

JOURNAL INTERVIEW 33

Conversation with Vincent Dole

In this occasional series we record the views and personal experiences of people who have specially contributed to the evolution of ideas in Addiction's field of interest. Together with Marie Nyswander, Vincent Dole pioneered methadone maintenance as a treatment for opiate dependence.

Addiction: *There are many people who would be interested in knowing how you got started in your famous studies of narcotic addicts.*

Dole: Sometime in the early 60's I began to feel that I was working in an oasis in Manhattan (at Rockefeller University) but commuting to it from the suburbs through an epidemic of drugs and poverty in the inner city. It seemed to me that this was a problem that should be considered by the medical community. And, particularly, since I was associated with an institute of medical research, it was mandatory that I try to understand the epidemic that surrounded us. So, I began to look into it. In the course of time my interests grew to the point that I decided to devote the full efforts of my laboratory to further investigation.

Addiction: *Did you see any addicts at 125th Street?*

Dole: Yes. I would come in from the suburbs and often times get off the commuter train at the 125th Street station and then take the Third Avenue elevated to the 68th Street station, which was near Rockefeller University. In the course of walking between stations on 125th Street, I encountered many derelicts. Bars were open at nine in the morning; there were people on the street who were obviously on drugs, and many buildings were abandoned and empty. As I rode the Third Avenue elevated, I would be given a moving view through the windows of the tenements that lined Third Avenue. I could see the barren insides of these homes and idle people

who should have been working or in school. Alcoholism and drug addiction obviously were contributing factors.

Addiction: *In terms of seeing this from a medical point of view, how did you come to treat the first addict patients that you were involved with?*

Dole: I realized that I didn't know anything about addiction in any medical sense. There was no training on the subject at Harvard Medical School, nor was there any experience in my internship which prepared me to understand the problem. So having acquired an interest in the problem, I decided to learn more by consulting experts and visiting treatment facilities. In the course of this research, I visited Lexington [the US Public Health Service Hospital in Lexington, Kentucky] among other places and talked with everyone who had a reputation of being an expert in the field.

I talked to Lewis Thomas who had been a colleague and friend at Rockefeller Hospital and, at the time, was head of the working group on narcotics for the Health Research Council in New York. Hearing of my interest, he said, "Why don't you take over the chairmanship of this group as I will be going on a year's sabbatical and leaving New York?" So I said "I accept. I'll learn more that way." In the course of a year of looking into what was known and what was being done, I decided to undertake the research myself—to study addict subjects in the hospital at Rockefeller, where as a member of the institu-

tion I had the right to admit patients for research studies.

I discussed procedures with Detlev Bronk, President of Rockefeller. I said that there was a real need for a study of addiction from a medical perspective. This condition had struck me as being a neurochemical disease needing medical treatment. Moreover, I said, because of legal constraints and institutional prejudices, there is no other hospital or research institution in the country, outside the prison hospital in Kentucky, that feels safe to deal with addicts. He asked me if I thought it could be handled here (at Rockefeller). I said, yes, I believe that we can. He said, then it is our job and we will begin immediately.

With that support, which never wavered in the course of our work, I was able to set up a clinical research program in the center of Manhattan. Fortunately, in the course of meeting many people in the field, I had discovered Marie Nyswander and persuaded her to join me in this endeavor.

Initially, we set up a ward at Rockefeller Hospital with elaborate security precautions because that was the arrangement everybody assumed you must have to study addict patients. In the course of time, this advice proved to be false. The normalizing effect of methadone was discovered. What originally was a locked ward became an open suite of rooms. The doors to the corridor were taken off because they impeded passage back and forth. And, then subsequently, since we used only part of the patients' time in studies of narcotic effects and measurements of tolerance, we permitted them to leave the hospital each day and work in part-time jobs. The patients developed pride in our program, no longer thinking of themselves as addicts. I recall an occasion when one of the patients reproached a nurse for her carelessness in leaving needles and syringes lying around. He said you never can tell when addicts might come into the area.

