some cases, and require intervenors to provide more factual evidence in support of their pleadings.

All of this, according to Szalay, is evidence that the NRC is making a "great effort to become more efficient." But he said he will not be convinced until he sees the NRC "put some force behind the management, the scheduling, and the staff resources." Asked to name a plant whose operation the NRC has delayed unnecessarily, Szalay could not come up with any examples. He said the worst of the backlog had been overcome and urged a reading of the "Bevill report," a curious document that the chairman of the House appropriations subcommittee on energy development, Representative Tom Bevill (D–Ala.), has required the NRC to publish every month since last November.

An effort in self-criticism, the report lists plants likely to be held up by NRC reviews. The July edition lists eight cases that will probably be delayed. Only one, a California project known as Diablo Canyon 1, is actually ready to run. The list is controversial because it is largely based on projections, some of which later turn out to be wrong. For example, a nuclear plant in North Carolina, called McGuire 2, was listed among the delayed cases for several months. Then, when the NRC granted it an operating license, the owners revealed that they were not ready to turn on the power anyway. When the Bevill report first came out, it showed that the NRC was responsible for an industrywide delay of more than 90 months. Now the estimate has been reduced to about 30 months and may go lower.

There has been no strenuous resistance to the proposed legislative or procedural changes, although the critics of nuclear power have made their opposition known. According to a House staffer who helped write the NRC authorization bill, the environmentalists decided not to engage in a confrontation this year but to compromise.

Ellyn Weiss, legal counsel for the Union of Concerned Scientists and the Natural Resources Defense Council, said that only one of the many proposals being offered this fall is "horrid." It is a procedural change that would require intervenors before the NRC to state all their factual allegations at an early date, defend each charge thoroughly, add no additional facts during the hearing, and be liable to summary dismissal on the basis of the facts as filed. Weiss says, "This clearly has the potential to do away with any meaningful public participation." The NRC made the proposal in June and has not decided whether or not to adopt it.

The long-term effects of accelerating the licensing process are unknown, of course. Szalay hopes that some changes will inspire investors and that "in perhaps a year or two" utilities will begin to order new nuclear reactors, something they are not doing at the moment.

Commissioner Gilinsky, speaking last June before the House subcommittee on environment, energy, and natural resources, warned that the industry may be doing itself a disservice. He said:

> It is a mistake to put too much pressure on this agency to crank out licenses. The people here are human; they respond to such pressures. The fact is, as a result of the priorities shift, in some undefinable way there is less attention given to certain safety matters that perhaps ought to have more attention given to them. . . . It is probably a good thing to remember that one of the reasons we have had problems with some of the plants we are dealing with now is that they also went through the licensing system at a time when there was a lot of pressure to crank out licenses, when there were complaints of delays. . . .

Perhaps in a decade we will know who was correct.—ELIOT MARSHALL

Hayes Intends Modest Reforms at FDA

The new commissioner is under pressure to grant regulatory relief to food and drug firms

When officials of the Reagan Administration went searching for a director of the Food and Drug Administration (FDA), they had in mind someone familiar with the industry who could adroitly and diplomatically chart a path of modest deregulation. These qualities were found in Arthur Hayes, Jr., a clinical pharmacologist who had previously steered clear of political issues, but who finds his views in line with those of his employers.

"It's not that I have any revolutionary ideas like 'this is all wrong, and I'm going to redo it,' " the new FDA commissioner says. "But I really felt that with the change of Administrations there would be an opportunity to make some changes in health policy that I think are important." Hayes wants to shorten the time it takes to review and approve new drugs, cut back on the amount of information the agency demands before a drug can be marketed, and possibly to eliminate FDA scrutiny of the early phase of clinical drug research, actions which he says will "encourage innovative research and stimulate the marketing of important new drugs."

Like most Reagan appointees, Hayes does not expect to be writing many new regulations. Any that are forced by unforeseen events will be channeled through Health and Human Services Secretary Richard Schweiker, Hayes announced shortly after his appointment. Before the saccharin imbroglio in 1977, FDA officials infrequently consulted with higher-ups in the department. But Schweiker, continuing a practice first begun under Joseph Califano, expects not only to be consulted but to have the right of final approval on FDA decisions. Hayes, citing his close personal relationship with Schweiker, says he is happy with the arrangement. But it has the inevitable effect of tightening political control over a predominantly scientific institution.

Perhaps to calm some fears, Hayes has promised FDA employees that he will never allow the agency's scientific work to be compromised by political purpose. His credentials as a researcher amply support this pledge. Hayes is the immediate past president of the American Society for Clinical Pharmacology and Therapeutics, and directed the hypertension clinic at Hershey Medical Center in Hershey, Pennsylvania, for 8 years prior to his FDA appointment. There he conducted pioneering research into the effects of such drugs as lidocaine and digitalis on heartbeat and cardiac arrest. His research was recognized by the Pharmaceutical Manufacturers Asso-

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ciation (PMA), which gave him a career development award in 1968. Hayes has also been a consultant on drug effects to the American Medical Association and the American Pharmaceutical Association. He was interviewed by HHS officials for the FDA job at the suggestion of former PMA president Joseph Stetler.

