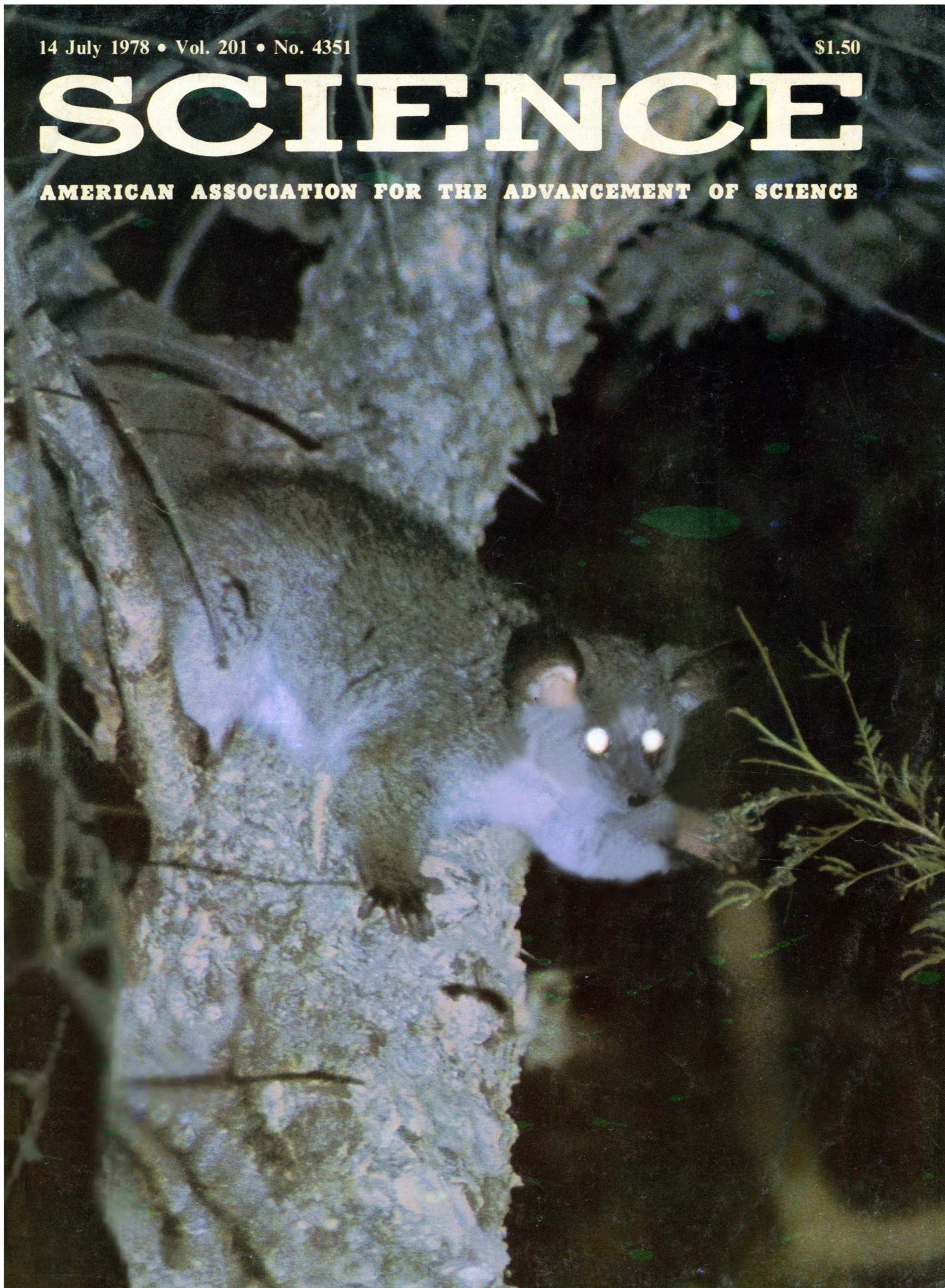


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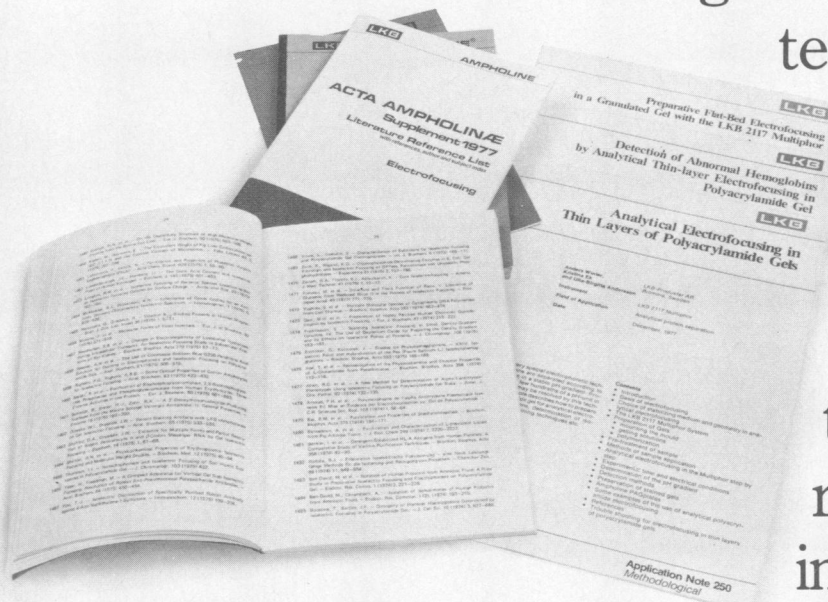
