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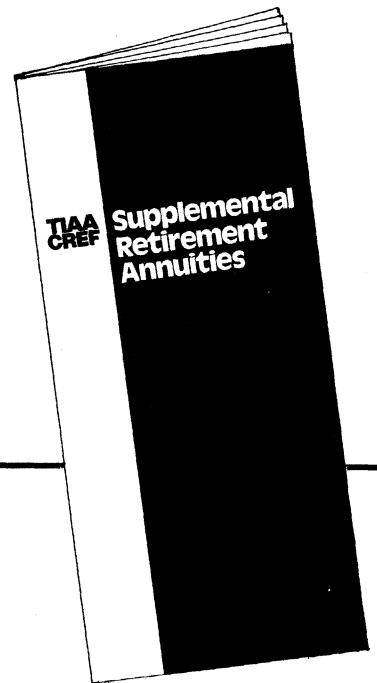
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Fundus of left eye of human ocular albino showing abnormally hypopigmented choroid and retinal pigment epithelium surrounding optic nerve head. Some pigment is present temporal to nerve head in region of hypoplastic macula. See page 931. [Terry George, Wilmer Ophthalmological Institute, Baltimore, Maryland]

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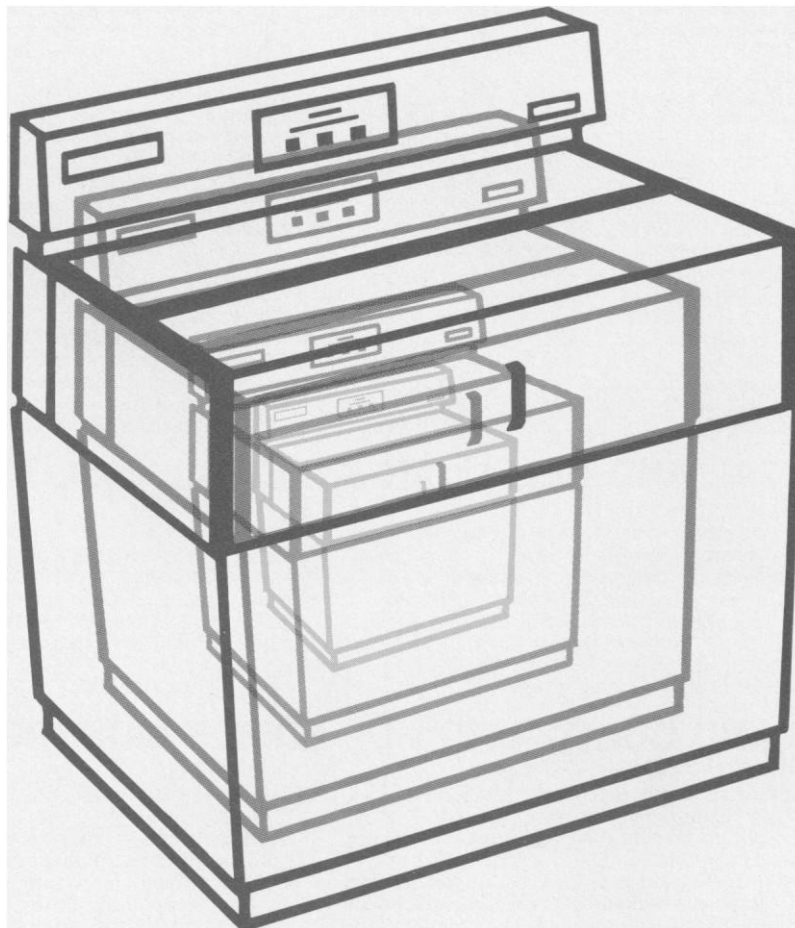
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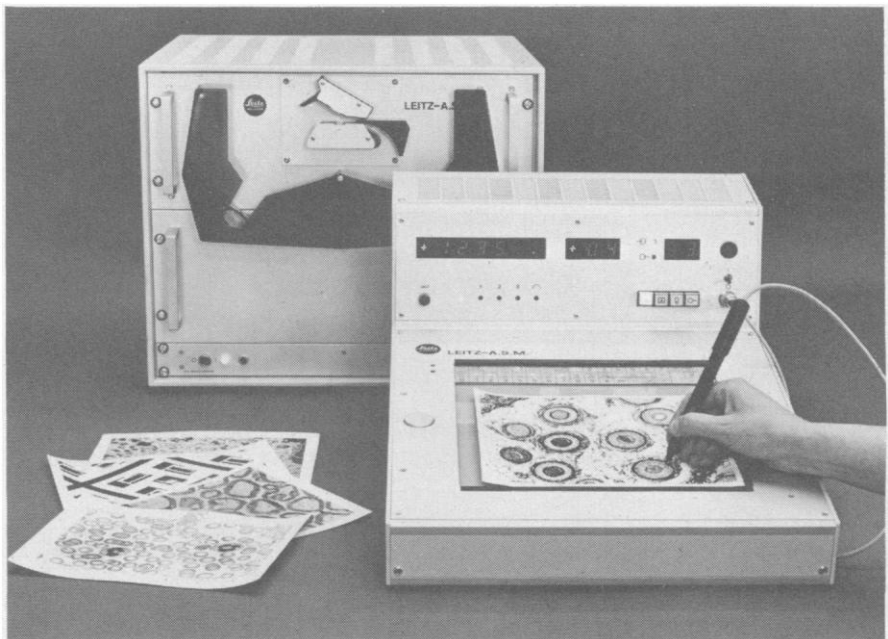
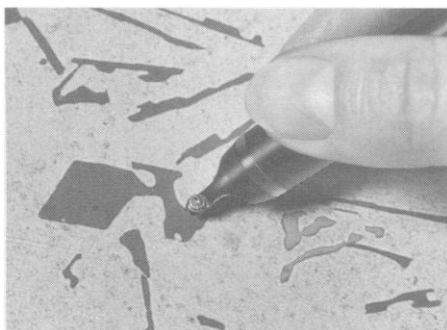
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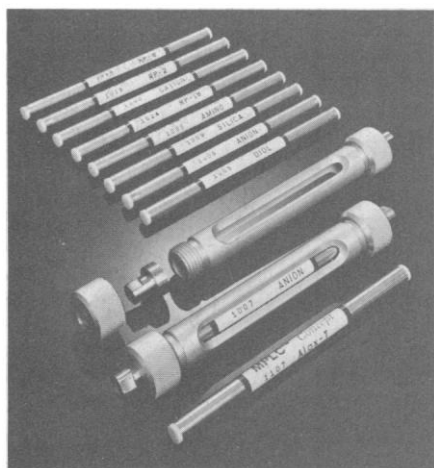
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LETTERS

