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TOO MANY REGULATIONS?

Out in Fairfax County, Virginia, where this writer resides, we enjoy—or are afflicted with, depending upon one's viewpoint—an apparent surfeit of dogs. Moreover, the owners of many of these pets exercise exceedingly little restraint or control over the canine population.

This situation has led to the county adopting a so-called "leash law," which requires every dog to be maintained on a leash whenever the animal is off its owner's property. After being in effect for a full year, however, we see no discernible change in behavior, simply because the police do not enforce the law and the malefactors who own the dogs are well aware of that fact. Consequently, what seemed to be a good solution in theory turned out to be an exercise in futility.

We also have certain main roads designated as "snow emergency routes," and any car getting stuck there due to ice and snow is subject to being ticketed. Well, this past February, the Washington, D.C., area was hit with its worst blizzard in 50 years. Although efforts were made to keep the main arteries open, this quickly proved hopeless due to stalled cars that were abandoned on the roadways, preventing the snow removal equipment from doing its job.

In one newspaper account, a reporter asked the traffic department why the offending cars were not being ticketed. The response offered by the police was that to do so would be "unfair because the cars were snowed in." But since no one gets stuck in snow purposely, why maintain such a law on the books if it is not to be enforced?

We are reminded of these examples because we recently heard an APhA member offer the same time-worn and simplistic solution that pharmacy often employs in an effort to solve some problem situation or behavior; namely, the "there-ought-to-be-a-law" syndrome.

A pharmaceutical company house organ publication crossed our desk a few weeks ago that carried an article, the heading of which was a direct quote from a book entitled "Spirit of the Law," written in 1748 by the French state philosopher Charles de Montesquieu. The quote read: "*Superfluous laws detract from the effectiveness of those that are necessary.*"

Increasingly, there are signs and evidence that the United States in general, and the health field in particular, are becoming the victims of over-regulation. Productivity and effectiveness are gradually being strangled by excessive regulatory requirements.

This problem has gotten to the point that the federal government itself, in the form of the Carter Administration, is initiating various reviews to assess whether this trend might be reversed. Although we may be pessimistic or even cynical about such pronouncements, it is encouraging that there is some recognition of the danger posed by unbridled policy to solve problems through imposing new regulations.

Moreover, Mary Munson Runge, quoted several months ago before assuming the APhA Presidency, expressed chagrin at the "overlegislated" state of the profession of pharmacy. Who is to blame for the mountain of mandates that is slowly taking shape throughout the country? She believes that pharmacists themselves are at fault: "*Pharmacists have brought some of these things on themselves by not doing them voluntarily. I understand fully the reasons for all the mandates that are being legislated, and I think it's the fault of the profession.*"

From our perspective, she is right on target. Most new statutes and regulations come about because something wasn't working as it should have been, and a need was perceived by someone to legislate a solution.

Requirements affecting the drug industry—and especially the Good Manufacturing Practices and Good Laboratory Practices regulations—can generally be traced to some sloppy or shoddy performance by at least a part of the industry.

Similarly, in this month's issue of APhA's professional periodical, *American Pharmacy*, there is an article titled "Kelsey's Commandos: FDA Investigates the Investigators." This article deals with all the rules that have sprung up in the past decade to regulate scientists who conduct clinical investigations on new drugs. Again, as the article reveals, these people brought it on themselves through the scandalous performance of some of their own.

But if it's any consolation, the investigators-of-the-investigators are increasingly getting rapped on their back-sides also! There have been several cases lately where FDA is being dragged into court to account for its alleged failure to perform and is being slapped with requirements to speed up certain processes, to release certain information, or to complete certain projects. A big headline in the March 9 issue of *The Washington Post* serves as a cryptic example: "Judge is Asked to Force FDA to Move on Ineffective Drugs." As the story notes, "More than 16 years and one court order" after Congress passed the provision that the government halt sales of any drug lacking substantial evidence of its efficacy, some 482 prescription products lacking such evidence remain on the market.

FDA's usual excuse is that Congress is quick to pass laws but slow to appropriate funds for their implementation.

We are not sure what the answer is to the over-regulation problem. But we suspect that much of the problem is preventable if people, organizations, and agencies all performed up to the reasonable standard expected of them by society. —EGF