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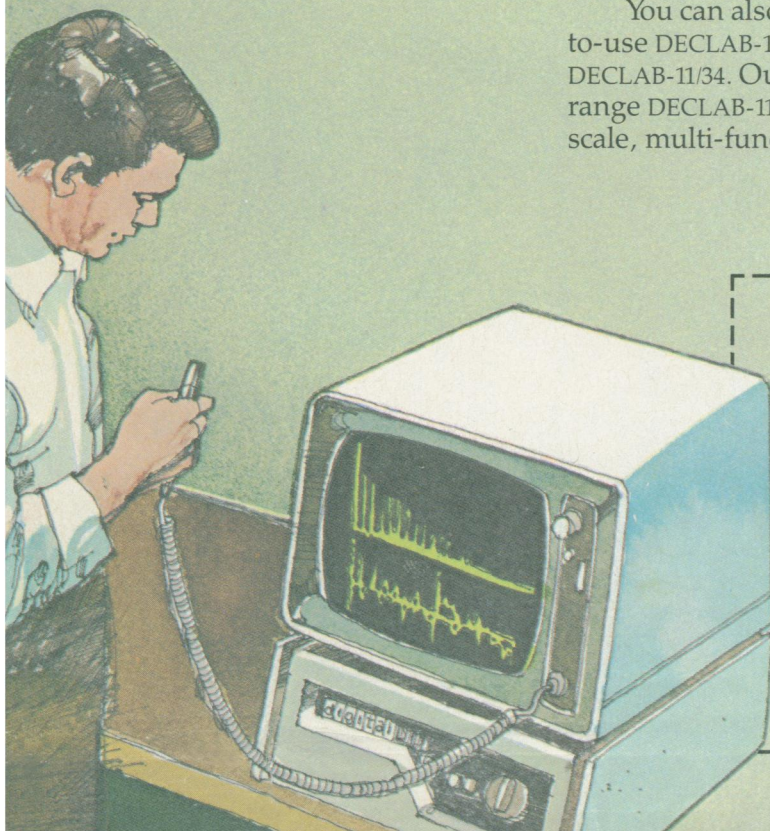
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