PERSPECTIVES

CHANGING OF THE GUARD

After two and a half years as senior editor and two years as editor of *Regulation* I am stepping down from the magazine to devote more time to my other job at the Cato Institute, director of regulatory studies. The change will give me more opportunities to promote deregulation through policy papers, forums, and conferences. I will keep my ties to the magazine as a new member of its editorial advisory board.

During my tenure at *Regulation* I have tried to feature articles of three kinds. The first were our bread-and-butter analyses of policies in such traditional areas as energy, environment, antitrust, and financial services. The second were on the regulatory process and have included reviews of recent reforms passed by Congress and of the problems that have arisen because Congress has delegated much of its lawmaking power to unelected bureaucrats. The third were cutting-edge pieces on under-explored regulatory issues, including articles by George Leef on privatizing unemployment insurance and governmental restriction of the right to practice law, by Lawrence Schonbrun on the class-action lawsuit con game, and by Michael Markels on privatizing and farming the oceans.

I have also tried to make the articles accessible not only to academic experts in the field but also to Capitol Hill staffers, journalists, entrepreneurs, and others who effect or are affected by regulations.

The record of regulatory reform over the past five years has been mixed at best. There has been some legislative progress, for example, in agricultural policy and to a limited extent in telecommunications. And recent court rulings, as in this year's *Pearson v. Shalala*, have extended commercial-speech rights.

But the breakdown of the rule of law in this country has enabled government agencies to expand their powers at will. The Food and Drug Administration's attempt to exercise jurisdiction over cigarettes is well known. Less visible exercises of the FDA's power have had equally deleterious effects on freedom. For example, it has asserted that judging a product's "efficacy" may take into account whether the product is economically efficacious—that is, whether there are less costly substitutes available—and, in the case of a home drug-testing kit, whether its use might cause family discord.

The most ominous regulatory trend has been the displacement of normal legislative and rulemaking processes by raw governmental extortion. The "war on tobacco" exemplifies the trend. Instead of proposing laws for legislative debate or rules for public comment, state attorneys general and federal officials have simply used their assumed powers to wear down cigarette manufacturers—who might eventually have won their cases but gone bankrupt in the process. The tobacco deal is neither traditional law nor traditional regulation. It is an arrangement extorted at the point of government guns.

Gun manufacturers are the current targets of the extortionate approach to regulation. Likely future victims include manufacturers of alcoholic beverages and foods that contain "unacceptable" levels of fat and calories. The common theme, of course, is that tobacco, alcohol, guns, and the rest are unacceptable to those who seek to control our lives and businesses.

It is evident that there will be no lack of stimulating topics for future issues of *Regulation*, whose new editor will be our current book editor, Peter VanDoren. Managing editor Ricardo Reyes is leaving as well. His replacement is Tom Anger. Good luck to all!

EDWARD L. HUDGINS

"IT'S THE FDA. WE'RE HERE TO BURN YOUR BOOKS."

In the best American tradition, Oscar Rodes had a better idea. Increasingly, health-conscious Americans were demanding "natural" products yet their only alternatives to sugar were artificial sweeteners such as saccharin and aspartame. Outside of the United States, a natural alternative was available: the sap of the South American stevia plant. Conquistadors observed its use by the Guarani Indians of Paraguay four centuries ago, and today it is the principal noncaloric sweetener in Japan and other Asian nations. Where its use is widespread, its safety has been well established due to experience and extensive scientific testing. Given that aspartame has more than seventy-two hundred possible adverse reactions associated with it, Rodes thought he had a winner. But as Rodes found out, the situation changes once the Food and Drug Administration gets involved.

Rodes performed the Herculean effort needed to obtain the FDA's approval to distribute stevia as a dietary supplement and was planning to distribute several thousand cookbooks concerning the use of the product. On the afternoon of 19 May 1998, Rodes received a fax from the FDA's district office. It started off well enough: "This agency appreciates Stevita Co.'s expressed intention to comply with the Law." Then it went downhill:

> However, a current inventory must be taken by an investigator of this office who will also be available to witness destruction of the cookbooks, literature, and other publications for the purpose of verifying compliance. Additionally, your stevia products currently

> in distributor and retail channels with the offending cookbooks, literature, and other publications continue to be in violation of the Federal Food, Drug, and Cosmetic Act.

What, did "cookbooks, literature, and other publications" have to do with the Food, Drug, and Cosmetic Act? In the never-never land of food and drug regulations, they apparently had quite a lot to do with one another.

The FDA is responsible for assuring that foods and drugs are not adulterated. The Agency's view on what constitutes adulterants, however, would do George Orwell proud. The law states that a food can be adulterated if "It is a dietary supplement or contains an ingredient that presents a significant or unreasonable risk of illness or injury under . . . conditions of use recommended or suggested in labeling." But that's not all. The law also states, "The term 'labeling' means all label and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or accompanying such article."

