

Califano "preferred the option of calling the drug an imminent hazard," Finkel says. Legally, this meant that phenformin's New Drug Application (NDA) was suspended, thus forcing the manufacturers to withdraw the drug from the market. Then an expedited hearing was held to justify continuing the suspension of the NDA. If the imminent hazard ban were not invoked, the hearings would come before the NDA was suspended.

In his order suspending phenformin's NDA, Califano cited four sources of evidence that the drug is hazardous: data submitted by the drug's manufacturers, foreign clinical data, data from a prospective study in the United States, and reports from individual hospitals in the United States, Australia, and Sweden. These various sources of data led to quite different estimates of death rates from phenformin, which is why the FDA's calculated death rate was so imprecise. The argument was that even the lowest estimated death rate was too high.

Opponents of the phenformin ban, who include a group of about 250 doctors and patients that calls itself the Committee for the Care of the Diabetic (CCD), stress the weakness of all of these data. They point out that, at the expedited hearing following Califano's suspension of phenformin's NDA, Administrative Law Judge Daniel J. Davidson dismissed most of Califano's evidence that the drug is harmful. For example, he dismissed as incomplete the foreign clinical data. These data had been obtained by a few trans-Atlantic telephone calls made by the staff of the FDA's general counsel.

Judge Davidson dismissed the data from the prospective study, known as the University Group Diabetes Project (UGDP), after hearing testimony on these data from Samuel B. Beaser, professor emeritus at Harvard University and former chief of the diabetes clinics at Massachusetts General Hospital and Beth Israel Hospital in Boston. Even though two FDA witnesses said at the hearing that the UGDP data were the best available because they came from a prospective study, Beaser argued that the government's "pivotal case" from the UGDP was virtually a textbook example of a person in whom use of the drug was contraindicated.

Davidson dismissed as unreliable the manufacturers' estimates of the risks of lactic acidosis. He accepted, however, data from one U.S. hospital, which were obtained by Frank Davidoff of the University of Connecticut School of Medicine. Davidoff estimated the expected

Soviet Jailings Hit by 2400

Years of hard labor and close quarters are the fate of Yuri Orlov, 55, and Anatoly Shcharansky, 31, two Soviet scientists who were condemned to long prison terms last summer for monitoring Soviet adherence to international agreements on human rights (*Science*, 17 November 1978, p. 731).

Now, in the largest protest of its kind, 2400 U.S. scientists have pledged to end or restrict their cooperation with the Soviet Union until the two prisoners are released. And these protests, according to several U.S. scientists, have already had an impact.

The group, known as Scientists for Orlov and Shcharansky (SOS), includes 13 Nobel laureates and 113 members of the National Academy of Sciences (NAS). They announced their protest at a press conference in Washington, D.C. on 1 March. More than 70 percent of the 2400 signed a pledge "to withhold all personal cooperation with the Soviet Union until Orlov and Shcharansky are released." The rest do not foreclose their participation in existing exchange programs, but commit themselves to passing up international conferences in the Soviet Union, to opposing the enlargement of U.S.-Soviet exchanges, and to campaigning against the transfer of sophisticated technology to the Soviets.

Said Nobelist Paul A. Samuelson of the Massachusetts Institute of Technology, one of the signatories: "Recent acts of bureaucratic repression of scholarship and science have done tremendous harm not only to the fabric of the international scientific community but to the power interests of the Soviet Union itself. . . . They [the Soviet authorities] misjudge the realities if they think that, after a brief period of agitation, emotions will settle down and scientists abroad will forget."

One of the organizers of SOS, Kurt Gottfried of Cornell University, said that "scientists were perhaps the first Americans to cross the chasms of the Cold War . . . we are now curtailing these contacts with the deepest reluctance, but the actions of the Soviet government appear to leave us no other alternative."

Since the convictions of Orlov and Shcharansky, says Gottfried, several international meetings in the Soviet Union have had to be canceled, and many others have had greatly reduced attendance. The transfer of technology, especially computers, added Joseph Weizenbaum of MIT, has also suffered. And according to Dan McCracken, president of the 40,000 member Association of Computing Machinery (ACM), the ACM Council has decided "not to cooperate with or cosponsor any meetings held in the U.S.S.R."

Others, however, were skeptical. Said one State Department source: "I personally doubt that a boycott will have the desired effect. Computer sales will be picked up by the Japanese and Germans, and the Soviets will go out of their way to show that they cannot be bullied."

One of the most prominent scientists to get out of the Soviet Union, Veniamin G. Levich, speaking in New York, said that Western critics of Soviet repression should be more careful to avoid exaggerated accusations, because Moscow seeks to undermine the credibility of criticism by exposing exaggerations. "Things in the Soviet Union are bad enough without having to make them seem worse," he said. "Also, when you demand Soviet respect for human rights, you have to be very specific what you mean, because the Soviet authorities constantly praise human rights themselves. But they mean something quite different from what you mean."

And there were other criticisms. Said Larry Mitchell, who runs NAS's U.S.-Soviet Inter-Academy program: "To cut off relations, in the long run, is probably counterproductive. It punishes individual Soviet scientists for circumstances over which they have no control."

But members of SOS, at their press conference, said that the Soviets used exchange programs as rewards for politically orthodox scientists, and that the work of these scientists was often mediocre.

Added Christian Anfinsen, a Nobel laureate biochemist at the National Institutes of Health, "The Orlov and Shcharansky cases were the last straw." — WILLIAM J. BROAD