been exceeded, but it should also provide the information needed to estimate population exposure to air pollution and the effects on the health of the population. Most air quality monitoring systems do not fully address population exposure to toxic air pollution. Health impact assessment combines estimates of population exposure with information on toxicity.

Given the importance of the availability of valid information on population exposure to air pollutants, the WHO European Centre for Environment and Health organized a working group to define the features of monitoring networks that allow their use in assessing the potential exposure of the population to air pollution from ambient air. This work resulted in this book. The principles outlined are intended to promote progressive modification of the networks monitoring air quality to improve their usefulness for health impact assessment.

This book is directed specifically to network managers, to those who design new networks or modify existing ones, to policy-makers, and to those who influence policy.

Guidelines for Preparing Core Clinical-Safety Information on Drugs, 2nd edition.* Including New Proposals for Investigator's Brochures. *Report of CIOMS Working Groups III (Revised) and V (New)

1999, 98 pages (available in English only), ISBN 92-9036-070-4, CHF 15.-/USD 13.50; In developing countries: CHF 10.50, Order No. 1840021.

This book is a revised and expanded edition of the first internationally agreed guidelines covering the minimum drug safety information that should be communicated by manufacturers to physicians and other prescribers. Originally published as the CIOMS Working Group III report, the "Core Safety Information" specified in the guidelines has been widely endorsed as a standard for the preparation of all official national data sheets, package inserts, product labels, and other official statements issued by manufacturers.

The original guidelines were produced in response to the need to harmonize drug safety information. As their principal objective, the guidelines aim to ensure that data sheets contain the information most needed to help prescribers balance a product's risks against its benefits, and thus make good therapeutic decisions.

The book also includes the new report of CIOMS Working Group V. This report extends the original guidelines to include recommended safety information on drugs undergoing investigation. Intended to guide the content of company investigators' brochures, this "Development Core Safety Information" then forms the basis for the core safety information eventually issued for the marketed product.

The report of Working Group V is published as an additional set of proposals for the assessment and presentation of safety information in investigators' brochures. Proposals, which follow the same practical approach used to produce core clinical safety information, are intended to provide researchers with all relevant clinical and nonclinical information and to assist pharmaceutical companies in meeting their reporting obligations. In addition, guidance is provided on the global distribution to investigators of new safety information, such as 7-day and 15-day alerts to serious, unexpected adverse reaction. The proposals should also facilitate the work of ethics review committees when assessing the benefits and risks to participants in clinical trials.

The book concludes with the text of the European Summary of Product Characteristics and a summary of the U.S. FDA Requirements, examples of illustrative drug scenarios used by the working group, and a model of Core Safety Information proposed for a fictitious drug.

Letter to the Editor

Prof. Donald Weaver wrote an interesting article (*Chemistry International*, January 2000, Vol. 22, No. 1, pp. 11–13), wherein he took to task a number of alternative medicine practices. In particular, he cited a number of instances from his own experience where patients ignored standard medical treatment for alternatives that led to their death or serious complications. In the cases he wrote about, it was clear that the patients made very poor choices. However, there are two areas of what some may consider alternative medical practices where the evidence of their benefit is quite clear.

The first of these is the research by David Spiegel, MD, who showed unequivocally[1] that psychotherapeutic support groups can have beneficial effects on *both* the mental and physical well-being of the patient. Because the readers of *CI* may not be aware of Spiegel's research, even though his seminal paper was published over eleven years ago, I will briefly summarize the work of his group and its outcomes. Spiegel's initial thesis was that a psychotherapy support group would probably be helpful in easing the burdens of cancer, but would have no effect on the physical outcomes of the disease. They enrolled 87 women who had fourth-stage metastatic breast cancer. Fifty women were in the in-

tervention group and 37 in the control group. All of the women continued to receive whatever medical treatments their doctors recommended. The women in the support group met weekly for one year. They were taught self-hypnosis for pain control, they could share whatever they wished during the meetings, were encouraged to communicate with group members outside of the meetings, and one of the group leaders was a woman who had breast cancer that was in remission. The ten-year followup showed that all of the women in the control group died, and that their average length of survival from the beginning of the study was 18.9 months (SD = 10.8). Three of the women in the support group were still alive ten years later. The 47 women in the support group who died had lived an average 36.6 months (SD = 37.6) from the beginning of the study. This work has been replicated and shows that a psychotherapy support group can have a significant effect on the longevity and quality of life of cancer patients. The important question here, given the evidence, is the following: "Why does not every oncologist prescribe group psychotherapy for his/her patients?" These support groups are probably *more* effective than any of the "standard" treatments for fourth-stage metastatic breast cancer.

Although there is little evidence for special diets and herbs for helping people with cancer and cardiovascular disease, there is a great deal of evidence that Dr. Dean Ornish's regimen of low-fat diets, support groups, exercise, and meditation[2] has a profound effect on the course of cardiovascular disease. Please note that Dr. Ornish does not recommend one diet, but a total lifestyle change in several areas. Ornish's work has stood the test of time, even though scoffers have pushed it aside as one of those alternative things. Again, the question is as follows: "Why doesn't every cardiologist encourage his/her patients to follow this regimen?"

My new book[3] cites the scientific evidence for mind/body interactions for healing, and emphasizes a multimodal approach to working with people who have life-challenging diseases. An important question is this: "How much does the placebo effect contribute to *both* traditional and alternative medicine?" A major component of all double-blind studies is to separate out the ever-present placebo effect from that of the "active" ingredient or treatment. The placebo effect is always significant, and there is a vast literature on it. (A summary of the placebo effect is in Chapter 4 of Reference 3.) Any alternative work, of course, should always be done in *cooperation* with medical doctors. As scientists, we need to be skeptical and look for scientific proof—such proof is available for the two "alternative" approaches described above.

References

1. D. Spiegel, J. R. Bloom, H. C. Kraemer, E. Gottheil. Effect of psychosocial treatment on survival of patients with metastatic breast cancer. *Lancet 2*, 8668, 888–891 (1989).
2. D. Ornish. *Dr. Dean Ornish's Program for Reversing Heart Disease*, New York: Ballantine Books (1991).
3. R. Battino. *Guided Imagery and Other Approaches to Healing*, Crown House Publishing, April 2000.

Sincerely yours,

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Reports from Commissions and Division Committees

Physical Chemistry Division Committee (I.0)

Summary of Minutes of Division Committee Meeting at IUPAC General Assembly, Berlin, Germany, 7–11 August 1999

The Physical Chemistry Division Committee (PCDC) devoted much time to discussing its future structure and function. The restructuring of IUPAC, with the abolishment of Commissions, will give the Division Committee a drastically changed role with much increased responsibility and work. The Division Committee will in the future be responsible for project generation and evaluation of proposals, followup and finalization of projects, and assessment of final results. Recruitment of Committee members and distribution of work among the members will be crucial for the work of the Division under the new organization. The number of projects that will be carried will be reduced when the Commissions disappear. It was suggested that the present structure of technique-oriented Commissions be replaced by one based on areas of physical chemistry, focusing on areas where IUPAC could contribute significantly. No