Higher and professional education is critically dependent on Soviet aid. As well as supplying funds for the professional schools, the Soviet "Progress Publishing Company" is to produce more than 200 university textbooks with a total print-run of 300,000 copies as grant in aid. (These will mostly be translations of existing Soviet texts). Moreover, although postgraduate courses up to master's degree are now available at the Kabul Polytechnic Institute and will shortly be introduced at Kabul University, most postgraduate training can still take place only in the Soviet Union. This year, some 1,500 graduate students began courses in Moscow, which, compared with the 4,155 freshmen enrolled this year, constitutes a sizeable proportion of the student body.

Vera Rich

FDA on overseas data

US drug market to open up?

Washington

New drugs may be approved for sale in the United States solely on the basis of foreign data under a proposed reorganization of the Food and Drug Administration (FDA) new drug application process. One effect may be to facilitate the entry of drugs developed abroad into the US market.

The proposed changes, published last week, have already provoked some strong reactions. Under current FDA rules, at least one of the clinical studies of a new drug must be conducted within the United States. Critics claim that FDA's proposal, increasing the admissibility of foreign data, flies in the face of evidence that foreign studies are difficult to verify and that standards for protection of human subjects are generally lower outside the United States.

In a discussion that accompanies the new proposal, FDA concedes that there are problems in accepting foreign studies. For one thing, genetic differences between foreign and US populations may render foreign results inapplicable; similarly, differences in medical practice and even in terminology (the definition of "depression", for example, is shaded by cultural differences from country to country) may also be significant. FDA admits, too, that the competence of foreign researchers is more difficult to judge than that of US scientists. FDA's proposed solution is to reject applications based solely on foreign studies when "the calibre of the key clinical investigators and facilities is unknown" or when there is "reason to believe" that genetic, medical or cultural differences affect the applicability of the results to the United States.

But a potentially more serious obstacle to the acceptability of foreign data is the difficulty of auditing foreign clinical trials. A House of Representatives subcommittee found last August (see *Nature* 12 August, p.598) that FDA investigators were unable to gain access to the medical records of a clinical trial in a Canadian hospital because of local confidentiality laws; and an audit of one Mexican study found patients' records destroyed.

FDA says it will reject applications if a "for-cause" inspection is considered necessary and then cannot be carried out because of such obstacles. But Dan Sigelman, who is on the staff of the House subcommittee that investigated FDA, says that this is a "Catch-22". FDA routinely conducts spot-check audits of domestic studies and these, according to Sigelman, are what normally turn up the cause for further "for-cause" inspections. "On what ground are you going to determine the need for an audit without an audit?" he asks.

Sigelman also questions FDA's assertion that US drug companies will continue to favour US studies so that they can acquaint US physicians with the new drug before it is marketed. "They can sit and argue all they want that drug companies won't go abroad, but if the trade-off is getting a drug on the market more quickly, you're just opening up the floodgates to foreign data", he says.

The change on foreign data had been pressed by the US drug companies' trade group, the Pharmaceutical Manufacturers' Association (PMA). PMA also got its way on another controversial point: FDA is proposing to drop the current requirement that case-report forms from clinical trials be submitted with new drug applications. In place of these forms, which are made out by the clinical investigator on each patient, a tabulation of the raw data would be submitted. Under this proposed change, FDA could still request the case-report forms, but only when a "legitimate need for them exists in order to conduct an adequate review of the application".

The only noticeable tightening of the rules in the FDA proposal concerns the reporting of adverse findings about a drug by its manufacturer. The current rules are vague on how and even whether adverse findings are to be reported to FDA once an application is on file for approval — as the case of Eli Lilly and Co.'s reporting of deaths among Oraflex (benoxaprofen) users demonstrated earlier this year.

FDA's proposal requires drug companies to file a safety report every four months when it has an application on file. FDA is also proposing to tighten its requirements on reporting of adverse effects of drugs already on the market: fatal and life-threatening effects would be reported to FDA within 15 days in "alert reports", other "adverse experiences" within 30 days.

Critics are calling these changes window dressing, however. Dr Sidney Wolfe of the Ralph Nader Health Research Group says, "my response to this whole stunt is that the more important issue is enforcing existing regulations". Wolfe cites FDA's continued failure to bring criminal charges against Lilly, as recommended by a former FDA investigator, for withholding adverse effect data on Oraflex and three other drugs.

FDA is accepting public comments on its proposed changes until 20 December. After digesting these — and possibly making some alterations — the agency will publish a final rule, probably in early spring. As the proposals stand now, though, it is clear that the big winners are the drug companies, which will be able to file less paper, receive quicker responses and have an easier time introducing drugs already marketed abroad into the United States.

Stephen Budiansky

Halley upstaged?

Washington

The US National Aeronautics and Space Administration (NASA) has set one of its spacecraft on a complex manoeuvring course that will enable it to intercept and study the Giacobini–Zinner comet on 11 September 1985 — six months before Soviet, European and Japanese spacecraft are due to meet Halley's comet.

The Giacobini–Zinner comet, which approaches the Sun every 13 years, will not be visible from the Earth, but the better known Halley's comet has already been detected with the 5-metre Hale telescope on Palomar Mountain.

NASA's plan is to move the International Sun–Earth Explorer (ISEE 3), which has been in a permanent orbit between the Earth and the Sun since 1978, measuring electric and magnetic fields. US scientists have been upset by the Reagan Administration's cancellation of the $250 million plan for a US spacecraft to Halley's comet. The NASA decision to use ISEE 3 to intercept another comet first may console them, because the United States will thereby be the first to provide valuable data that others can use in analysis of Halley's comet.

ISEE 3 has already been moved to the side of the Earth away from the Sun and on 6 February next year it will be directed on a course that will take it past the Moon. It will then be brought close to the Moon to use its gravity to give the spacecraft a push towards the comet. After the Giacobini–Zinner probe, ISEE 3 may be used to measure the solar wind extending from the Sun towards Halley's comet at the time when the other probes reach that comet early next year.

Deborah Shapley

0028-0836/82/430772-01$01.00