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THE EDITORIAL POLICY of this JOURNAL is to record the progress of the law in the field of food, drugs and cosmetics, and to provide a constructive discussion of it, according to the highest professional standards. The FOOD DRUG COSMETIC LAW JOURNAL is the only forum for current discussion of such law and it renders an important public service, for it is an invaluable means (1) to create a better knowledge and understanding of food, drug and cosmetic law, (2) to promote its due operation and development and thus (3) to effectuate its great remedial purposes. In short: While this law receives normal legal, administrative and judicial consideration, there remains a basic need for its appropriate study as a fundamental law of the land: the JOURNAL is designed to satisfy that need. The editorial policy also is to allow frank discussion of food-drug-cosmetic issues. The views stated are those of the contributors and not necessarily those of the publishers. On this basis contributions and comments are invited.

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FOOD DRUG COSMETIC LAW JOURNAL

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FOOD DRUG COSMETIC LAW JOURNAL

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REPORTS

TO THE READER

Eighteenth Annual Educational Conference of the FDLI and FDA. The following papers were presented at the 18th Annual Educational Conference of the Food and Drug Law Institute, Inc., and the Food and Drug Administration, which was held in Washington, D. C. on December 3rd and 4th, 1974.

In colorful style, *H. Thomas Austern*, who is with the law firm of Covington and Burling, presents a generic review of the administrative aspects of consumer protection, focusing on scientific expertise, cost-benefit analysis and advisory committees. His article, entitled "Congressional and Legal/Regulatory Developments Under the Federal Food, Drug, and Cosmetic Act," begins on page 588.

"Twenty Questions for the Commissioner" is a tongue-in-cheek self-presentation of a day in the life of one—*Alexander M. Schmidt*, Commissioner of Food and Drugs. Underlying the humor of his portrayal, Dr. Schmidt seriously considers some of the vital issues confronting him in his role as the head of FDA. His article begins on page 596.

Marsha N. Cohen, attorney for the Consumers Union of the United States, summarizes the legal developments concerning food products and how they affect the consumer. Her paper touched on the importance of stronger legislation, food surveillance programs, safety assurance standards and stricter penalties. Her article, which begins on page 604, is entitled "Legal/Regulatory Developments Affecting Food—Perspective of the Consumers Union."

Vol. 29, No. 12 December, 1974

Food·Drug·Cosmetic Law
Journal

Congressional and Legal/Regulatory Developments Under the Federal Food, Drug, and Cosmetic Act

By H. THOMAS AUSTERN

Mr. Austern Is with the Law Firm of Covington & Burling in Washington, D. C.

DESPITE MR. GOODRICH'S overly generous introduction, the sad fact is that age offers few victories. Instead, it engenders cerebral sclerosis, a failing and often treacherous memory, and increased pain in regularly penetrating hundreds of pages of *Federal Register* fine print on the Food and Drug Administration (FDA) proposals, preambles, and postponed preliminary or tentative final orders.

Equal myopia develops in reading those elongated Congressional hearings castigating the Agency, those court opinions condemning even while condoning FDA regulatory action, and those intensive though often ignorant and distorted press reports.

That effort can hardly be compared with the sheer joy of perusing those weekly Biblical and pontifical reports in the *Food Chemical News* and the *Pink Sheet*.

A Generic Approach to Administrative Control

Fortunately, in this morning's session, you are invited *not* to probe any regulatory detail, but instead to take a generic, and indeed a philosophical approach, in an overall view of this entire area of administrative control, the protection of the consumer's pocketbook, an activity in which, of course, we are all involved, or perhaps submerged, or at the very least often confused.

If you can crystallize your baselines of policy and controlling concepts and your mastery of the operative and more pragmatic detail, the work sessions this afternoon and tomorrow will be vastly facilitated. Let us therefore climb to an administrative Mount Olympus, survey the entire scene, and try to discern where FDA, Congress, and the courts have taken the Agency and the regulated industries, and perhaps what the future may offer.

Let us throughout also remember Dr. Schmidt's insistent and valid plea that criticism should not only be negative but also constructive.

My problem in my allotted few minutes resembles that of the mosquito in the nudist camp: The area is so vast and inviting, I don't know where to begin.

The spectrum is very broad, indeed almost circular. Wherever one turns, every valley and peak commands major attention.

Each of us must therefore face very tough questions: What is the effect on FDA, and on each of you, of those constant, continuous, and widely publicized critical Congressional investigations of FDA, and of those in industry who work with it? Is FDA in any way the unwitting captive of the regulated industry and, as charged by some, inept at best or dishonest at worst? Or is FDA now instead overly sensitive and unduly responsive to organized and highly vocal consumer critics?

Is the current demand for completely visible "goldfish bowl" agency procedures productive or disruptive, delaying, or even destructive of sound and timely resolution of vital issues? What impact will the now amended Freedom of Information (F. O. I.) Act have in the long run on FDA, which reportedly is developing 300 pages of F. O. I. preamble and regulations on how that Act is to be honored, or evaded?

