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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the case even though no formal arrangements have been made. There is no need for formal committees, Mr W. Hyde, Secretary of the Chest (finance officer) at the University of Oxford, says the "old boy network" will suffice. **Robert Walgate**

Polish students abroad

A helping hand

Polish University students stranded in Britain by the declaration of martial law last December should be able to continue their education in Britain under a scheme launched by a group of academics at the London School of Economics (LSE). Following a personal appeal to university principals by Lord James of Rusholme, thirty universities and colleges have offered free places to Polish students unable to continue their studies in Poland.

A preliminary count of students last spring suggested that between forty and fifty places would be needed. Since 22 July, however, when General Jaruzelski made it clear that there would be no early end to martial law, some fifty more students have applied for assistance.

Most of the students had come to Britain on temporary leave of absence from their universities in order to learn English. Many of them, at the same time, had been appointed as roving delegates of the Independent Students' Association (NZS), which hoped to build up strong ties with students unions abroad. NZS was outlawed last January (unlike Solidarity, which technically is only "suspended"), a factor which has undoubtedly influenced the students' decision to remain abroad.

Incorporating the Polish students into the British university structure involves a number of difficulties, even with science students where the curriculum differences are least. Poland has no bachelor's degree; university courses normally last five years, ending with a master's degree.

A compromise has been worked out, whereby students who should be beginning fourth or fifth year work in Poland will enter the second year in British universities, while their juniors will begin again from the beginning. The students themselves seem fairly happy with this plan, since a few terms of what is essentially revision will offset the difficulties of studying in English.

The LSE team, which is acting as an unofficial placement board, feels confident that places will be found for all Polish students who genuinely wish to continue their studies in Britain. The main problem is now that of maintenance; the team estimates that, to take advantage of the places so far offered, it will have to raise some £200,000 for the students' maintenance over three years. A charitable trust — the Polish Students' Appeal Fund — has been launched, and possibilities such as local authority rent rebates are being explored. **Vera Rich**

Nature guide to bio-riches

As a service to readers working in biotechnology, to those who may have invested in this new technology or who may regard its commercial fortunes as an indicator of the success with which bright ideas can be turned into commercial reality, *Nature* will in future publish a monthly listing of the stock performance of 15 representative biotechnology companies in the United States.

This scoreboard of performance will appear in the second issue each month, and will record the price of each of the stocks as traded on the last Friday of the month immediately preceding, the traded price at the end of the preceding month, and the high and low prices during the calendar year.

Where the stocks concerned are traded on the New York Stock Exchange or the American Exchange, the prices listed are those traded. For stocks traded over-the-counter, the prices listed are the bid prices.

***Nature* will also publish once a month a weighted index of the listed stocks, taking an initial value of 100 as of 25 June 1982. In the calculation of this index, the contributions of the 15 listed stocks to the index are weighted according to the total value of the issued stock.**

Between the Fridays of 25 June and 30 July, the *Nature* Biotechnology Index increased from 100 to 102.7.

The data (as of 25 June 1982) on which these calculations will be based are shown in the following table.

Market value of biotechnology stocks, 25 June 1982

	Outstanding shares (millions)	Closing price 25/6/82 ($)	Total market value ($ million)	% of all total market values
A.B. Fortia	19	23.375	444.1	21
Bio-Response	5.5	4.25	23.4	01
Cetus	22	8.0	176.0	08
Collaborative Research	8	8.0	64.0	03
Collagen	5.1	17.875	91.2	04
Damon	6.6	6.5	42.9	02
Enzo-Biochem	5.0	14.75	73.8	04
Flow General	8.0	8.5	68.0	03
Genentech	8.1	32.75	265.3	13
Hybritech	8.8	12.5	110.0	05
Molecular Genetics	4.0	8.5	34.0	02
Novo Industri A/S	16.6	38.25	635	30
Monoclonal Antibodies	2.0	9.5	19	01
Genetic Systems	13.7	2.75	37.7	02
Bio Logicals	5.9	2.75	16.2	01
Total			2,100.6	100

From time to time, *Nature* will also publish graphical analyses of the performance of stocks of particular interest, perhaps because the corporation is going through an eventful period or because the industry as a whole is at some turning point.

The stocks listed have been selected from among the much larger number for which data are available on somewhat arbitrary criteria — because of the volume of transactions, for example. It is intended to review the listing from time to time.

***Nature* is grateful to E.F. Hutton and Co., Inc., for advice on the design of this service and for assistance with the compilation of the data. Suggestions from readers will be welcome.**

Performance of biotechnology stocks, 30 July 1982

1982 high	1982 low		Close previous month	Close July 30	Change
28	16 1/8	**A. B. Fortia**	23 3/8	25 3/4	+2 3/8
7	3 5/8	**Bio-Response**	4 1/4	4 7/8	+ 5/8
14 1/8	8	**Cetus**	8	9	+1
11	6 1/8	**Collaborative Research**	8	8 3/8	+ 3/8
21 7/8	14 3/4	**Collagen**	17 7/8	17 3/4	- 1/8
8 7/8	5 3/4	**Damon**	6 1/2	6 1/4	- 1/4
17 1/4	11 1/4	**Enzo-Biochem**	14 3/4	11 1/4*	-3 1/2
28	6 5/8	**Flow General**	8 1/2	7 5/8	- 7/8
37 3/4	26	**Genentech**	32 3/4	30 3/4	-2
17 7/8	9 5/8	**Hybritech**	12 1/2	13 3/4	+1 1/4
9	6 1/4	**Molecular Genetics**	8 1/2	6 3/8	-2 1/8
44 5/8	34 7/8	**Novo Industri A/S**	38 1/4	39 5/8	+1 5/8
12 3/8	8	**Monoclonal Antibodies**	9 1/2	9 1/4	- 1/4
3 3/8	2 1/4	**Genetic Systems**	2 3/4	2 3/4	0
8	2	**Bio Logicals**	2 3/4	3	+ 1/4

Close of month prices at the close of business on the last Friday of the month. Where stocks are traded over the counter, the price quoted is the bid price. For stocks listed on the American and New York Stock Exchanges the price quoted is the actual transaction price.
*High or low for the calendar year.

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