

JOURNAL OF PHARMACEUTICAL SCIENCES



MARY H. FERGUSON
Editor

SHELLY ELLIOTT
Production Editor

EDWARD G. FELDMANN
Contributing Editor

SAMUEL W. GOLDSTEIN
Contributing Editor

BELLE R. BECK
Editorial Secretary

DAVID BOHARDT
Director of Publications

L. LUAN CORRIGAN
Assistant Director of Publications

EDITORIAL ADVISORY BOARD

JOHN AUTIAN	HERBERT A. LIEBERMAN
NORMAN R. FARNSWORTH	DAVID E. MANN, JR.
WILLIAM O. FOYE	GERALD J. PAPARIELLO
WILLIAM J. JUSKO	EDWARD G. RIPPKE

The *Journal of Pharmaceutical Sciences* is published monthly by the American Pharmaceutical Association (APhA) at 2215 Constitution Ave., N.W., Washington, DC 20037. Second-class postage paid at Washington, D.C., and at additional mailing office.

All expressions of opinion and statements of supposed fact appearing in articles or editorials carried in this journal are published on the authority of the writer over whose name they appear and are not to be regarded as necessarily expressing the policies or views of APhA.

Offices—Editorial, Advertising, and Subscription: 2215 Constitution Ave., N.W., Washington, DC 20037. Printing: 20th & Northampton Streets, Easton, PA 18042.

Annual Subscriptions—United States and foreign, industrial and government institutions \$50, educational institutions \$50, individuals *for personal use only* \$30; single copies \$5. All foreign subscriptions add \$5 for postage. Subscription rates are subject to change without notice. Members of APhA may elect to receive the *Journal of Pharmaceutical Sciences* as a part of their annual \$70 (foreign \$75) APhA membership dues.

Claims—Missing numbers will not be supplied if dues or subscriptions are in arrears for more than 60 days or if claims are received more than 60 days after the date of the issue, or if loss was due to failure to give notice of change of address. APhA cannot accept responsibility for foreign delivery when its records indicate shipment has been made.

Change of Address—Members and subscribers should notify at once both the Post Office and APhA of any change of address.

Photocopying—The code at the foot of the first page of an article indicates that APhA has granted permission for copying of the article beyond the limits permitted by Sections 107 and 108 of the U.S. Copyright Law provided that the copier sends the per copy fee stated in the code to the Copyright Clearance Center, Inc., P. O. Box 765, Schenectady, NY 12301. Copies may be made for personal or internal use only and not for general distribution.

Microfilm—Available from University Microfilms International, 300 N. Zeeb Road, Ann Arbor, MI 48106.

© Copyright 1978, American Pharmaceutical Association, 2215 Constitution Ave., N.W., Washington, DC 20037; all rights reserved.

RESEARCH FRONTIERS REMAIN RIPE

A hundred years ago, it is reported, some adventurous fellows complained that "there are no more new worlds to conquer!" In their view, the golden age of discovery and exploration which started with Columbus' epic voyage in 1492 had run its course; it had come to an end, they thought, because everything discoverable had been discovered, and everything explorable had been explored.

In the intervening years, however, we have learned that we really still don't know much about the polar regions, about the ocean depths, and about remote regions of mountains and jungle. For example, entire tribes and cultures, previously unknown, have only recently been found in the Philippine Islands and in South America. And all of this is aside from the dramatic space explorations of the last twenty years.

So, too, in the field of science, researchers are purported to have lamented at various times that all the great discoveries have taken place, and the well of innovation has literally run dry.

We were reminded of all this in September when we read the truly dramatic announcement that human insulin had been produced in a California research laboratory by bacteria through application and use of recombinant DNA research and methodology. The process involves the insertion of a synthetic gene into *E. coli* organisms, which are then grown *via* normal fermentation processes. Insulin is produced by the bacteria during the fermentation, and it is subsequently isolated and purified. The resulting product appears to be identical to human insulin.

Consequently, this discovery has several potential beneficial aspects:

- *First*, when the process is ultimately refined and made practical from a production standpoint, it should require far less time, equipment, and effort to produce insulin by this method compared to existing procedures; this translates into major cost savings.
- *Second*, availability of insulin will no longer be dependent upon the risky supply of vast quantities of animal organs—pancreas glands of cattle and swine—from which the hormone presently is obtained by extraction procedures. This means that any concern over future supplies of critical raw material would be eliminated.
- *Third*, the resulting form of insulin is structurally identical to that produced by the normal human pancreas, as well as being free from any animal protein or other animal by-products; this means a more effective product and virtually eliminates the possibility of allergic reactions.

Considering these remarkable advantages, we are tempted to offer the facetious comment that the people who think up slogans for automobile bumper stickers ought to design one reading: "Bacteria do it better!"

Seriously, however, the accomplishment is really magnificent, and all those who in any way contributed to the success of this feat have our sincere congratulations and compliments. It is recognized (a) that this test-tube scale laboratory success must yet be converted into practical production and manufacturing processes, (b) that considerable animal and clinical testing needs to be performed to demonstrate the safety and effectiveness of the product, and (c) that regulatory approvals also will be needed before the product can be marketed.

Nevertheless, the scientific breakthroughs reflected in this accomplishment constitute major achievements in hormone or protein synthesis (insulin) as well as genetic research (application of recombinant DNA). Either aspect by itself would be considered most noteworthy; coming together in a single stroke, the result is virtually mind-boggling.

This makes it the most convincing proof imaginable that there remain many scientific frontiers of research and discovery that simply await the attention of adventurous minds and imaginative approaches.