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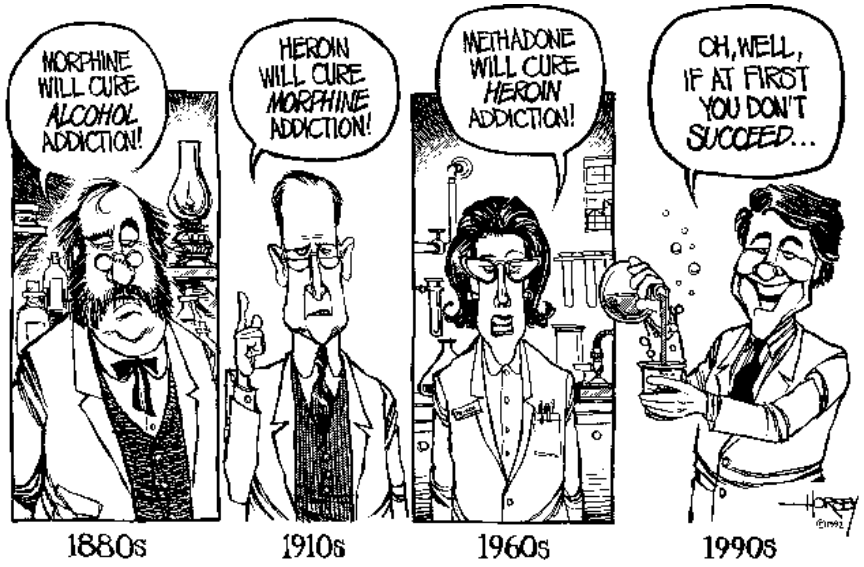
Pharmacotherapy: Millions Spent, Little Gained



Current private and federal research priorities emphasize developing drugs to solve the riddle of addiction.

by Max Ben, Ph.D.

Drug abuse is a complex problem, and approaches to solving it have been as varied as the faces of addiction itself. In the wake of rehabilitation failures, law enforcement officials increasingly speak of the need for harsh punishment of drug offenders, including first-time users.

Ironically, national tension and confusion surrounding drug abuse are not unlike the tension and confusion that may propel individuals to drug dependence. The irony of this is reflected in the fact that current private and federal research priorities emphasize developing drugs to solve the riddle of addiction.

In a September 1989 *Science* article, senior officials of the National Institute on Drug Abuse (NIDA) and pharmaceutical executives spoke enthusiastically of a "Manhattan Project for chemists" in the war on drugs. This apparent determination that drug development is the most promising approach to the nation's drug abuse problem has been mirrored in a series of actions by Congress, thus infusing a political component in attacking the basic problem of drug addiction.

These events have received little public attention or scrutiny, yet the hundreds of millions of taxpayer dollars being proposed for pharmacotherapy addiction research will, to a large extent, define the type of treatment available to the population in the immediate future. Given the uncertain history of pharmacotherapy as a treatment for addiction, the lack of responsible debate is inexcusable.

A strategy for the 1990s

On Dec. 13, 1989, the U.S. Senate Judiciary Committee, chaired by Joseph Biden (D-DE), released a report titled "Pharmacotherapy: A Strategy for the 1990s." The executive summary states, "Any idea, any program that might help drug users conquer their addiction must be explored."

However, the report is not specific about which ideas deserve further exploration and recommends that $1 billion be spent on pharmacotherapy research to help drug users over the next 10 years. An effort of such magnitude might be justified on the basis of a verified research breakthrough, but the document unfortunately does not offer convincing evidence along these lines.

In fact, a section on the "Definition of Addiction" states, "The National Institute on Drug Abuse does not yet have a standard definition of addiction for research purposes." Given this admission, it is unclear why NIDA (or pharmacotherapy supporters in Congress) would recommend vigorous pursuit of a chemical cure for addiction. Moreover, a discussion several pages later of private sector reluctance to do pharmacotherapy research states, "the scientific community currently has a limited knowledge of how chemicals affect the nervous system."

