of as aging today," he writes, "is actually disease and illness, and not a part of fundamental physical aging." Arteriosclerosis, for example, is found in all age groups. Senile dementia is a grab-bag term applied to a condition that can arise from vascular or neural disorders, or from easily reversible conditions such as poor nutrition or lack of mental stimulation. Many diseases of the elderly result from deterioration of the immune system, a deterioration that may be forestalled. But aging itself "is not a disease." If optimal physical and social conditions were achieved, writes Butler, "we should see for the first time that flow of human life from birth through death truly called aging." Old age would then be "a gradual and fairly predictable decline toward eventual death."

Butler is also concerned about learning how to help people die properly, but he has warned that belief in the "right to die" is in danger of being yet another cop-out. It is important to "understand how often the right to die is really an issue and the extent to which preoccupation with the right to die is . . . a way of avoiding more effective diagnosis and more effective care maintenance."

Despite the increase in societal interest in matters pertaining to aging and death, Butler does not believe that creation of the NIA came about as a result of new enlightenment. He believes it is a purely practical reaction to the "explosive" growth in the elderly population. People over 65, now numbering 10 million, will number 30 million by the year 2000, and will constitute an unprecedented 25 percent of the population. Over-85-year-olds are now the fastest growing age group. And Butler predicts the demand for health and social services will rise even faster as the current generation of old people is replaced by generations that are better educated, more politically sophisticated, and more demanding of their rights.

Butler, who has a whimsical turn of mind, believes strongly in serendipity. He notes that the greatest cause of mortality among wild animals is dental disease because they lose all their teeth and can't eat. Now, if the wild animals set up their own aging institute and found a way to prevent dental caries, this would be heralded as a momentous breakthrough in aging research!

Wider Applications

He sees great potential for spinoff of NIA research to other age groups—discovery of how cells age could be applied to cancer research (cancer cells aren't programmed for extinction after a certain number of proliferations, as are normal cells), and, in the behavioral field, think of the benefits to all "if we gained a profound understanding of the nature of grief."

Butler stresses that all research at NIA must be interdisciplinary. He sees no need to duplicate what is going on in other institutes (a fear voiced by critics of the NIA proposal), and he expects the NIA to engage in cooperative research with other institutes such as the National Cancer Institute and NIMH. Among his particular interests are investigations of changes in drug sensitivity manifested in older people, and of how people make adjustments to retirement. (Actually, Butler doesn't believe in retirement at all—he thinks work, education, and leisure should alternate throughout life.)

Among his most immediate plans is to add women and, later, members of ethnic groups to the group of subjects in the Baltimore Longitudinal Study of Aging. The Baltimore study is a major activity of the Gerontology Research Center in Baltimore, which now houses NIA's intramural research program. It was started in 1958 with a cohort of 600 men, ranging in age from 20 to 96, who spend 2½ days at the center every 18 months and receive extensive clinical, biochemical, physiological, and psychological tests. Researchers have found that this type of study yields far more accurate knowledge about the aging process than do cross-sectional studies in which members of different age groups are compared.

Butler hopes the day will come when treatment of aging and the aged will not have to be segregated from that of the rest of the life cycle. "Hopefully, after some decades, the body of knowledge in principle will be absorbed [by the health professions] and geriatrics will become self-liquidated."

For now, he says, "the very fact we have the NIA is in itself a momentous step. Given half a chance, this institute is going to be the best in the world studying the mysterious, fascinating, and implacable process called aging." Butler says demographers predict that the year 2030 is going to be the "big moment in terms of the demographic revolution" when people over 65 in the United States will number 50 million and the population (it is hoped) has stabilized. "It is historically an important event that this nation has committed itself to this magnitude and broad a mandate long before the real crunch."—CONSTANCE HOLDEN

FDA: Review Panel Faults Commissioner's Defense of Agency

Who is running the Food and Drug Administration (FDA)? The agency or the drug industry it is supposed to regulate? No one knows for sure, and if the latest in an endless series of FDA investigations is any indication, no one is going to find out very soon.

