EEC DRUG-MAKERS CLAMOR FOR EUROPEAN FDA

Many American industrialists will learn with dismay that some of their counterparts across the Atlantic are falling over each other in their eager demands that a body like the U.S. Food and Drug Administration be created in the bureaucratic powerhouse of Brussels. Particularly perplexed will be those U.S. pharmaceutical companies which feel that, over the years, they have faced needless frustration over the FDA's meticulous but time-consuming demands. Why should Europeans establish a mega-agency in the image of the FDA if such a monster has not been necessary in the past? Is this not just asking for trouble?

These are reasonable questions. But there are reasonable answers to them, too. They lie in the unreasonableness of one of the difficulties now facing bio-industries in Europe. Consider the position of a drug or enzyme manufacturer, keen to capitalize on the continent's vast potential market, stretching from the North Sea in the West to the River Elbe in the East. Whether located in a member country of the European Economic Community, established under the Treaty of Rome in 1958, or in one of the countries still outside of this so-called Common Market, the company will have to seek approval for its product over and over again. If marketing and sales are to be achieved in France, West Germany, Holland and Great Britain, for example, the separate and sometimes conflicting requirements of French, German, Dutch, and British authorities will need to be met, one by one. This is all time-consuming, expensive, and boring. There is more than a passing chance that data satisfying one authority's protocols will be rejected by another. This is not an enticing prospect for an aggressive young biocrat.

It's hardly surprising, therefore, that there are growing calls for a single system of control throughout Europe. One of the most recent people to voice a concern shared even by competitors was Mogens Hilmer-Nielson, senior research advisor to Novo Industri A/S. Speaking at a symposium held in Brussels by the Centre for European Policy Studies and the Commission of the European Communities, he argued for an FDA-style body authorized to approve products for sale across the entire continent. "If such an institute could be set up—manned by the best European experts in the different areas—a big step will have been taken towards the creation of a European home market," he said. "Although all countries ought to be involved, including non-members of the EEC, the Commission should take the initiative in setting up such a body."

Closely allied to Dr. Hilmer-Nielson's argument is another, about legislation concerning the industrial applications of recombinant DNA organisms. Again, uniformity would be prudent. In the case of the controlled release of genetically engineered microbes and plants, which do not respect political barriers imposed by *Homo sapiens*, it may be essential. Paradoxically, it is in Hilmer-Nielson's Denmark that the relevant government departments have taken draft legislation to a more advanced stage than in any other European country. The thought of having to alter, unpickle, or harmonize such laws *after* they have been placed on the statute books by diverse national assemblies is one that few wish to entertain. Let us hope that common sense prevails.

Returning to a Euro-style FDA, however, I wonder whether this is really such a good idea after all. Curiously enough, neither the relevant trade association (the European Federation of Pharmaceutical Industries' Association) nor even some of those officials who already work in the Commission's monumental Brussels headquarters appear to be all that enthusiastic about the proposal. Many smaller biotechnology companies also contemplate with marked distaste the prospect of having to deal with another huge, remote, and unfriendly bureaucracy in the Belgian capital.

What actually matters, surely, is the end rather than the means. If today's grotesquely untidy arrangements can be swept away *without* creating a Mega-Administration, then so be it. The obvious alternative is that all of the countries of Europe should agree to recognize each other's standards. This would allow companies to secure Europe-wide approval from their national authorities with less expense and wasted time than under present arrangements or even under a future Mega-Administration. The savings in paper alone would be astronomical. Indeed, plans along these lines have been placed before the European parliament. The reason why they have been overshadowed recently by demands for a Euro-FDA is the perilously slow progress they have made so far, and the possibility that factional infighting will ensure that they never come to fruition.

As Dr. Hilmer-Nielson reminded us during the Brussels conference, it is 150 years since the French historian Alexis de Tocqueville predicted in his book *De La Democratie en Amerique* that two great nations, America and Russia, would come to dominate the world by the 20th century. Although that prophecy had been fulfilled, Hilmer-Nielson said, Europe today would recognize that it possessed the population, cultural background, and intellectual capacity to join the super-powers as a world leader. But to do so would mean disparate nations uniting their forces. "If we fail to do this, Europe will be in a position like that of Greece during the time of the Roman Empire: it will become no more than a supplier of artists, scientists, and philosophers to the great ruling nations of the world."

It may seem mundanely inappropriate to move from such lofty if pessimistic sentiments to the practicalities of product regulation. Not at all. The catalysis Europe clearly needs may well come from sober reflection on the internal barriers, erected by its member states, which are significantly reducing their dividends from biotechnology. Urgent action is required. But I doubt whether that means creating new cadres of bureaucrats.

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