Does the prevalent American monetary superstition apply here —that increased budgets of themselves get things done, or that FDA, whose appropriations have increased forty-fold in two decades, can,

with increasing dollars alone, better fulfill its cardinal responsibilities? Do we too often confuse activity with achievement? Or, put in the current fashion of President Ford, is there over-regulation of those regulated industries to the disadvantage of competition, the consumer, and the battle against inflation?

You may have seen Chairman Engman's recent public criticism of the inflationary effect of the Interstate Commerce Commission (ICC) and the Civil Aeronautics Board (CAB) actions even though, curiously, he did not mention his own Agency, the Federal Trade Commission (FTC), or the FDA.

Well, to get on with our key inquiries: Perhaps paramount is the required accommodation between the need for in-depth scientific evaluation against both industry demands for prompt determinations and that cacophony of Congressional criticism and accompanying lurid adverse publicity. Here the trees too often obscure the forest.

A Qualified Scientist

A prickly bramble bush that obstructs the path to wisdom is the threshold question as to who is a qualified scientist. The extraordinary fact is that today despite international political crises and a national economic toboggan, an amazing amount of national press coverage can, as the Commissioner recently put it, "be captured by one person expressing just an opinion—even an opinion contrary to existing but ignored factual data and contrary as well to the views of that individual's scientific peers."

As a corollary, why do consumer critics and too often the general public readily assume that a food technologist employed by or advising a manufacturer, or a doctor consulting with a drug company, is lacking in integrity and competent scientific objectivity? Even with qualified and unbiased scientists, the administrative road is bumpy.

Should those scentists function as advisory committees or review panels whose recommendations might buttress an FDA determination or advise further research and delay? Or, instead, should the scientists confront the Agency with a conclusion that a Congressional committee staff may consider immutably engraved in stone? Should FDA recognize the concept of a scientific consensus in those advisory groups and, is that concept comparably applicable to food additives as well as to drugs? Is a scientific advisory panel more competent to make an economic cost-benefit analysis on a food additive than the Agency itself?

Cost-Benefit Analysis

As some of you may be aware, at the recent Economic Summit Conferences, a proposal was advanced that every federal agency should be required to accompany every regulatory proposal with a cost-benefit analysis, setting forth its views as to whether the accomplishments of the regulation would overbalance its cost to industry and, ultimately, to the consumer. That novel concept has met with considerable enthusiasm in many quarters. Last Wednesday the President issued an Executive Order to the same effect, with authority in the Office of Management and Budget (OMB) to implement it. What its impact upon FDA might be, and whether it might operate differently on drugs as compared with foods or cosmetics, will present an interesting and timely question. Perhaps the recent FDA extension of the date for compliance with its new labeling regulations, because of inflationary cost considerations, is a harbinger for the future.

Now, running through all of those scientific issues are other basic questions that still seem to float unanswered. How safe is "safe"? Are the same criteria applicable to foods which are ingested daily as to drugs which for some may be toxic if they are to be therapeutic? How much data is enough? Completely exhaustive and definitive research does not exist on every detail of science or of life, nor can scientific research ever be static. That problem is perhaps but another facet of any risk-benefit analysis, when realistically applied to the specific problem at hand.

As a footnote, when should a suggested allergenic reaction control administrative determinations? Does an individual idiosyncracy found in one in a million warrant banning an ingredient or should that man or woman avoid a particular food ingredient on his own? On drugs, when would bold and adequate label warnings minimize similar risks?

Tomorrow afternoon there will also be a workshop on cosmetics. All that one might offer on that beautiful area of regulation is that the Lord help the FDA if it ever gets indirectly tangled up in measuring the efficacy of a cosmetic. Beauty is always in the eye of the beholder, and a cost-benefit analysis about selling faith and hope would indeed be difficult.

Another charge too often ventured is that the FDA is now suffering a unique form of operating paralysis in finally deciding even the most routine matters. Whether that charge is warranted, or in

many cases represents merely an understandable impatience in getting prompt decisions, is well worth your examination. To some degree, I suspect official inaction or the safety of a denial and the fear of a further Congressional committee assault may impede administrative efficiency.

Interaction of Agencies

Looming also on the horizon are sticky problems of inter-agency cross-ups and confrontations rather than coordination. One may readily foresee confused or contradictory overlapping between the FDA and the Department of Agriculture, the Environmental Protection Agency (EPA), the FTC, and the somewhat publicity-oriented Consumer Product Safety Commission. Perhaps the proposed National Commission on Regulatory Reform could contribute to avoiding that overlapping.

Now, President O'Keefe has told me that at least half of this audience has had the benefit or the disadvantage of a formal legal education. Therefore, venturing some legal observations may also be in order.