A panel of highly regarded scientists and lawyers has just concluded an investigation of an investigation of FDA with a recommendation that there be another investigation. Only the panel chairman, Thomas C. Chalmers, dissenting from his six colleagues, says another investigation of specific allegations of drug industry influence would be a waste of money.

The FDA perennially is subject to allegations that it is servant to the drug industry, and those allegations are forever being looked into by some group or another. In fact, there have been more than 20 formal reviews of agency operations in a little less than 40 years.

The most recent anti-FDA onslaught of consequence came on 15 August 1974 when 11 FDA scientists—to the surprise of the agency leadership—testified before the Senate that they were harassed by agency officials—allegedly pro-industry—whenever they recommended against approval of marketing some new drug. As FDA Commissioner Alexander M. Schmidt said later, "The announced subject of the August 15 hearing [wheth-

er the introduction of new drugs in the United States lags behind use of new drugs in other countries] provided no warning of its ultimate focus." Schmidt, who did not attend the hearing that day, was left to hear about it first from secondhand sources. Most of the allegations brought by the 11 scientists concerned events that had taken place several years before their appearance in the Senate that August day, but there were rumblings that the improprieties of which they spoke were still par for the course at the beleaguered agency.

Commissioner Schmidt, who was then relatively new to the agency, forthrightly acknowledged the seriousness of the charges bared before the Congress and stated his intention of investigating them, all the while offering assurances that, whatever may have happened in the past, the FDA's integrity now is sound. Schmidt's investigation, which lasted a year and resulted in the publication of a 900-page report in October 1975, essentially exonerated FDA management of impropriety, and dismissed allegations of the agency's 11 accusers as being complaints from disgruntled employees.

While Schmidt's investigation was going on, the Secretary of Health, Education, and Welfare, with Schmidt's concurrence, called for an additional review of agency operations and policy. Four scientists and three lawyers* were named to a panel to scrutinize the FDA's drug approval process and to assess the fairness and objectivity of the report that Schmidt would produce. Chalmers, dean of the Mount Sinai School of Medicine in New York, is chairman of that panel—the one that is asking for an investigation of Schmidt's investigation, which it found deficient in many ways.

*Allen V. Astin, director emeritus, National Bureau of Standards; Thomas C. Chalmers, Mount Sinai School of Medicine; Marsha N. Cohen, attorney, Washington, D.C.; Norman Dorsen, New York University School of Law; Robert W. Hamilton, University of Texas School of Law; David P. Rall, National Institute of Environmental Health Sciences; Norman Weiner, University of Colorado Medical Center.

Interior Releases New Standards for Surface Mining

Interior Secretary Thomas Kleppe last month announced new environmental regulations governing the strip-mining of coal on federally owned lands in the West. The regulations are part of the Administration's new coal leasing policy, signaling the end of a moratorium on federal coal leasing that has been in effect since 1971.

The regulations, which have been endorsed by the Council on Environmental Quality and the Environmental Protection Agency (EPA), contain mining and reclamation performance standards that are supposed to ensure that miners leave the land in at least as good shape as they found it and to minimize interference with valuable surface and underground water supplies. Reclamation is required contemporaneously with mining operations.

The government is seeking prompt development of the vast western coal reserves to fulfill its energy independence strategy, which calls for doubling domestic coal production from the current 600 million tons a year to 1.2 billion tons. Kleppe predicted that federally owned lands, mostly in the West, would be yielding 500 million tons a year by 1985. Last year 32 million tons were taken from federal lands.

