



Flying Below the Radar Screen: The Absence of Information About the FDA

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**Flying Below the Radar Screen:
The Absence of Information About the FDA**

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Submitted to:
Mr. Peter Hutt, Esq.
Food and Drug Law
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raw afternoon is rawest, and the dense fog is densest, and the muddy streets are muddiest near that leaden-headed old obstruction, appropriate ornament for the threshold of a leaden-headed old corporation, Temple Bar. And hard by Temple Bar, in Lincoln's Inn Hall, at the very heart of the fog, sits the Lord High Chancellor in his High Court of Chancery.

Never can there come fog too thick, never can there come mud and mire too deep, to assort with the groping and floundering condition which this High Court of Chancery, most pestilent of hoary sinners, holds this day in the sight of heaven and earth.

Charles Dickens, *Bleak House*¹

Introduction

IT MAY SEEM SELF-EVIDENT to many American lawyers who spend their life's work serving their government that their time is well-spent. The cause for which they are working, after all, is the public cause. They spend years in underpaid positions, toiling away in cramped and badly supplied offices while their private sector counterparts benefit financially and perhaps socially from their corporate titles and the trappings of

an upper-class life. Why have those who work for the government chosen to do so? Because they believe the work they are doing is important; it is important to them, and important to other people, and perhaps even important to our shared future.

Yet the American lawyer who works in government faces a central challenge in maintaining this public-spirited vision of himself: how can he know he's doing a good job? Lawyers spend their lives working in an arcane and quite specialized profession, whose tools and concepts are alien to laymen. Only once a person attends law school does he learn the legal significance of words which would otherwise seem like harmless adjectives—like “reasonable” and “foreseeable.” Court decisions drone on for hundreds of pages, choosing certain Latin phrases for emphasis that have little significance outside courtrooms or law schools. Why write in Latin? Only 10 percent of Americans speak a language other than English with fluency,² and the so-called “dead languages” like Latin are hardly among the most popular. Even Americans with a college education would have a hard time understanding court decisions or regulatory language. Moreover, people don't have free time to invest in translating legalese. It is no wonder that one of the most vivid and lasting images of the legal profession was painted by Charles Dickens in *Bleak House*, when he described the site of the English bar as the area around which “raw afternoon is rawest, and the dense fog is densest, and the muddy streets are muddiest.”³ The law is, for most people, unclear, obtuse, and inaccessible.

The legal profession's opaqueness isn't just a problem for the public, though: it creates significant problems for lawyers who nominally serve the public interest, because they cannot know how well they're serving the public interest. If the public doesn't understand what its lawyers are doing, then the public cannot provide feedback to even the most well-meaning government lawyer. But the problem of communication between the lawyer and his public client is deeper still in the context of government work: the tools for communication from citizen to government are limited, and quite blunt. Every so often, Americans vote—but, of course, not

²See, e.g., John Freivalds, *The Art of Guerrilla Linguistics*, 5/9/00 J. COM. ABSTRACTS 5 (2000).

³Dickens, *supra* note 1.

all Americans vote, and the percentage of Americans who vote has been declining for years.⁴ Additionally, even though some Americans participate in politics with specificity (by contacting local officials, attending rallies, donating money to political organizations, or working on campaigns), most of these forms of public speech have little to do with the specifics of law-making. Thus, many lawyers who serve inside government are left without a clear measure of how well they're serving the public interest.

This paper examines one example of the problem of communication between lawyers and their public constituency: the Food and Drug Administration (FDA). The FDA has been entrusted with a deeply important public goal: to “promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner.”⁵ The economic and personal importance of the agency's work is staggering when one considers that more than 25 cents of every consumer dollar is spent for products that fall within the categories regulated by the FDA.⁶ Some critics have charged the FDA—and government lawyers in general—with being unconcerned about the public interest, notwithstanding the scope and public significance of their work. As scholar Robert Higgs notes:

Even if the FDA could know the infinitely varied and changeable information it would require to promote the public interest, one would be naïve to suppose that it would act on the basis of that information. . . Do we have any reason to suppose that the people who work for the FDA are any more public spirited than those who work for the Bureau of Land Management, the Export-Import Bank, or the Postal Service?”⁷

Yet those who accuse the FDA of being unconcerned with the public interest are in fact asking the wrong questions. Such critics take FDA employees to task for ignoring what “the public”⁸ thinks about the agency;

⁴See Federal Election Commission, *Voter Registration and Turnout Statistics*, <<http://www.fec.gov/elections.html>>

⁵Food and Drug Administration, *FDA's Mission*, <<http://www.fda.gov/opacom/morechoices/mission.html>>.