To begin with, there is the controversial issue of hearings. Perhaps Dean Christopher will tell us whether in the future the courts will permit FDA blithely to deny a formal hearing where Congress has ordained that one should countenance the further emasculation of Section 701(e). In my view, the real value of a hearing, provided that the proposal does not bite off more than any group of people can handle and that there is also a qualified Hearing Examiner in charge, lies in the fact that the experience of centuries has demonstrated that only on the anvil of cross-examination can loose fact assertions, data, and unfounded opinions be effectively tested.

I do not regard the kind of rhetorical confrontations now being suggested and occasionally practiced at the presentation of advisory committee or panel reports as constituting a real hearing.

Of course, if a new Consumer Protection Agency is created, and I believe one soon will be and even rebaptized as the Agency for Consumer Advocacy, or ACA, I am confident that every hearing, formal or informal, will be expansively elongated and made even more diffuse.

For those lawyers interested in fees, their future hymn may be "Nearer My ACA To Thee."

More Lawyers?

Next, does the FDA really need more lawyers? I believe they now have 35 and want to have more than double that number. What cannot be challenged is that the legal review and paper production will expand to occupy the time of whatever number they get.

Perhaps in those basic questions that I have presented, and there are many more, there reside enough issues to be provocative either of thought or of remonstrance. As hazardous as it may be, I will conclude by offering a few personal, tentative, and timid answers.

As to Congress, I think we should all work to achieve a new and needed reform. No one challenges the right and the duty of Congress to investigate and to supervise federal agencies. Why every subcommittee has to get into the act may be questioned. Yet whenever the wisdom of any specific FDA action or inaction is to be questioned, or whenever any issue involving the internal efficiency or the charged ineptitude of FDA personnel or who overruled whom is to be explored on Capitol Hill, the hearings should be *in camera* in a closed session.

Executive sessions, precluding political publicity and headline hunting, are the practice on national defense and on much of the Central Intelligence Agency (CIA) and the Atomic Energy Commission (AEC) activity. The scientific difficulty, the delicacy, and the importance of those FDA decisions warrant similar treatment rather than highly publicized second guessing on the Hill. That reform alone would cut down the magnetic attraction of making political headlines or bringing the Agency and those it regulates into public disrepute.

The *Dotterweich* Convention

As to record-keeping, access, and required reporting to FDA, many recognize their need if the Agency is to act as an aggressive policeman where necessary. To do so warrants factory inspection and FDA access to maintained manufacturing records and processes. But so long as FDA still insists upon the *Dotterweich* rule of absolute criminal liability for natural persons, I continue to have constitutional law trouble about self-incrimination of an individual who neither knew of nor intended the violative act. Perhaps in the *Park* case, the Supreme Court will reexamine *Dotterweich*. Of course, the cardinal issue arises in a case where the president of a national food chain,

employing 36,000 people, doing business through 874 retail stores, and maintaining 16 warehouses, was fined merely $250 on five guilty counts. That may not overly excite the Supreme Court, even if it recognizes that a second conviction is a felony.

But never forget that what is really involved is the potential of jail sentences, as well as fines, for top company officials who must delegate operating responsibility and are now to be held to the fuzzy concept of a "responsible relation to the situation." If the FDA can hang a company president who perforce must delegate merely by writing him a letter, all of the qualifying judicial dicta becomes meaningless.

No greater service could be rendered to the Supreme Court than for every interested industry realistically to examine those issues and perhaps contribute an *amicus* brief.

Advisory Committees

As to advisory committees, I remain baffled. One may readily grant the need for obtaining the widest scientific assistance. But the FDA cannot abdicate its responsibilities. I also have some difficulty in finding a place for consumer advocates and lawyers on a scientific advisory panel. Effective democracy, however, is very often a matter of compromise, and I suspect that within an advisory panel there will always be some compromises. If, as some insist, there must be full minutes kept, and public exposure of what was compromised, I have some apprehension that the hoped-for usefulness of those advisory groups may be markedly diminished.

On the issue of Federalism, sometimes called "preemption" or the old-fashioned "states rights" issue, I would agree with Mr. Goodrich who urges uniformity, with the states limited to enforcing federal regulations. The interstate barriers embodied in having every national food product labeled under a Pennsylvania State Department of Agriculture regulation should no longer be tolerated. Yet whether full federal uniformity, binding on all states, can be politically achieved still seems dubious.

Above all, I harbor the feeling that FDA should now endeavor to digest all of the regulations and new concepts it has recently developed, many of which Mr. Hutt has so brilliantly conceived within or without the statute. For FDA to seek new and expanded

legislation, to confirm what has been done or what the courts have rejected, will open a Pandora's box of public controversy and create new consumer uncertainties and lack of confidence in both the FDA and the regulated industries.

Finally, as I have often urged in the past, one should approach all of those questions with an abiding sympathy for those in the FDA who must cope with them. Criticism comes easy. Objective and reflective remedial proposals are very difficult to develop.

