CORRESPONDENCE

MICROENCAPSULATION CLARIFICATION

To the editor:

I would like to clarify some of the history behind the developments described in Jennifer Van Brunt's article, "Vivotech Makes a Bioartificial Pancreas" (October 1985, p.853).

The article described the work currently underway through Vivotech, a joint venture between Connaught Laboratories Ltd. and Damon Biotech, but neglected to mention that the original concept of encapsulating living cells within semi-permeable membranes was invented by Dr. Franklin Lim, then a faculty member at the Medical College of Virginia. Dr. Lim was under contract with Damon Biotech to develop encapsulation techniques for living cells. He is the sole inventor on two patents covering this technology which issued in 1982 and 1983, and are owned by Damon Biotech.

Dr. Anthony Sun of Connaught, who is identified in the article, collaborated with Dr. Lim on the application of this technology to the encapsulation of Islets of Langerhans and their implantation into diabetic animals. As indicated in the article, Dr. Sun's subsequent work succeeded in extending the *in vivo* life of the microcapsules, pioneered by Dr. Lim, and patents have been filed in various countries based on Dr. Sun's work.

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LILLY *IS* MAKING KS1/4

To the editor:

Arthur Klausner's article on "Taking Aim at Cancer with Monoclonals" (March 1986) presented the information in an organized and easily understood manner. It also achieved something we rarely see: it placed the technology in the proper perspective for the patient.

We do have one correction that we would appreciate your printing: The article (page 187) states that KS1/4 monoclonal antibody is being "produced under contract by Damon Biotech." While that is true for the KS1/4 being tested at Scripps Clinic, Lilly is successfully producing KS1/4 in-house for its own conjugation purposes.

Early on we did have contracts with Damon Biotech and several other firms for producing KS1/4 as part of a program evaluating the various technologies available, i.e., encapsulation, hollow fiber, air lift, etc. It was our conclusion that our own in-house capability was more than adequate for KS1/4 production.

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EUROPEAN FDA

To the editor:

Dr. Bernard Dixon's "Commentary" in the January issue discusses establishing a European "Food and Drug Administration" corresponding to the American FDA. One gets the impression that he has considerable sympathy towards the idea, but is frightened by the consequences of another mega-bureaucracy.

I share Dr. Dixon's concern with regard to bureaucracy, but one must bear in mind that we already have an immense regulatory bureaucracy in the 17 countries constituting Western Europe. Each country has its own regulatory body for approval of drugs and food and feed ingredients. If one adds together all the officials involved, a very large number will appear. Evaluating new food and drug applications is very difficult today, requiring many specialists, and it is doubtful whether each country is able to recruit sufficiently skilled people to make the profound and careful evaluations needed. By the establishment of a European FDA, it should be possible to recruit an adequate staff of highly skilled toxicologists, pharmacologists, and other needed specialists, thereby securing a fully satisfactory evaluation procedure. I believe that the number of officials in such a centralized organization would be considerably smaller than the number that are working today in the regulatory bodies all over Europe.

European companies will also have the advantage of applying for approval with only one regulatory body—not with 17 as is the case today. This will be especially advantageous to the small- and medium-sized companies for which the application costs are a heavy burden. Because this applies less to big companies, establishing a European FDA would remove this form of competitive distortion.

If we are earnest about the creation of a European Home Market, something must be done very soon. Bearing in mind the success of the European Patent Office in Munich, I think that a European FDA will be the right solution.

The United Kingdom would be a good place for the European FDA. The country has a very high standard with regard to toxicology and pharmacology, and, therefore, it should be possible to recruit a substantial part of the scientific staff from Britain itself.

The health and welfare of its citizens is the main concern of every government, so it is not easy for a country to leave the vital regulation of the food and drug trade to a supernational organization. A psychological barrier has to be broken down, but it is time to do so if a true European Home Market is to be created within this century.

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A "SINGLE" MISTAKE

To the editor:

We recently sent a news release announcing an achievement by scientists at United AgriSeeds, Inc. This resulted in a note in the January "Chronicle" section (p. 11). Unfortunately, the release contained a key clerical error in the lead paragraph stating that the research team achieved regeneration of whole soybean plants from *single* somatic cells. In reality, the research team did not regenerate whole plants from *single* somatic cells. We regret the error—the word "single" should have been deleted.

But our client's research team did develop a somatic embryogenesis process that works for all soybean genotypes and allows for consistent regeneration of viable, seed-bearing plants.

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