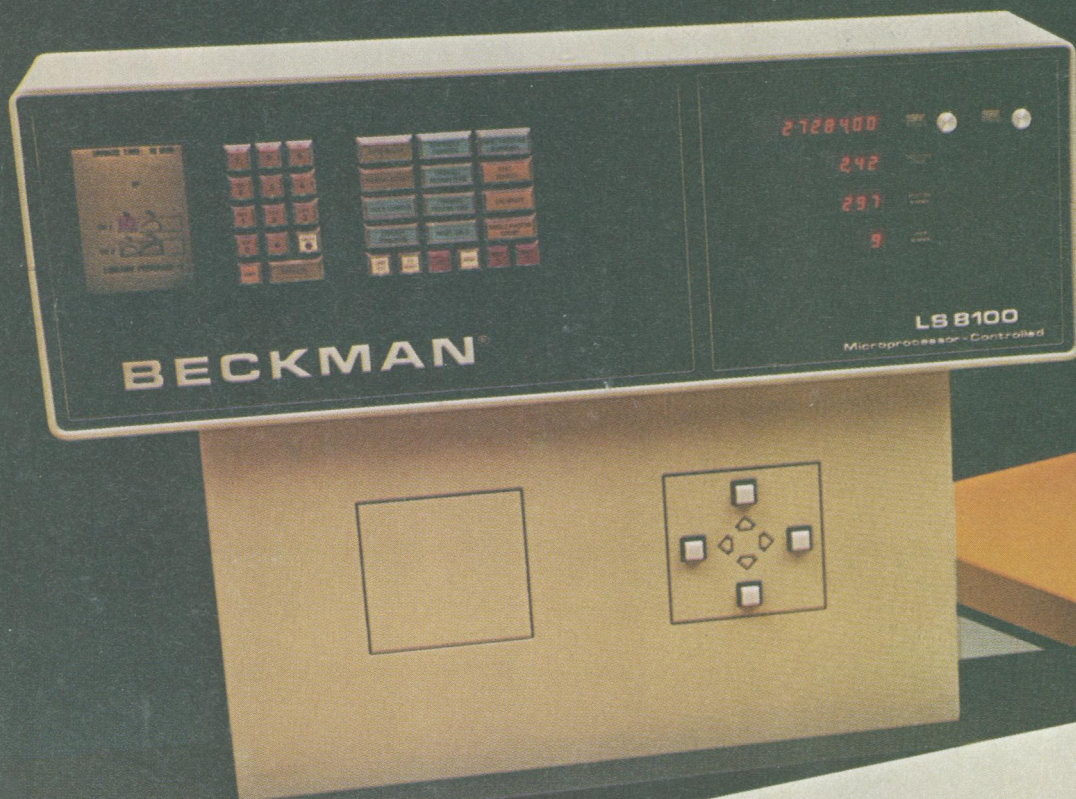
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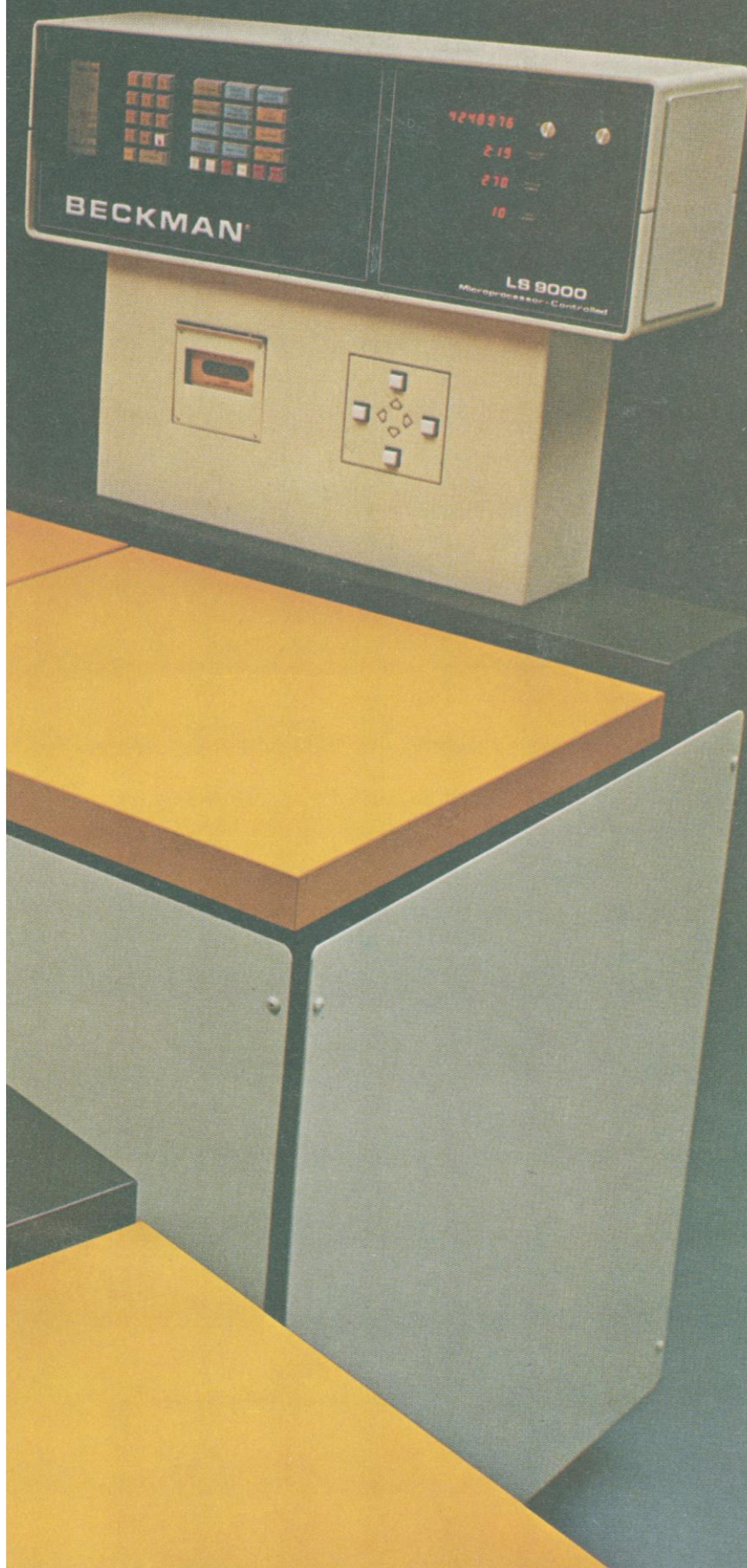