The Ballad of Dr. Vecchio

That approach was poetically put by Dr. Vecchio in the Harvard Medical Alumni Bulletin. He was no Shakespeare, Dryden, or Shelley, but he did write this:

"The FDA is plagued by fears
And likes to ruminate for years.
They get no thanks for prompt approvals
But lots of press for drug removals;
And constantly go through the mill
Of those committees on the Hill.
Their necks are always in a noose.
By saying 'nay' they keep it loose.
But if they err in saying 'yea'
The noose is tightened straightaway.
Their sign of victory not a 'V'
But a thumb directed downwardly.
Now would you be a 'yea' or 'nay'-sayer
If you were an FDA-er?"

[The End]

Twenty Questions for the Commissioner

By ALEXANDER M. SCHMIDT

Dr. Schmidt Is Commissioner of Food and Drugs.

LAST YEAR, I spoke before this conference as a freshman commissioner. During my remarks, I cited the question most often asked of me by my friends. The question was: "Why on earth did you take *that* job?"

The past twelve months really isn't a very long time, but events sometimes make time seem much longer than it is. Anyway, a lot has happened—to FDA and to the world—since December 1973; and I find the question most often asked by my friends has changed. When they see me now they ask: "Are you *still* with FDA?" And I'm waiting for someone to add, "Why?"

I thought it might be fun this evening to share with you some of the other questions I hear most often as commissioner. As you might imagine, I meet a great many people in my job; many of them at gatherings like this. More often than not, I'm asked to do what I'm doing now—talk! So, naturally, one of the questions I hear most often is, "Commissioner, how long are you going to talk?"

Now, that's a lot easier to answer than the one about why I'm still in this job—and I can answer with a lot more assurance. You'll be relieved to know the answer is "less than 20 minutes!"

All Types

The truth is that to me, one of the most interesting things about this job is the questions it attracts. They come from little ole ladies in purple hats and red tennis shoes, and from hard-nosed newsmen; they come from hard-headed consumer activists who won't be satis-

fied with *any* answer, and from innocent-looking congressmen who already *know* the answers.

Some of the questions are easy; some impossible. I haven't learned all the questions yet, much less all the answers; and I doubt I ever will. But I think I've learned enough not to be surprised.

"Stuffed With Answers"

Not long ago I was invited to speak to the National Press Club. This was soon after Senator Kennedy had held a series of hearings critical of the FDA; and I went before the Washington newsmen with a nervous understanding that I was in for a good grilling. I coached myself at home nights, and during the days my staff and I went over every possible question we could think of. Finally, when the big day came, I thought I was ready for about anything. My brain was stuffed with answers about DES (diethylstilbestrol) and intra-uterine devices (IUD's), about why we planned to approve this and why we haven't already approved that. I was full of facts and figures for facing this sophisticated audience.

You can imagine my letdown and chagrin when one of the first questions was: "Dr. Schmidt, do you make house calls?"

My answer, incidentally, was, "Yes, and Senate calls, too."

However, I haven't always been so well-prepared. I remember vividly the question I got from a famous Washington hostess during my first month as commissioner.

I really can't mention her name here tonight; but there lives in Washington a tall, elderly, famous, marvelously elegant grande dame, often quoted in the press, who resides in the center of social and political power, regardless of who or what party is in office. She is friend to the famous; she has sent bowls of chicken soup to each of the past eight presidents, when they have had a cold. Seven of the eight have drunk it, and got well.

An invitation to one of her dinner parties is an invitation to fame, if not fortune. One sups with those who literally hold the destiny of the world in their hands.

Well, you can imagine how I felt upon receiving one of her coveted invitations. I attended with great trepidation. Before dinner, she drew me aside and whispered conspiratorially in my ear, "I *must*

see you after dinner, alone." Hardly daring to wonder what grand scheme was brewing, I thought to myself, "Well, this is how it happens. This is how raw power is exercised in Washington. This is it!"

Imagine my suspense, my excitement, when later, she beckoned me to her side, and then said: "I *have* to know. You *must* tell me. *Is* Bayer aspirin *really* better than all the others?"

All I could think of for reply was that one of the reasons I'd taken the job was to discover the answer to that very question, myself.

I say I've learned not to be surprised, but I must confess that two weeks ago a middle-aged consumer in New Orleans came about as close to surprising me as anyone has in recent months.

New Orleans "Welcomes" the FDA

We were in New Orleans to test the concept of an FDA-sponsored "Town Meeting." The idea was to give us a chance to talk face-to-face with some honest-to-goodness consumers. The meeting was a part of our continuing effort to get better public input to our decisions.

It was a big affair. The Mayor of New Orleans opened the city council chambers for the meeting. There was a lot of advance publicity and we finally sat down with several hundred consumers from Louisiana and five nearby states for some serious discussion of what was on their minds.

