FDA General Counsel Hutt: A Man Trying to Serve Two Masters

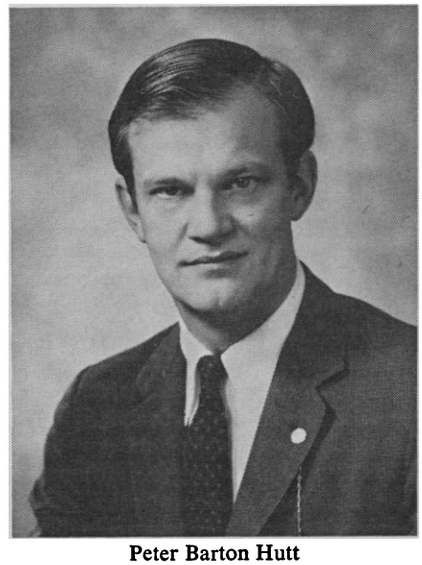
Perceiving an easy issue on which to exhibit the Administration in an unflattering light, Senator Edward M. Kennedy last month devoted a morning's hearing to the carcinogenic beef ingredient diethylstilbestrol (DES). Lined up in front of Kennedy were his intended victims—the commissioner of the Food and Drug Administration (FDA) and several of his top officials. But the senator made less of a killing than the issue had promised. Doing most of the talking for the FDA was its new general counsel, Peter Barton Hutt. Courteous but insistent, deferential but admitting to nothing, Hutt let Kennedy score scarcely a point off the FDA's visibly hole-ridden strategy for regulating DES.

The irony of Hutt's able defense of the FDA is that for 11 years he was a rising star in Covington and Burling, the Washington law firm that is the FDA's chief adversary. Any food or pharmaceutical company that doesn't like the way the government proposes to regulate it beats a path to the doors of Covington and Burling, since, in the words of consumer advocate Robert D. Choate, "Covington and Burling lawyers are among the best trained and the best paid in the field of defending industry from governmental and consumer intrusions. They are as practiced in the fine art of lobbying as they are polished in courtroom techniques. Peter Hutt is no exception."

General counsel to the FDA is a position that ranks second only to the commissioner's in influence over the agency's affairs, and in many respects, since the FDA is a regulatory agency, the word of its chief law officer tends to be final. Hutt's transmogrification from tying up the FDA's regulatory process for the benefit of manufacturers to becoming general counsel of the FDA is a switch of some proportions, comparable to going from poacher to gamekeeper—or, if not that, at least from poacher's adviser to gamekeeper's chief strategist. Has Hutt really changed sides? Does the consumer really stand to benefit from having one of the food and drug industries' foremost defenders installed in the second most powerful position in the FDA? Is it to industry's advantage to be regulated by a regulator who understands its problems from the inside?

Questions such as these surfaced prominently in the inevitable storm of protest that greeted the announcement of Hutt's appointment a year ago. To avoid dealing with his former clients, wrote Ruth Desmond, president of the Federation of Homemakers, in a letter to the Secretary of Health, Education, and Welfare, Hutt "will have to run the general counsel's office of FDA by remote control, with a ouija board, from a south sea island retreat for an unspecified period of time." Ralph Nader and Representative Benjamin S. Rosenthal (D–N.Y.) in a joint statement posited it as a cardinal axiom of regulatory government that "an arm's length relationship between regulator and regulatee has to be the desired norm." Rosenthal expressed a common criticism when he said, "No lawyer, no matter how much integrity and competence he possesses . . . can totally divorce himself from his former friends, clients, and biases."

The doubts over Hutt's new role were not alleviated by the parallel appointment of William W. Goodrich, the retiring general counsel of the FDA, to a job with one of Hutt's chief clients, the Institute of Shortening and Edible Oils. It was Goodrich who first encouraged Hutt, while still a student at Harvard Law School, to take up food and drug law; later, when the young graduate was offered jobs at the FDA, the Federal Trade Commission, and Covington and Burling, it was Goodrich who counseled him to take the latter. "A shameful switcheroo," "musical chairs," "an Alphonse and Gaston mutual benefit act," were some of the descriptions leveled at the changeabout of Hutt and Goodrich.



