



Bureau of Voluntary Compliance Advisory Committee

Members Present:

C. Douglas Chavous, *Chairman* (ASC); Tom M. Houchens (KY); Carl Lyons (OK); Ann Peden (TX); Mary Ann Wagner (IN).

Ex-Officio Members:

Michael T. Bogumill, *Consumer Product Safety Commission*; George Heil, *SmithKline Beecham Pharmaceuticals*; Jon May, *Food and Drug Administration*; William Reinig, *Drug Enforcement Administration*.

Others Present:

Llyn A. Lloyd, *Executive Committee Liaison*; Carmen A. Catizone, *Executive Director*; Janice Teplitz, Anna Geraci, *NABPF Staff*.

Introduction:

The Bureau of Voluntary Compliance Advisory Committee met December 14, 1991, at NABP headquarters in Park Ridge, Illinois, and again on February 29, 1992, in Phoenix, Arizona. The BVC Advisory Committee is overseen by the National Association of Boards of Pharmacy Foundation. Its mission is to initiate, develop, and execute programs that promote voluntary compliance with state and federal pharmacy drug laws. This year, the Committee renewed its commitment to its charge.

The charge of the Bureau of Voluntary Compliance Advisory Committee remains as follows:

1. Promote voluntary compliance with state and federal drug laws by all health care professionals.
2. Plan, organize, and conduct the BVC Annual Seminar, an educational seminar held in conjunction with the NABP Annual Meeting.
3. Strengthen and increase communications between boards of pharmacy and practitioners and pharmacy students by:
 - a. Promoting and maintaining state participation in the BVC State Newsletter Project; and
 - b. Expanding the Newsletter Project to include participation by all boards of pharmacy so that they may provide information concerning compliance issues to all licensees/registrants.
4. Strengthen and increase communication between boards of pharmacy by:
 - a. Expanding the role of education in obtaining voluntary compliance and exploring alternative opportunities open to BVC involvement; and

- b. Exploring opportunities to develop programming that will enable, encourage, and aid boards of pharmacy in developing their own efforts aimed at obtaining voluntary compliance from their licensees.
5. Promote and maintain continuing liaison and dialogue with the federal agencies primarily impacting on the practice of pharmacy: for example, the Food and Drug Administration; the Drug Enforcement Administration; and the Consumer Product Safety Commission.

1992 BVC Seminar

The BVC Advisory Committee carefully considers current issues before choosing a topic for its annual seminar. Thought is given to the topic's timeliness, importance, and appeal to board of pharmacy members. This year's Seminar topic, Compounding/Manufacturing, seemed to be particularly appropriate in light of the Food and Drug Administration's recently released *Compliance Policy Guides on the Manufacture, Distribution, and Promotion of Adulterated, Misbranded, or Unapproved New Drugs for Human Use by State-licensed Pharmacies*. The *Guide*, which takes a strong stance against large-scale generic drug compounding in the pharmacy, has generated a great deal of interest on every level of the profession, including the boards of pharmacy, which bear the responsibility for enforcing the regulations.

While planning the Seminar, the Committee sought to include all points of view on the compounding issues. A representative from FDA was invited to explain the proposed *Compliance Policy Guides* and to hear comments from Annual Meeting delegates. To provide a balanced view of the various concerns involved, the Committee added Seminar speakers representing a prescription drug manufacturer, a manufacturer of bulk drug products, and a pharmacy practitioner who compounds medications in his pharmacy for use by his patients.

NABP has worked cooperatively with FDA to resolve the controversy surrounding the compounding/manufacturing issue. The Association has staunchly defended the right of pharmacists to compound, both pursuant to, and in anticipation of, bona fide prescription orders from prescribers wherever a prescriber/patient/pharmacist relationship exists. NABP has been just as resolute in defending the right of state boards of pharmacy to regulate activities defined as compounding within the practice of pharmacy.

As a result of its discussion with FDA, and in response to input from its members, NABP developed definitions of manufacturing and compounding, which will be introduced as part of the *Model State Pharmacy Practice Act* during the Association's 88th Annual Meeting. The BVC Advisory Committee believes that the 1992 BVC Seminar will provide Annual Meeting participants with clear understanding of the FDA *Compliance Policy Guides*. Conversely, the FDA will gain a better understanding of the Boards' concerns.

State Newsletter Project

The BVC State Newsletter Project serves 33 state boards of pharmacy through the distribution of a quarterly, four-page newsletter that provides in-depth state and national licensing, regulator, and disciplinary information to the pharmacists and pharmacies in those states that participate. These nationally recognized publications are a joint effort of the state boards of pharmacy and the NABP Foundation.

1992 Institute for Teachers of Pharmacy Law

The biennial Institute for Teachers of Pharmacy Law will be held in conjunction with the American Association of Colleges of Pharmacy (AACCP) Annual Meeting, July 9-10, 1992, at the J.W. Marriott Hotel in Washington, DC. Topics for this year's Institute will include the evolving legal and professional duties of the practicing pharmacist; a discussion of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) and its liability implications for pharmacists and the practice of pharmacy; and the role of the FDA in the practice of pharmacy.

Committee members anticipate that the 1992 Institute program, which was developed by a planning committee composed of BVC Advisory Committee representatives and teachers of pharmacy law, will duplicate the success of past meetings.

The BVC Advisory Committee extends its grateful appreciation to SmithKline Beecham Pharmaceuticals, who has once again provided a grant to fund the 1992 Institute.

Other Activities

The BVC Advisory Committee has approved two new projects that will be developed under the NABP Foundation umbrella. The first of these, an initial series of four continuing education articles that will address the Drug Utilization Review and patient counseling provisions of OBRA '90, will be developed by Foundation staff and U.S. Pharmacist through a grant from Gaxo Inc. Each quarter, a different article will be prepared for insertion into the state BVC newsletters. If successful, the continuing education program could help defray some of the costs associated with the newsletter project that are now being borne by the participating states.

The Foundation will also oversee the production of a video/workshop project. Funded through a grant from Roche Laboratories, this continuing education venture will utilize video situations accompanied by role-play workshop to familiarize pharmacy practitioners with OBRA 90's provisions. The program will be prepared by staff from the NABP Foundation in cooperation with representatives from Groteleuschen & Associates, and Roche Laboratories.

Summary

The BVC Advisory Committee provides a forum in which the state boards of pharmacy, the Food and Drug Administration, the Drug Enforcement Administration, and the Consumer Product Safety Commission may exchange information and ideas in an atmosphere that encourages cooperation and understanding. The resulting relationship has enabled the state boards of pharmacy to participate in the development of those federal regulatory and legislative initiatives that will determine the future of pharmacy.