-modern society applies to our ultra-modern practice of law: "And all the time — such is the tragi-comedy of our situation — we continue to clamour for those very qualities we are rendering impossible. ... We castrate and bid the geldings be fruitful."[13]

Some Good News

Addiction is treatable. Addicts can recover. Even better, persons headed toward alcoholism, addiction or depression can change course. Lifestyle changes often can prevent the fall into addiction and other mental and physical illnesses.

In Delaware, we are blessed to have a strong Lawyer Assistance Program ("LAP").[14] Our Supreme Court has consistently and strongly supported our LAP. The mission of the LAP is "to provide *confidential* assistance to Judges and lawyers in order to help them identify and address problems such as depression, stress, substance abuse/dependence, gambling addiction and other illnesses and to assist them in developing effective solutions that culminates in a workplace atmosphere that encourages professional growth, excellence and maintains the integrity of the legal profession."

Any Delaware lawyer can talk to LAP Executive Director Carol Waldhauser, both free of charge and confidentially. Carol offers a wide range of assistance, ranging from a compassionate, listening ear to arranging in-patient treatment.[15] We also have a Lawyer Assistance Committee ("LAC") consisting of volunteer attorneys who are available to assist lawyers in distress. You can find contact information for Carol Waldhauser and the LAC members on the Delaware State Bar Association website.[16] Please know that communications between attorneys and Ms. Waldhauser or members of the LAC are strictly confidential. They are protected with the same force and dignity as attorney-client communications.[17]

The LAP and LAC recently have established a fund to assist attorneys who cannot afford treatment. We have received generous contributions of $50,000 from the Delaware Supreme Court and $25,000 from the Delaware State Bar Association. We hope to have the ability to arrange for the treatment of any Delaware lawyer who needs it, regardless of their ability to pay.[18]

We practice a dangerous profession. We must monitor ourselves. We should periodically assess, as objectively as we can, our lifestyle. How much do we sleep, eat, exercise, drink and tend to our relationships and spiritual needs?

We also can watch out for our fellow lawyers. We can recognize when they are not themselves, when they have major behavioral change. "Be clear-minded and alert; your adversary the devil is prowling around like a roaring lion looking for someone to devour."[19]

Delaware has just fewer than 3,000 active attorneys. If Delaware's attorneys suffer alcoholism at the same rate as other American lawyers (~20%), we could have more than 500 alcohol-

see **Drugs and Lawyers** *continued on page 27*

Mark S. Lally
CEO, First State Compassion Center

What's in Store for Delaware's First Medical Cannabis Dispensary

Though authorized in Delaware, dispensing cannabis for medical purposes is adversely affected by restrictive federal laws.

The First State Compassion Center ("FSCC") will open its doors in Wilmington this Spring. For the first time in modern history, Delawareans with serious medical conditions that may benefit from administration of medical cannabis will have a sanctioned resource within their home state.

Delaware law now authorizes the use of medical cannabis to treat or alleviate symptoms of several qualifying conditions including amyotrophic lateral sclerosis (ALS or Lou Gehrig's disease), cancer, AIDS/HIV, chronic pain and post-traumatic stress disorder.

The FSCC holds the first of three medical cannabis licenses awarded as part of the Delaware Division of Public Health's ("DDPH") implementation of the Delaware Medical Marijuana Act ("DMMA"), which became effective July 1, 2012.[1] FSCC is committed to creating a facility that provides safe access to high-quality, affordable medical cannabis to licensed patients who are Delaware residents. The FSCC will include industry-leading protocols for security, patient access, compassionate care and regulatory compliance.

DDPH Director Dr. Karyl Rattay has stated: "FSCC has assembled an experienced team with a high level of competency in the field of medical marijuana." FSCC selected its team and undertook the other steps necessary to opening a medical cannabis dispensary with guidance from MariMed Advisors, a national consulting firm specializing in assisting state-licensed companies in the designing and building of state-of-the-art, regulatory compliant dispensaries and cultivation centers. The MariMed consultants developed the Thomas C. Slater Compassion Center in Rhode Island, which serves as a model of excellence for the industry.

