vestigations and efforts were unwarranted," Moss added, "but I do believe you have responded with . . . integrity and forthrightness."

Hutt told a reporter from the *National Journal* last December, "My new client is the general public, through the FDA, and I intend to represent that client as well as any lawyer can—I don't regard myself as a friend of anybody but the agency." The FDA's interest is to follow the easiest course between the pressures impinging on it, which is not invariably identical with the public interest. Where the two differ, as in the case of DES, Hutt will defend his FDA client. But he has managed to persuade at least some of the agency's critics that he can successfully serve two masters.

—NICHOLAS WADE

Methadone: New FDA Guidelines Would Tighten Distribution

The Food and Drug Administration (FDA) is currently swimming through a tsunami of comments generated by its announced intention to alter the regulations concerning the dispensation of methadone.

The 6 April announcement follows several years of discussion on what to do about methadone. The new guidelines basically recognize methadone as a safe and effective drug, but surround its use with restrictions aimed at curbing a black market that has been spreading at an alarming rate.

The synthetic opiate methadone, developed by the Germans as an analgesic in World War II, has been approved for over a dozen years for use as a pain-killer, a cough medicine, and a detoxicant for heroin addicts.

But methadone's career as a maintenance drug, or long-term substitute for heroin, began only in 1964, when Vincent Dole and Marie Nyswander launched an experimental program at Beth Israel Medical Center in New York City. For this purpose, methadone was classified as an Investigative New Drug (IND). At present, about 450 programs—ranging from private physicians with a clutch of addict patients to huge urban programs with a variety of drug and drug-free treatment services—are licensed to use methadone for maintenance, and about 50,000 addicts are being maintained on it.

Methadone is wholly or partially responsible for enabling thousands of former heroin addicts to gain control over their lives. But because of the anomalous quality of control over distribution of the drug, methadone, when carelessly dispensed or sold on the black market, has been responsible for a number of deaths and a significant number of cases of primary methadone addiction. Doctors, through carelessness or ignorance, have dispensed prescriptions for methadone tablets that are promptly sold for up to $10 apiece so that the "patient" can buy more heroin. Nonaddicts have had no trouble signing up with some maintenance programs because of sloppy admission procedures. Some addicts have played the game of registering at several treatment centers at once. Maintenance patients sell the top off their take-home doses (the amount above that actually needed to curb withdrawal symptoms) and use the money to buy heroin. A New Orleans program that employed patients to handle its methadone supplies was found to be 20 percent short in its inventory—the rest was being sold out the back door. A few unscrupulous doctors with licenses to conduct "maintenance" programs have made fortunes by taking on thousands of patients. The crowning scandal was the case of a methadone program that was advertised for sale in New York—1000 patients for $75,000.

The FDA and the Bureau of Narcotics and Dangerous Drugs (BNDD)—which is responsible for seeing that drugs stay in legal channels—have in the past 2 years put a number of programs out of business, but abuses still flourish.

The new regulations were formulated through cooperation between the FDA, the BNDD, the National Institute of Mental Health, and the Special Action Office for Drug Abuse Programs, which was created last year by President Nixon for the purpose of coordinating federal antidrug abuse efforts.

The proposed regulations acknowledge that methadone can hardly be considered "investigative" when 50,000 people are being treated with it. They therefore propose a unique and unprecedented category that would make methadone a New Drug Application (NDA), while maintaining some of the IND restrictions. Pharmacies would no longer be allowed to dispense the drug unless they are located within hospitals or are the approved supply outlet for a program. Private physicians may no longer prescribe methadone for any purpose unless they are affiliated with a methadone program. The drug may still be used as an analgesic, but not as an antitussive. A "closed system of distribution" with little chance for black market leakage is the envisaged result.

The regulations contain instructions for methadone handling and administration: a new patient must get his dose and drink it daily at the clinic (it is usually dispensed in liquid form, mixed with a fruit drink) 6 days a week for the first 3 months; thereafter, he must come in at least twice a week, which means he can never take home more than a 3-day supply. Urine samples must be taken at least once a week, under direct observation, to check for the presence of other opiates. Other strictures tighten up record-keeping and admissions policies.

Methadone has never been an uncontroversial drug. On one hand are those who see methadone as a cop out. These people say it is merely a substitution of one addiction for another, that it avoids dealing with an addict's psychological and social problems, that it differs from heroin only in that it is legal, and that it is a sinister form of social control in that its only purpose is to cut down on addict-related crime.

On the other hand are those who have hailed methadone as being to drug addiction what insulin is to diabetes—an attitude that fails to take into account the psychological aspects of drug addiction.

