animal studies into the clinical protocols and failing to report properly to FDA.

Dr Hensley's memorandum of 29 September 1981 concludes that for a third drug, drobuline, proper case report records were not maintained, and protocols were not followed. In the case of the fourth drug, monensin, the FDA documents charge that Lilly failed to report adverse effects in animals and humans exposed to the drug, or delayed reporting these effects by as much as 23 months. Lilly was issued a notice of adverse findings on monensin on 6 July 1981.

At the subcommittee hearings, Lilly issued a statement to reporters denying the charges. "Eli Lilly and Company takes vigorous exception to any implication that it withheld data, maintained inadequate records, or failed to comply with the requirements of the FDA".

Stephen Budiansky

FDA regulations

Saving time, but carefully

Washington

The Food and Drug Administration (FDA)'s plans to relax some of its requirements for new drug applications came under congressional scrutiny last week during two days of hearings that also raised serious questions about Eli Lilly and Company's reporting of adverse effects of its drugs (see p.597).

FDA Commissioner Arthur Hull Hayes Jr, testified that the proposed changes in FDA procedures should shorten the approval process for the average application by six months. It now takes nearly two years. An FDA spokesman said, however, that the new procedures would probably have little effect on applications for drugs deemed important, since they are already given expedited treatment.

Representative L. H. Fountain (Democrat, North Carolina), chairman of the House subcommittee that conducted the hearings, focused strongly on two of FDA's proposed changes. One would drop the requirement that drug companies submit the detailed "case report forms" from clinical trials of the drug; the other would allow FDA to approve a new drug application on the basis of foreign studies.

At present, applicants are required to turn over to FDA all case report forms. These are the reports made by the clinical investigators on each patient; according to FDA, they make up 70 per cent of the applications now, often running into hundreds of volumes. FDA is proposing that, instead, the drug companies should be allowed to submit tabulations of the raw data, and only submit the case reports for cases that raise significant safety questions, such as patients who died, or dropped out of the study because of an adverse effect. The companies would still have to supply the case reports if requested by FDA.

Dr Robert Temple, acting director of the office of new drug evaluation, assured the subcommittee that FDA would not lose anything in the change. But detailed reports "will still be asked for as they're needed", he said; and Commissioner Hayes argued that tabulation of the raw data is "more consistent with current scientific practices".

Subcommittee staff members, however, noted that two in-house reviews at FDA found tabulations which did not agree with the case reports they were supposedly drawn for. They were also concerned that FDA reviewers might be intimidated by the prospect of having to make a special request for the case reports, if for no other reason than the time it would take.

On the issue of foreign data, FDA officials similarly tried to be reassuring that the proposed changes would not undermine FDA's ability to make a thorough evaluation. FDA rules now allow foreign studies to be accepted if the investigators are "well-qualified" and if they make background data available to FDA. But in almost all cases, at least one domestic study is also required.

That would change under the new rules. A drug could be approved solely on the basis of foreign data; Hayes suggested that this would be especially important when requiring domestic trials would "cause an unjustifiable delay in the drug's availability to the public", would result in "unnecessary or duplicative testing", or would present an "unnecessary burden on the drug sponsor".

Foreign data would still have to meet US standards and be the product of "investigators of recognized competence". Critics worry that standards will nonetheless be lowered. Dr Sidney Wolfe of Ralph Nader's Health Research Group, said, "The main problem with the use of foreign data is that the drug laws and the protection of human subjects are weaker everywhere in the world" than they are in the United States. And according to Dr John Nestor, a retired FDA employee who worked for many years reviewing drug applications in the agency's cardio-renal drug division, the main effect of the change will be that "the drug companies will be getting their studies done in Mexico and Canada and everywhere else because it's easier to escape surveillance by FDA". At the subcommittee hearing, Representative Fountain released evidence that FDA had encountered just such problems when it attempted to investigate studies done in Mexico and Canada.

The changes FDA is planning appear to enjoy support in Congress. But there are some reservations. Representative Elliot Levitas (Democrat, Georgia) enthused about the benefits of deregulation, and then implied that the only weapon against the drug companies is vigilance.

Stephen Budiansky

Venture capital investment

Now Monsanto

Britain now has one of the best environments in Europe for innovation, a director of the US chemicals company Monsanto said last week. And Mr Richard A. Onians has put Monsanto's money where its mouth is, investing £4.75 million in a new £9.7 million venture capital fund launched last week in London (see *Nature* 5 August, p.505).

Onians describes Monsanto's investment as a window on European technology, but what the company will see through it is mostly British work. The fund is to be managed by Advent Management, which already controls another £10 million fund, Advent Technology, now 15 months old and with ten British investments already under its belt. Monsanto will have no control over the new fund, but Advent Management will use Monsanto for technology assessment.

Monsanto itself seems to have been tempted to Britain for its "window" because of government willingness to allow foreign investment (France would not let Monsanto invest there, in spite of a desperate need to rebuild the French chemical industry), low capital gains taxes and because of what Onians called British inventiveness. There are probably plenty of potential British entrepreneurs as well, he thinks, if only the money is made available.

Sir Kenneth Cork, the accountant and ex-Lord Mayor of London who is chairman of the new fund, believes Britain could make good use of £500 million of venture capital, ten times the total probably now on offer. "But the Trades Union Council plan of £1,000 million from government and £1,000 million from industry just wouldn't work", he said; venture money needs to be hard to get.

Advent Management has certainly found it harder to raise the money for Advent Eurofund than it was two years ago to raise it for Advent Technology, an essentially similar fund. The fashion among finance houses and insurance companies for investing in such funds seems to have been short-lived, says Advent director David Cooksey.

University investment in high technology venture funds seems, however, to be new — new certainly for Cambridge (£500,000) and Oxford (£100,000). St Andrews, Imperial College London, the Nuffield Foundation and Boston University (Massachusetts) have also invested, reaching a total academic interest of £1.5 million. Some 20 other British universities were interested, said Cooksey, but they had not got the cash.

From the universities' point of view, these investments are dealt with like any other but offer a chance of protecting assets against inflation. Cooksey, however, clearly sees them as a window on potential invention, and this is bound to be

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