Drug Regulation

Louis Lasagna (26 May, p. 871) presents his usual brisk and thorough defense of the pharmaceutical industry position on new drug development. I have only two quarrels with it; one minor, the other more significant. At one point, Lasagna accuses me of having indicated my "intention to hold a series of hearings in various cities to 'demythologize' the medical profession," an assignment that he finds strange for the head of a regulatory agency. I have, in at least one speech, suggested that it would be a good idea to take some of the myth out of medicine; and I have held hearings, and intend to hold more, on such subjects as food standards and labeling, the use of antibiotics in animal feeds, and a variety of other regulatory issues. I do not know how these two matters relate to one another, but I want to assure Lasagna that I have no intention of holding hearings to "demythologize" the medical profession.

On the more serious issue, the most striking thing about Lasagna's article is that it takes so little account of current events. Nearly 10 months ago, two important things happened. First, an influential panel that advised the Secretary of Health, Education, and Welfare on new drug evaluation released the results (1) of the most extensive external investigation of the Food and Drug Administration (FDA) yet made. Second, partly in response to that undertaking, we announced that the Administration would work with Congress to provide the drug regulatory enterprise in this country with the statutory base that the Secretary's panel said it so badly needed. There followed a series of public hearings at FDA late in 1977 and various announcements of the general shape of the new legislation. Draft copies of the developing bill were widely circulated for comment and have been publicly available since the introduction of the Drug Regulation Reform Act of 1978 in early April. In the course of these discussions almost every one of the issues touched on in Lasagna's article has been analyzed, debated, and refined well beyond the level at which he treats them. Perhaps the timing of *Science's* publication is at fault, or perhaps Lasagna was not quite as agile as he would like FDA to be. Whatever the reason his article is an anachronism. Readers of *Science* who are seriously interested in the public policy issue surrounding the new drug approval process

in the United States should try to follow the developing debate on S. 2755 (H. 11611), and examine the Executive Summary of the Secretary's panel report.