This, of course, happened only after we had found the beneficial effects of stabilization on methadone. Originally, when we admitted these addict patients, they were very much the same as addicts are everywhere else—namely, always thinking about where they could get their next shot of drugs. When, in the initial studies,¹ they had been given controlled doses of various narcotic drugs, such as morphine and heroin and other short-acting narcotics, they would be content for only two to four hours and then begin to

get restless and demand another injection. It wasn't until we got to the stage of the study in which we were testing methadone that the beneficial effects of a medical treatment became evident.

Addiction: *What year was this?*

Dole: The studies were started in 1963, and extended into 1964. At the end of 1964 and going into 1965, I realized that we had *potentially* a medical treatment for heroin addiction²—one that could normalize the function of otherwise hopeless addicts and get them back into the mainstream of life. But it wasn't clear how this treatment could be generalized. The studies were being conducted by people who were experienced, and within the limits of a research institution. The question was whether the treatment would be feasible in the setting of a general hospital.

I pulled our data together, made an appointment to see Dr Ray Trussell, Commissioner of Hospitals for the City of New York, and showed him what we had done. I asked him whether it would be possible to attempt a replication of this work in the context of a general hospital. He looked at my papers, smiled in an enigmatic way and said, "Well I can assure you that you wouldn't get to first base if you went to any of our city hospitals. But I will send you to Beth Israel where you will have suitable space to give this a try." He also said, "I think this may be what I've been waiting to see."

At his suggestion, I took a cab to Beth Israel Hospital. In the meantime, Trussell had telephoned the director. When I arrived, I was received hospitably by him and told that the Commissioner had requested that he provide facilities that would be paid for by the City. What did we want? I said that we would like to have a ward in the general hospital and the privilege of selecting our support staff. I told him that we would like to choose this staff in order to escape established prejudice. We were given an empty ward, as requested.

At the beginning, Marie Nyswander and I helped the patients clean the ward and make their beds. Gradually, Marie chose staff. They were an exceptionally fine and dedicated group. Together we built up a unit. There was a great deal of pride in it and in its accomplishments. It became a showplace that physicians and administrators from all over the country came to see.

The patients developed into a loyal and supportive group, many of whom today are old friends that I can call on anytime to give help when needed. And, in fact, some years later (jumping about seven years ahead in the story), the chance came for me to go into prisons and set up treatment for the addicts being taken into detention. All I had to do was ask a half dozen of these older patients and I had an experienced team that was ready, in a course of one weekend, to take over the medical treatment of hundreds of addicts in the detention jails.

The first five years of the methadone program were an extraordinary period. There was no governmental bureaucracy; we established the rules, which were both conservative and flexible. We were fortunate to have this opportunity to work under optimal conditions and thus discover the potential of good treatment. Having seen this, one cannot be content with anything less successful.

Addiction: You mentioned the individuals who supported you in the early years. What were some of the problems you encountered?

Dole: One problem was the bitter opposition from the Federal Bureau of Narcotics, which was absolutely opposed to the idea of doctors having authority to prescribe narcotics for addicts. Addiction was their turf. The condition in their view was not a disease, but criminal behavior. Any doctor who prescribed a narcotic was subject to prosecution by them, and, indeed, a number of physicians had been prosecuted.

Early in our work, I realized that we would fall foul of this attitude on the part of the Bureau. They were professional enforcers who had become unemployed by repeal of laws prohibiting the manufacture and sale of alcoholic beverages, so they moved into narcotic enforcement. I asked the counsel for Rockefeller Institute to advise me on relevant law. He provided a thorough legal brief outlining the significant statutes and precedents. The brief made it plain that the purported authority of the Federal Bureau of Narcotics at that time was based upon a self-determined interpretation of law which gave them more powers than could be justified by a strict legal interpretation. The courts had consistently held that physicians are not to be indicted for treatment "in the course of medical practice". So the issue turned on the criteria of legitimate medical practice.

Since the research we were doing had been initiated by the Health Research Council of the City of New York and was funded by it, and since I had consulted medical leaders (all of whom endorsed the idea of legitimate medical research), I didn't feel insecure. Also, I had solid backing from the President of Rockefeller University, Detlev Bronk, and advice from the university counsel.