Federal Prohibition Against Marijuana Remains

FSCC shares the challenges faced by all state-licensed cannabis facilities around the country. It must navigate past many obstacles in its path to be able to open and operate, not the least of which is that medical cannabis remains classified by the United States federal government as a Schedule 1 drug, the most restrictive of five groups established by the Controlled Substances Act of 1970 ("CSA").[2] Other drugs in this category include heroin, LSD and ecstasy.

The Schedule 1 classification means such drugs are deemed to have no accepted medical use in the United States, have a high potential for abuse and are subject to tight restrictions on scientific study. In short, they remain flatly prohibited and subject to criminal punishment under federal law.

This federal law is in direct conflict with statutes legalizing medical cannabis passed by 23 states and the District of Columbia (as well as statutes in four states – Delaware is not among them – legalizing recreational marijuana). Nevertheless, following the scaling back by the United States Department of Justice ("DOJ") of its enforcement efforts over several years, on December 16, 2014, the federal prohibition on medical cannabis was further eroded when President Obama signed legislation that prohibits the DOJ from using federal funds to prevent such states from implementing their own medical cannabis programs.[3]

Even with the advent of this more favorable enforcement environment, existing federal law discourages many qualified individuals from applying for licenses or working in the cannabis industry as an employee or consultant. Many professionals and healthcare providers have been reluctant to participate in aspects of working with companies such as FSCC. These deterrents impede efforts to establish and grow this type of business. The opposition and difficulties to being in the industry have been described as horrific.

Financial Challenges Abound

Imagine the challenge of opening up a company and not being able to have a bank account? How do you pay your bills? How do you deposit your retail receipts? How do you get the use of credit cards? How do you secure bank loans or lines of credit?

Most banks are registered and licensed through the federal banking system. That allows them to process transactions through the funds transfer system operated by the United States Federal Reserve Banks. This system enables financial institutions to electronically move funds between its participants. Further, banks are insured by an independent agency of the federal government. Accordingly, most banks are particularly sensitive to the need to remain in compliance with federal law.

Historically, banks that did business with marijuana distributors were at risk of civil and criminal penalties for money laundering and other violations of federal law. Many cannabis businesses do not always disclose that they are in this business. Indeed, one Colorado state bank known for allowing dispensary clients terminated more than 300 accounts after the DOJ warned in 2011 that it would pursue money-laundering charges.[4] Without a bank account, dispensaries have no traditional means of paying employees or banking. They must operate exclusively in cash.

Marijuana businesses have had to find back doors into the banking system. Some dispensary owners have set up holding companies with names that obscure the nature of their businesses, while others have opened personal accounts to be able to bank. However, once the bank learns the account is connected to a medical marijuana business, they close it. Some dispensaries are trying to form their own banking cooperative to skirt these restrictions.

Medical cannabis businesses without a banking relationship are further challenged by their inability to secure traditional bank loans. They may also have difficulty borrowing funds from nontraditional lenders, and are forced to self-finance from family, friends and private investors or through creative financing.

In addition, medical marijuana entrepreneurs have not been able to open credit card accounts and some may have been blacklisted from any credit card use. Historically, most major credit card companies have kept away from the medical marijuana industry, refusing to process transactions at dispensaries and even closing merchant accounts for medical marijuana centers. Many dispensaries set up credit and debit processing in affiliated companies to meet this challenge and navigate around another roadblock.

Existing federal law also creates unique tax challenges for a medical cannabis business. The IRS will not allow deductions for ordinary and necessary business expenses for sale of drugs deemed illegal by federal law.[5] Therefore, marijuana businesses have not been able to deduct any of their business-related expenses even though they pay taxes. This has made medical marijuana businesses very expensive to operate.

The FSCC and others entering or operating in the medical marijuana field now have reason for cautious optimism in view of recent steps by the federal government to eliminate interference in states' efforts to implement their own laws legalizing and regulating medical marijuana. It will take some time, however, for the changing legal environment to have a concrete impact on how medical cannabis dispensaries are operated.

Medical Research Has Been Stunted

Another frustrating issue created by the classification of marijuana as a Schedule 1 drug is that it has made independent medical research next to impossible. Research is critical for precise dosing, strain selection and delivery methods. Such research also is critical in determining the effectiveness of it on specific symptoms and disease states.

To obtain cannabis legally, according to a recent *New York Times* article, researchers must apply to the Food and Drug Administration, the Drug Enforcement Administration ("DEA") and the National Institute on Drug Abuse ("NIDA").[6] NIDA, citing a 1961 treaty obligation, administers the only legal source of the drug for federally sanctioned research, at the University of Mississippi.