That definition gets us to "cookbooks, literature, and other publications." Since stevia is intensely sweet, reportedly three hundred times as sweet as sugar, it is important to know exactly how much to use in any food or beverage. Recognizing that need, Rodes offered to sell his customers three books, all from third party publishers: *The Stevia Cookbook*, N*ature's Sweet Secret*, and *The Stevia Story*. The third, being a political treatise highly critical of the FDA, was particularly offensive to the agency.

The FDA said that because the books were often sold to the same individuals who purchased Rodes' stevia product, they constituted part of the label. Worse, since the books suggested that the product might be used in food, it altered the nature of stevia, transforming it from a dietary supplement, which Rodes had permission to sell, to an unapproved food additive. Rodes, had fallen into a regulatory Catch-22.

According to FDA regulations, there are dietary supplements and there are food additives. Dietary supplements include such things as vitamins, herbal products, and other items that are taken by themselves. Food additives like food dyes and artificial sweeteners are incorporated in foods and subject to extensive regulations and testing requirements. Meeting those requirements can cost hundreds of millions of dollars. Many products that were in use prior to 1958, including most spices, fall into a third category "generally regarded as safe (GRAS),"and are exempt from regulation. Even though eight years prior to its actions against Rodes the FDA had been provided with information documenting stevia's use during the past four centuries, it has refused to confer GRAS recognition on the sweetener.

In essence, the FDA was saying that if people wanted to consume ten pounds of stevia extract a day as a supplement, that was fine, but if they put just one drop in a cup of coffee, alarm bells would sound. Further, it did not matter how widely the substance was used outside the United States, or how much testing it had undergone. If stevia did not jump through the FDA's bureaucratic hoops, it would not be approved.

On the afternoon of 19 May 1998, the FDA's thought police arrived at Rodes office to burn the offending books. Rodes protested that he did not have a burn permit for Arlington County, Texas, and he asked if the books could be put in his dumpster instead. The FDA officers agreed, but only after they had marked the offending books so that they could not be resold. As they began, Rodes took his video camera in hand to record the incident, which gave the regulatory minions pause. After marking only a half dozen books, they decided to consult with headquarters and soon after abandoned the project for that day.

As the question of the cookbooks worked its way up the FDA food chain, the incident was beginning to get publicity. More important, First Amendment attorney Jonathan Emord petitioned the FDA on behalf of health advocate Julian Whittaker and *Nature's Sweet Secret* author David Dean Richard, to order their Dallas field office to stop attempts to burn the books.

On 28 June 1998, the FDA threw in the towel. Officials told Rodes he was free to sell the books as well as his product, which the FDA had also put on hold. President Clinton seems to tacitly agree with this important victory: "Agencies of government charged with protecting the food supply and the rights of consumers have paradoxically limited the information to make healthful choices in an area that means a great deal to over 100 million people." Correcting this ill is a task that remains undone.

MILT COPULOS
Producer on the "Freedom Line with Mike Hambrick" radio program

FREE SPEECH VS. THE FDA: DIRECT-TO-CONSUMER ADS

What does a woman's voice have to do with male impotence? Well, the Food and Drug Administration claims that having a woman talk about the risks of using an injectable impotence treatment does not fully convey the dangers associated with the therapy. As a result, the FDA has ordered the manufacturer Vivus to pull its television commercial for the product called Muse until it replaces the woman's voice reading risk information with a man's.

According to the FDA's Division of Drug Advertising and Communications Branch Chief Nancy Ostrove, having a woman talk about possible risks is a way of softening the blow. She said, "Notice how women's voices are so much more reassuring then men's. They always—well not always, but in many cases—have women's voices reading the bad stuff. It's very interesting."

Surreal is more like it. This foray into the production values of TV commercials is part of the FDA's growing effort to regulate direct-to-consumer ads about prescription pharmaceuticals. The FDA seems to be on a collision course with the Constitution's First Amendment, a confrontation that it is likely to lose.

SUPPORTING FREE SPEECH

In recent years courts have issued important decisions upholding rights to commercial speech. In the 1996 case of *44 Liquormart Inc. v. Rhode Island*, the Supreme Court struck down a state law that imposed a blanket ban on alcohol retail price advertising. The Court ruled that such bans on truthful, nonmisleading information violates the First Amendment. In 1998 U.S. District Court Judge Royce Lamberth, in *Washing-ton Legal Foundation v. Friedman*, ruled against the FDA's ban on pharmaceutical manufacturers communicating truthful information about their products to physicians and other health care providers. Before that case, a manufacturer might run afoul of the FDA, for example, by giving a doctor an article from a peer-reviewed medical journal concerning test findings for one of its products. In January, 1999 the U.S. Court of Appeals for the District of Columbia held that the FDA's restrictions on advertising dietary supplements did not meet the Constitution's First Amendment test.