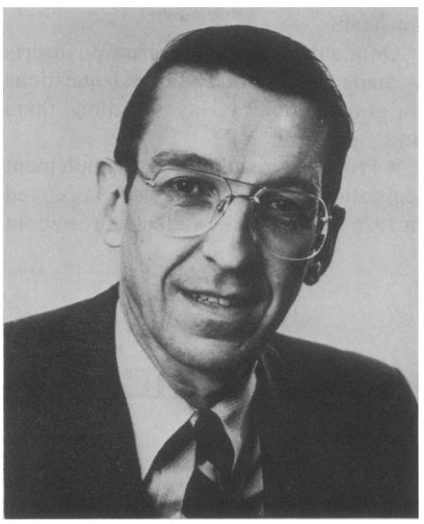
An interesting illustration of Hayes' regulatory philosophy is provided by the growing concern over the amount of salt in processed foods—a problem, as he says, "that I don't need explained." Soon after taking office, Hayes announced that he wanted food manufacturers to use less salt and to let consumers know the degree of risk they faced by listing an estimate of salt content on labels. He has since met with food industry groups in an attempt to persuade them to adopt the labeling suggestions voluntarily. Some are showing resistance, partly because they feel that it would lead to lower sales. Hayes emphasizes that "we're not trying to put people out of business, or to make them do the impossible." But he threatens to force the labels through regulation if the bulk of industry does not go along.

On drug topics, Hayes' decisions will be colored by his experience as a clinical investigator. He thinks that FDA sometimes demands the wrong kind of information from drug firms, and also often demands too much. "In some cases—when the drug appears to be of great value—it is not fair and appropriate to prevent it from getting on the market until you have accumulated all that wisdom through premarket testing," he said in a recent interview. He is particularly sensitive to what he describes as the "problems and frustrations" of drug firms that must obtain FDA approval for research protocols during the first phase of a clinical investigation, when drug absorption, distribution, metabolism, and excretion are examined in a handful of volunteer patients. Even though FDA scrutiny is already loose and sometimes takes place after the research is completed, the PMA says that eliminating this requirement will shorten the time to approval for a new drug by as much as a year and free agency personnel for more important work. The FDA's Bureau of Drugs was examining the proposal even before Hayes arrived, as part of its ongoing exhaustive review of all its drug approval requirements. But Hayes' appointment has quickened the pace.

Other reforms being considered by the FDA include the omission of a requirement that clinical investigators submit raw data on individual patients, and a system for reviewing the applications in which different portions are given only to persons with the relevant expertise. Hayes appears to be skeptical of two additional reforms sought by industry: the acceptance of a foreign clinical trial as the pivotal study of safety or effectiveness; and the resolution of scientific disputes by a review mechanism outside the agency. Hayes says that he will resign before he will let the agency's scientific and regulatory responsibilities be divided. "Science has got to be the basis of what we do," he told agency employees recently, and promised to try and obtain more funds for scientific journals and travel.

The drug industry is particularly anxious to learn whether Hayes plans to criticize overprescribing and misuse of drugs to the extent that his predecessor, Jere Goyan, did. Consumer and public interest groups have noted that in a 1974 speech to the American College of Clinical Pharmacology, Hayes said that physicians were caught in a gap "between solid pharmacologic principles and individual bedside therapies," which may depend on "isolated, often biased observations." Hayes says he plans to speak out about "overprescribing, misprescribing, and underprescribing. I've gone to an awful lot of medical association meetings to try to educate physicians on the effects of drugs—time that would be wasted if I stopped talking about it now." He uses the anti-arhythmic drug digitalis as an illustration. "It's terrible to give too much, and equally terrible to give so little that the patient is up half the night. The goal is not just to prescribe less, but to do it correctly."

Last November, the FDA announced a program to test the effects of placing correct drug-use information in patient packages. The requirement grew directly out of Goyan's concern about overuse and misuse of drugs, and he considers it his greatest achievement at the agency. This spring, the Reagan Administration deferred the regulation under pressure from the PMA and the individual companies whose products would be included: Eli Lilly & Co., which manufactures the pain-killer Darvon; the SmithKline Corporation, which manufactures the ulcer drug Tagamet; and the American Home Products Corporation which makes the cholesterol-lowering drug Atromid. The proposed package insert rule recently achieved the distinction of becoming one of the top 20 regulations most odious to American industry, according to a tally by the Commerce Department. Hayes and Schweiker have promised to make a final decision on it this fall. Richard Cooper, the FDA legal counsel under Donald Kennedy, remarks that "an Administration committed to shifting decision-making from the government to the people cannot jettison or pare down the patient–package insert program without inviting the comment that it has no consistent philosophy at all."



Arthur Hayes, Jr.

"Science has got to be the basis of what we do."

Hayes wants to shorten the time it takes to review and approve new drugs.

The decision is troublesome for Hayes for another reason. The program was to eventually include the drugs Valium and Librium, which are made by Hoffmann–La Roche, Inc. Hayes is disqualified by the Ethics in Government Act from making any direct decision involving Hoffmann–La Roche or its products for 1 year because the firm paid $66,000 of his salary last year and $16,000 in the first 3 months of this year, under a supporting grant to the Hershey Medical Center. He intends to decide on the broad patient package insert question anyway.