Is this a sufficient foundation for "Manhattan Project"? In common-sense terms, a much better case could be made for investing $1 billion in job training and career counseling for inner-city residents.

The legislative trail

The Judiciary Committee recommendations for funding pharmacotherapy research were incorporated into Senate Bill 2649, the Drug Abuse Treatment an Improvement Act of 1990. In addition to providing funds for research into blocking the effect of illicit drugs through pharmacotherapy, S. 2649 proposed the development of medications to "prevent under certain conditions, the initiation of drug abuse." If any provision deserved more debate, it certainly is the clause that suggests giving drugs to people who don't use drugs in the hope of prevention them from becoming drug abusers. No action was taken on the bill in 1990.

In June 1991, Sen. Edward Kennedy (D-MA) introduced a bill (S. 1306) that called for the restructuring of the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA). In addition to calling for the establishment of a "Medication Development Program" to be funded through the year 2000, Kennedy's bill suggested that federal research programs in the area of mental health and substance abuse be placed under the direction of the National Institutes of Health (NIH). It also proposed that ADAMHA be reorganized as the Alcohol, Drug Abuse, and Mental Health Service Administration to oversee mental health and substance abuse service programs.

Science magazine (April 24, 1992) reported that the reorganization plan grew out of a Bush Administration promise to protect ADAMHA research programs "by putting them together with those of NIH, rather than forcing them to compete for scarce funding with politically popular mental health and substance abuse programs. "

A July 1991 conference report from the Senate Committee on Labor and Human Resources offered the following explanation of the need for the proposed reorganization:

"It might seem logical to keep research and services under the same roof in order to facilitate 'technology transfer,' the process by which research findings are applied in the field. In practice, however, the research and service enterprises are so different that they cannot be effectively administered in one agency. Researchers and service providers share a common goal, but they speak a different language and thrive in different professional cultures. "

This passage raises disturbing questions as to just how far afield research utilizing a medications approach could go. Does it not need to be concerned with the experiences, needs, and practices of service providers? If research and service communities are already unable to coordinate their efforts, it would appear that an organizational separation of their activities would aggravate the problem. Again, rational debate is in order.

The language of S. 1306 was amended in two subsequent conference reports from the House. The final conference report (June 3, 1992) was approved by the Senate on June 9, and by the House on July 1 by a 358-60 vote.

In the version of the bill that has now become law, the Medications Development Program is funded only through fiscal year 1994 (rather than 2000); its allocation for fiscal year 1993 is $85 million; for 1994, $95 million. These appropriations are in addition to the NIDA budgets for fiscal years 1993 and 1994-$440 million and "such sums as may be necessary," respectively.

Drug substitution: The revolving door

For more than a century, physicians have advocated substituting supposedly benign (or at least "less harmful") drugs to prevent or halt the destructive course of addiction. Time and again, these remedies have failed to meet expectations, and often they led to new addiction and in some cases, serious social problems prevailed.

In the late 19th century, morphine was advocated as a solution to alcohol abuse. "Is it not the duty of a physician when he cannot cure an ill, when there is no reasonable ground for hope that it will ever be done, to do the next best thing—advise a course of treatment that will diminish to an immense extent great evils otherwise irremediable?" observed *the Cincinnati Lancet-Clinic* in 1889. "The use of morphine in the place of alcohol is but a choice of evils, and by far the lesser."

The realization that morphine abuse had itself become a considerable social and medical problem led to the search for less addictive drugs. A promising so-called substitute was found. "Heroin will take the place of morphine without its disagreeable qualities," Dr. Maurice B. Ahlborn wrote in the *New York Medical journal* in the summer of 1901. "There seems to be no craving for the heroin awakened by its continual use, as the subsequent gradual withdrawal after its substitution has been attended with no particular craving."