Interior has been trying to promulgate new regulations for the past 3 years. These regulations cover much the same ground as two national strip-mining bills that were passed by Congress but vetoed by President Ford. They are, however, more "flexible," says Kleppe. They will apply to leasing in more than 1.3 billion acres of federal land, mostly in eight states: Montana, Wyoming, Utah, Colorado, North Dakota, New Mexico, Oklahoma, and Alabama. Kleppe said much of this land is already under federal lease but that it is not being mined because of various economic and environmental impediments. The new policy will include termination or activation of existing leases.

Environmentalists are unhappy with the new regulations and would much prefer legislation setting minimum national standards for all strip-mining, on lands public and private. The latest congressional action in this direction, H.R. 9725, is currently stuck in the House Rules Committee.

The new regulations are somewhat more stringent than those proposed in the past. A major change, for example, has been the deletion of the phrase "maximum extent practicable" in reference to reclaiming strip-mined land. Under pressure from the EPA, this has been replaced by detailed performance standards and a two-part variance procedure.

But according to Louise Dunlop of the Environmental Policy Center, many problems remain. She says, for example, that a variance will be permitted if "unusual physical conditions" prevail at a mining site. She calls this a "wide-open loophole" that will permit "strip-mining without any reclamation at all."

Kleppe says "an important innovation" of the new standards is contained in a provision that state mining regulations can supersede the federal ones if they are at least as stringent and "provided that the state does not sit on its hands and attempt to block or lock up federal coal reserves that can be mined in an environmentally sound manner." If the state does sit on its hands, the Secretary can give the go-ahead for mining if such action is deemed in the "overriding national interest." To critics, this means the Interior Department can walk right over state laws at its own discretion.

Another of the many environmentalist complaints, according to Dunlop, is that the regulations do not sufficiently protect precious western water supplies. The regulations say companies must use "best practicable commercially available technology" to minimize adverse effects on water quality and flow. "The word 'practicable' is obviously a euphemism for the word 'convenient,' " says Dunlop. Representative John Melcher (D–Mont.), a leading fighter for strip-mining legislation, goes even further—he has been quoted as saying "these regulations could leave us dry."

The coal industry does not like the regulations either, calling them "unduly restrictive." William Hynan of the National Coal Association says the industry objects in particular to the requirement that lands be restored to their "approximate original contour," which it believes not always to be necessary or even desirable.

Congressional efforts to get out a new bill will continue. Meanwhile, Interior will shortly issue new regulations governing leasing, which is expected to resume in about 10 months.—C.H.

project had been exhaustively reviewed and commended by all the appropriate bodies, he said. He deemed it an irony that Congress, "possibly the least expert group of Federal employees to gather together in one building," seemed now "to have taken upon itself the role of grand inquisitor with regard to scientific research." He asked his colleagues, whatever they might think of this particular project, to refrain from damaging the integrity of the peer review process.

Senator Charles Percy of Illinois rose to defend his constituents, though with more down-to-earth reasoning. The project should be funded, he said in effect, because if it proved that pot was bad for sex, the weed would take a dive on the market. But, his listeners must have asked themselves, if vice versa, would vice be worse?

Senator McClellan said he did not know which way the experiment might go. But it occurred to him "that the man who uses marihuana can best determine for himself what effect it is having on his sex life."

Senator Magnuson seemed to be under an impression that Dr. Rubin was asking more of congressmen than just dollars. "But to ask us to participate in this sort of project," he warned, "makes us look a little bit ridiculous in using taxpayers' money."

Hathaway, recognizing a thumbs-down sign when he saw one, begged Magnuson to agree that "the Senator does not consider this a precedent for further incursions into the scientific peer review process; and that this is not going to be an everyday affair where one Senator or another picks on this project, that project, or another project, and has it deleted through amendments to an appropriations bill."

"That is absolutely correct," Magnuson graciously replied.

Whereupon the Senate, by voice vote, followed the House in denying federal funds to Rubin's study, probably the most frequently and intensively approved of any project to pass through the peer review system.

