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Mr. Chairman, members of the committee, it's a privilege to be here this afternoon. My name is Charles O'Keeffe. I'm a professor in the Department of Preventive Medicine and Community Health in the School of Medicine and a member of the Institute for Drug and Alcohol Studies at Virginia Commonwealth University. These remarks are my own and not a position of Virginia Commonwealth University.

Others testifying today will address more directly the measurement of addiction treatment effectiveness. I hope to provide the committee with a perspective on overall treatment policy. Together, these perspectives will, I hope, help the committee in its deliberations about the best strategies to improve drug addiction treatment. The main point I wish to make is that federal policy is not optimal for the development and deployment of new treatments. There have been some recent improvements, but much more needs to be done.

As you know well, Mr. Chairman, because of longstanding strong federal regulation, the system for treating opiate dependence has evolved as one separated and even isolated from the normal practice of medicine. This has resulted in a disconnect between the findings of the research community and the practices of treatment providers and the health care community.

For the first half of the 20th century, a strict law-enforcement-centered policy for dealing with addiction prevailed, based on the belief that strict control of the availability of narcotics would result in the disappearance of the problem of addiction. The theory was that if there were no illicitly imported heroin and no excess supply of other narcotics, there would be no drug addicts. This highly restrictive policy was clearly less than successful in preventing opiate addiction.

Following seminal research by Drs. Dole, Nyswander, Kreek, and their colleagues at Columbia University in the early 1960's proving the effectiveness of methadone treatment for opiate dependence; some physicians began treating patients with this medication, both off label and sometimes under dubious research INDs. By the late 1960's, several thousand patients were being treated with methadone, and federal law enforcement agencies became concerned. The departments of Treasury and Justice continued to favor interdiction and believed that treatment was reckless; FDA did not find the data generated by the INDs sufficient to demonstrate safety and effectiveness; and social experts were concerned that the availability of pharmacologic treatment would decrease support for addressing issues such as unemployment, education, and adequate housing, and that such treatment failed to recognize the psychosocial and behavioral origins of addiction. Many recovering addicts who had achieved recovery in a drug-free residential treatment setting felt that pharmacologic treatment threatened that effective treatment method. Additionally, there were no standards of practice and some physicians were reported in the press to be prescribing methadone to patients who were not appropriate for treatment.

In response to congressional and community concerns, FDA established stringent regulations governing methadone INDs in 1971. This action allowed physicians to continue using methadone in a “research” context.

In 1972, thanks to the work of the country’s first “Drug Czar,” Dr. Jerome Jaffe, proposals relating to appropriate use of methadone as an addiction treatment were included in the Nixon administration’s initiative on drug abuse. This initiative established stringent regulations regarding eligibility for treatment, dosage to be administered, level of counseling, length of treatment, and criteria for take-home dosing. To prevent abuse and diversion of methadone, the subsequently promulgated regulations created a “closed” system that allowed treatment only through specialty clinics. According to Dr. Jaffe, however, “The drafters of the regulations did not intend for medication dispensing to be forever limited to a few large clinics. Although they recognized that access to treatment by individual physicians might temporarily be limited, they believed that the regulations would be revised as knowledge expanded and as opioid maintenance treatment became less controversial”. (Jaffe, 1975, 1997, 2003) Sadly, this was not to be the case. Those “temporary” regulations remained, and were expanded, over the subsequent 30 years.

We learned in the 1960’s that treatment could be effective. However, because of the portrayal of patients addicted to opiates as degraded individuals with an incurable disorder, treatment was commonly confined to a small number of specialty clinics, generally located in larger metropolitan areas, and controlled by stringent regulations. This depiction of patients usually led communities to resist allowing treatment programs to locate in any but the least desirable areas. Physicians were reluctant to treat addicted patients, because of both the treatment locations and the complexity of the regulations. Consequently, a non-physician-oriented treatment system began to develop. Addicted patients became “clients” of programs that eventually developed a fortress mentality. Because treatment moved further away from the mainstream practice of medicine, and more and more clients were seen by counselors and advisors instead of physicians, more and more regulations were needed to assure that appropriate treatment protocols were followed. Treatment programs became increasingly insular under a maze of complicated rules, further distancing physicians and the general health care community from the care of these patients.