Since 1968, the United States has had a federally funded medical marijuana farm and production facility at the University. The resulting cannabis cigarettes and other purified elements from this site are used for NIDA-approved research. NIDA also manages the distribution of cannabis to the seven surviving medical patients grandfathered into the U.S. government's medical marijuana research program, Compassionate Investigational New Drug program (established in 1978 and cancelled in 1992). The program offered relief to AIDS patients, as well as those suffering with other diseases like glaucoma and bone tumors.

It is evident that the patient population would benefit from further independent research concerning medical cannabis. For example, Mahmoud ElSohly, Ph.D., the head of the marijuana research program at the University of Mississippi since 1981, is working on a new method of administering delta-9-tetrahydrocannabinol ("THC"), the main therapeutic component in marijuana. A small transmucosal patch will be put inside the mouth above the gum line. It is believed that this means of delivering THC will promote better absorption with less variability, thereby overcoming problems some patients experience with taking the drug other forms.

Ironically, even though the CSA deems marijuana not to have any legitimate medical use, the U.S government owns one of the only patents on marijuana as a medicine. The patent, commonly known as "the 507 Patent," claims exclusive rights on the use of cannabidiol ("CBD"), one of the cannabinoids identified in cannabis, for treating neurological diseases conditions, such as Alzheimer's disease, Parkinson's disease and strokes, as well as diseases caused by oxidative stress, such as heart attacks, Crohn's disease, diabetes and arthritis.[7]

KannaLife Sciences currently holds an exclusive license agreement with the National Institutes of Health – Office of Technology Transfer for the commercialization of this patent. The existence of this patent – issued more than a decade ago – and its licensing for commercial purposes mean that the federal government is at least nominally aware of the potential health benefits of CBD.

The contradiction of the federal government holding a patent that touts the therapeutic applications of a cannabis-derived compound while simultaneously classifying cannabis as a Schedule 1 controlled substance has not escaped the notice of the popular press. For example, CNN's Chief Medical Correspondent, Dr. Sanjay Gupta, recently questioned: "How can the government deny the benefits of medical marijuana even as it holds a patent for those very same benefits?"[8]

The Continuing National Trend Toward Legalization Of Medical Cannabis

Recent legislative activity strongly suggests that there is now a broadening awareness in Congress of the federal government's incompatible positions on medical marijuana and, perhaps, the political will to address them. On February 20, 2015, the *Huffington Post* reported that two congressmen have filed separate House bills that together would legalize, regulate and tax marijuana at the federal level, effectively ending the U.S. government's decades-long prohibition against the plant.[9]

One of these bills, the Regulate Marijuana Like Alcohol Act,[10] introduced by Rep. Jared Polis (D-Colo.), would remove marijuana from the CSA's schedules, transfer oversight of the substance from the DEA to the Bureau of Alcohol, Tobacco, Firearms and Explosives, and regulate marijuana in a manner similar to the regulation of alcohol in the United States.

If this bill passes, it will enable scientists to begin intensive research on this promising medicine that could help millions of citizens who suffer from disabling diseases. In addition, it will remove the fear many physicians have that the federal government will take away their ability to prescribe narcotics if they recommend medical marijuana.

At a local level, with the passage of the DMMA and the DDPH's implementation of its Medical Marijuana Program, Delaware has taken an important step forward by providing its citizens with another treatment choice for serious illnesses and conditions. Yet, as currently written and applied, the Delaware law is not perfect. For instance, it prohibits individuals under the age of 21 from working in a dispensary. This eliminates the opportunity for most college students to have internships and learn about this emerging field.

In addition, Delaware law prohibits a registered compassion center from having more than 150 marijuana plants, irrespective of the stage of grow, or from possessing more than 1,500 ounces of usable marijuana, regardless of formulation. These restrictions may adversely impact the ability of registered dispensaries to produce enough medicine.

Despite these obstacles and challenges, the FSCC anxiously looks forward to opening this spring to serve the citizens of Delaware. It will bring the highest level of professionalism, the tightest security, the most knowledgeable staff, the highest quality medicine and a state-of-the-art facility that will be a replicable model of best practices for the rest of the country.

