Approaches of Nine Federal Health Agencies to Patients' Rights and Consumer Participation

An overview of responses of agency representatives to an interview survey

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IN PREPARATION for a symposium on patients' rights and consumer participation, the Bureau of Quality Assurance (BQA) of the Health Services Administration sought basic information about current trends and experiences with those issues in nine Federal health agencies. BQA selected the agencies to be surveyed and hired Health Policy Perspectives, Inc., to interview representatives of these agencies.

The interviews were conducted in September 1975 with representatives who had been designated by the appropriate administrators as knowledgeable about agency approaches to patients' rights and consumer participation. Interest in patients' rights was found to be an expanding trend, and currently there is a wide range of experience with consumer participation in the various agencies.

The agencies surveyed were the Food and Drug Administration (FDA), the Health Resources Administration (HRA), the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA), the Center for Disease Control (CDC), the Health Services Administration (HSA), and the National Institutes of Health (NIH)—all components of the Public Health Service; the Medical Services Administration (MSA) of the Social and Rehabilitation Service; the Bureau of Health Insurance (BHI) of the Social Security Administration; and the Veterans Administration (VA).

This summary is not intended to catalog all patients' rights and consumer participatory activities; only representative examples of approaches are presented. The terms "consumer," "patients' rights," and "consumer participation" were intentionally not defined by the interviewers so that they could obtain information on the range of definitions currently accepted.

Protectionist Trends

Based on the interviews, we found four protectionist trends in the patients' rights and consumer participation activities: direct regulation, promulgation of patients' rights, consumer education, and consumer advocacy. We consider these trends "protectionist" because they emanate from the agencies rather than from consumers. They represent efforts to assure a protected environment in which the consumer receives services.

Direct regulation. An example of direct regulation as a protectionist activity is FDA's product control, which is oriented toward protecting consumers from unsafe or ineffective drugs, foodstuffs, and biologicals. Similarly, the Center for Disease Control program to assure quality in the nation's laboratories can be seen as protectionist in that medical care based on laboratory findings will be more effective if those findings are accurate. Within CDC, the National Institute for Occupational Safety and Health performs applied research as the basis for creation of standards in Federal regulations to protect workers' environments.

Promulgation of patients' rights. Within the health bureaucracy, promulgation of patients' rights is also essentially protectionist and a burgeoning field. The following six examples were elicited from the interviews.

- Protection of human research subjects has been the focus of considerable effort, especially by FDA, NIH, ADAMHA, and CDC in their biomedical research activities.
- The Veterans Administration reports a "Code of Patient Concerns" similar in scope to the patients' bill of rights sponsored by the American Hospital Associa-

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tion. In the context of long-term care, a patients' bill of rights has been adopted by regulation under the aegis of the Bureau of Quality Assurance within HSA for use in Medicare-financed nursing facilities.

- Procedural rights were also cited; for example, within the Bureau of Health Insurance, beneficiaries have access to a process for review of grievances arising from payment of Medicare claims.
- Protection of patients' civil rights is of concern, particularly for mental patients. Efforts are being focused specifically on this concern in the Mental Health Care Financing and Services Branch of the National Institute of Mental Health.
- Confidentiality of medical records, especially records of drug abuse and alcoholism, is a concern of ADAMHA—as demonstrated in recently published Federal regulations assuring safeguards.
- More informed consent of patients, other than in the context of biomedical experimentation, is the goal of at least two agencies. CDC has a new, more aggressive informed-consent program that is aimed at supplying more information to patients participating in nationwide immunization programs for which CDC gives technical and financial assistance. FDA has taken a new approach to informed consent by requiring inclusion of printed inserts with certain prescription drugs; these inserts inform the patient about proper use of the drug and its potential side effects. A prominent example is the requirement of inserts with oral contraceptives. Previously, informing patients about prescription drugs was considered to be solely a function of the physician.

Consumer education. Provision of relevant information to consumers is another example of protectionist trends within the health agencies. Consumer education is provided in many forms. In the FDA it includes distribution of numerous pamphlets, brochures, and flyers on drugs, food, and medical devices. FDA also employs approximately 54 consumer specialists in its regional offices; their mandate is liaison with and educational activities for consumer groups. CDC's technical assistance to State and local health departments focuses heavily on consumer education for prevention of diseases such as venereal disease and tuberculosis.

The Medical Services Administration's efforts in consumer education concentrate on consumer entitlements to benefits and rights to assistance. The Health Resources Administration has undertaken substantial new activities, as well as specialized training of consumers who will be participating in the new health planning functions of health systems agencies under the National Health Planning and Resources Development Act. The Health Services Administration has designated a special assistant to the Administrator for Community Affairs, who is charged with the responsibility of relating to consumer groups for education as well as policy input.

Consumer advocacy. Consumer advocacy on an in-house basis, although not directly protectionist, is not consumer participatory either because it emanates from the agency rather than from consumers. The Health Resources Administration is studying the potential role of an Office of Consumer Health Advocacy as part of any national health insurance program. The Medical Services Administration has created the position of in-house advocate, a special assistant to the Commissioner, who functions as a consumer advocate as well as an ombudsman according to the requirements of a given situation. The Mental Health Care Financing and Services Branch of NIMH is seeking to stimulate consumer advocate proposals. The Branch has received some proposals, but at present it does not have the funds to support them.