Hayes has also disqualified himself from making decisions on drugs made by Merck Sharpe & Dohme, as well as the Ciba-Geigy Corporation. Merck paid him $12,000 last year to organize and participate in lectures around the country on cardiovascular ailments and drugs, and he received $300 from Ciba-Geigy to deliver a single lecture on hypertension therapy. All decisions involving these firms will be made by Edward Brandt, Jr., the HHS assistant secretary for health.

Once a decision on prescription inserts is made, a slew of additional questions await resolution by Hayes. Among them are:

- Proposed regulations to implement legislation on medical devices approved in 1976, in the wake of disclosures about the Dalkon shield and faulty pacemakers. The Health Industry Manufacturer's Association has complained that a requirement for reporting of virtually all device problems is too burdensome, and that certain restrictions on the sale of devices are unjust. Hayes is likely to grant some relief.
- FDA appointments. Hayes must find persons to direct the Bureaus of Drugs, Veterinary Medicine, and Medical Devices. He recently hired Thomas Scarlett, a former HHS lawyer, as general counsel. Scarlett came to the FDA from a private Washington law firm, where he represented food and drug firms including The Salt Institute, Knoll Pharmaceutical Co., Richardson-Vicks, and the Generix Drug Corp. Scarlett says he will not take part in the FDA's deliberations on the sodium content of foods.

Hayes' success in bringing about reform at FDA will depend in part on how sharp a change he intends and the manner in which his reforms are presented. Surveys taken by the Yankelovich, Skelly, and White polling firm after the election show that public support for vigorous food and drug regulation remains extremely high, almost the only exception to the general appeal of deregulation. So he may have to tread carefully.

Thus far, Hayes has demonstrated a willingness to hear from spokesmen of groups on both sides. Participants report that he affects an inquiring, almost deliberately bland style. His coolness will undoubtedly stand him in good stead in the months ahead.—R. JEFFREY SMITH

Aspartame Approved Despite Risks

New FDA commissioner's first major decision reveals his distaste for regulatory delay

The most important decision made thus far by Arthur Hayes, Jr., as the new commisisoner of the Food and Drug Administration (FDA), was to approve the use of aspartame, a low-calorie sweetener, in foods. The decision ends for the moment a controversy about aspartame's safety that bedeviled the agency for 8 years.

At issue were long-standing allegations by John Olney, a scientist at Washington University in St. Louis, that ingestion of the additive might cause nerve cell and brain damage, and possibly brain tumors. Even Olney concedes that the evidence to justify these claims is not great, but the food law places a strong burden on the manufacturer of an additive to establish that no significant risk exists. In Olney's view, aspartame's manufacturer—G. D. Searle & Co.—had not gone far enough to prove this.

Last year, a special panel of expert scientists appointed by FDA discounted the risk of nerve and brain damage, but agreed with Olney's claim that a link between aspartame and brain tumors could not be ruled out. It recommended that approval be withheld pending further study. Hayes disagreed with this conclusion, but it is noteworthy that two of the three panelists reversed their opinions after reading his decision, and now approve of the additive's prompt release into the marketplace. Notwithstanding this erosion of support, Olney says he is upset by the approval and expects to challenge it in court.

Had Hayes accepted the panel's report, Searle might have brought a lawsuit. But accepting it still would have been the more cautious and therefore probably the easiest choice. Hayes' rejection of that course is probably illustrative of his philosophy. "It is wrong, and I'm not just singling out aspartame here, to say well let's just wait further and further for more evidence or a unanimous opinion," he says. "The question is, are you really trying to assure a zero risk? Though the expectations of the American public are very high, I do not think most people expect zero risk. I'm not prepared to say there is no risk from aspartame—I'd say that for very few things. But I thought it had been demonstrated that there was not a significant risk."

His decision clears the way for the use of aspartame in breakfast cereals, chewing gum, powdered beverages, whipped toppings, puddings, gelatin, and as a table-top sweetener. The additive, formed by a synthetic combination of two naturally occurring amino acids, will not be used in soft drinks because Searle has yet to find a way of keeping it stable for the duration of a soda's shelf life. Consequently, analysts expect it to occupy only about a quarter of the market presently held by saccharin. As such, the approval of aspartame does little to lessen the political pressure behind the moratorium on a saccharin ban.

Olney, a professor of psychology and neuropathology, became interested in aspartame because of his research on the effects of additives on the brain. One of the aspartame hazards that he points to involves an estimated 15,000 persons who suffer from phenylketonuria, a genetic disorder that prevents them from metabolizing phenylalanine, one of aspartame's two major components. Victims of the disorder, almost always detected shortly after birth, experience brain damage and mental retardation unless they are immediately placed on a phenylalanine-restricted diet. There is general agreement that special labeling required by the FDA for all products containing aspartame should be sufficient to warn these persons away.

Where Olney and Hayes split is on the risk to a fetus, in which the disease cannot be detected. In most instances, according to the FDA's calculations, a pregnant woman would have to consume a huge amount of aspartame—akin to

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