Now, while I refuse to admit surprise, I will at least confess to having been startled when our first questioner demanded to know: "Commissioner, who invited you to New Orleans, anyway?"

It was several minutes before I recovered enough to remember that I hadn't exactly had to break down the gates to get in. In fact, the mayor had given me the keys to the city. After that, I felt a little better.

Consumer Questions

I suppose that of all the people who question me, the consumer is most likely to get testy and I can understand that. After all, it's his health, his safety, and his rights with which the FDA is so often involved.

He's interested, and he asks questions! So, it really isn't inappropriate that thousands of irate consumers write about the vitamin

regulations and with various shades of passion and bluntness of language ask the same basic queston: "Just who do you think you are, telling me how to eat?"

At the same time, there are limits to one's patience and I'm sometimes tempted to answer by asking: "Who does one *have* to be in order to give sound advice on how to get better food for your money?"

But consumers are not always so blunt. They can be as foxy as a Senator in using the rules of inquiry to make little speeches all neatly wrapped up in question marks. Consider this little gem that I got as a "question" during a recent meeting:

"Staff members of your own department admit," said this lady, "that it was a mistake to call vitamins a drug. The United States Court of Appeals for the Second Circuit stayed the regulations until June 30, 1975, for further study. Amendment number 1880 offered by Senator Proxmire carried by a vote of 81 to 10, and *25 million consumers* want freedom of choice."

Then, after this little editorial, she zinged me with the question: "In view of the above isn't it fair to ask that you as a wise and gracious gentleman call off the regulations you intend to put into effect—*knowing how wrong it is to have them?*"

I'll bet there's not a lawyer in the house who could've done better.

The techniques vary and it sometimes comes out funny, but most consumers are deeply concerned and deeply serious. Their questions reflect this. As long as there are difficult "benefit-risk" judgments to be made, and as long as someone has to make them for everyone else, then the beneficiaries of that decision making have every right to question and demand responsive answers.

Occasionally, however, there is the clown. This one is most often encountered at cocktail parties, usually nearer the end than the beginning, and his question almost always goes like this: "Hey, Doc, you banned any mushrooms lately?"

This is the same guy who read that we've declined the invitation to put cyclamates back on the market and his mushroom question is now likely to be followed by this one: "I hear you banned cyclamates again. What happened? The sugar lobby sweeten the pot?"

Either question is always accompanied by a "yuk, yuk" and a knowing elbow in the ribs.

It's not my favorite experience.

Who Really Runs the FDA?

Of course, the consumer is not the only one with questions for the commissioner. Perhaps my favorite nonconsumer question is the one that the reporter always asks when he wants to show me he's really got inside dope: "Mr. Commissioner," he asks, "who really runs FDA—you or Peter Hutt?"

For the few of you who may not know, I'll explain that Peter Hutt is FDA's general counsel. He's also a very intelligent and articulate person who's *not* known for long periods of silence, or inactivity, or reluctance to express his views.

In fact, Peter's brains, his boundless energy, and his passion for hard debate and capacity for work can at times be absolutely awesome.

From time to time I've reflected that if Peter had been a physician, he'd be a cardiovascular surgeon, doing 6 cases in 3 rooms before I got up. But when I practiced cardiology, and did get to the hospital, it was often to bail the heart surgeons out of trouble.

Peter and I work very closely, and we do so as a part of my concept of the team approach to management. We both operate as part of a 16 member group of key FDA leaders and it is this group, serving as the FDA Policy Board, that sets the major policy directions for the Agency. Peter is an excellent counsel to the Commissioner and to the Policy Board. I know I am content with—and grateful for—the general excellence of his advice.

Peter Plays the Game

At the same time I have to admit that Peter plays his own game of "Questions for the Commissioner." It usually works this way:

If *I* want to do something and *Peter* doesn't, his question is: "Commissioner, you don't expect me to defend that in court, do you?"

On the other hand, if *Peter* wants to do something and *I* don't, his question—admittedly rhetorical—usually goes like this:

"Whatta' ya' mean, ask Congress? We already *have* the authority!"

The Grill from Industry

However, interested consumers, skeptical reporters and dedicated associates are not the only ones who ask hard questions of an FDA

commissioner. The regulated industry has its own list of favorite queries. My twenty minutes won't let me cite the whole list but surely among the top ten are the following:

—"When are you going to approve my NDA [New Drug Application]?"

—"Why do you always pick on the little guys? If I were General Mills I bet you wouldn't worry about a little botulism."

—"Don't you realize, Commissioner, that if you enforce that standard, you'll put me out of business in a month?"

—"Well, if I do agree to a recall will you agree to no publicity?"

—And, of course, "Who really runs FDA, you or Peter Hutt?"