DONALD KENNEDY

*Food and Drug Administration,
Rockville, Maryland 20857*

Reference

1. Review Panel on New Drug Regulation, *Final Report* (Department of Health, Education, and Welfare, Washington, D.C., 1977).

Kennedy's letter starts with unseemly innuendo and ends with the reddest of herrings. He misrepresents my personal critique of the present sorry state of drug innovation as a "... defense of the pharmaceutical industry position. ..." If *Science* had wanted the latter, a more knowledgeable and appropriate protagonist could easily have been recruited from the ranks of industry. It is depressing to see the Commissioner of the Food and Drug Administration (FDA) politicizing so readily, in an apparent attempt to brush aside a concern which an ever increasing number of academic clinical pharmacologists have.

In several speeches, Kennedy has referred to the need to "demystify" science and medicine and to "demystify the relationship between the physician and the patient" (1). In a speech (2) on 19 January 1978 before the Consumer Federation of America, he coupled his perceived need for "a concerted effort to 'demystify medicine'" with his announcement of a national project on consumer access, to be "launched simultaneously in seven cities." I am delighted to hear that no anti-physician hearings are scheduled.

Now let me comment on Kennedy's "more serious issue." The Commissioner implies that everything I discussed has changed so drastically in the last 6 months that my article is an "anachronism." What has brought about this miracle? Answer: The Dorsen Panel report, the proposed Drug Reform Act of 1978 (which was introduced in the Congress *after* my article was sent to *Science*), and the discussions concerning these documents. If Kennedy in fact believes that these events have "refined" out of existence the long list of troubles identified in my article, the FDA is in worse shape than I imagined in my blackest moments.

On 11 July 1978, some of the country's most knowledgeable experts from government and academia convened in Washington, D.C., to discuss the proposed drug reform legislation. The group included two former FDA commis-

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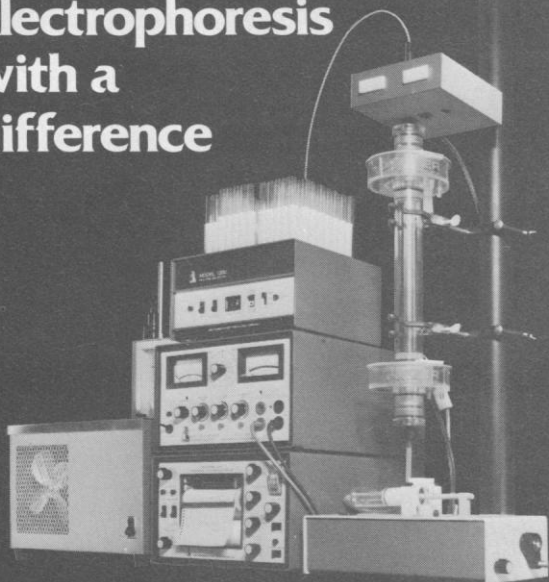
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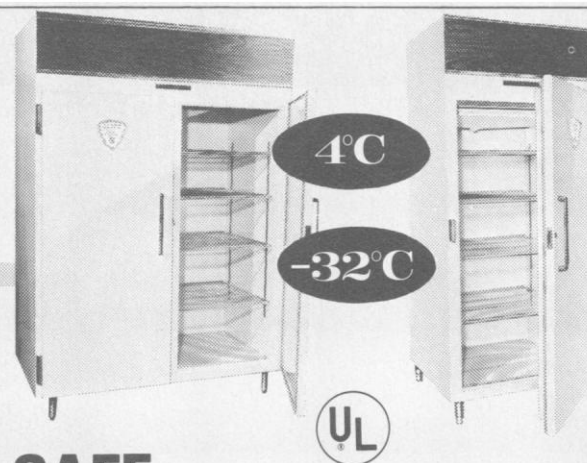
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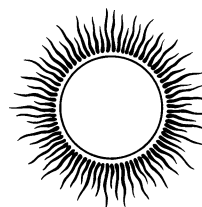
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sioners (a third phoned in his comments) and two former general counsels for the FDA. There was unanimous agreement among these former public servants that the major problems besetting the FDA have little or nothing to do with drug legislation and cannot be corrected by statute.

