

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.

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## 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 prac-

ticable" 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.