Peter Barton Hutt

Faced with such opposition, Hutt volunteered to appear before the consumer subcommittee of Senator Frank E. Moss (D–Utah). At the hearings held last September, a few weeks after he had taken up his new office, Hutt answered all questions with complete candor (save that he declined to reveal the names of six former clients, at their request). To the objection that he was changing sides, Hutt replied that lawyers are quite used to representing all kinds of different interest groups without sacrificing their independence. Indeed, he himself had represented both the milk industry and the edible oil producers, whose interests had often been on the opposite side of the same question. His relationship with Goodrich was in fact distant—they had not even lunched together in the last 11 years—and he had had no part in Goodrich's new appointment. As for the question of conflict of interest, he would disqualify himself from all cases involving his former clients.

The consumer subcommittee did not take a vote on Hutt's appointment, but Moss, at least, was favorably impressed. A youthful-looking 37, with an open and urbane manner, Hutt does not outwardly conform to the role of robber baron's accomplice being built up for him by the consumer movement. Also going for him was a distinguished record of *pro bono* work in the field of alcoholism. Hutt is the attorney of record in two classic cases, known as the Easter and Driver cases, which secured a legal basis for treating alcoholism as a disease instead of a crime.

Public service is the reason Hutt gives for accepting the general counsel's job. "What made me leave Covington and Burling for a job at half the salary and twice the vexation?" he asks. (At the FDA he receives between $32,000 and $35,000.) His answer: "Because I thought there was a job I could do." Anita Johnson, an attorney

with Ralph Nader's Health Research Group, offers another motivation: "Most of the FDA officials are worried by controversy, but you should see Hutt once a fight gets started—he really loves it. He probably saw more fights going on in the FDA than in defending people like Abbott Laboratories."

The chief fights with which Hutt has been associated during his 10 months as general counsel are the DES controversy and the Freedom of Information Act. It is rumored that Hutt was not entirely happy that the FDA had gone so far down the line in defending the carcinogenic additive. Be that as it may, it was he who devised the legal tools for keeping DES on the market up until last week's belated decision to ban it. More important than DES in the long term is the new information policy Hutt has engineered for the FDA. Under the Freedom of Information Act of 1967, all federal records are meant to be open to the public, except for specified exceptions such as trade secrets (*Science*, 4 February 1972). The FDA's policy until this May had been to suppress everything, including the vast amounts of scientific information supplied by industry, which, in theory, form the basis of the FDA's regulatory decision-making. Although unfortunately illegal, this policy had the advantage of preventing consumer advocates and other intrusive members of the public from second-guessing the bureaucrats' decisions. But the secrecy was also self-defeating from the viewpoint of public relations, about which the FDA has recently begun to care more.

"The first thing Commissioner Edwards asked me to do was to tackle the problem of secrecy," Hutt told *Science*. Hutt's solution, a set of regulations stipulating what kinds of information the FDA will make available to the public, is an acid test of his and his agency's intentions. The new regulations, he said in a recent speech, are the "cornerstone of a new openness at the FDA . . . [which] forces us to make better decisions and permits the public an opportunity to understand our decision-making." The new regulations will, in fact, make available some 90 percent of the data in the FDA's voluminous files. The information that would be withheld is chiefly the safety and efficacy data submitted by manufacturers in support of new drug applications (NDA's). Yet, in the view of the consumer advocates, this is precisely the information that the FDA should not withhold from the public.

To make available the scientific data submitted with an NDA, Hutt argues, would be to give an unfair advantage to a manufacturers' competitors. In answer to the consumer advocates' objections Hutt points out he is requiring manufacturers to submit a summary of the NDA data. The summary, vetted for accuracy by FDA officials, will be made public. This solution does not sit well with the consumers. "Hutt is a master of liberal rhetoric," scoffs Johnson, the Nader Center's resident expert on the Freedom of Information Act. "The summaries will be perfectly useless. No competent scientists trying to assess the safety or efficacy of a drug would rely on summarized data."