The State of Delaware has committed itself to support the FSCC in the implementation of this pilot program as it deems necessary to support the legislation and to provide the best medical cannabis products to qualified patients in a safe, secure and professional manner. ◆

FOOTNOTES

1. *See* Del. Code tit. 16, ch. 49A.
2. 28 U.S.C. § 801 *et seq.*
3. *See* Consolidated and Further Continuing Appropriations Act, 2015, Pubic Law No. 113-235, § 538 (2014).
4. *See* John Ingold, *Last Bank Shuts Doors on Colorado Pot Dispensaries*, Denverpost.com (Oct. 1, 2011, at 1:00 a.m. MDT, updated Oct. 19, 2013, at 11:11 a.m. MST), http://www.denverpost.com/news/marijuana/ci_19016660.
5. *See* 28 U.S.C. § 280E ("No deduction or credit shall be allowed for any amount paid or incurred during the taxable year in carrying on any trade or business if such trade or business … consists of trafficking in controlled substances … which is prohibited by Federal law ….").
6. *See* Serge F. Kovaleski, *Medical Marijuana Research Hits Wall of U.S. Law*, N.Y. Times, Aug. 9, 2014.
7. Cannabinoids As Antioxidants And Neuroprotectants, U.S. Patent No. 6,630,507 B1 (issued Oct. 7, 2003).
8. Dr. Sanjay Gupta, *Medical Marijuana*, CNN.com (March 6, 2014, at 8:40 a.m. ET), http://www.cnn.com/2014/03/05/health/gupta-medical-marijuana.
9. *See* Matt Ferner, *Two House Bills Would End Federal Prohibition Of Marijuana*, The Huffington Post.com, Inc. (Feb. 20, 2015, at 4:27 p.m. ET, updated Feb. 20, 2015, at 4:59 p.m. ET), http://www.huffingtonpost.com/2015/02/20/marijuana-legalization-congress_n_6722686.html.
10. H.R. 1013, 114th Cong. (2015).

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Helping "Orphans" Grow: Fostering Rare Disease Drug Development

From identifying sufferers to marshaling funding to attracting researchers, rare diseases pose unique challenges.

The FDA defines an orphan disease as one affecting less than 200,000 individuals in the United States in any given year. Under that definition, the National Institutes of Health estimates that as many as 7,000 orphan diseases exist, affecting approximately 25 to 30 million Americans. Genetic diseases comprise the majority of this category, as the etiology of diseases are better understood and diagnostic tests become more prevalent and affordable.

The majority of orphan diseases begin to show symptoms in childhood and are progressively disabling, leaving patients and their families with both substantial physical and psychological impacts. Commonly known examples of orphan diseases are Duchenne's muscular dystrophy, Huntington's disease, and Cystic Fibrosis. Therapies for most orphan diseases are either marginally effective or non-existent, making research and development simultaneously a high priority and a tremendous obstacle.

The rare nature of these diseases historically has presented a number of unique regulatory, developmental and commercial challenges. To combat these issues, governing bodies have created legislation to provide regulatory and financial incentives for organizations developing orphan drugs. In 1983, Congress passed the Orphan Drug Act (the "ODA") to provide such incentives, successfully increasing the number of orphan drugs either in development or commercially available.[1] Prior to the ODA, only 10 new treatments had been approved by the Food and Drug Administration ("FDA") in total; since its enactment, more than 3,000 products in development have received orphan designation, and more than 450 have been granted FDA approval for clinical use.

The influence of the ODA has created an environment in which orphan drug development is realistic and attainable. Despite these advancements, however, nearly 95% of orphan diseases lack an approved therapy and numerous significant challenges remain.

Patient Identification

Orphan diseases are defined by their small patient populations. Complicating this problem is the challenge of identifying these specific diseases in each individual patient. Orphan diseases often share similar symptoms with each other or with more common diseases, which can create a substantial diagnostic challenge, not to mention the rarity of the disease itself.

Often, the first physician to examine a rare disease patient is seeing that disease for the first time, making the proper diagnosis unlikely. In fact, in an April 2013 study by Genetic Alliance UK, rare disease patients reported a delay in correct diagnosis between five and seven years, seeing on average eight different physicians before arriving at the correct diagnosis.[2] These diagnostic delays not only take an emotional and psychological toll on patients and their families, but also create significant costs to patients and the health care system.