Even Kennedy's own staff overwhelmingly indicated, at a 23 May Senate hearing on S. 2755 held at FDA's Parklawn Building, that the bill will actually slow down drug approval, despite the fact that the correction of delays is a prime goal of the legislation. Indeed, most knowledgeable drug experts predict that the unbelievably complex legal instrument proposed in March would only aggravate most of the problems I enumerated.

No one wishes more fervently than I for the rapid obsolescence of my critique. I see no hope for this, however, unless current FDA leadership is willing to learn from the lessons acquired so painfully by previous top FDA officials. The public will not be well served by mere rhetoric, no matter how clever. The squid's inky cloud is splendid for purposes of obfuscation, but who wants to move forever backward?

LOUIS LASAGNA

*School of Medicine and Dentistry,
University of Rochester,
Rochester, New York 14642*

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Smallpox Eradication

In the article "Biological warfare fears may impede last goal of smallpox eradicators" by Nicholas Wade (*News and Comment*, 28 July, p. 329), the implication that the Walter Reed Army Institute of Research-U.S. Army Institute of Infectious Diseases is retaining variola viruses for other than archival purposes is both unfortunate and a misrepresentation of the facts. It is neither my personal view nor that of the Center for Disease Control that U.S. military researchers are engaged in offensive biological warfare activities.

The Center for Disease Control is presently completing an initial and voluntary national control effort to further limit the number of facilities retaining or

working with variola viruses. More stringent controls will be necessary when global eradication is certified as being achieved. Until then, the two facilities currently retaining variola viruses for archival purposes will continue to do so.

JOHN H. RICHARDSON

*Office of Biosafety, Center for
Disease Control, Atlanta, Georgia 30333*

Pluto's Neighbor

The skepticism attributed to me in Richard A. Kerr's article (*Research News*, 11 Aug., p. 516) about the apparent discovery of a satellite of the semi-major planet Pluto correctly reflects the opinion that I held at the time of my conversation with him, but it must be remembered that this was only shortly after the U.S. Naval Observatory (USNO) press conference, and I had very little information. Over the course of several years, however, the Outer Planet Satellite Project, of which I am director, has accumulated a small number of observations of Pluto. Frankly, we were not interested in Pluto, and the observations were taken primarily because they represented very little additional effort, and could eventually be useful to someone, somewhere, sometime. One of the splendid advantages of the photographic plate is its capacity for storing enormous amounts of information for essentially indefinite periods of time, an advantage that has been greatly highlighted by the story surrounding the discovery of minor planet Chiron. Since talking with Kerr, I have examined the few Pluto plates that we have, but most are of inadequate quality to detect such a small deformation of the image as is required by Harrington's proposed orbit of the double system. Three of those plates, however, did seem to be of sufficient quality to merit further examination, one from December 1976 and two from May 1977, all taken by P. J. Shelus. According to Harrington's predictions, two of those plates should show stellar-like images, and the other should show an elongation in the declination direction. This is exactly what we found. This apparent support for the USNO finding causes me to withdraw my name from the ranks of the unconvinced. I retain some reservations about the semantic situation, but not about the physical reality of the second body.