One day a grim-looking fellow, wearing a detective-style trench coat, entered my office, put his hands on my desk and said, "You're breaking the law. If you don't stop we'll put you in jail." I suggested that perhaps we differed in our interpretation of the law. Since my understanding differed from that of the Bureau, then the option for them was to sue me and let the issue be decided in court. At that point, his face dropped and he said, "I'll talk to you later." He stood up abruptly and left.

About a month later, he came back and said the Bureau had discussed my situation and they were willing to allow a limited amount of research, but that I must outline the studies ahead of time and report the results to them. I said that we again have a difference of opinion, because it is not the way I can do research. He left.

The Federal Bureau then circulated the rumor, to the effect that we were operating under their jurisdiction and with their permission. This fiction didn't survive long, but they did what they could to keep the posture of control. Meanwhile, they appeared to be the source of rumors about what we were doing, such as denying our reports of success in treatment. On one occasion they attempted to seize our clinical records.

Some ten to fifteen years later, when the Freedom of Information Act enabled people to examine the contents of Federal records, a lawyer with our group offered to apply for disclosure of reports in Bureau files. After a long delay, we did get some photocopies but with so much of the text blocked out that there was absolutely no content to the records; about 80% was deleted.

Despite opposition from the Federal Bureau of Narcotics, and subsequently from the State Narcotic Control Commission, the program went forward because it was producing results. Physicians and legislators who came to visit us were favorably impressed. Programs were established around the country. By 1968 we were able to convene the first National Methadone Confer-

ence. Methadone maintenance quickly became a recognized, legitimate treatment.

Paradoxically, new laws were passed to limit the treatment. With the collapse of the authority of the old Bureau of Narcotics, responsibility for supervising maintenance treatment passed to the Food and Drug Administration (another federal agency). By asserting that maintenance treatment was experimental and not adequately tested (although by then thousands of people were in treatment and the results had been carefully documented), the FDA was able to limit treatment to programs that were licensed by it. Ultimately it became necessary to rectify this anomalous situation. Laws were passed to replace the investigational permits with a set of restrictive and punitive regulations, euphemistically called "guidelines."

I was excluded from the formulation of these regulations which established a much more intrusive control over methadone treatment than the Federal Bureau of Narcotics had pretended to have. They encouraged a punitive, controlling attitude on the programs. These [FDA] regulations would have destroyed the treatment except that methadone, even under the worst conditions, is a limited success. Addicts were so desperate to get help that they kept applying and hanging in even though many of the programs were functioning at a sub-optimal level with prescription of inadequate doses of methadone, punitive rules and pressure on patients to terminate treatment. Abstinence, not rehabilitation, was the goal of treatment.

Addiction: *Was the medical profession itself involved in any way in these new FDA regulations?*

Dole: No. Practically all the input for the FDA regulations came from non-medical sources. Of course the regulators always could recruit a selected number of people with MD degrees to support punitive restrictions, but on the whole, the medical profession was simply absent from this problem. And to a large extent, it still is.³

Addiction: *So you're saying that the role the medical profession has played in the development and advancement of methadone maintenance treatment in the United States has been one of benign neglect, or how would you describe it?*

Dole: I would say neglect.

Addiction: *You mentioned the role of the federal*

government over the years and the role of the medical profession. Thinking about the present time, why has it proved so difficult to get methadone maintenance treatment programs to prescribe adequate doses for patients?

Dole: The pharmacological rationale has never been effectively conveyed to the medical profession. From a medical perspective, a medication is prescribed to enable the patient with a chronic disease to be as functional as possible, to live as effectively as he can, for as long as he can, with whatever pharmacological support optimizes his functional state. Now, addiction has never really been accepted in these terms by the medical profession, despite our efforts to identify addictions as chronic, relapsing diseases in every publication⁴ and speech for the last 25 years.

The philosophy that has prevailed is that addiction is a disorder of behavior, that somehow or other drug seeking behavior is evidence of a psychological defect or weakness, and that the only acceptable goal of treatment is total abstinence. This approach puts the emphasis upon the chemical and not upon the person. I hope that someday it will be possible to bring to addiction the same perspective that applies to the medical problems of chronic heart disease, diabetes, gout, arthritis, and the like.