With today's knowledge, it is obvious that heroin would prove to be addictive. In the 1960s, methadone was offered as the panacea to the plague of heroin addiction. For years, methadone appeared to be a true pharmacotherapeutic success, yet the passage of time has raised serious

questions about its merits. Treatment specialists have found that weaning addicts away from methadone can be just as difficult as heroin withdrawal—in many cases more difficult. Perhaps this should not be surprising: methadone use, or "maintenance," was originally intended by many to continue throughout an addict's life.

However, evidence exists that some addicts use methadone in addition to heroin, rather than as a substitute for it. A NIDA monograph, "Drug and Alcohol Abuse," examined the patterns of multiple drug use in 1,544 cases from the National Drug/Alcohol Collaborative Project:

"Regular users of illegal methadone appear to the most involved with other drugs in that some 91.3 percent are also regular users of heroin; more than half are also regular users of cocaine, alcohol, and marijuana; and more than 40 percent are also regular users of other opiates and barbiturates. "

The monograph also ranked illegal methadone users as most likely (55 percent) to commit crimes to support their habit. Like morphine and heroin, methadone has undergone a metamorphosis from "prescribed medicine" to illicit substance.

As long ago as 1975, the *International Journal of Pharmacology* noted, "It must not be forgotten that methadone is a powerful narcotic analgesic (slightly more powerful than heroin) with an addiction liability all its own ... In fact, some addicts readily admit that they prefer methadone as their drug of abuse. " According to the Bureau of justice Statistics report, "Drug Use and Crime, " "heroin, methadone, cocaine, LSD, and PCP are classified as major drugs based on their addictive nature, high cost, and the legal penalties for their use and sale. "

Despite this history, the search for pharmacotherapeutic agents (such as clonodine) for use in "detoxification" of individuals dependent on methadone has continued—without success.

Alternative approaches

The federal government's determination to spend hundreds of millions of dollars on punitive measures and medications development—despite a century of failed efforts along this line—does not have unqualified support in the drug rehabilitation field. Though many researchers and treatment professionals agree that addiction has a physiological component, not all agree that substitute drugs per se are the answer to this problem.

Joan Matthews-Larson, MD, CCDP, is founder and executive director of the Health Recovery Center, a Minnesota based treatment program that emphasizes biochemical repair and restoration of body systems. "I was really enthusiastic in the '60s, when a whole issue of the *New Yorker* was devoted to a woman doctor's findings on how she could handle heroin addicts," she recalled. "They'd go on methadone, and that would be the end of it. But after seeing it up close, it isn't the end at all. They're on another drug; their nervous system and the damage that's been done from their drug addiction are still causing them a lot of misery. They're not stable; there's been no repair at all."

In reviewing hundreds of studies of the success rates of treatments that do not address biochemical factors, Larson found that the mean rate of abstinence was 22 percent. By comparison, a long-term follow-up study of graduates of her program found "abstinent and stable" results at one to three-and-a-half years for 81 percent of the graduates. "it keeps hovering around chance, no matter what you do, until you move into treating a physical disease with some physical tools," she said.

Alfred Libby, Ph.D., director of the Libby Institute, also has had success by restoring the chemical balances of the body. "When I originally published in 1977, we came up with a word that

applies very succinctly to the drug and alcohol patient: 'Kwashiorkor.' It's from an East African dialect. It means that they're literally starving to death from protein malnutrition."

Using such tools as ascorbic acid and amino acids, Libby addresses these physiological deficiencies. "Traditional medical people ignore this altogether, because they're looking for the 'magic bullet,' for an application that introduces foreign toxins into the system, further complicating the problem. If you supply the body the right substances in the right amounts and at the right time, at the cellular level, the body will repair itself."

Research chemist Richard Dan, Ph.D., is president and CEO of Diatech, Inc., in New Hampshire. "There's a tendency in certain sectors of the scientific community to think that you can solve all problems with substances. I think it's a false solution, something that hasn't been looked at rigorously. I don't think policy makers have been properly informed on pharmacotherapy; it's an inappropriate way to spend money right now, " he said.