J. DERRAL MULHOLLAND

*Department of Astronomy,
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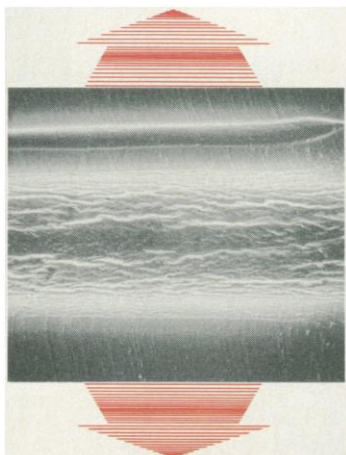
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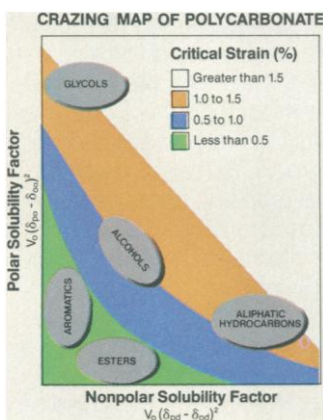
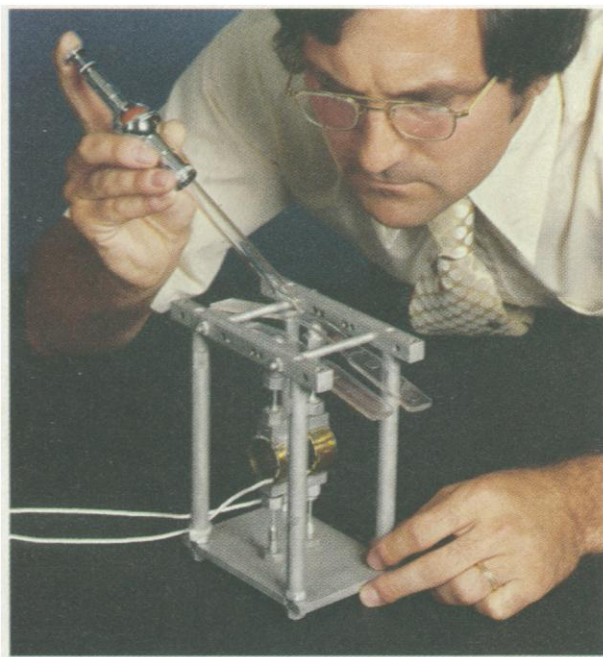
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Policy analysis establishes an important link between the worlds of science and public policy. Obviously, it has other important components, having to do with consideration of social, economic, and political factors. However, the treatment of scientific evidence is of critical importance for the quality of the total analytical effort. Policy analysis belongs to the realm of science to the extent that it makes use of the analytical tools of various scientific disciplines. But, given its location and function in the policy process, the standards and methods of other scientific activities do not necessarily apply to it.

Policy analysis is in heavy demand in government. Much of the work is conducted in specialized units in government agencies, or by staff members of legislative committees. Independent research organizations, universities, and professional associations participate in the production of policy studies. While the level of activity is increasing, little is known about the quality and impact of its results. Most of the work is not subjected to the traditional quality control system of the scientific disciplines. Publications often take the form of memoranda and reports. Funding is mostly outside the peer review system. To urge that review and funding mechanisms be formalized would be counterproductive, since much of the work must be completed under deadlines and in proximity to the needs of decision-makers. It would also be difficult to find competent judges. However, quality standards acknowledging the special functions of policy analysis need to be developed.

For one, scientific evidence must be summarized in an objective, comprehensive, and verifiable manner. Contradictory evidence must be included. Preliminary, incomplete, or inconclusive evidence must be qualified as such. If information is missing, the fact must be stated. A clear distinction needs to be drawn between the scientific evidence itself and its interpretation for possible action. Analysis should be designed to precede action or evaluate previous decisions. It should be inadmissible to contract for policy studies to provide justification for decisions already made. Mission-oriented agencies, which are major consumers of policy analysis, need to avoid overspecification of what they expect contractors to find. There is a growing tendency to let contracts for policy studies with such narrowly defined terms of reference that the quality of the product is bound to suffer. The advantage of involving outside researchers is lost under such conditions.

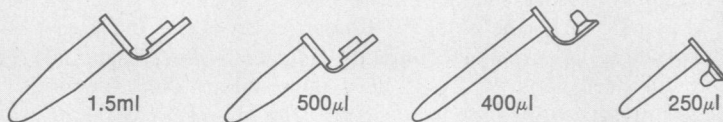
It is time for the government jointly with the members and associations of the scientific community, to examine the role of policy analysis and appropriate arrangements for its organization, funding, and quality control. An important part of this task is of direct interest to the readers of *Science* and the membership of the AAAS: the responsible "translation" of scientific results for the purpose of reaching informed and workable public policy decisions.—JURGEN SCHMANDT, *Lyndon B. Johnson School of Public Affairs, University of Texas, Austin 78712*

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Gold Film Mercury Detector

The gold film mercury detector is used to analyze the content of mercury in organic and inorganic samples, water, or ambient air. The device is portable and easy to calibrate. It offers highly reproducible results and is adaptable to geochemical, medical, or industrial applications. It features an absolute sensitivity to as little as 25×10^{-12} grams of mercury and is free of interferences common to atomic absorption techniques. Jerome Instrument. Circle 669.