EXCUSES FOR RESTRICTIONS

Apparently, FDA officials are hoping that court precedent will not be applied to their current actions against DTC ads for prescription drugs. Proponents offer a number of rationales for restrictions on advertising. They suggest that drug ads are dangerous because they lead people to demand products that they do not need. They contend that patients could be induced to use higher priced products when less-costly generic products are available. Yet another justification for restrictions is that patients might he induced to seek certain products without proper consultation with a physician thus undermining the doctor-patient relationship. According to the FDA's Division of Drug Advertising and Communications Branch Chief Nancy Ostrove, "If in fact these advertisements are encouraging people to believe that they can make these kinds of decisions without the intervention of a learned intermediary, that is problematic. We don't think that that is necessarily a good thing for the public health. That's something we'd like a little bit more data on."

Those rationales rest on more basic premises held by FDA officials. They apparently believe that ads for prescription drugs are inherently misleading. Manufacturers thus cannot defend an ad simply by demonstrating that their products work as advertised, assertions already approved by the FDA. Manufacturers must demonstrate that the ads themselves, not the products, will contribute to better public health.

The effects of those FDA beliefs are seen today in many commercials. In the past, drug ads provided listeners with information on the benefits and risks of their products without a lot of detailed information of interest only to doctors and pharmacologists. A simple warning to "consult your physician first" was enough to convey that only certain individuals under certain conditions might benefit from the product. Now ads contain detailed information that probably confuses more than it helps.

DEFENDING COMMERCIAL SPEECH

The FDA's case for censorship suffers from a number of fatal flaws. To begin with, there are no empirical studies to support the FDA's contention that ads cause listeners to take or switch to medications that are inappropriate for their medical conditions. The FDA simply expresses the concern and acts on it without showing that a problem actually exists.

Further, the FDA's assumption that listeners must be protected from truthful information is unlikely to pass judicial muster. In his ruling, Lamberth noted that "to endeavor to support a restriction upon speech by alleging that the recipient needs to be shielded from that speech for his or her own protection, which the gravamen of the FDA claim here, is practically an engraved invitation to have the restriction struck." Quoting a Supreme Court opinion voiding the Rhode Island law that banned liquor price ads, Lamberth wrote that "if there is one fixed principle in the commercial speech arena, it is that a `State's paternalistic assumption that the public will use truthful, nonmisleading commercial information unwisely cannot justify a decision to suppress it."

The FDA's premise that prescription drug advertisements as such must be treated as wasteful or dangerous unless those ads can demonstrate beneficial effects has regulatory implications that also are unlikely to be upheld by courts or backed by policymakers. For example, will ads have to show that oatmeal causes a reduction in cholesterol among the general population; that antibacterial dish soap reduces the number of cases of strep throat and ear infections; that toothpaste directly contributes to a reduction in cavities and tooth decay? Why not require that all ads for fat-free food show that it causes people to lose weight?

In fact, there is no evidence that advertising misleads and confuses consumers about a drug's risks and benefits. On the contrary, a recent survey conducted by *Prevention* magazine found that as consumers shift towards more self-care "they like direct to consumer advertising because it helps them reach that goal." Indeed, the *Prevention* survey shows that consumers are not naive, as proponents of censorship believe. Seventy-four percent of all consumers believe that ads can help them become more involved and educated about their health. However, they are unlikely to talk to their doctor about a medication if they do not think the ads do a good job of discussing benefits and risks. Consumers are most confused about ads that simply mention a product without a discussion of benefits or risks.

Moreover, consumers note that advertising has contributed to improved medical treatment. In the *Prevention* survey, nearly one in four "report that the ads make them more likely to take their medicine and that ads remind them to have their prescriptions filled." Failure to take medicines properly is the most common reason for treatment failure or the return of a disease. Clinical studies show that reminding people about the benefits of taking medications as prescribed leads to increased compliance. So to the extent drug ads improve medical compliance they improve well being.

Further, as Lamberth notes in his decision, the market for pharmaceuticals is unique. Physicians ultimately determine what medications people should take. Advocates of censorship seem to believe that doctors will be brainwashed by drug ads.

Again, there are no studies or other empirical evidence to suggest that ads are leading doctors to prescribe drugs in ways that pose a direct threat to the public health. The *Prevention* magazine survey found that while 80 percent of doctors are inclined to honor requests by patients for particular drugs, they discuss those medications first. Judge Lamberth asserted that doctors are smart enough and caring enough to prescribe medications without government interference.

Even if drug ads harmed the public health, according to Judge Lamberth, any suppression of information has to "directly and materially advance" the FDA's interest in protecting people. Patients cannot purchase prescription drugs without first seeing a doctor, obtaining a diagnosis, and obtaining a prescription. And the right to distribute information about pharmaceuticals to doctors was affirmed in Lamberth's decision.