Consumer Participation

When consumer participation in health agency affairs was explored in the interviews, the following five approaches were discovered.

Direct participation. Direct participation by consumers in the implementation and operation of health care programs sponsored by Federal agencies is the first and most basic approach. The new health planning law requires consumer participation in the health systems agencies under HRA jurisdiction. HRA is working with consumers in program implementation and in preparing for their participation in the programs. ADAMHA is engaged in a similar activity with community mental health centers, whose board members must include consumers. Under HSA, family planning programs have been required to include consumers among board members, and neighborhood health centers—now under HSA jurisdiction—also have consumer participatory boards.

The VA engages in wide-ranging consumer-participatory and consumer-responsive programs. An example is the requirement that veterans' advocates be given hospital space in VA hospitals to insure their active and continued participation in hospital activities and programs. MSA's Early and Periodic Screening Diagnosis and Treatment Program for Medicaid children requires an outreach component, and consumers have performed this function.

Although the Center for Disease Control is primarily a technical assistance agency, it provides promotional and organizational support to community groups that work on public health programs. This support has included provision of meeting space and financial support for some 700 to 800 health managers employed in local and State health departments who are charged with organizing community groups. Some of these groups have progressed from public health programs to other health-care-related activities.

Participation in policy making. Policy-making participation takes place formally through the comment process on Federal regulations, but is also sought more specifically and earlier in agencies such as MSA, FDA, and the VA which use this approach on a continuing basis. In the Bureau of Health Insurance, a proposal is under consideration to mandate consumer participation earlier in the policy-making process.

Advisory committees. Another kind of approach is the advisory committee that includes consumers. Such committees are prevalent, and the following are only a few examples. In the Veterans Administration, consumer-veteran advisory committees are used in the hospital review process. The FDA has at least 61 separate committees on particular types of drugs over which the FDA has control, as well as a national committee and similar regional committees. CDC uses advisory committees in its research activities; although the work of these committees is technical, they include knowledgeable laymen. NIH has more than 130 "public" advisory groups consisting of nonfederally employed experts.

Activities of interest groups. Almost everyone interviewed reported that interest groups seek to influence agency policies. The following are two examples of agency response to such activities. CDC always hears from interest groups of longstanding on its public health programs aimed at control and prevention of diseases such as venereal disease and tuberculosis. The opinions of these interest groups are always taken into account in the formation of CDC policy regarding these programs. FDA has formed an ad hoc group consisting of interest group and agency representatives, including the Commissioner. The ad hoc group has been meeting in Washington on an ongoing basis for 3 years to deal with issues of concern to consumer interest groups. Plans are underway to hold similar meetings on regional and local levels.

Research and study activities. The basic research and study activities sponsored by the Health Resources Administration are a final example of agency attention to consumer participation. The studies are focused on problems inherent in proposed changes in the health care delivery system. HRA recently supported a study of four examples of consumer participatory health care delivery programs ("Consumer Participation; How It's Working" by Paul Danaceau). The agency is also focusing on concepts of self-care, that is, approaches to health care that lessen consumers' dependency on health professionals. Concurrently, the agency is studying the effects of such shifts in health care responsibility on national health manpower needs.

Issues and Obstacles

In addition to problematic issues, such as fiscal barriers and priority determinations, the agency representatives discussed several philosophical issues.

Achievement of a comfortable balance between attention to group rights and recognition of an individual's separate rights is sometimes elusive. An example is the FDA's disapproval of the sale of Laetrile, a drug alleged to cure cancer. The agency officials believe that the drug is totally useless and possibly harmful because people's reliance on it could cause them to delay seeking professional medical care. In a recent court case, *Stowe* v. *United States* (W.D. Okla. Aug. 14, 1975), a person who sued in a class action for himself and others obtained a temporary injunction against the FDA by alleging that the agency's denial of access to the drug was an infringement of their rights to be cured of cancer. The FDA appealed the decision. (The Court of Appeals upheld the lower court's decision.)

The Center for Disease Control has faced similar problems in the context of public immunization programs. Several lawsuits have been brought by persons who alleged that they would not have accepted vaccination if they had known of the potential harm that could result. (In some cases, people contracted the diseases that the vaccinations were supposed to prevent). However, if the agency recognizes a person's right to refuse immunization, the community in which this person lives is at risk for the particular disease.

The interviewees frequently cited difficulties in identifying legitimate consumer representatives. Some of the agencies that have had considerable interaction with consumer advocates and consumer group representatives question the legitimacy of the representatives' positions, that is, whether their positions are typical of those that the consumers themselves would put forth. In some situations, agency representatives expressed the belief that the most vocal advocates have personal political goals. Although the views of advocates are important among the diverse interests to be sought out in agency activities, some administrators suggested that these views may not in fact represent the individual consumer's interests. A related problem is that of reconciling the inconsistent policy responses and recommendations of consumers. Different consumer groups have different interests—sometimes they are in direct conflict. Therefore, how does an agency make policy responsively, giving consideration to these diverse and legitimate positions?

Finally, consumers and administrators often expect immediate and great changes in programs as a result of consumer participation in policy making and program implementation. Some agencies have found that change is incremental over time, yet it is measurable and real. But dissatisfaction as a result of thwarted expectations has sometimes hampered consumer-oriented activities. A common conclusion among administrators was that they and consumers must work together to aline expectations with achievable goals.