But most of the comments coming into the FDA have been from professionals who hold the middle ground and who see the drug as a useful tool, the best now available, for helping an addict control his physical addiction to heroin and drawing him into an environment where he can be helped to change the entire pattern of his life.

Even among these professionals there have been widely varying reactions to the proposed regulations. Many believe that the strict requirements for urine inspection and restrictions on take-home dosages reflect more of a political than a medical approach. They, Dole among them, say this indicates a lack of trust in patients, clogs up a program so fewer new patients can be admitted, and is a waste of money (urinalyses cost between $2 and $6 apiece). Robert Newman of the New York City Health Department's Addiction Services testified before a Senate subcommittee last May that tight controls on take-home doses would only boost the black market. "If my wife had to go 7 days a week into a government-run clinic to pick up her birth control pills, I would be out on the street buying them for her," said he.

Several professionals have pointed out to *Science* that law enforcement agencies rather than doctors have had total control over illegal drugs and drug abusers until very recently, and that this, along with the questionable moralistic argument that some drugs are "bad" while legal ones (such as alcohol and barbiturates) are all right, has prevented people from having a realistic attitude toward methadone. One doctor, who asked not to be identified, said flatly: "The FDA guide-

FDA Invents More Tales about DES

The Food and Drug Administration (FDA) last week announced a slow-step, partial ban on the use in meat animals of the synthetic hormone diethylstilbestrol (DES). In doing so, the agency had the courage to reverse its previous all-out defense of the carcinogenic beef ingredient (see *Science*, 28 July) but covered its retreat with a smokescreen of contradictions and untruths.

The explanation given for last week's sudden volte-face was that new data had been received just 5 days earlier from the Department of Agriculture (USDA). The data showed that even if DES is withdrawn from an animal's feed 7 days before slaughter—the statutory time specified by the FDA—residues of the hormone will still remain in the animal's tissues at the time of death. FDA Commissioner Charles C. Edwards announced last week that in light of this finding he had no choice but to ban DES from cattle feed. Because there is no imminent danger to human health, Edwards said, the ban will not become effective until the beginning of next year. DES will continue to be permitted in the form of a pellet implanted in the animal's ear.

A Seven-Day Wonder

The remarkable feature of the FDA's rationale is the extent to which it contradicts the agency's previous position on DES. FDA officials have persistently explained the presence of DES residues in beef samples as the result of cattlemen neglecting to withdraw DES 7 days before slaughter. At hearings last year before the House intergovernmental relations subcommittee chaired by Representative L. H. Fountain (D–N.C.), Edwards categorically rejected the alternative explanation—that it takes longer than 7 days for DES to be cleared from an animal's body. At the time of the hearing, and for 17 years previously, the withdrawal period for DES was, in fact, only 2 days. Edwards assured the subcommittee that even the 2-day period was completely adequate for clearance of DES. His words to the committee were:

> We advised you in March that sound scientific data did substantiate the safety of DES at the 10-milligram level with a 48-hour withdrawal period. . . . Since that time, numerous scientific articles have been published and data submitted with other NDA's [new drug applications] for DES that confirm the fact that the use of 10 milligrams of DES per head per day, combined with a 48-hour withdrawal period, will result in no residues in meat tissues.

Edwards offered this specific assurance despite the fact that several scientists in his agency did not believe that the 2-day withdrawal period was sufficient and, moreover, considered that the available evidence, inadequate as it was, indicated that even a 7-day withdrawal period would probably be insufficient.

The fact that new scientific data, which the FDA now accepts, indicates that a 2-day withdrawal period is, after all, insufficient casts the gravest doubts on the competence of Edwards' senior advisers, since in this case they plainly drew the wrong interpretation from data they failed to recognize as inadequate.

In last week's announcement, Edwards stated that the ban would not apply to DES in the form of implants because the "USDA has never detected a residue when implants were used as the sole source of DES." According to Fountain, this statement is both misleading and untrue. It is misleading because the USDA does not include implants in its regular sampling program for DES residues; it is therefore not surprising that residues are not being detected when the USDA is not looking for them, Fountain says. Edwards' statement is also untrue in that a USDA inspector in June 1970 did detect a DES residue of 60 parts per billion in beef liver, a fact which was reported before Fountain's subcommittee last March.

Another reason for the FDA's belated change of position may be not entirely unconnected with the fact that, on the day following its ban, the Senate health subcommittee passed a bill proposing a complete and immediate ban on DES. Maybe the FDA decided to act against the carcinogen before Congress did it for them.

—NICHOLAS WADE

lines are primarily a political document, not a medical document."