Overcoming this hurdle is extremely difficult, requiring better education of and awareness by health care providers, as well as improved diagnostic testing. Genotyping (the process of determining differences in an individual's genetic make-up by examining the individual's DNA sequences), genetic screening and identification of disease-specific biomarkers are helping the effort to reduce this trend.

Still, these tests often are expensive and require the education of health care providers regarding their availability and necessity. Continued evolution of these diagnostic strategies will increase their utilization and cost-effectiveness.

In addition, concerted efforts should be made through continuing medical education to inform healthcare providers of strategies to identify orphan diseases and begin the proper diagnostic process at early stages of disease progression.

Patient Advocacy

The timely and accurate diagnosis of patients has greater implications for the development and success of patient advocacy efforts that drive research. While research grants for common medical illnesses can be found through multiple public and private organizations, the responsibility to fund rare disease research frequently falls to the patients.

Patient organizations attempt to fill this role, joining patients and families together to promote fundraising efforts that can provide substantial grants, in addition to providing advocacy, education and support groups. These patient-driven organizations often form scientific advisory boards to assist and enable proper evaluation and selection of research proposals that patients and individual donors may not be equipped to perform.

One such organization is my group, the Choroideremia Research Foundation ("CRF"). CRF has developed via this path, connecting patients and families affected by this rare blinding disease. A small group of affected individuals formed the CRF in 2000 by breaking away from the much larger non-profit conglomerate Foundation Fighting Blindness that serves millions of individuals with myriad blinding disorders. In less than 15 years, the CRF has grown from a few individuals to an international organization of hundreds with growing fundraising efforts, membership and research.

Despite its remarkable success, the CRF continues to struggle with reaching a broader membership – out of an estimated 6,000 individuals in the United States affected with the disease, less than 10% have joined to date. The root causes of this low level of participation likely include the disease's rarity, misdiagnosis and simply lack of awareness of this resource in the ophthalmic community.

Further membership growth is critical to the CRF's grass-roots structure. Our annual event, Cure in Sight, a Wilmington must-attend wine tasting event that benefits CRF, forms the foundation for our outreach and fundraising. With so few members, the CRF, like other orphan disorder patient groups, relies entirely on its members to build the infrastructure, spread awareness and raise the necessary dollars to carry out the mission of funding and finding the cure. Every year at Cure in Sight we meet new patients and recruit new members. Over the last four years, Cure in Sight has raised more than $100,000 for the CRF.

Umbrella organizations like the National Organization for Rare Disorders ("NORD"), Genetic Alliance and others provide support to orphan disease patients and the disease-specific organizations that represent them through a variety of resources and advocacy efforts. Continuing support of this grass-roots organizational development is critical to the momentum of rare disease research and therapy development.

The evolution of the internet and social media platforms has contributed to the proliferation of small patient advocacy organizations. While each group provides value, the splintering of patient advocacy into smaller organizations has negative effects as well. These small populations of patients are often limited in their ability to fundraise, educate and lobby due to lack of manpower. Even further, some rare diseases find their patient populations split into multiple advocacy groups, geographically or otherwise.

With a limited pool of donations available, it is essential that orphan disease groups with identical or shared goals collaborate to maximize the benefit of their dollars spent. Such collaborative undertakings could involve the entirety of their research programs or a particular area of research that could benefit multiple diseases simultaneously.

Disease Understanding

While the basic understanding of most orphan diseases has improved, the physiologic mechanisms and natural history of disease progression are often poorly understood. Patients with an orphan disease are few in number and spread geographically, making it difficult for a single investigator to obtain enough data to undertake a sufficiently powered study.

Using animal models for research can aid this process; however, these are expensive to create and maintain, and often do not exactly reflect the human condition. Natural history studies can take years to provide significant insight into the disease process, but the knowledge gained can substantially alter future therapy development. As an example, the identification of a common cause for all types of Lou Gehrig's

disease (amyotrophic lateral sclerosis or ALS) in 2011 — the culmination of a quarter of a century of research at Northwestern University — has opened doors to the underlying disease pathophysiology and identified more specific foci for testing experimental therapies.[3]

Natural history studies can also highlight the most effective timing of therapies by better understanding the progression of diseases both as a whole and at a cellular level. By identifying ideal windows for the treatment of disease, scientists can optimally target experimental therapies to prove efficacy in clinical trials.