Federal Register Publications

Among the more persistent and serious questions from both consumers and industry in recent months are those concerning the FDA position on tolerance levels or action guides for poisonous substances unavoidably present in certain foods. Well, it's taken a lot of time and a lot of hard work, but I think we've come up with at least a partial answer. This week I will sign and publish in the *Federal Register* a series of documents that will:

(1) Provide an umbrella procedure for controlling poisonous or deleterious substances unavoidably present in the food supply;

(2) Formalize permanent tolerances or interim action levels for mercury in fish and shellfish and lead in evaporated milk; and,

(3) Lower the permissible tolerance for aflatoxin in peanuts and peanut butter from 20 ppb to 15 ppb.

Within the next few days I expect to meet with the press and consumer groups to try to explain this significant series of actions, and it won't be easy. I can already anticipate the first question:

"Commissioner, aren't you making it legitimate for industry to produce and sell food with known cancer-causing residues in it?" Or, more plaintively, "You mean that it's okay to have rat hairs in my oregano?"

The perfectly straightforward answer is, of course, "Well, yes and no; but . . . " The "but" in this case is essential but hard to explain. It involves the very practical fact that we are doing the best we can to keep to a harmless minimum the residues of various

harmful or obnoxious substances that science and technology find impossible to eliminate. The new regulations will give us reasonable tools with which to do this.

A Mixed Bag

There are three more questions on the most popular list that I'd like to mention briefly. Two have been around for a long time and have good, solid answers to them. The third is something else again. The three questions admittedly are a mixed bag.

The first I call the "chickie poo" question, and it demands to know when the FDA is going to come up with regulations to control the recycling of animal manure so that it can be fed back to animals as part of their feed.

The answer to this question is, "Just as soon as we can devise the means of assuring that the animal that eats the manure is safe, in his turn, to be eaten by humans." But I figure that if a tomato plant can do it, so can a chicken.

The second question is the one that wants to know when we're going to publish our Freedom of Information Regulations.

I am, seriously, quite proud to say to you tonight that these landmark regulations will now be published within days. These regulations are the most extensive and specific such guidelines ever published by any agency of the federal government. They spell out in exquisite detail exactly how the public can gain access to the information base for the decisions made by the FDA in the name of consumer protection. The new regulations undoubtedly will serve as a model for "openness in government," and will put the Agency in the forefront of those in government who are trying to respond to the Congressional mandate for conducting public business in public. Needless to say, I'm very proud of these regulations, and the way FDA management went about preparing the document. I think our Freedom of Information regulations will stand as a monument to Peter Hutt's superb draftsmanship, and, as well, to the wisdom of FDA Bureau Heads and Office Directors, and my staff, who refined the basic policies during a series of very long and tough meetings. When you do see the regulations, you will be impressed by the fact that the entire FDA Policy Board, as a working committee, went over each and every paragraph.

The next, immediate task for the Policy Board is to go through the same process for our procedural regulations, which should be coming along within a few weeks.

Kennedy v. the Commissioner

Now for the final question. It is put in different ways, but perhaps the most common variant runs something like this: "Commissioner, what in the world did you ever do to get Ted Kennedy so ticked off?"

Well, that's not really a very good question since, to my fairly certain knowledge, he isn't. What Senator Kennedy and his aggressive staff have done is to surface in a very challenging way a number of issues that have existed within FDA for a long time; issues that must, and can, be resolved for the betterment of the Agency. Like it or not, though, all the issues that we will be dealing with as a result of the hearings have come from FDA employees, not anyone from the outside.

Senator Kennedy has said that I have "reacted angrily and defensively to the hearings." In one sense, he is right: I have reacted to the fact that the hearings to date have been conducted with questionable fairness. However, I have consistently said that I take the allegations made at the hearings very seriously; that I will investigate each and every one in a thorough, unbiased, and totally open fashion. I have said that FDA needs and welcomes constructive criticism; that the Kennedy hearings have served to spotlight certain errors in our drug approval process; and that FDA will be better and stronger because of the hearings.

When I have completed my investigation, I will do at least two things. I will make the results of my investigation public, just as I am making public the materials that I am gathering just as soon as I receive them.

I will also submit the results of my investigation to an outside group for review; that group will shortly be appointed by Secretary Weinberger. Finally, I will take all administrative, legal or other good and necessary steps to see that deficiencies or inequities proved by the evidence are corrected.

For I am determined—absolutely—that in the future, if I'm asked another question—namely, "All in all, do you think the Kennedy hearings did FDA more good than harm?"—I'll be able to answer, "Yes, they did indeed!" **[The End]**

Legal/Regulatory Developments Affecting Food—Perspective of the Consumers Union

By MARSHA N. COHEN

Ms. Cohen Is an Attorney for the Consumers Union of the United States.