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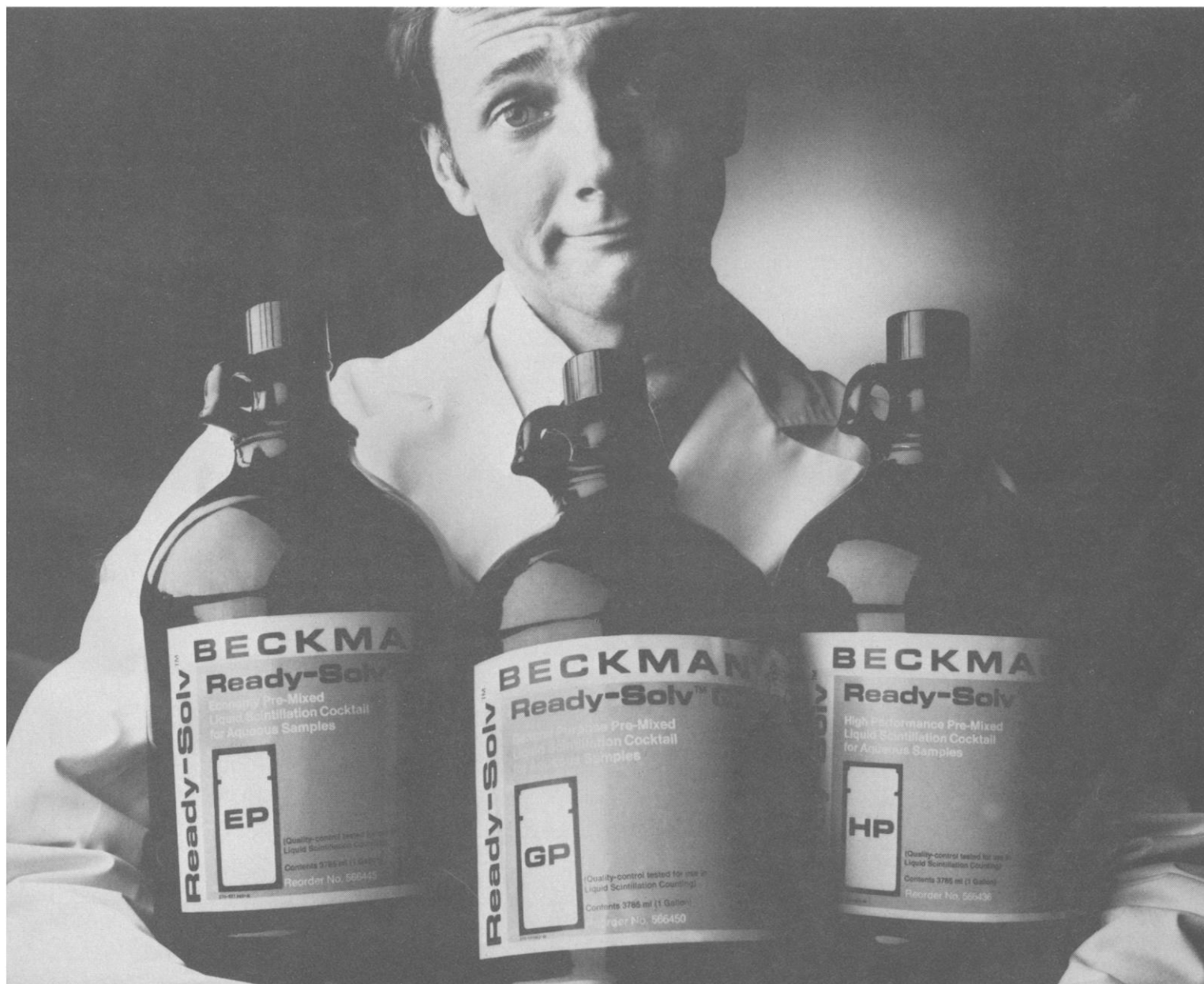
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LETTERS