"The most successful program I've seen is the Hubbard program, utilized at Narconon, which gets drug abusers off drugs without putting them on additional substances, " he added. The 26-year-old Narconon program uses vitamins as well as a detoxification procedure to eliminate accumulated drug residues from fat tissue.

Bernard Rimland, PhD, director of the Institute for Child Behavior Research in San Diego, said, "Pharmacotherapy should be a treatment of last resort. There are some instances where it's necessary, but I think it's far more rational and far more defensible to try working with nutrients first, with substances that are normally present in the human body."

"Every drug has a series of adverse effects-sometimes short-term and sometimes long-term, some of which are known and most of which are unknown which it is hoped will be less damaging to the body than the supposed advantages of giving the drug. It's a compromise situation. But there is no question that these effects are a real danger."

"A lot of people were drawn to drugs because they didn't feel well," recalled Stephen Langer, MD, from his experiences as medical director of California's Contra Costa County drug-abuse program. "They were either tired all the time or they were suffering from depression or they just felt like hell, and the only time they felt better was when they used drugs. They didn't think about the addiction, they just felt that for an hour or two they felt like human beings. By the time they became addicted, it was too late."

"There are many sophisticated types of tests to qualitate and quantify exactly what people's deficiencies are and to treat their imbalances," Langer said. "Over a period of time, they start to feel like human beings again and lose the overwhelming desire to keep using drugs to feel better, because they're feeling pretty well to begin with."

"This is a gross oversimplification of something that's a very complex type of approach," he cautioned, "but I would definitely recommend an applied nutritional approach along with critical lifestyle changes. Keeping people on long-term methadone or a long-term substitute for coke, if they find one, is totally bankrupt in the long run. It's a way to sweep the problem under the carpet; it is in no way going to curb the desire for drugs. We had people who were taking methadone and shooting heroin at the same time."

Joseph Beasley, MD, medical director of Brunswick House, New York state's largest private alcohol treatment facility, recalls a recently published study on alcoholism treatment conducted by researchers at the University of Texas, involving patients from a rehab facility. "They took one group,

did no nutritional intervention, didn't change the diet, gave them no nutrient supplements, no information. They took another group three months later—they had the same hospital, same nurses, same everything-and they changed their diet. They got them eating more frequently, got them on whole foods, got them off sugar, caffeine, refined carbohydrates, excessive salt, and excessive chemical food additives, and got them on nutrient supplements, taught them how to shop. There was a 100 percent greater recovery rate in the second group, just doing those things with all the other variables maintained as stable.

"We have published an article in the *Journal of' Substance Abuse* on a group of people with alcoholism and gross addiction to drugs," Beasley said. "Forty percent were cross-addicted with drugs; all had alcoholism. Some were on eight different drugs; all had failed in the hospital in at least one 28-day program. Some had failed as many as 20 times. Sixty-five percent had liver disease.

"They were a group of patients who were thought to have almost nil prognosis," he said. "By a very broad approach we were able to get 75 percent of them stable at the end of 12 months."

Future directions

Whatever questions might be raised regarding the merits of pharmacotherapy, both Congress and the current administration have placed their weight and considerable resources-behind the search for antiaddictive medications.

Unlike industry or other private sector initiatives, the priorities for research programs funded by public monies should not be set behind closed doors. The promise of nutrient-based therapies certainly warrants serious investigation; the potential social-and health-consequences of a new generation of drug substitutes are sobering. There is an urgent need for discussion and debate as to whether the millions of Americans whose lives are affected by drug abuse are well-served by NIDA's search for magic bullets. As monies for research are scarce, we must adopt a position of taking a balanced look at the best treatment approaches for the country's most damaging problem-drug-addicted individuals.

Max Ben, Ph.D., has served as director of corporate research at Miles Laboratories and as director of research and development for Rost Company. He has conducted research programs for the National Institutes of Health and has authored more than 90 publications on the subjects of toxicology, pharmacology, shock, and endocrinology. He has directed clinical data management programs and has had extensive interaction with regulatory agencies.