I AM PLEASED that the Food and Drug Law Institute included a consumer representative on this panel exploring food legislation, because the consuming public relies heavily upon the government to assure the safety and honest labeling of the food supply. Food adulteration, for example, is not usually apparent to the eye and often not to the palate, and thus consumers cannot easily protect themselves against it. I think that the public generally has had considerable confidence in the American food supply, but its confidence has been severely shaken in the recent past because of the problems of some vichyssoise and many mushrooms—not to mention the revelations of my own organization about filth in such products as tuna fish and lead in evaporated milk. The public's increasing skepticism about food safety is probably justified, not by the isolated reports about one company or one food, but by the weakness of the federal legislation governing food safety. Consumers Union is extremely hopeful that the Congress, with the support of the Food and Drug Administration (FDA) and the deserved support of all responsible food processors, will soon remedy some omissions in the law by passage of strong food surveillance legislation. New authority, properly utilized, could help restore the now waning public confidence in the food supply.

In order to keep these opening statements short, I will just highlight those aspects of proposed reforms which are of particular importance to consumers.

Importance of Legislation

Although assurance of food safety requires that processors themselves bear primary responsibility, legislation is needed to strengthen the incentive provided by the prospect of government enforcement. Increasing this incentive, we feel, is to the advantage of the careful and caring processor as well as to the consumer. It is not, after all, without cost that certain food processors are particularly careful in the processing and handling of foods. If others in the industry care less, they will save money thereby which others spend on consumer protection. A strong law would revoke this unfair competitive disadvantage now suffered by the safety-conscious processor and would provide greater safety assurance for the consumer than now exists.

Turning now to the specifics: The food surveillance provisions of S. 2373, as passed by the Senate, offer a reasonable legislative scheme for the improvement of FDA's food safety powers. They rely, for safety assurance in the first instance, upon processor development, implementation, and maintenance of safety assurance procedures, which must be reported to the government. The industry substitute, which requires *only* development of procedures, must be rejected as an emasculation of the purpose of reliance upon industry cooperation. Further, the processor's system should not be created only (and I quote from the industry bill) "to the best of his ability"—whatever that is. Nor should the processor identify control points only to assure that food "will not be unsafe or rendered injurious to health." Such a standard would eliminate the preventive function of this legislation, which more properly focuses, as in the Senate bill, on control points "important in the prevention of adulteration." The difference is, I would contend, very significant.

Safety Assurance Standards

The proposed additions to FDA authority constitute the incentive to adequate industry self-surveillance, and thus need to be strong and enforceable. The idea of a safety assurance plan is an interesting one, because it will cast the sanitizing glow of sunshine into a process now all too often obscured by nonpublication of variously-described "tolerances" and "guidelines." The FDA's power to promulgate safety assurance *standards* will allow the accomplishment of the goals in its safety assurance plan. It will allow interested parties, both industry competitors and consumers, to initiate action leading to regulaton in this important area hitherto consigned almost exclusively to the Agency itself. The House bill speaks of "critical

control points standards," which are to me less satisfactory than "safety assurance standards," as the Senate bill denominates them, because the latter appear to encompass a broader spectrum of problems. The House would institute an "offeror" program to write its critical control points standards, in language more than vaguely reminiscent of the Consumer Product Safety Commission (CPSC) offeror program. The CPSC has yet to promulgate a standard prepared by an offeror, and there are considerable difficulties in the program from the consumer point of view. For instance, there are few technically competent consumer group offerors in the product safety field, although some consumer groups have teamed up with standards-writing organizations and others for this purpose. Nevertheless, we are outgunned. Financing standards development is expensive, particularly if you are a voluntary organization with no profits to be gained from the field. These problems would be magnified in the very technical area of critical control points standards, because the subject of the standards would be process, which takes place wholly behind industry's doors. At least lawnmowers and architectural glass and the like are and have been observable apart from their place of manufacture. So we would favor the route chosen by the Senate instead of an offeror plan.

Inspection of Records

Records crucial to food safety should be subject to inspection, and so should records bearing upon the accuracy of label statements. With the advent of nutrition and other consumer labeling programs, it is imperative that FDA have access to the data necessary for enforcing compliance.

The notification procedure, another protection borrowed from the Consumer Product Safety Act, must also be incorporated in the law. The Senate provision goes only part way. Processors should be required to report information which reasonably supports a finding of adulteration, but the government, not the processor, should, upon notification, make the determination whether the apparent adulteration is, in fact, a violation of the Act or regulations.

The detention authority, increased civil penalties, the right of citizens to bring civil suits against the government or any person allegedly in violation of the regulations, are all important to the consumer. The broad exemptions in the law—such as for retail sales and fresh produce—should be carefully reexamined.

All the bills refer to Section 1905 of title 18, U. S. Code, on information release matters. That Section has been held only to

implement other sections of the law prohibiting disclosure, and may by itself mean nothing. Instead, the law should incorporate the protections of the Freedom of Information (F. O. I.) Act.