A Scientist-Senator on Recombinant DNA Research

I wish to express great concern about the broad implications for scientific research in this country if the regulation of recombinant DNA research is expanded in the manner proposed by Senator Edward Kennedy and others (News and Comment, 23 June, p. 1368). As a scientist as well as a Senator, I feel obligated to offer views on the desirability of legislative or executive action which would restrict recombinant DNA research activities more severely than do the current National Institutes of Health (NIH) guidelines.

For the past 2 years Congress has debated the need for and ramifications of the regulation of recombinant DNA activities. This has been an enlightening and worthwhile experience which has assisted Congress and the public in understanding the nature of scientific research and the benefits of a new field of scientific inquiry. After Senator Stevenson and I took the procedural steps necessary to postpone Senate consideration of hastily conceived DNA legislation, we jointly agreed to hold 3 days of oversight hearings on this issue by the science, technology, and space subcommittee during November 1977. These hearings were particularly useful in establishing the scientific basis for calculating the conjectured risk of recombinant DNA research.

The use of recombinant techniques to modify genetic codes in DNA offers great promise for all of mankind through improved understanding of biological processes and varied applications in such fields as medicine, industry, and agriculture. Nevertheless, as with any new field of scientific research, it is impossible at this stage to say with absolute certainty that there is no future hazard from such research. On the other hand, our understanding of natural recombinant processes, evolutionary processes, bacterial genetics and ecology, and pathogenicity all indicate very strongly that there is little to fear. The situation is very similar to the extremely remote possibility of pathogenic organisms being returned to Earth by the Apollo missions. Reasonable safeguards were imposed then without regulatory or legislative action.

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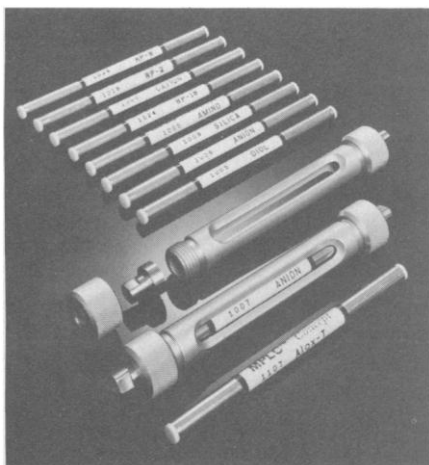
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aberrant DNA strains. There have been no illnesses or any other harm associated with recombinant DNA research. However, we cannot ignore the theoretical risks, nor can we ignore the necessity to assure the public that its health and safety and that of the environment are not reduced from that which exists naturally.

The general thrust of testimony from the more than 20 witnesses who appeared at the subcommittee hearings was that, if there is determined to be a need for legislation, it should be directed toward extending the NIH guidelines to nonfederally funded research on recombinant DNA. I generally agree with that conclusion. However, I am concerned that any action more restrictive than the NIH guidelines might initiate unnecessary and unreasonable restrictions on the conduct of basic scientific research in this country.

The initial fears of potential harm raised by concerned scientists led to what many consider to be premature legislative proposals which would, if enacted into law, unduly restrict the conduct of this valuable research. Subsequently, more broadly based analysis and review of advancements in knowledge about recombinant techniques led to a reassessment of the need for formal government regulation. Many of the scientists who originally raised concerns about the safety of such research have since modified their position in light of more complete information and have concluded that there is little, if any, hazard resulting from recombinant DNA research, particularly when performed under the NIH guidelines. Their assessments of the practical benefits from such research continue to be more and more favorable.

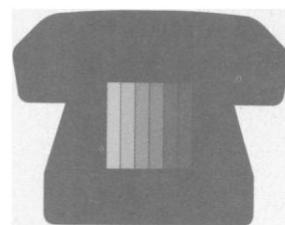
Faced with the continuing controversy over the need for legislation regulating recombinant DNA research, Senator Kennedy and others have suggested that it might be preferable to encourage action by the Executive Branch under the presumption that statutory authority exists, specifically Section 361 of the Public Health Service Act (42 U.S. Code 264). This section authorized the Secretary of Health, Education, and Welfare (HEW) to regulate activities related to the spread of "communicable disease." While the delegation of authority to the Secretary under this section is admittedly broad, there are numerous legal uncertainties and scientific inadequacies associated with its application to recombinant DNA research.

HEW Secretary Joseph Califano has

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indicated on several occasions that he feels the use of Section 361 to regulate recombinant DNA research is inappropriate and inadequate. On 4 May, I wrote to Secretary Califano asking for his specific legal views on the application of Section 361 to recombinant DNA activities. Although I have yet to receive a response from him, I have acquired information from HEW which strongly suggests that application of Section 361 to recombinant DNA research would be inappropriate and ill-advised.

Some of my personal concerns with Section 361 are as follows:

- Application of Section 361 would serve as a bad precedent for Congress by encouraging unilateral and unauthorized action by the Executive Branch to regulate an area of basic scientific research.
- Section 361 would give the Secretary unbridled discretion to promulgate and enforce regulations controlling basic research without adequate safeguards against regulations which would be unnecessarily restrictive. In an 18 May let-

ter replying to my request for his views on the use of Section 361 for regulating DNA research, Frank Press, director of the Office of Science and Technology Policy, said, "Section 361, of course, was not written to regulate research. Its use in this regard may provide precedent for broad intrusions into the research environment. . . ."

- The Congressional Research Service, responding to my request for an analysis of Section 361, agreed with the conclusions of the Federal Interagency Committee on Recombinant DNA Research that "... no single legal authority or combination of authorities currently exist that would clearly reach all research and other uses of recombinant DNA techniques. . . ."

- Under Section 361, there would be no preemption of local law regulating recombinant DNA research, a condition thought to be necessary by many researchers; I am personally uncertain whether preemption is a critical factor.

- Use of Section 361 is likely to lead to much litigation and delay in U.S. research and applications in the recombinant DNA area.

- Section 361 would authorize the Secretary to impose sanctions of up to \$1000 in fines and 1 year's imprisonment, which is wholly unreasonable in view of the purely hypothetical nature of the suggested risks of recombinant DNA research.