Persistence by academic institutions and the pharmaceutical industry to pursue natural history studies is crucial to the eventual development of therapies and must continue to be a priority.

Identifying and Connecting Researchers

As disease populations decrease, so do the number of scientists interested in studying those diseases and the availability of directed research grants for each specific disease. As large government grants typically focus on more common illnesses affecting large populations, rare disease research often must be funded by patient advocacy groups. Despite the networking power of the internet age, advocacy groups often lack the administrative structure and marketing capability to optimally connect themselves with the scientists most capable of supporting their cause.

Limited research funds also puts a priority on cooperation among scientists and their institutions to limit duplication of effort, promote sharing of information and eliminate barriers to the transfer of biological materials through highly restrictive material transfer agreements. These barriers have encouraged the development of research consortia to foster collaboration among scientists and the sharing of research findings without the delay often attendant to following the traditional route of publishing them in research journals.

Consortiums also can promote the sharing of biological products to further research. As an example, the Cystic Fibrosis Foundation created the CFTR Folding Consortium to enable distribution and development of reagents and assay methods critical to understanding causes of the disease, removing obstacles to further scientific study.[4]

Paralleling this trend is the increased number of biobanks, which are repositories of biological specimens and associated health information that enable greater access for research. While recognizing the significant ethical, regulatory, legal and privacy concerns,[5] biobanks and similar programs to share biological products between laboratories can significantly shorten timelines for product development and, in turn, decrease the cost of research.

Translating Research into Medicine

Current estimates suggest that it takes up to 17 years for a new scientific finding to be further studied and translated into an approved therapy.[6] Barriers that cause these prolonged timelines include issues such as the transition of research from academia to industry, the transfer of drug manufacturing from the research laboratory to good manufacturing practices (GMP) facilities, and the lack of experience of academic scientists with the regulatory constraints of early stage clinical trials.[7]

The FDA has made efforts to improve this process, culminating in the publication of a strategic plan for the advancement of translational medicine in 2011. Continued effort on behalf of the FDA to improve and promote this plan, and on behalf of scientists and institutions to collaborate on regulatory affairs, will shrink this gap and benefit the research process.

A significant opportunity in the orphan disease community revolves around the common pathways used in therapy development for the preponderance of genetically based diseases. Gene and cell therapies often utilize the same group of delivery systems, such as viral and bio-particle vectors. Scientists performing proof-of-concept studies for individual diseases using these validated delivery systems still must face overlapping steps, both scientific and regulatory, which require time and funding to perform.[8]

Fostering conversation among scientists, federal agencies and institutional review boards can lead to more efficient development of therapies, reduction in regulatory workload, and a more cost-effective and timely delivery of treatments to a waiting patient community.

Clinical Trial Challenges

The largest obstacle to overcome when planning clinical trials for an orphan disease lies, again, in the small size of the patient population. The historical standard set by the FDA for regulatory approval involves a three-phase clinical trial, including two adequately powered phase III clinical trials to demonstrate efficacy and reproducibility of results.

Trials on orphan disease populations have historically needed to meet these standards despite a much smaller pool of appropriate patients from which to choose, frequently causing prolongation of clinical studies due to delays in patient recruitment and enrollment.

The most powerful clinical trials — those involving a population of patients receiving placebo therapy as a control — further exacerbate this problem while also unearthing the ethical dilemma of leaving patients with progressive illnesses untreated.

Those treatments that do obtain regulatory approval enter the market at extremely high per-patient costs due to small patient populations and the high cost of drug development. This conundrum results in high costs to the health care system, as well as for the patients who cannot reasonably afford such expenses. This is a complex and multi-layered problem that weighs the need for proper safety and efficacy testing versus the unmet time-sensitive need for treatments of many orphan diseases.

