Letters

MS-222: Vanished and Banished?

After having used MS-222-Sandoz for some 15 years as an anesthetic for cold-blooded vertebrates (fish, frogs, and others), I (and apparently several hundred colleagues across the country) was thunderstruck recently when our purchasing department received a form letter from the Sandoz Pharmaceutical Company (the only manufacturer of the drug) stating that they would no longer supply the drug. As an explanation of this abrupt and unusual action, the company pointed out that the Food and Drug Administration had declared MS-222 a "new drug" in the veterinary category, and demanded a New Drug Application (NDA) before any further shipments could be made. The letter claimed that the company does not have adequate facilities to test veterinary drugs for an NDA.

Although the latter claim sounds phony, to say the least (any pharmaceutical company with inadequate testing facilities should not be in business), the company obviously does not want to be saddled with the red tape, paperwork, and expense of complying with FDA demands on a drug that has such a small market and limited potential as this one. Yet this action very effectively puts me and many other investigators out of business. I cannot meet my contractual research obligations without it.

Not only has Sandoz backed out of an unprofitable deal, but, according to its own announcement, the FDA has declared MS-222 a "new" drug despite the fact that it has been around for some 40 years, is used exclusively for experimental studies in cold-blooded vertebrates, and has, to my knowledge, never been implicated in any health or pollution problems. . . .

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The Food and Drug Administration recognizes that MS-222 has been used for many years in research. The drug was labeled and sold for that purpose, and its distribution, therefore, was in compliance with the Food, Drug, and Cosmetic Act. Recently, however, use of the drug was proposed in food fish, such as salmon and trout. It is this kind of change that can make an "old" drug a "new" drug. Under the law, a veterinary new drug application is required in this circumstance because the proposed use of the drug may result in the ingestion of residues by man. Data demonstrating that the proposed use is safe must be part of such an application. The FDA has not told the manufacturer to discontinue distribution of MS-222 to bonafide investigators. On the other hand, the agency cannot require any firm to continue distribution of a product it no longer chooses to market.

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"Spin-offs" of Federal Research

"Civilian technology: NASA study finds little 'spin-off' " (1 Sept., p. 1016) prompts me to call your attention to a continuing study of this problem by our Subcommittee on Science and Technology. In a recent report, "Policy planning for technology transfer," we found that the opportunity for secondary applications of technology generated in federal research and development programs was considerable. Specific examples are apt to oversimplify the complex sequence in converting science to sales. There is a lack of feedback response from users (perhaps to be remedied by projects such as the Denver Research Institute report) which makes it difficult to judge a particular transfer method.

However, these facts remain. Public funds support two-thirds of all scientific and engineering effort in the United States, and in the past decade the federal investment has totaled $100 billion. The government has a responsibility to get full benefit from the resulting technology. These research and development results do have appreciable utility to industry and to other public programs at all levels of government.

Public hearings are being held to elicit further discussion which we hope will lead us to a uniform policy among federal agencies for technology transfer. Despite the recognized difficulties, the potential for economic growth and for meeting our society's needs suggests that continued effort is warranted.

JENNINGS RANDOLPH
United States Senate,
Committee on Public Works,
Washington, D.C.

The NASA study of "spin-off" of benefits to civilian technology may have missed the mark if the questions were phrased as your report suggests. Respondents apparently stated that they relied on trade publications and professional journals much more than on government publications. Many, or perhaps even most, NASA research accomplishments are reported both in a research report, which may serve as a preprint, and also in a trade or professional journal. The latter publication is counted by most journals as the "official" one, because it is usually subject to refereeing, is better edited, and is easily located in libraries. Also, perhaps, editors favor their own brand of products. These journal publications bear an acknowledgment to the sponsor, and should properly be counted as a product of NASA's programs. Later, they will be culled for textbook and handbook material. Unless specifically instructed to include these, most professionals would not call them "government publications," although the government paid for the research and the page charges. If the study was primarily one of NASA's dissemination program *via its own channels*, it may be accurate, but then it is not a study of "spin-off."

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Scientists' Views on Vietnam

Replies have still been coming in recently to my letter (18 Aug.) in which I asked for a response from those scientists who would be willing to give a percentage of their time to aid our effort in the Vietnam war. The respondents ranged from a high school freshman to a college president. Of the 179