The FDA's attack on prescription drugs ads demonstrates an inconsistent application of its authority. Over-the-counter drugs such as aspirin products and cold medications are much more likely to be misused than prescription drugs. Why then are ads about drugs that can be purchased directly by consumers a lesser threat to the public than are ads about medications that require a doctor's prescription before purchase?

There seems to be more to the FDA's attack on drug ads than whether a menacing Darth Vader voice instead of a women's voice discusses the dangers of injectable drugs for erectile dysfunction. FDA officials seem to believe that individuals might make decisions that are different from the ones that the officials would make. Lionel Trilling wrote in *The Liberal Imagination*, "We must be aware of the dangers which lie in our most generous wishes. Some paradox of our nature leads us, when once we have made our fellow men the objects of our enlightened interest, to go on to make them the objects of our pity, then of our wisdom, ultimately of our coercion." Those who favor censoring truthful information about pharmaceutical products have fallen into this perverse ethic. Of course, with television commercials, individuals can just change the channel. But with the FDA's recent power grab, individuals will be left with fewer choices and less medical freedom than ever before.

ROBERT M. GOLDBERG

A TANGLED WEB: IOLTA AND THE BANKS

With its June 1998 decision in *Phillips v. Washington Legal Foundation*, the U.S. Supreme Court rebuffed the organized bar to uphold private property rights. By five to four, the Court declared that the interest generated by deposits lawyers hold for clients belongs to the clients, not to the lawyers. The proponents of the bar's IOLTA (Interest on Lawyers' Trust Accounts) program have claimed for nearly twenty years that the interest on nominal deposits held for short periods of time could be siphoned off without the knowledge or consent of the client for "socially desirable" programs approved by the organized bar. The Court has now affirmed that the interest is the property of the owner of the principal.

Earlier in this century, citizens would have deemed such a decision a matter of common sense. The common law dictum, "interest follows principal," dates back at least to 1750. That the margin of the Court's decision should have been razor thin suggests the magnitude of the shift in legal thinking over the past century. It should make all who believe private property essential to freedom profoundly uneasy.

Although the Court has spoken, implementing its decision may be difficult. The case has been remanded to the lower court to determine whether there has been a "taking" from plaintiffs to whom compensation is due. That court, buttressed by the organized bar, may allow extended debate on that secondary issue. If it does, IOLTA's infrastructure will remain in place. The bar is unlikely to give up quickly a program it has nurtured since its creation in Florida in 1981. IOLTA funnels about $100 million annually—more if times are "good" and interest rates are high—into the coffers of attorneys to stoke the engines of preferred social and political causes. Like the Wizard of Oz, the bar may try to avoid disclosing the mechanism behind its charities, hoping that it will somehow be able to keep the mechanism working and generating money.

Overlooked in that eventuality is the role of the banks. Never compelled to participate, banks have taken part in IOLTA as "good citizens." In that guise they have collected the interest on clients' deposits, forgone frequently the fees they could have charged, and turned over the interest to the attorneys. Public relations aside, however, IOLTA has been a money–losing proposition. The banks have detested the IOLTA accounts and the badgering from bar officials they have entailed

The Supreme Court's decision gives them an opportunity to withdraw from IOLTA on the grounds that continued participation could open them to a charge of conversion, that is, of depriving owners of their property without permission and without just cause. True, the responsibility of the banks is secondary. A client seeking indemnification for interest withheld would look first to the attorney who instructed the bank to place his retainer in an IOLTA account. Nevertheless, should a number of clients file complaints against individual banks on the grounds that they had appropriated the interest on funds deposited in IOLTA accounts, the complaints could snowball into a massive class action against all banks for the value of the income stream generated in the wake of the Court's decision. Such a total could include the value of the interest forgone, plus the interest that those funds could have earned.

However unlikely, the specter of such an action might lead a cautious bank attorney to counsel his client to withdraw from IOLTA. Heeding that admonition, and with the security of its stockholders in mind, a bank might find it prudent to rethink its position, initiating a domino effect. If the bar were unable to find a safe repository for funds destined previously for IOLTA, it too could find itself compelled to retrench.

Concerned banks may find unexpected allies in practicing attorneys. In the nearly thirty states with compulsory IOLTA, a

lawyer refusing to participate in the program could face disbarment. What will happen when he faces a client who demands that the interest on his deposit be returned to him? If the attorney pleads the threat of disbarment, he may find an irate client declaring, "That's *your* problem, not mine. It's *my* property." Will the possibility of disbarment prove an adequate defense? That seems unlikely.

For banks and practicing attorneys alike, the Supreme Court's decision changes the rules of the game. The vindication of property rights now protects the clients that the attorneys were always supposed to serve but had subordinated to "good causes." Those clients may well prefer to decide for themselves which charities to support.

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