Meanwhile, the research community, led by NIDA, was making inroads to understanding the disease, developing new treatment methods, pharmaceutical products, and improvements in the treatment of co-occurring diseases. These developments led to new products, new uses for older products, and new approaches to the treatment of this chronic relapsing brain disease.

It is essential that federal policy now ensure that these new and emerging developments be transferred to the practice of medicine as quickly and responsibly as possible so more patients will have access to treatment.

The most recent SAMHSA Household Survey shows that while 7.7 million Americans are in need of substance abuse treatment, only 1.4 million patients are currently receiving it. Treatment is effective. Even less-than-ideal treatment is more effective than no treatment. Every treatment method can demonstrate efficacy. Individual patient response may vary from one treatment method to another, but the scientific literature is clear: treatment works.

Notwithstanding this evidence, over 5 million Americans affected by this disease remain untreated. This untreated population continues to impose a significant burden on both the criminal justice system and the public health system. Both NIDA and CSAT have recognized this treatment gap, and are working toward closing it. These efforts are commendable, but the Executive Branch is constrained by legislative requirements, mandates, and restraints; the patchwork of regulations has grown so complex that very few physicians are willing to begin treating patients because of the infrastructure required by the rules. In a sense, over time, we've created a monopolistic system which has arisen from the complex regulatory environment, and that system now discourages new treatment providers from entering the field, with the consequent effect of denying patient access to treatment.

Congress, recognizing this problem, as well as the NIDA-enabled research successes, enacted the Drug Addiction Treatment Act (DATA) of 2000, which for the first time in over 80 years provides an opportunity for qualified physicians to treat addicted patients in their own office or clinic settings.

While this legislation was a major step in bringing the treatment of addiction closer to the practice of medicine – and your bill, Mr. Chairman, will correct some of the oversights of DATA – we are not nearly at the end of the road. There are crucial next steps, not the least of which is the daunting task of encouraging and enabling 5 million Americans to seek effective treatment for their disease.

It is estimated that nearly half of the 2 million individuals who are currently in prisons or jails were in need of treatment for alcohol or drug abuse or addiction at the time of their arrest. Yet our penal system, with some notable exceptions, has not taken the opportunity to begin treatment that could stem some of the pervasive recidivism experienced in this population. An example of the exception to this dilemma is a successful program in Henrico County, Virginia, designed to do just that.

We know that the stigma associated with disease abates when effective treatments become available. It was not long ago that depression was an unmentionable malady whose victims dared not discuss it. Today, nearly all of us are aware of some friend or relative who has been effectively treated for depression. And that effective treatment is ongoing; it is not a single course of treatment that ends the disease. A couple of decades ago, epilepsy was a dread affliction that no one talked about. Today, epilepsy is a chronic recurring and treatable brain disease for which patients seek and receive effective treatment.

Drug addiction is a disease, Mr. Chairman. It is a chronic condition that, although it has complex causation, can be treated. Providing an environment conducive to offering treatment is critically important to assuring its success. Health care providers need to be trained to recognize this condition and to develop appropriate treatment plans tailored to each patient. Creating a social perception that recognizes addiction as a disease rather than bad behavior is one of our greatest challenges, second only to correcting the overly restrictive regulatory system. DATA began the process of de-stigmatizing addiction and the treatment of addiction, but it did not end that process. This Committee, in its deliberations on drug addiction treatment policy can help assure that policies, priorities, and funding are all conducive to effective treatment.

Perhaps it's time for a reexamination of existing treatment policies and their consequential regulatory requirements that discourage adequate treatment. NIDA and the Institute of Medicine have the ability, and access to the expertise to provide recommendations for sorely needed policy and regulatory change that they lack authority and incentive make. The public health as well as this committee would be well served by seeking their advice on legislation designed to remove existing impediments to effective treatment.