James S. Turner is another consumer advocate who is unimpressed with Hutt's new regulations. "All he has done is eliminate some of the FDA's more outrageous restrictions." Turner has a suit pending against Hutt (Morgan *v.* FDA), in which he is invoking the Freedom of Information Act to prize open the FDA's files on birth control pills. A suit calling for all the FDA's files to be opened (Turner admits that the FDA should be allowed a few secrets) has been filed by Ralph Nader's Center for the Study of Responsive Law. Hutt is looking forward to this upcoming legal scrap. In fact, to make it a better fight, he asked the Pharmaceutical Manufacturers' Association to file an *amicus curiae* brief contending that the FDA should reveal nothing. This way, the full spectrum of positions, from total secrecy to total openness, will be presented to the court. The FDA has not yet made firm its position on the Freedom of Information Act.

Hutt has been assiduous in trying to establish rapport with the consumer movement. He and Edwards hold a monthly meeting at which they thrash things over with consumer advocates. "I appreciate the work these people do and there should be more of it," Hutt says. Despite the harsh words the consumerists had for Hutt's appointment—Choate called for his nomina-

Briefing

Senate Bans Use of Weather, Fire as Weapons by DOD

Probably one of the most formidable friends of the Department of Defense (DOD) in Washington is Senator John Stennis (D–Miss.), who presides over the Senate Armed Services Committee. With his authority over the annual DOD budget, and his committee's traditional sympathy to the military's point of view, Stennis has been a major obstacle in the past to Senate doves seeking to tack end-the-war amendments and other favorite liberal items onto the authorization bill.

Yet, to the surprise of many, on 28 July, Stennis accepted without objection or even debate an amendment to the 1973 authorization bill proposed by Senator Gaylord Nelson (D–Wis.) which would prohibit use of the funds for creating "so-called firestorms or fires over a large area" or weather modification techniques as modes of warfare. The amendment would bar DOD from "entering into or carrying out any contract with" anyone else who might do so. Nelson introduced the legislation in the wake of allegations that both of these tactics had been employed in the course of the Vietnam war (see *Science*, 16 June, 21 July).

Why Stennis, who traditionally presents a stony facade to liberals' potshots at the Pentagon, suddenly accepted the amendment is something of a mystery. One theory is that, since the Mississippi Democrat is one of the few members of Congress who has been given a classified briefing on military use of weather modification, he cannot discuss it freely, and accepting the amendment outright was a means of limiting debate on the Senate floor.

Two problems remain. One is that the amendment will probably go by the board when the House and Senate confer on the authorization bill next week. Even should it slip by, however, and find its way into law, the amendment could be virtually unenforceable. Despite references in the *Pentagon Papers*, whether the military has used weather modification in Indochina has been remarkably difficult to prove. Presumably, proof will be equally elusive in the future to lawmakers tracking down alleged violations.—D.S.

tion to be withdrawn; Turner, according to Hutt, viewed the Senate hearing "as an adversary proceeding in which he should use every attempt to discredit me"—Hutt evidently bears no rancor and seems to have established cordial relations with his former critics. He praises Choate's exposé of the nutritive deficiencies of cereals ("one of the most brilliant pieces of testimony I know—I read it twice, something I rarely do") and is sympathetic to Turner's investigation of the Division of Biologics Standards (as a result of which the division was transferred from the National Institutes of Health to the FDA). Hutt is now drafting regulations allowing for a review of every single decision made by the Division of Biologics Standards and its predecessor agency since 1902.

"Mr. Hutt is one of the most competent food and drug lawyers in the United States," stated his critic, Representative Rosenthal, at last September's hearings. It is hard to cite the specific feats or forensic triumphs that have won Hutt this reputation, since it is not the general practice of the food and drug companies to do their confronting of the FDA in open court. But one example of Hutt's skills at mediation is the program of self-regulation he drew up for the cosmetics industry and persuaded both the industry and the FDA to accept. (Consumer advocate Joseph A. Page describes the program as a "no-law law," full of written-in loopholes, designed for the purpose of taking the heat off the cosmetics industry.) Another testimonial to Hutt's skills is the list of his former clients, which includes such food and drug interests as the Cosmetic, Toiletry, and Fragrance Association, the Institute of

Russians Reserve Doubts: Is Fort Detrick Really De-tricked?

If conjunctions of opposites make an occasion historic, then such was the moment last week when the Russian minister of health walked freely around what was once this country's secretmost center for waging biological warfare. The Soviet minister, Boris V. Petrovsky, was escorted around one of the several buildings at Fort Detrick in Frederick, Maryland, which are being converted to research on cancer. The particular laboratory inspected by Petrovsky was formerly used for research on tularemia, a bacterial disease of rabbits that can be fatal in certain human populations.