While many doctors object to the rigidity of some of the guidelines, many of these same doctors feel that FDA is placing too much emphasis on methadone as a treatment rather than, as one put it, "a precondition for [therapeutic] relationships to start to occur." According to Ed Senay, head of the Illinois Drug Abuse Program and successor to Jerome Jaffee, who now heads the Special Action Office, any program that dispenses just methadone, without supportive services, merely replaces an illegal pusher with a legal one. Senay says the National Association of Methadone Program Directors (of which he is an officer) wrote the FDA to object to its statement that "methadone presently represents the only drug for which there is substantial evidence of effectiveness in the treatment of heroin addiction." The statement should be changed to read, according to the letter, "Methadone used in conjunction with rehabilitative services is an effective drug in the treatment of heroin addiction."

But there is disagreement on the logical consequence of this. Dole says it would be unrealistic for the regulations to stipulate that a licensed program include supportive (rehabilitative, group therapy, job placement, and so on) services, because it would be impossible to find a common denominator for, say, a bunch of suburban teen addicts and prisoners who had just emerged from the Tombs.

Such a requirement would inevitably decrease the number of patients treated at each center, and most drug experts appear to agree that it is important, particularly in big cities, to reach as many addicts as possible. Peter Bourne, head of the Georgia Narcotics Treatment Program, points out matter-of-factly that methadone is competing on the marketplace with heroin, and that methadone has the great advantage of being free. The more people on methadone, the less demand for heroin, which means that the heroin supply must be reduced in order to keep the prices up, which means, in turn, that there is less heroin around to seduce new users.

There are no end of theories and no end of disagreement. When does methadone produce euphoria? Do addicts buy it on the streets because they can't get in a program, or do they merely add it to their arsenal of kicks? (Or, how many addicts want to stop?) Is it harder to get off methadone than heroin? Should methadone be used as preventive medicine, say, with a teenager whose habit is not yet heavy or a prison addict who has been off the stuff during his term, or should it be withheld until clear signs of addiction are present?

There are, in addition, more basic questions: for example, could it be that the only reason society is in such a tailspin about heroin is that addicts commit crimes and cannot be ignored —unlike alcoholics, who merely get in accidents and beat their wives?

One reason that there is so much conflict is that authoritative data are practically nonexistent. There are no precedents to go by, and the patient population is constantly shifting. Because of the need for keeping patients' identities confidential, heroin addiction constitutes a unique epidemiological challenge. One of the main concerns of the Special Action Office is to develop a uniform national data system in order to pinpoint environments conducive to drug abuse and locations appropriate for treatment centers, as well as to eliminate duplication among patients. The Narcotics Treatment Administration, in Washington, D.C., is now using a footprint system of identification—similar to the FBI's fingerprint system, but totally unconnectable with criminal records —which could conceivably be expanded nationwide.

Meanwhile, the FDA is laboring to perfect its guidelines, and endless new vistas of controversy are opening before methadone. The comment period was over on 6 July, but it looks now as though there will be no final word until October or later, if public hearings are held. The Special Action Office says no hearings are planned, but they are a "possibility."

—CONSTANCE HOLDEN

McGovern: Conversion Plans Spell Upheavals for Scientists

There is an anecdote on Capitol Hill concerning a questionnaire, sent out in the late 1950's by Senator Hubert H. Humphrey (D–Minn.), querying leading defense contractors about their plans for conversion. According to the story, the results of the survey were never released because the plans turned out to be few or nonexistent. Today, however, Senator George McGovern (D–S.D.) has beaten Humphrey in the race for the Democratic presidential nomination and he has all sorts of plans for conversion.

By 1975, McGovern says he would limit the defense budget by $33 billion to $54 billion and, at the same time, attain full or 96 percent employment. While his plan for a less defense-oriented economy would obviously cause great upheavals in the national work force, McGovern says his goal is to "take the pain out of peace."

Writing a national science policy is not exactly a presidential candidate's first priority—he has had other more important things to do—such as choosing a vice presidential running mate. Moreover, during the primaries-through-convention period, a candidate's organization concentrates on winning—with whatever bare bones of a program are needed. Only now is the McGovern campaign group taking on a staff of specialists in many important areas. For example, the organization set up a research and issues division, separately staffed, to hammer out details of various proposals since the convention. And finally, McGovern's positions on some issues may shift and evolve as the campaigning becomes more serious and extensive. Hence, only a few elements of what could happen to research under a McGovern administration can be inferred at this time.

McGovern's past voting record includes opposition to the space shuttle, the antiballistic missle (ABM), the