

such as Medicare, seek to contain government expenditures for medical care.

Allan N. Johnson, Vice-President and
Acting Chief Administrative Officer
Council of Community Hospitals

Health Regulation: A Vital Function

To the Editor:

In his recent excellent article entitled "Health, Science, and Regulation: The Politics of Prevention," former FDA Commissioner Donald Kennedy asks a very important question: "To what degree may the state intervene in the private behavior of citizens in their own interest?" This, as he notes, is not a simple question to answer nor, for that matter, is it a new one. It has plagued civilizations for millennia, and was probably raised the first time by a member of a prehistoric clan who didn't want to go along with the others. All that mankind and its governments appear to have learned in the interim is that state intervention in such affairs courts controversy at every level and can be effective only insofar as it has the support of those governed.

It is a sad and incomplete lesson as evidenced, for example, by the fact that the history of our country is replete with examples of highly lucrative forms of food and drug quackery, many of which were, and still are, defended today under the rubric of "freedom of choice." Although I have never heard anyone argue in favor of the freedom of choice to ingest a can of olives contaminated with botulism toxin, there were many who waved this banner when it came to a can of saccharin-sweetened soda pop. This, despite evidence that saccharin was a potential carcinogen.

Some maintain that these differences in attitude are attributable to "time frames." The disastrous effect of botulism toxin is immediate, well publicized, and undeniable. Not so with saccharin. Today's sip of saccharin-laced soda pop is by no means tomorrow's tumor. Thus the long period of time required for a chemically induced cancer to arise, and consequent questions of causality, distorted the public perception of the issue and led to havoc when the Food and Drug Administration (FDA) moved to ban it. In fact, the agency found itself in the unique position of being ridiculed by Congress for enforcing an act of Congress, the so-called Delaney Clause, a law that unambiguously mandates the elimination from the food supply of any additive known to cause cancer in man or animals. Interestingly, Congress resolved the paradox by directing FDA to ignore its own mandate in the case of saccharin.

Kennedy expresses his belief that this outcome was at least partially due to the general "antiregulatory" mood of the country, brought about by disillusionment with economic regulations. I, for one, feel that he does not take sufficient credit for the success he, along with other agency heads, had in increasing public awareness of the distinct differences between economic and health regulations. Indeed, a number of studies over the past several years since his time as commissioner of food and drugs have consistently shown the American people to be highly supportive of health regulation, especially those areas regulated by the FDA.

Yet, the agency does fall from public grace at times, usually over issues in which it is made to appear foolish. As an example, the soft drink industry, in its zeal to hold on to saccharin, mounted an advertising campaign depicting a huge pile of sugar-free soft drinks, amounting to, perhaps, several hundred gallons. A written message implied that according to the studies conducted by FDA, one would have to drink the contents of the entire pile every day to be in any danger from saccharin. Although any scientist could have deflated this preposterous notion with a few words, the advertisement had a profound effect on the attitude of the public: they saw it as a silly issue and began to laugh. Congress heard their laughter and moved, unfairly I believe, to slap FDA's hands.

Every commissioner faces at least one saccharin-like issue. Mine came in the form of lead, or to be specific, as a hair-darkening product known as "Grecian Formula." Agency scientists determined that there was evidence that this product could cause cancer in animals but that the risk, when extrapolated to man, was less than one chance in one-hundred million over a lifetime.

Although I was advised to ban it on the basis of the Delaney Clause, I disagreed. I felt then, as I do now, that the risk was trivial, and that it was not the intention of the architects of Delaney Clause that FDA commissioners should take leave of common sense. Additionally, I firmly believed that a ban on this product would accomplish little or nothing in regard to public welfare, but that it would assuredly result in a lessening of the agency's credibility and consequent effectiveness in the future.

In another section of his discussion, Kennedy notes the mismatch in the rates between development of different scientific capacities and the rates of social and political expectation. This mismatch is particularly apparent and difficult in the case of epidemiologic evidence. The current efforts of the cigarette industry to discredit the linkages between smoking and health certainly call this to our attention. Although science has produced any number of convincing epidemiological smoking guns, industry steadfastly maintains that while there is smoke and a gun, the relationship between them is an open question. There is a definite mismatch in someone's rate of development.

This brings me full circle to freedom of choice and the question posed by Kennedy regarding the extent to which the state should intervene in the private affairs of the citizenry on their own behalf. There are those who maintain that our government has no business superimposing its will over the inalienable right of American citizens to do anything to or for themselves insofar as others are not harmed and society is not burdened. This is a doctrine that assumes that one understands the choices. But does one? There is considerable evidence to the contrary. For example, despite widespread knowledge that helmets provide significant protection against head injury, large numbers of motorcyclists choose to ride bareheaded because these devices diminish the pleasure of riding in the open air. Did the hundreds of unhelmeted bikers who are killed every year by head injuries realize that they were actually choosing death? I doubt it; it is a knowledge acquired only by the experience, and then it is too late. Similarly, I find it difficult to believe that a cancer-riddled smoker would reach for that very first cigarette if given the opportunity to relive his or her life. In situations such as these, a far-sighted government has a responsibility to protect a citizen from the hazards of the misguided belief that “it will never happen to me.”

I also think we sometimes forget that our freedom of choice decisions are often influenced by powerful persuasions that have only one interest in mind: their own. We are inundated with information that encourages us to suspend reality—tobacco advertisements, for example—and in too many instances we lack the sophistication to see through the smoke. In situations such as these, there is room for a second persuasive force—that of government, whether it be in the form of information or regulation.

In my view, health regulation is a vital function of the federal government and a form of intervention that the public desires, although not always consciously. However, such interventions as these will always be politically difficult, as is well documented in Kennedy’s eloquent presentation.

Jere E. Goyan, Dean
School of Pharmacy
University of California, San Francisco

Reproduced with permission of copyright owner. Further reproduction prohibited without permission.