The result is a defeat for science, but perhaps not a total wipeout. Rubin is following one of Senator McClellan's suggestions—that he seek private funding. And while Congress may brag about having struck a blow for decency, the research community got something like a promise that Congress won't do it often again.—N.W.

From its inception, Schmidt's investigation of the FDA had one fatal flaw. It was an internal study. Agency personnel had charged, among other things, that

- their recommendations to approve new drugs had never been questioned, but their recommendations to disapprove were almost always challenged by agency higher-ups;
- their efforts to disapprove drugs resulted in repeated harassment from FDA officials; that files were altered to delete negative data; and
- they were all removed from the review process and/or transferred to another division after recommending disapproval of specific drugs.

Such charges are, at best, difficult to prove, especially since there are a number of reasons for reassigning individuals within large bureaucracies. But the last people who can be expected to come up with a credible assessment of the situation are agency people themselves.

Internal Study "Ill-Advised"

Last month, when the Chalmers panel completed its review of Schmidt's report, it took him to task on a number of points. It found that he was "ill-advised" in deciding to conduct his own investigation; that his report left unresolved important accusations against the FDA; that his broad defense of agency policy and behavior was unsupported by the evidence; and that fundamental questions about the relationship between the industry and the FDA were virtually ignored.

The commissioner's internal investigation of the FDA cost $196,000. The Chalmers panel's assessment of the commissioner's report cost, depending on whom one talks to, another $140,000 to $200,000. The investigation for which panel members, minus Chalmers, are now calling is estimated to cost yet $100,000 more, and even some of those who would like to see this third investigation take place admit that it may never be possible to resolve questions about "who struck John" back in 1968 and 1969 when some of the incidents in question took place.

The situation is not encouraging. As one panel member put it, "you have an inconclusive 900-page report followed by an inconclusive 545-page report. No wonder people wonder about the whole bunch of us." For all that money and verbiage, the cloud that hangs over the FDA, damaging its reputation, hangs as darkly as before and the force of the review panel's findings are diminished by the inability of the majority and dissenting chairman Chalmers to come together on what each side sees as some very fundamental issues.

First, it should be said where the panel majority and Chalmers agree. He, as he states clearly in his dissenting report, joins the majority in saying that the allegations made by the 11 scientists point up "important administrative deficiencies not sufficiently appreciated by the Commissioner . . . ;" that Schmidt should never have conducted an internal investigation; and that, having made that poor choice, he should have at least looked more deeply into many of the specific allegations of harassment and improper reassignments before concluding that they were without substance.

From here, Chalmers and his panel part company. What it amounts to is that Chalmers thinks the panel devoted too much time and effort to a critique of the commissioner's report, with a needlessly heavy emphasis on its inadequate methodology. Chalmers does not think that the panel's methodology was a whole lot better. He accuses the panel of approaching the commissioner's report in a "prosecutorial manner," putting the burden of proof on FDA management rather on those making allegations of wrongdoing.

The panel, quite simply, disagrees, both with Chalmers' position and with his assessment of theirs. Suffice it to say that the panel members believe it is important to try to resolve allegations of past impropriety and that the way to do so is to conduct an outside investigation. Perhaps they should hire Harry O.

What it all amounts to so far is that FDA has been investigated yet once again and it is not clear that anything has come of it. Panelist Norman Weiner, in a comment on the panel's report and the chairman's dissent, says quite aptly, "It is commonly stated that a 'camel has the appearance of an animal put together by a committee.' This report has attributes of a camel."

What happens next is up to HEW Secretary David Mathews, who has to decide whether to empower the panel to conduct another investigation. It is hoped that he will have made up his mind by 7 June when the panel meets again. For all the arguing that has taken place about the commissioner's report, very little attention has yet been paid to questions about the basic ways in which FDA conducts its business and there is still a chance the panel will pull itself together and address them constructively. As one panelist commented, "I hope that at our next meeting we can rise like Phoenix," but he is not at all sure about it.

—BARBARA J. CULLITON