Treatment should aim to normalize function, and its value should be measured by results. Lack of recognition of this objective has been a serious block to understanding maintenance treatment. Many times in the past 25 years we have presented data showing cessation of heroin use and normalization of function under maintenance treatment, patients returning to school, getting jobs, taking care of their families and so on, and yet the question that almost always comes from the audience is, yes, that's all right, but "when are you going to get them off methadone?"

There is an obsession with the chemical and not a concern for the human being—that's why it's difficult. Data that show normal function and constructive behavior on the part of people who used to be addicts⁵ do not persuade critics who still keep asking the question—yes, but when are they going to stop using methadone?

Addiction: *I think your answer helps explain this emphasis on methadone dosage on the part of the public—an emphasis which is not common in medicine with other medications.*

Dole: A wrong belief exists in the general public and in the medical profession, and even, I'm sorry to say, in many methadone programs around the world. This is the illusion that by giving a very low dose you facilitate the evolution of this treatment into complete abstinence. The opposite really is the truth.

Unless patients can become well stabilized physiologically, and live a normal life both physiologically and socially while in treatment, there is little chance of successful abstinence after withdrawal of methadone. Even under the best conditions, I think that people who have been habitual addicts, damaging their nervous system with the ups and downs of high-dose heroin, may never recover normal nervous function. Only under conditions of being stabilized by a long acting medicine such as methadone do they return to normal function. Withdraw the stabilizing medication, and they once more relapse to the unstable neurological condition that leads them to use illicit narcotics.

Addiction: Many methadone programs are utilizing non-therapeutic dosages which are too low. Is this because they just are not getting the correct information? What is the reason that we are finding it so difficult to get this knowledge implemented at the program level?

Dole: I regret to say that dosage decisions are frequently made by people who do not understand the pharmacology of methadone. They're made on behavioral, sociological and ideological bases by uninformed people who see the medication as an instrument of reward and punishment. The adverse behavioral effects of low dosages, including use of illicit drugs, are rarely interpreted as being due to inadequate doses. Unfortunately in the practice of medicine, if a patient fails to respond to the therapist, the patient is likely to be blamed rather than the treatment.

Addiction: You've said that addiction is a chronic disease. Why has it proved so difficult to convince both the public and professionals about the need for long-term treatment for heroin addicts?

Dole: Understanding of addiction has not advanced much beyond what it was 50 years ago. Addictive behavior is attributed to weakness of character. The argument is a logical circle: If the treatment fails, the addict is responsible and the

failure is taken as evidence showing his weakness of character.

What your question is asking is: "How is it possible for the medical profession to learn nothing from fifty years of failure?" The answer is that it is easier to blame patients rather than wonder whether a treatment is at fault.

Addiction: You mentioned the FDA regulations and how methadone maintenance treatment started here at Rockefeller Institute. Looking over the last 25 years, what would you say have been some of the other turning points, or key events, in the development of methadone maintenance treatment?

Dole: Rather than dramatic turning points, I see a slow evolution of understanding. Despite mistakes at all levels of administration, there nonetheless has emerged a body of experience and wonderful, caring clinicians, counselors, nurses, and brave patients.⁶ Today there is a moderate-sized community of people who know what to do and how to do it. What gives me the greatest feeling of pride is the quality of people who have emerged under conditions of discrimination and opposition.

Politically the climate has changed with the emergence of AIDS as a frightening threat. Curiously enough, this change in attitude has revealed the inner thinking of some people who previously have been opposed to methadone. Many people who in the past have been ideologically opposed to methadone maintenance treatment now are advocating, albeit in a begrudging way, support of methadone programs as a public health measure because it is the only treatment with demonstrated large-scale efficacy in controlling intravenous narcotic use. This is no great surprise. In past years some politicians who have been on record as opposing methadone treatment have also quietly arranged that their addicted relatives were admitted to methadone programs.

The AIDS epidemic and political necessity have revealed a recognition underneath some of the anti-methadone propaganda that methadone maintenance is an effective treatment.