One solution could be "adaptive licensing," which recommends a restructuring of the clinical testing program to allow for more individualized approaches to each therapy. While adaptive licensing would require the FDA to approach the evaluation of such programs with more flexibility, there are significant potential benefits to accelerating drug development while maintaining safety and lowering costs.[9]

Conclusion

The orphan disease community has made significant strides over the last 30 years and will continue to progress. Collaboration between the invested parties — patients, scientists, industry, and regulators — will help to address many of the obstacles to disease understanding and drug development by fostering a singular vision and a greater sense of cooperation. ◆

FOOTNOTES

1. Orphan Drug Act of 1983, Pub. L. No. 89-670, 96 Stat. 2049 (1983).

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ics. In recent years, the LAP has had about 60 new cases annually. Most of the cases involve neither alcoholism nor drug addiction. In 2013, there were 16 cases related to alcohol abuse and five drug cases.[20] We obviously need to spread the message of alcohol and drug abuse awareness and the availability of help to the members of our Bar.

We can avoid drug abuse. We can recover from addiction. We must be mindful of ourselves. We must take care of others. We must seek help when we need it. ◆

FOOTNOTES

1. National Institute on Drug Abuse, *The Science of Drug Abuse and Addiction: The Basics*, http://www.drugabuse.gov/publications/media-guide/science-drug-abuse-addiction-basics (last visited March 10, 2015).

2. *Id.*

3. *See* World Health Organization, *Global Status Report on Alcohol and Health*, ch. 3, at 48 (2014).

4. Centers for Disease Control and Prevention, *Fact Sheets – Alcohol Use and Your Health*, http://www.cdc.gov/alcohol/fact-sheets/alcohol-use.htm (last visited March 10, 2015).

5. *Id.*

6. "Occupations and the Prevalence of Major Depressive Disorders," 32 Journal of Occupational Medicine 1079 (1990).

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8. www.Nation.time.com/2014/01/20/lawyers-suicide.

9. Benjamin, G.A.H., Darling, E.J., Sales, B. (1990). The Prevalence of Depression, Alcohol Abuse and Cocaine Abuse Among United States Lawyers. International Journal of Law and Psychiatry, 13, 233-46.

10. *Id.*

11. Legal Professional Assistance Conference, Drug and Alcohol Abuse & Addiction in the Legal Profession; www.lpac.ca.

12. *Id.*

13. C.S. Lewis, The Abolition of Man, 26 (Harper Collins 1944).

14. *See* http://www.de-lap.org, for more information.

15. The LAP offers help for any addiction, as well as other illnesses and life changes.

16. *See* http://www.dsba.org.

17. Delaware Lawyers' Rules of Professional Conduct, Rule 8.3(d).

18. To learn more: www.de-lap.org/fund.htm.

19. 1 Peter 5:8 (ISV).

20. The majority of LAP cases involve depression, stress, anxiety and mental illness.

Of Counsel *continued from page 28*

ously with their pronouncements and provides updated sentencing information to prisons, law enforcement and other relevant agencies within minutes.

Judge Herlihy also stayed abreast of developments on the Drug Court over the 19 years that his friend and colleague, Judge Goldstein, oversaw it. Nearing the end of his second and final term in 2012 (though having reached an age by which most people are well into their retirement), Judge Herlihy was considering options for the next stage of his career. Judge Goldstein then approached him and asked if he would take over the New Castle County Drug Court. It took just one day to decide that serving on the Drug Court was the best way to cap a career devoted to public service in Delaware.

Anyone who has opened a newspaper during the last few years knows that Judge Herlihy assumed his current position at a critical juncture for the First State. Delaware has been and remains in the grips of a heroin epidemic driven largely by the narcotic's comparatively cheap cost and its highly addictive properties. By all accounts, Judge Herlihy and the good people at the Drug Court have been up to the task.

Judge Herlihy is mindful that one of the primary missions of the Drug Court is to reorient offenders and their families from the destructive trajectory driven, in large part, by addiction. In Judge Herlihy's words, they aim to "get these folks back to productive status."

Though the spread of heroin addiction in Delaware, in Judge Herlihy's experience, has made "treatment tougher and longer," he and his team at the Drug Court continue to fight the good fight for all of Delaware's citizens. ◆

OF COUNSEL: Judge Jerome O. Herlihy

We struck upon the idea of profiling the Honorable Jerome O. Herlihy — who currently presides over the New Castle County Drug Diversion Court, part of the Superior Court's Drug Diversion Court Program (the "Drug Court") — because it would be in keeping with the focus of this issue. Yet, as we became acquainted with Judge Herlihy, we found that there was much, much more to this attorney and jurist who has dedicated the vast majority of his working life to public service in Delaware.