Food Labeling

Other issues abound here. Food registration is, I think, universally recognized as a necessary and reasonable proposal. Also, it should be almost without controversy that the law should require the listing on food labels of the optional ingredients in standardized food products. I believe that the Senate bill properly includes food colorings in this requirement, and also properly requires that a determination be made about the feasibility and necessity of full ingredient labeling of spices and flavorings. The Senate bill's inclusion of open dating would be extremely useful to consumers anxious to save food dollars, by helping to prevent the purchase of outdated food. Although statutory authority is not needed for nutrition and percentage ingredient labeling initiatives, I am pleased to see them affirmed in this legislation—although I might be interested in some rewording to assure that FDA's powers are not limited by these inclusions.

Preemption

Just one more item requires attention, and that is the preemption section of this law. As I indicated in testimony on the Senate bill, preemption is a sort of two-edged sword. On the one hand, it is the consumer who suffers if proliferating regulations, all in conflict, increase product costs. On the other hand, complete preemption prevents experimentation on a small scale which might be too risky to initiate on a large scale without a test; it also prevents forward-looking legislators in states and cities from trying to deal with problems which they encounter in their jurisdictions. I believe there should be a preemption clause, but with an exemption section that would truly allow exemption, as the Senate's would hardly do. As written, someone seeking an exemption from the Senate's rule would have to argue that the desired law or regulation is "inappropriate for promulgation by the federal government" but desirable for the locality—a somewhat anomalous position to be forced to take. I propose instead that the locality need only show that the proposal imposes a higher level of performance and does not unduly burden interstate commerce. Nothing more is required for the protection of industry, yet this proposal would allow some deviations from federal takeover in the field. **[The End]**

FDA EXTENDS EFFECTIVE DATE FOR NEW FOOD LABELING REGULATIONS

In a notice published in the *Federal Register* on October 10, 1974, the Food and Drug Administration established procedures to be followed for granting delays in the December 31, 1974 uniform effective date for compliance with certain new food labeling and food standard regulations. Recent developments, such as President Ford's program for identifying and eliminating federal rules and regulations that increase consumer costs without good reason, as well as objections from the milk, grocery, and canning industries, have caused the FDA to reconsider portions of that notice. The FDA concluded that the uniform effective date should be extended through June 30, 1975 for many of the products covered. The effective date for 21 CFR 1.8d, *Food labeling; information panel*, was postponed by the Administration until December 31, 1975 for products for which no other labeling changes have been or will be made after March 14, 1973. With regard to an inability to comply with the new uniform effective date because of unforeseeable intervening events, extensions up to, but, except in extraordinary circumstances, not exceeding six months beyond June 30, 1975 will be granted on a case-by-case basis if good cause is shown. There are no changes from the original notice in regard to products subject to pending rulemaking, except that the deadline for receipt of requests has been extended to May 1, 1975 and no exception will be granted beyond December 31, 1975 except in special circumstances. The FDA also advised that there were no changes from the original notice in regard to food for special dietary uses.

CCH FOOD DRUG COSMETIC LAW REPORTER, ¶ 41,263

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EXEMPTION FROM LABELING FOR READY-TO-EAT FOODS PROPOSED

Ready-to-eat foods prepared and sold in food service establishments would be exempt from the requirement that nutrition information be included in the package label provided that such information is conspicuously displayed where the food is sold, according to a proposal issued by the Food and Drug Administration. The proposal states that the label would be required to carry either complete nutrition information or none at all, in which case off-package labeling, such as placards and posters, would be required to contain complete nutrition information and be prominently and conspicuously displayed along with the menu and in any dining areas on the premises. McDonald's Corp., Oak Brook, Ill., filed a petition with the FDA requesting the labeling exemption for ready-to-eat foods on the ground that the packaging for the foods is not suitable for such information since it is soiled by contact with the food and therefore unlikely to be read.

Interested persons may file comments on the proposal until February 3, 1975.

CCH Food Drug Cosmetic Law Reporter, ¶ 45,228

NADA RECORDKEEPING REVISION PROPOSED

The holder of an approved new animal drug application (NADA) for a new animal drug in animal feed would be required to keep either a copy of the NADA or appropriate identification of the approval and the labeling specified at each establishment to which the approval applies, according to a proposal issued by the Food and Drug Administration. The agency said that present requirements do not permit a ready determination that an animal feed produced at a facility is in compliance with an approved NADA since many applications provide for manufacture at more than one facility and the NADA is usually kept on file at the home office or other central facility of the firm. Views and comments on the proposal, which would also update new animal drug regulations to refer to the latest revised FD Form 1800, may be filed until January 21, 1975.

CCH Food Drug Cosmetic Law Reporter, ¶ 45,225

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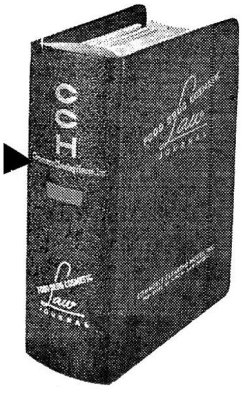

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