Addiction: I thought what you just said was crucial: that over the years what has happened with regard to methadone maintenance treatment is that we built a body of knowledge and an experienced cadre that provides a nucleus for addressing a lot of the problems

that we now face in the USA about drug abuse problems.

Dole: No doubt. There is no question that with really good-hearted, honest support at social and political levels, one could increase the amount of services being provided in this area. But the problem is huge, and even under the best of circumstances, it is doubtful that within a reasonable time that we could expand treatment to reach everyone who could benefit. Nonetheless, there is no question that within, say, a three or four year period, it would be possible to treat four times as many people as are now receiving methadone. What's more, with a rational allocation of resources, to see to it that a coordinated public health campaign reached out to these persons most in need of help—namely, those on the streets, in shelters, and jails. The return to society would be many fold the expense of the effort. It is really a matter of political will.

Addiction: How important has research been in the development of methadone maintenance treatment?

Dole: At the beginning, it was important to be sure that this treatment was normalizing people and not simply stupefying them or creating other medical problems. So our research on the functional effects of maintenance was intensive during the early years. We were especially concerned about the alertness and coordination of patients given large doses of a narcotic over long periods of time. Could they safely drive a motor car or work in a factory? All of this has been thoroughly examined by now. The results of many tests show that methadone has a normalizing effect—the patient is not impaired in intellectual or motor function. He does not feel narcotized. He is functionally normal.⁷

We then looked at health problems. As an example, women who typically become amenorrheic while using heroin return to normal rhythms and fertility. That concerned us in the early days of the program. What would happen to babies conceived by mothers receiving methadone? Fortunately it turned out that the pregnancies and the babies were quite normal. Some of the children have been followed for two decades. It is now well established⁸ that both mother and newborn under a methadone program are in far better shape than they would be if she were not in treatment.

Furthermore, ongoing studies show that some disabilities that have been attributed to metha-

done (e.g., low birth weight) are actually due to such other causes as smoking (a practice common to most drug users) or concomitant use of other drugs. Follow-up studies of the early patients in treatment show that they have lived longer than their untreated peers.⁹⁻¹¹

Addiction: What should the United States do now, today, with regard to methadone maintenance treatment, or drug abuse treatment in general?

Dole: That really is too big a question to answer. One must be careful not to lose perspective. Methadone is a specific treatment for one kind of drug addiction (namely to narcotic drugs) and not necessarily for all people addicted to narcotics. It's for people who want the treatment. It should never be compulsory. It's for people who have advanced to a hopeless stage of addiction where it is clear that maintenance is a better option for them than attempted abstinence. What to do about the so called "drug problem" in the USA, when the question is asked in that way, can't be answered because there are several different drug problems to be considered and different treatments are indicated. It would almost be like asking the question, what does one do about "the infectious disease problem"?

Addiction: But what about methadone maintenance, what needs to be done there?

Dole: The number of people who could benefit from methadone maintenance, properly conducted, (and society would benefit from having them in good programs) is somewhere between five and ten times the number of people now in treatment. That is a very rough estimate, but the practical question is what is feasible?

One limiting factor is the lack of qualified personnel. There is no sense in multiplying programs that are administered by people who do not understand the pharmacology of methadone, or who lack a feeling of compassion and a grasp of what it is to be an addict. You need competent people to staff good programs; even today only a limited number of programs are adequately staffed. I don't see that there are enough qualified personnel available for a rapid, massive expansion of methadone programs, and enough administrators capable of directing programs of large size.

A second major impediment is the attitude of the public. Communities refuse to have treatment programs in their neighborhoods even

when there is a demonstrated local need. It has been impossible for the last 15 years to open a new methadone clinic anywhere in the city of New York.

I was reading in the paper the other day that a community in New York rose in opposition to having a residential facility set up for orphan babies. If they consider the babies a threat, how would they react to a clinic that treats addicts? In public health terms we have reached a stage in the drug problem at which society is getting what it asks for. It is not just a question of funding for treatment. The limiting issue is political will to confront the problem and put to work what we know about it.

Addiction: *Are you optimistic or pessimistic about the years ahead in this regard?*

Dole: In this business, one cannot afford to be anything but an optimist.

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