Fort Detrick, which was open for the first time since its partial conversion to peaceful purposes, impresses the visitor by its sheer size. The fort consists of several hundred buildings, some of them multistory edifices, set out along streets with homely names such as Wood Street, Beasley Drive, Sultan Street. New buildings were still going up when President Nixon renounced aggressive forms of biological warfare in November 1969.

Within the fort's outer perimeter is a smaller enclosure surrounding an inner citadel of buildings. It was here that germ warfare agents were developed and produced and antidotes against them sought. The largest of these edifices, designated Building 560, is a two-story structure built in the shape of an E. In each arm of the E are two suites of laboratories, isolated from each other and from the rest of the building. The self-contained nature of the six suites allowed a single agent to be studied in each, with minimal risk of cross-contamination. An integral feature of the design was that every laboratory worker was heavily immunized against the organism under study in his suite. Tularemia, staphylococcus endotoxin, and pestis (the agent of bubonic plague, the medieval black death) were among the agents being worked on in Building 560.

The building's most notable safety feature was an atmospheric pressure system which ensured that no air left the laboratories except by way of an incineration system that is lethal to any airborne organisms. Rooms housing infected animals could be kept at lower pressure than laboratories, so that organisms exhaled by the animals did not infect their keepers. Men entering the animal rooms used to wear masks feeding air at higher than ambient pressure. All material that entered the laboratory suites in Building 560 left via an autoclave. Laboratory workers changed clothes and showered before leaving. The typical laboratory room consists of boxed-off bench areas to which access is gained through arm-length rubber gloves inserted in the walls.

The fence around Fort Detrick's inner sanctum is now being torn down to symbolize its conversion, and the guard post at the entrance stands empty. Building 560, now in the possession of the National Cancer Institute, was the scene of last week's visit by Petrovsky, his wife, and Nicolas N. Blokhin, head of the U.S.S.R.'s leading cancer institute. The Russian party saw the building much as the Army had left it, as the conversion to cancer research has hardly begun. But if the Russians were impressed by the significance of the switch, they failed to show it. Maybe they suspect that offensive biological warfare research still continues. At any rate, Petrovsky was handing out no plaudits to his hosts for their conversion of the warfare center to health research. His most gracious comment was that, having participated as a surgeon in the fight against Nazi fascism, he welcomed the undertaking. At the press conference following his tour of Building 560, he referred to the "superficiality" of his visit. To the question of whether the Soviet equivalent of Fort Detrick was being converted to peaceful uses, Petrovsky told *Science* he could only answer for the ministry of health and that the ministry had no such facilities.

Petrovsky may have had other problems on his mind last week. On the eve of his departure from Moscow, he received a letter from the renowned Russian nuclear physicist Andrei S. Sakharov, chairman of the unofficial committee on human rights, complaining of the practice of keeping political prisoners in psychiatric institutes. Sakharov's plea was for two civil rights activists, judged sane by a medical commission in Moscow 2 years ago, who now "are dying in the Leningrad psychiatric prison hospital. Without your intervention there are no forces capable of saving them," Sakharov wrote to Petrovsky.

Petrovsky is visiting the United States "in keeping with the spirit and purposes of the joint U.S.–U.S.S.R. agreement on health cooperation".—NICHOLAS WADE

Shortening and Vegetable Oils, the National Association of Chewing Gum Manufacturers, ITT Continental Baking Company, and the Squibb Corporation.

Of his own background and that of the FDA, Hutt says: "Goddard [FDA commissioner 1966–68 was a better PR man than an administrator. Things looked good under him but little really happened. Herb Ley (commissioner 1968–69) is a very bright guy but he had a hard time making decisions. In some cases it's more important to make even the wrong decision than make no decision at all. When Edwards came in, the place was in a shambles. It took Edwards 2 years just to sort the place out and bring new people in. When Bill Goodrich left, Edwards wanted someone who knew the place and could get started at once. I'd been watching the FDA for 10 years, and I knew what needed doing."