Precipitous action such as that proposed by my Senate colleagues could seriously damage basic scientific research in this country at a time when the rest of the world is moving rapidly to reap its benefits. Premature regulation of scientific research based on hypothetical risk assessments would have vast implications for all of science and technology. We must move cautiously and, at the same time, fully explore all of the alternatives to and ramifications of such regulation before embarking on this course.

Until we fully understand the implications of stretching Section 361 to include recombinant DNA activities, it would be imprudent to recommend or allow its application. If we are not more far-seeing and more cautious in our use of regulatory authority, we may find the United States becoming irrelevant, first in the advance of science, then in the advance of technology, and, finally, in the advance of the best of human civilization and freedom.

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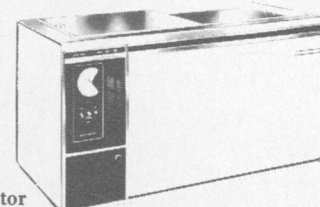
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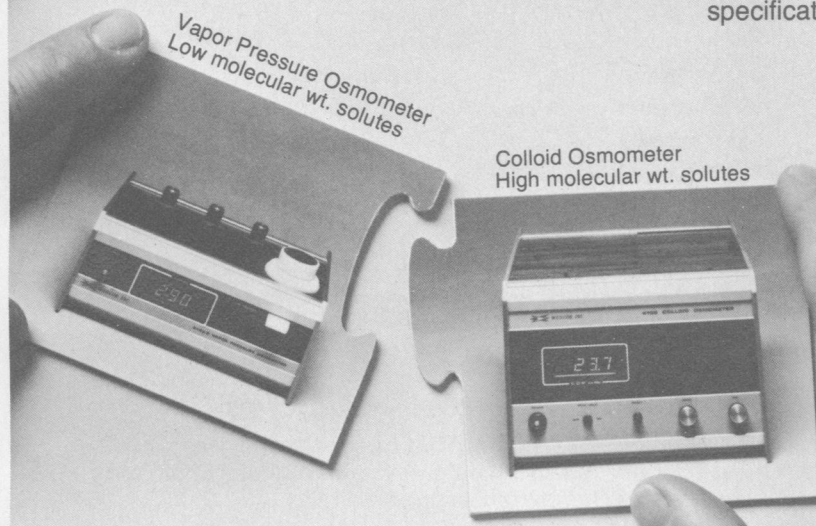
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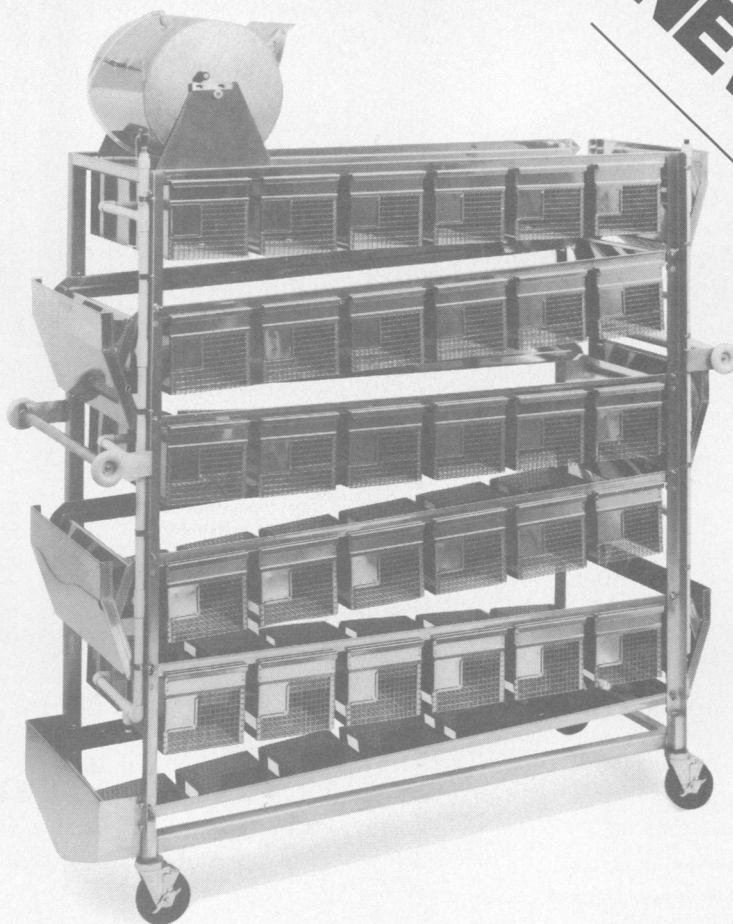


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Public and Private Policies for R & D

AAAS held its third annual R & D Policy Colloquium in Washington in late June. Once again, the academic and industrial sectors mingled and debated with key spokespersons from the White House, the Office of Management and Budget (OMB), and Congress. This was no public rally to wring more money out of the government's hard-pressed purse. On the contrary, the colloquium struggled with large and vexing uncertainties which pervade the many-sided structure of U.S. research and development, and the give-and-take was refreshingly frank.

