FDA's proposal is justified. "You can assume that most people would approve of using investigational trials," he says, under the conditions FDA specifies.

Before any trial could receive a waiver, the FDA proposal calls for a review by an independent physician and a hospital's institutional review board (IRB)—a committee of experts and laypeople. They would have to agree on several points: that the trial addresses a life-threatening situation, that the experimental treatment is at least as good as conventional therapy, and that the condition of patients is likely to be such that it would be very difficult to obtain consent in advance. As added protection, the proposal requires consultation with representatives of the community from which the subjects will be drawn, advance public notice of all waived studies, an independent board to monitor the studies as they progress, and publication of all results.

While IRBs had authority to grant waivers in the past, the new rule will make such decisions easier by providing specific guidelines. One leading advocate of this change, Michelle Biros, research director of the department of emergency medicine at Hennepin County Hospital in Minneapolis, says she is pleased with the proposal. She says it incorporates many recommendations made by a coalition she heads that is made up of emergency medicine professionals, patient advocates, and bioethicists.

Although it has been well received so far, the new rule may have a practical drawback, according to Caplan: It may overburden the IRBs. "The FDA is requiring the IRB to take a close look at the research, justify a waiver, and monitor what's going on. That is asking a lot of a board that is already under tremendous workload pressure," he says. But Pendergast thinks that few studies will be eligible for a waiver under the FDA's guidelines, and few researchers will apply.

Unless it hears a strong objection, the FDA plans to finish collecting public comment on 6 November and put the new rule into effect shortly afterward.

–Lori Wolfgang

SPACE SCIENCE

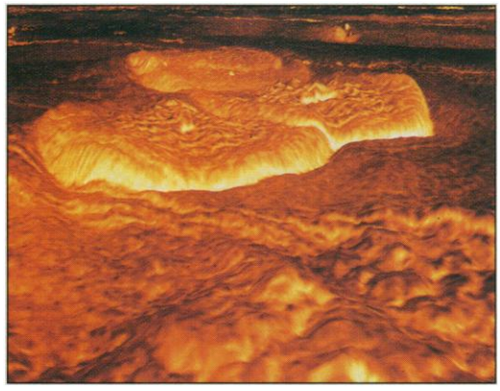
Panel Critiques NASA Science

An 11-member independent panel of industry managers and academic researchers has come up with a litany of criticisms of how the National Aeronautics and Space Administration conducts science—but senior NASA officials will probably see it as a vindication. For starters, the panel says, the agency should give its chief scientist greater authority and come up with realistic priorities to match the agency's slowly declining budget. The panel also urges NASA managers to combat what it calls the "insular culture" at the agency's far-flung centers and to subject technology to more exacting peer review. But far from implying a new direction, agency officials say, most of those recommendations match the course that NASA Administrator Daniel Goldin had already set for the agency's $3 billion worth of research each year in astronomy, life science, and other fields.

Released last week, the 18-month study was spurred by the major reorganization of NASA science that Goldin undertook in 1992. Complaining that programs were taking too long, cost too much, and lacked thorough review from the scientific community, Goldin removed Lennard Fisk, the popular chief of NASA science programs, and chopped the single science office up into three pieces (*Science*, 23 October 1992, p. 540). The apparent downgrading of science angered Senator Barbara Mikulski (D–MD), a Fisk supporter whose appropriations subcommittee requested the NRC review of NASA's science the following year.

The NRC panel, chaired by former IBM research director John Armstrong, backs Goldin's revamped organization but calls for the chief scientist to have a greater say in formulating the agency's scientific direction. The chief scientist position has only rarely been filled in NASA's 37-year history, and then it was largely a ceremonial one. Last year, however, Goldin appointed Pennsylvania State University astronomer France Cordova to the job and elevated its status. "We have a more informal way of doing things, and they recommend we formalize that," Cordova told *Science*.

Another recommendation may also have a familiar ring to NASA managers: that Goldin improve the quality of science at the NASA centers by expanding their contacts with the outside community and promoting greater competition among research projects. "The administrator was very receptive to this," Armstrong says. At Goldin's request, a team of agency managers has been putting together a plan in recent months to set up independent institutes at the centers that would boost the quality of NASA science. "The whole business of these institutes [is] to make sure we're not insular," says Cordova.



NASA

Hot topic. Management of NASA science efforts, which include the recent Magellan mission that mapped the surface of Venus, is under scrutiny.

Armstrong warns, however, that the plan must be carefully put together to ensure that the institutes have a good measure of financial and managerial independence from the centers. "It's naive to think good intentions are all it takes," he says. His panel also emphasized that NASA headquarters should maintain a firm grip on peer review and overall science oversight, despite Goldin's push to downsize the Washington headquarters drastically in coming years.

Likely to be more controversial is the panel's advice that NASA be more strict in making awards for technologies that affect science programs—such as spacecraft design or propulsion. "This means peer review by engineers, not by scientists," says Armstrong. But one NASA official decries the recommendation as a "grab" by the scientific community to extend its control over technology efforts and budgets. "You don't go to the universities to develop a new propulsion system," he says. "You try and do it cooperatively with industry—and then you can't peer review it," as companies are nervous about giving away their technical secrets to potential competitors. Cordova says NASA will set a clear policy on technology peer review early next year.

On a broader scale, Armstrong's panel also calls for NASA to set up a more formal mechanism for choosing future missions in an era of tightening budgets. "The basic problem up to now is that [members of] the science community have been willing to choose what they believe are the most important projects within a discipline, but not across disciplines," he says. The study proposes a more open and structured process for making these choices that could avoid some bloodletting between disciplines.

Cordova was unwilling to discuss NASA's reaction to the report in detail until she discusses it in depth with Goldin and the agency's science managers, but she praises the report as "responsive to the issues" and full of some "creative suggestions." Of course, advice is especially welcome when it confirms what you are already doing.

–Andrew Lawler