Despite his familiarity with the FDA and its arcane ways, Hutt reckons it took him 4 months to get settled into his new job. Since then he has issued regulations covering such matters as methadone, the food GRAS list, food labeling, and environmental impact statements by the FDA. In addition two major efforts have been regulations on over-the-counter (OTC) drugs and on the Freedom of Information Act. Both are hefty chunks of legal prose that run for pages in the *Federal Register.* Hutt personally drafted these positions, he says, partly because of their importance and partly because of the smallness of his staff (he has only 22 lawyers under him and needs 44). Another potential constraint—disqualification from cases involving former clients—has been less irksome than predicted; Hutt says he has had to disqualify himself from only 2 percent of the cases crossing his desk.

Hutt believes there is a place for creativity in the world of regulatory law. "The chief failing of the FDA people, like other bureaucracies, is lack of imagination. They have no idea of being able to start from first principles and say, 'How can we regulate this or that substance in a rational, sensible way?' " Hutt's own regulatory creativity is evident in his compromise solution on the availability of safety and efficacy data on NDA's.

What kind of impression has Hutt made on his various constituents during his 11 months in office? For the most part, consumer activists, who do not bestow praise lightly on government officials, if at all, say that it is too early to tell what Hutt's true colors are. "I'm not convinced he has addressed some of the basic issues in a way that is not pro-industry," is Turner's double-negative verdict, based on Hutt's defense of DES and his position on the Freedom of Information Act. Bruce J. Brenan, general counsel of the Pharmaceutical Manufacturers' Association, also disagrees with Hutt's position on the Freedom of Information Act, although from the other direction. "Hutt is not industry's man in that job," Brenan says.

Hutt has earned significant accolades on Capitol Hill. He has favorably impressed Delphis C. Goldberg and Gilbert S. Goldhammer, the two expert FDA-watchers on the staff of the House intergovernmental relations subcommittee. Says Goldberg, "Hutt is attempting to do a fair and objective job. He is not industry-oriented and is probably trying to protect the consumer." And Hutt has received a notable vindication from Senator Moss, chairman of the subcommittee that hauled Hutt over the coals in September.

In a recent letter to Hutt, Moss wrote that, although he and other consumer advocates might not agree with everything the FDA had done since Hutt became general counsel, nonetheless "we certainly can feel confident of your objective handling of all cases. . . . I do not think our in-

An October Summit for Science

Presidential science adviser Edward E. David, Jr., has announced that the first meeting of the new Soviet-American Commission on Scientific and Technical Cooperation, agreed upon at the Moscow summit in May, will be held in Washington in late October. In a brief news conference, David said that initially the new joint commission would focus its attention on six specific topics of mutual interest to the two countries. These are: energy technology; agriculture; the application of computers to management; water resources; microbiological technology; and applied and basic work in chemical catalysis.

In addition, David disclosed that Soviet officials had expressed an interest in "technical and financial participation" in the worldwide deep-sea drilling project being carried out by the Scripps Institute of Oceanography, in La Jolla, California. Over the past 5 years the project has produced the first drill cores of sea-floor basement rock, and its findings have been of major interest to geoscientists, evidently including those in the Soviet Union. David said that officials of the National Science Foundation (NSF), which supports the project and provides funds for the drilling ship *Glomar Challenger,* will meet their Soviet counterparts for talks on the subject "in the near future."

David's announcement follows a week-long visit to Moscow, which he and a small delegation of American scientists and engineers made in early July to work out protocol for the October session. He described talks with his counterpart, V. A. Kirillin, the deputy chairman of the U.S.S.R. Council of Ministers, and others, as "very friendly, very easy."

Working groups of scientists and engineers have been set up in both countries to draw up specific proposals for cooperative research and information exchanges to be considered by the joint commission. Representing the United States at the October meeting will be David, as chairman of the U.S. delegation; James B. Fisk, president of Bell Telephone Laboratories (and David's old employer); Harvey Brooks, of Harvard University, representing the National Academy of Sciences; H. Guyford Stever, director of the NSF; and Herman Pollack, the State Department's director of international scientific and technological affairs.

The Soviet side of the commission will consist of Kirillin; V. A. Trapeznikov, first deputy chairman of the State Committee on Science and Technology (SCST); M. D. Millionshchikov, vice president of the U.S.S.R. Academy of Sciences; N. F. Krasnov, first deputy minister of Higher and Secondary Education; and D. N. Pronskiy, director of foreign relations for the SCST.—R.G.

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.