Though Judge Herlihy formally retired from the Superior Court of Delaware on May 18, 2013, since then, pursuant to a special part-time appointment, he continues his life in public service presiding over New Castle County's Drug Court. This court gives qualifying defendants the opportunity to participate in drug treatment programs, and then closely monitors their participation to ensure compliance. Its comprehensive approach is designed to expedite cases and get participants into treatment as soon as possible.

Delaware's Drug Court has a proven history of success since defendants began entering the New Castle County Drug Court program in April 1994 and since Delaware's Drug Court, the first such statewide court in the nation, was established in 1997. Recidivism rates for graduates of Delaware's Drug Court program are significantly lower than for drug offenders without the benefit of such intervention (for 2012, 13.9% vs. 48% after two years).

In 2014 alone, the Drug Court had 512 entries and 288 graduates. In its history, the court has processed more than 10,000 cases. Judge Herlihy has been and remains a vital part of the success of the program.

Looking over Judge Herlihy's storied career, it almost seems preordained that he would one day take on this formidable challenge. Back when he was just Jerry Herlihy, the younger son of Thomas Herlihy, Jr., the long-serving Chief Judge of the former Municipal Court of Wilmington, Judge Herlihy witnessed his father's progressive approach to addressing alcohol abuse issues. As Judge Herlihy recalls:

> My father's efforts in Municipal Court played a big part in the decision to [serve on the] Drug Court. I was aware of it while in college and law school …. My father's efforts were aimed at treatment for persons with alcohol problems charged with "drunk and disorderly." The Salvation Army was a huge and willing partner, much like Brandywine Counseling is now to the Drug Court in New Castle County.

Further, by the early 1970s, as Chief Deputy, Judge Herlihy had joined forces with Delaware's Attorney General, W. Laird Stabler, Jr., to help reform and modernize Delaware's criminal statutes governing substance abuse.

This, however, was just one aspect of Judge Herlihy's early contributions to the development of Delaware criminal law and procedure. He, with Attorney General Stabler, also played a critical role in advancing Delaware's 1973 adoption of the Model Penal Code. Moreover, Judge Herlihy served as the Attorney General's representative on the advisory committee, chaired by then Superior Court Judge Joseph T. Walsh, that developed the Superior Court's pattern criminal jury instructions, which are still in use today.

After leaving the Delaware Department of Justice, from September 1974 until he was appointed to the bench in 1989, Judge Herlihy assembled an impressive record of accomplishments in private practice. Yet helping those afflicted by addiction was never far from his mind. For several years, Judge Herlihy served on the board of Wilmington's Limen House, a pioneering halfway house for homeless men recovering from alcohol and drug addiction.

In the late 1980s, the State again came calling and Governor Castle nominated Judge Herlihy to fill one of two newly created vacancies on the Delaware Superior Court. With his investiture on August 22, 1989, Jerome O. Herlihy became the 15th judge in the history of the Superior Court.

Within a few years, Judge Herlihy was at work with the primary architects of the Drug Court, Superior Court Judges Richard S. Gebelein and J. Carl Goldstein, helping to lay the foundation for Delaware's Drug Court. His contributions included visiting drug courts in Brooklyn, New York, and several leading treatment facilities throughout the nation to better understand how to make a diversion program work in Delaware. Soon thereafter, the New Castle County Drug Court was up and running and, by 1997, Delaware's statewide Drug Court was in place.

Judge Herlihy went on to serve two complete terms as a Superior Court Judge. During his three decades on the Court, Judge Herlihy would oversee a considerable and diverse docket that on several occasions required him to tackle issues of first impression under Delaware law. One of his most memorable civil cases involved a massive insurance coverage dispute between Intel Corporation and certain of its insurers arising out of an anti-trust action filed against Intel. Another case that still resonates with him is the capital murder trial of James E. Cooke, who was twice convicted and sentenced to death for the brutal rape and murder of Lindsey Bonistall, a 20-year-old University of Delaware student.

Despite his heavy caseload, Judge Herlihy found the energy to help make lasting improvements to the administration of the Superior Court. Notably, Judge Herlihy oversaw the development and implementation of the Automated Sentencing Order Program ("ASOP"), another first for Delaware. ASOP enables judges to issue sentencing orders simultane-

See **Of Counsel** *continued on page 27*

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