The framework for the colloquium was set by the special AAAS "R & D Report" prepared by Willis Shapley and Don Phillips, analyzing President Carter's budget decisions on research and development and exploring the indicative evidence concerning industrial research and the connections between R & D and the performance of the national economy. Aside from its merits in sizing the current government mind-set toward R & D, the report provides a unified view of the disordered terrain that we like to call "science and technology policy." It is important reading.

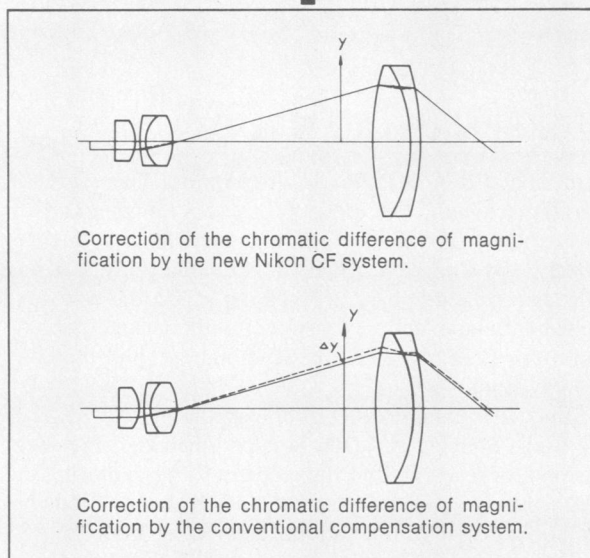
The colloquium made several things clear. Government is now reaching for consensus approaches to national science and technology policies. There is still some life left in the system of checks and balances in the relations between politics and science. It is up to the scientific and technological communities to get into the act and help to construct the terms on which the United States will both pursue the search for knowledge and reach a less ambiguous view of the contributions of R & D to the technology base of the nation's economy. Equally clear are the risks associated with underinvestment in basic research, the confusion among public policies that promote science and others that discourage innovation, and the vulnerability of R & D as discretionary outlays in the emerging national distemper toward the high price of government.

But the colloquium suggests something else that is on the cheerful side. As we look at the federal government, in a number of ways the quality of policy management for R & D begins to be impressive. There is, at this point, an unmistakable search for a better architecture of science and technology policy, on the part of the Executive as well as Congress. We begin to see a blending of science policy with economic and budget policies, together with a definite tilt toward multiyear fiscal strategies, starting with the 1980 budget. Even in the area of science and technology indicators there is evidence not only of lively development but also of intentions to link such indicators directly to policy management. None of this signifies that public policy for science and technology has done more than turn the corner, much less that it is settled or complete. What it does indicate is that public policymakers, few of whom are at home with science, are trying very hard to cope. The White House study of the problems afflicting industrial risk-taking, in an environment of public policy uncertainty, is sufficient evidence of this.

One example of the candor displayed at the AAAS colloquium was OMB's revelation that the 1980 budget, now being scripted, will be exceedingly tight because of inflationary danger signals. Research and Development may well feel the pinch, barely 1 year after experiencing a growth budget. This exemplifies the predicament assailing the whole process of public policy-making: an itch for durable science policies on the one hand, and the mischief created by near-term discontinuities on the other. But if there is bad news, there is good news too, and it is the new awareness by government of research and development as necessary public and private investment and as very good economics. That constitutes high ground for science and technology in the long run, and it is ground that can be held.

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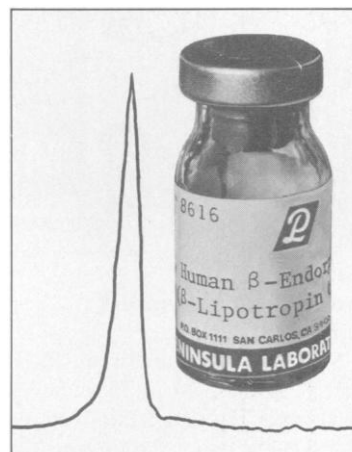
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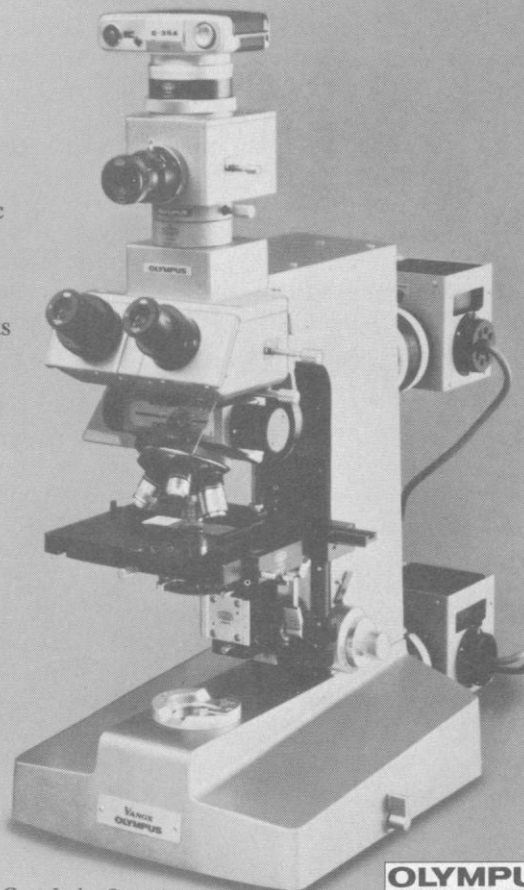
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Literature

