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RELIABILITY OF SCIENTIFIC DATA

It is late Friday afternoon as this editorial is being written. In doing so, this writer has been reflecting on the numerous and varied occasions during this past week that he had occasion to make a judgment, or to base some decision, or otherwise to draw upon the research reports and laboratory findings of fellow scientists.

Just a few such examples might be mentioned by way of illustration: (*a*) we reviewed a draft monograph in APhA's Bioavailability series, (*b*) we examined in proof form a chapter for the new edition of the *OTC Drug Handbook*, (*c*) we assessed drafts of several abbreviated drug interaction monographs for the supplement that is now underway for *Evaluations of Drug Interactions*, (*d*) we provided advice and recommendations to a state government agency regarding inclusion of certain drugs in its state drug formulary, (*e*) we supplied information for inclusion in a background paper for one of the APhA policy committees, (*f*) we participated in the decision on whether a certain research report was sufficiently novel to warrant journal publication, and (*g*) we were involved in staff meetings, telephone inquiries, correspondence, and outside meetings too numerous to mention—all of which, in some way, involved a scientific component based upon somebody's research findings.

No matter how one views it, that is a lot of reliance on the findings and reports of others. And, we suspect, if our readers were to perform a similar exercise, many if not most of them would probably find that they have also depended very substantially on reports in the literature, personal communications, or other sources of information which have been drawn upon and utilized in carrying out their own activities.

Having said all this, what is our point? Simply put, it is that the workings of our whole scientific system rest on the fundamental assumption that scientists have integrity and that their reports can be accepted as being honest, factual, and reliable. Anything less will destroy the entire process and turn it into veritable shambles.

Fortunately, it has been exceedingly rare that scientists have violated this self-imposed code. In fact, in recent memory the only intellectually dishonest acts—in contrast to morally questionable research which is an entirely different matter—that come to mind were charges that certain people plagiarized the results of others to their own advantage, such as to complete requirements for a graduate degree. But as reprehensible as this practice may be, at least it did not introduce false and erroneous information into the body of scientific information.

People have observed that nothing is sacred any more. So perhaps it should not come as a surprise or disappointment that recent revelations have disclosed falsified, dishonest research reports. We refer to the recent disclosures by Food and Drug Administration spokesmen that data submitted to the agency to demonstrate the safety or efficacy of a number of drugs have been altered, "fudged," or otherwise falsified.

Although these deficient data have been submitted to FDA by pharmaceutical companies, in fairness to them it should be pointed out that for the most part the invalid data came from outside sources such as consulting laboratories. In accord with traditional scientific practice, the pertinent drug company innocently accepted the reports at face value and submitted them to the FDA as supporting documentation.

FDA Bureau of Drugs Director J. Richard Crout initially revealed the problem last fall in connection with agency action to review the approval of a new antiarthritic drug: *"We have learned that we cannot accept the test results submitted by drug sponsors on faith alone. Recent history has convinced us that we must look more closely at the validity and quality of the research done by industry."*

Subsequently, the FDA Commissioner has issued proposed new stringent regulations described in the press as an *"impressively detailed and sweeping Good Laboratory Practice code that would cover all labs carrying out preclinical studies intended to be submitted to the agency."* The new rules set forth standards for organization and personnel, buildings and facilities, equipment, testing facility operations, quality assurance, protocols, study implementation and conduct, recording and handling of data, and records and reports. Penalties for not following good laboratory practices range all the way to criminal prosecution.

In his preamble, the Commissioner cites several examples of problems which FDA staff have recently uncovered in the supporting data submitted by drug sponsors. Hence, corrective action clearly is needed.

However, we are grieved that this last bastion of honesty and reliability has fallen into question and disrepute. Until now, scientific research was virtually unregulated simply because it had never been felt necessary to impose regulations and controls. That has now all changed and, in the process, every scientist has lost an intangible little something. Perhaps this denouement is simply part of technical progress and the development of a more complex society. But still it leaves us just a little sad.

Edward G. Feldmann