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## PREDICTION: NEW DRUG LAW COMING

Washington, as the focal point of the federal government operation, has often been characterized as a "three-ring circus." That's probably a fair characterization, and it would be equally fair to say that, in recent years at least, one of those three rings has been devoted exclusively to health care-related issues. Moreover, from our own particular point of interest, it is difficult to recall very many of these issues that didn't involve drugs and pharmaceuticals partially, if not exclusively.

Not surprisingly, therefore, various bills have been introduced each year both in the House and the Senate calling for some revision of the principal law that deals with pharmaceuticals—namely, the Federal Food, Drug, and Cosmetic Act. But of the hundreds of such bills sponsored, only a few relatively minor ones have been enacted.

Historically, the present law was passed in 1938, and it represented the first and only major overhaul of federal drug legislation since the original Pure Food and Drugs Act became law in 1906. Furthermore, the Drug Amendments of 1962—which, among other things, added the concept of efficacy as a condition of new drug approval—constituted the last major change in the 1938 Act.

Virtually all bills subsequently put into the legislative hopper have gone nowhere, although some of them enjoyed serious consideration to the point that congressional hearings were conducted with APhA witnesses and others trooping dutifully to Capitol Hill to present views and testimony on the particular proposal at hand. In the words of one cynical association spokesman, "Senator X snaps his fingers, and like so many trained show dogs we all go through our routine, knowing full well nothing will come of it, but fearful that if we don't we'll appear to be asleep for not voicing our views on the subject!"

Well, it now looks to us and to at least some other long time "Washington-watchers" that the preliminaries are about to end and 1978 may well be the year that we see a top-to-bottom new drug law go on the books. Congress has become increasingly restless, involved, and concerned. Public controversy has been stirred by issues such as the proposed saccharin ban, the efforts to keep laetrile off the market, the purported drug lag, the allegations of disgruntled FDA employees, and a barrage of lawsuits filed against the FDA and its parent department by diverse groups ranging from consumers to professional societies to the drug industry.

In the case of many issues that get into the congressional mill, there is some division along party, philosophical, or interest lines as to a group seeking new legislation and a group wishing to thwart new legislation. However, regarding drug legislation, the situation in the past few years is reminiscent of comedian Jimmy Durante's famous line: "Everybody wants to get into the act!" Liberals and conservatives, Republicans and Democrats, urban representatives and rural representatives, have all sponsored various proposals for major changes in the current drug laws.

If this were not indication enough that something might be going to happen this time around, the odds became enormously greater with a minor bombshell announcement this past October.

HEW Secretary Joseph A. Califano, Jr., unexpectedly came out with a call for "a top-to-bottom, thorough overhaul" of the nation's drug regulatory laws. And in the year that Mr. Califano has been on the job, Washingtonians have come to know that when this cabinet officer speaks, he means business. Consequently, not only is there philosophic support from the Carter administration for drug reform legislation, but it most likely will benefit from the push of one of the most activist people in the current administration.

Mr. Califano's statement was greeted warmly by a broad spectrum of interested parties. These ranged from consumer organizations to drug industry trade groups. The public press reported that "top staff members for Sen. Edward M. Kennedy and Rep. Paul Rogers, said that the two chairmen of the key health committees in the Senate and House were enthusiastic about the proposed changes outlined by Califano." Other congressional figures were also identified as voicing their concurrence.

Collectively, these developments lead us to the prediction in the headline of this column. A member of Senator Kennedy's staff speculated that Califano's position meant that a bill would pass the Senate by mid-1978; he added, "The key point is that this is the first time since 1962 that all the major actors are in agreement." Or as the astrologists would put it: "The stars are right!"