Radioimmunoassay Instrumentation describes the RackGamma counting instrument for analysis of double-labeled samples, enabling the operator to count gamma emitting isotopes of cobalt, selenium, chromium, iodine, and iron in addition to iodine-125. LKB Instruments. Circle 672.

HPLC Detectors are listed on separate data sheets that include design specifications and individual features. Micromeritics Instrument. Circle 673.

Camera Microscope is devoted to the Ultraphot IIIb which is suitable for all biological and metallographic applications. Carl Zeiss. Circle 674.

Absorption Spectrophotometry reports dual-element determinations with the IL 751 atomic absorption spectrophotometer in 25 analytical laboratories. References are included. Instrumentation Laboratory. Circle 675.

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Biological Stains also lists indicators, embedding and mounting media, buffers, fixatives, and reagents. Atomergic Chemetals. Circle 676.

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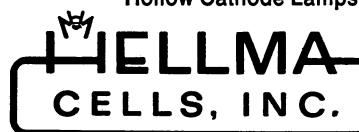
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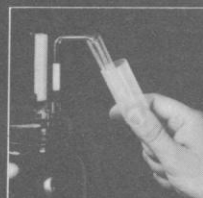
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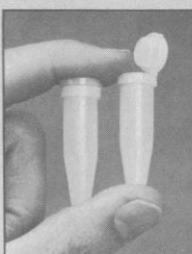
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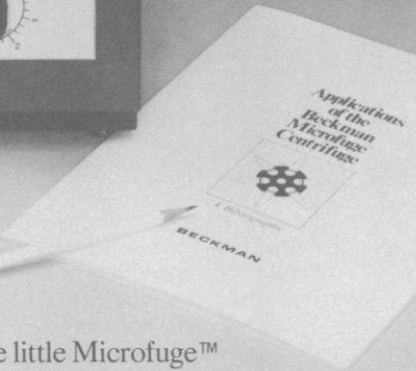
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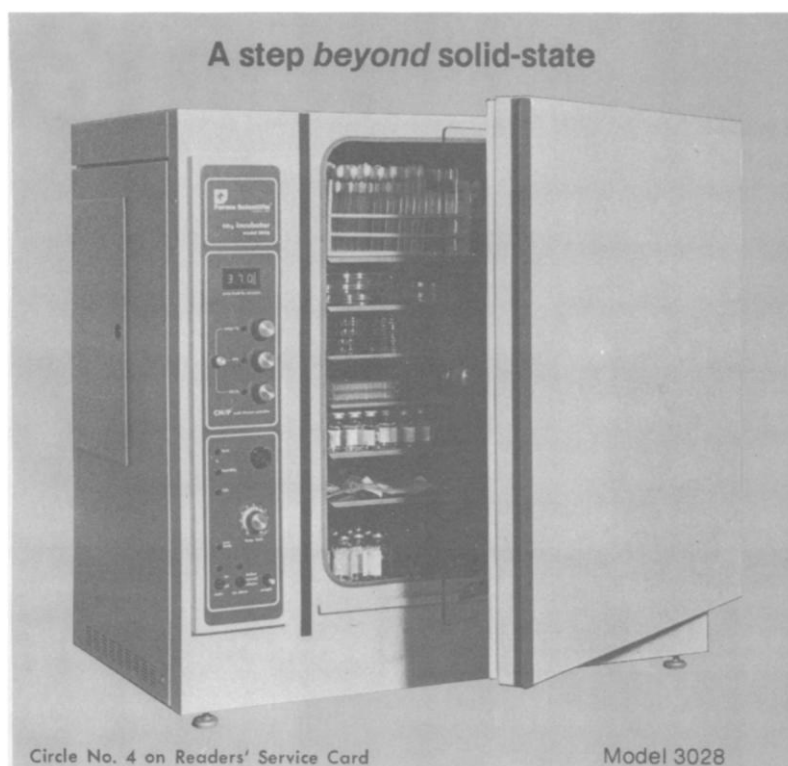
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