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Model 160 is a single-channel, battery-operated unit that allows injection of drugs or dyes manually or by automatic external control. Constant current output is used in the Retain or Eject modes in two ranges of 0 to 100 nanoamperes or 0 to 1000 nanoamperes which will drive into 1000 and 100 megohms, respectively. Each mode may be set for the current desired. Polarity of the output currents is automatically reversed when modes are switched. W-P Instruments. Circle 671.

Literature

Guide to Essential Test Instrumentation for Medical Equipment is a reference for clinical and biomedical engineers, biomedical technicians, and others interested in maintaining medical apparatus. Quest Publishing. Circle 672.

Powder Diffraction File, Set 28 contains 1500 inorganic patterns and 500 organic and organo-metallic patterns. Joint Committee on Powder Diffraction Standards. Circle 673.

Dualcount describes a radioimmunoassay kit for simultaneous determination of folate (with iodine-125) and vitamin B12 (with cobalt-57). Diagnostic Products. Circle 674.

Total Output lists 47 printers, plotters, and combination printer-plotters and details their advantages and applications as well as their design specifications. Versatec. Circle 675.

Antisera includes systems that consist of primary antiserum, titrated normal carrier serum, and precipitating antiserum. Research Products International. Circle 676.

Liquid Scintillation Counters gives operational details and technical specifications of the RackBeta line of microprocessor-controlled counters. LKB Instruments. Circle 677.

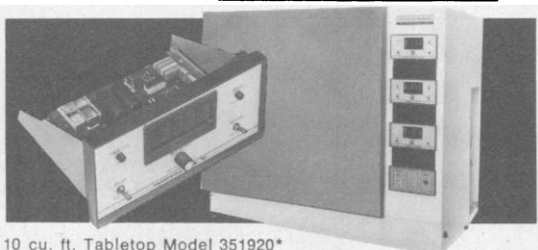
Fiber Optic Components, Accessories and Systems includes fibers, bundles, light guides, connectors, sources and detector building block systems, and terminating and polishing supplies. Math Associates. Circle 678.

Newly offered instrumentation, apparatus, and laboratory materials of interest to researchers in all disciplines in academic, industrial, and government organizations are featured in this space. Emphasis is given to purpose, chief characteristics, and availability of products and materials. Endorsement by *Science* or AAAS is not implied. Additional information may be obtained from the manufacturers or suppliers named by circling the appropriate number on the Readers' Service Card (on pages 870A and 934A) and placing it in the mailbox. Postage is free.

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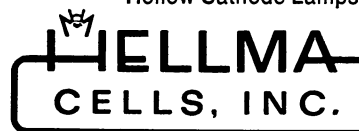
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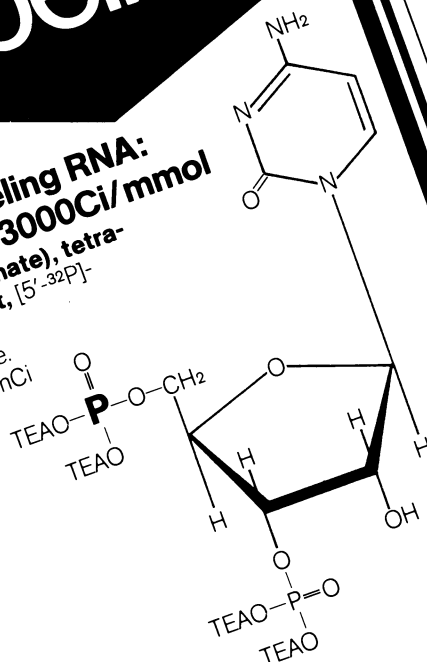


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(Continued from page 900)

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