⁶PETER BARTON HUTT & RICHARD A. MERRILL, *FOOD AND DRUG LAW* v (2d ed. 1991). This figure was confirmed by the FDA on its Internet web site as of the date this paper was submitted.

⁸By putting the term “the public” in quotations, I mean to signify that the analysis performed in this paper is aimed at determining what an average person knows about the FDA. This paper does not define an average person sociologically; that is, it makes no assumptions about “the public's” racial composition, educational level, average salary, or other demographic

but this assumes that “the public” actually *knows* something about the FDA, and that it has enough basic facts to form an opinion about the kind of job the agency is doing. As this paper will show, most Americans don’t have enough information about the FDA’s role, its regulations, or its policies to judge the agency at all.

In order to determine what most people know about the FDA, this paper engages in a study of the major media’s coverage of a particular set of drug recalls which occurred near the time of the passage of the 1997 FDA Modernization Act (Modernization Act).⁹ One underlying assumption motivating this analysis is that most people obtain information about government agencies (and about the FDA in particular) through the mass media. Certainly many people will learn about the legal/political system through their own personal experience. Yet given the fact that most people do not work within the legal/political system and that most of their daily activities are not, therefore, focused on research about regulatory agencies, their main source of information about an agency like the FDA is likely to be the mass media.

The Modernization Act was one example of ongoing attempts by the FDA to respond to those who argued that the agency’s drug approval process worked too slowly to provide people with the medications they urgently needed. Under a plan implemented by the FDA in early 1989, the agency created a “fast track” drug approval process for medicines that showed sufficient promise in early testing and targeted serious and life-threatening diseases, like cancer and AIDS.¹⁰ In 1992 Congress enacted the Prescription Drug User Fee Act (PDUFA),¹¹ which collects fees from companies that produce certain drug products, providing the FDA with enough additional revenue to hire more reviewers and support staff, upgrade its information technology, and ultimately speed up the application review process.

information. My only assumption about “the public” is that members of the public have no *special* access to scientific, regulatory, or other information.

⁹111 Stat. 2296 (1997).

¹⁰See 21 C.F.R. 314(h).

¹¹106 Stat. 4491 (1992), 21 U.S.C. 379(g), § 735 of the FD&C Act.

However, the Modernization Act was particularly noteworthy because during the Act’s passage and within the year that followed, the FDA recalled four different drugs from the marketplace due to unanticipated adverse reactions—Redux, Pondimin, Posicor, and Duract.¹² The fact that these recalls occurred so quickly after one another (when recalls are quite rare),¹³ and the fact that they tracked the passage of the Modernization Act so closely, raised a flag for many who monitor the FDA. To even the most casual observer, these recalls highlighted the underlying tension the FDA has continually faced between (a) ensuring drug safety and (b) speeding up the drug approval process.

Yet the recalls did not necessarily create a moment of crisis or great controversy for the FDA—which is why it serves as an excellent vehicle to examine what people know about the FDA. Certainly there are controversial issues, such as the approval of the so-called “abortion drug” RU-486, which attract enough media attention to saturate many (if not most) American neighborhoods. But an examination of the media coverage surrounding RU-486 isn’t representative of the media coverage surrounding the FDA more generally, because abortion is such a distinct and heated political issue in America. The media’s coverage of RU-486 reaches far beyond a simple analysis of FDA policy.

An analysis of the media coverage of the 1997-98 drug recalls, however, reveals that with regard to fundamentally important (though not “hot-button”) issues—such as the speed of drug approval vs. drug safety—average people do not have access to enough information to even begin to assess the FDA’s performance.

Put aside the question of whether the FDA is responsive enough to the public interest; the American public

¹²Also known chemically as dexfenfluramine, fenfluramine, mibefradil, and bromfenac, respectively. Redux and Pondimin were withdrawn on September 15, 1997; Posicor was withdrawn on June 9, 1998; Duract was withdrawn on June 22, 1998. The anti-allergy drug Seldane (known chemically as terfenadine) was also recalled during this period, but the reason for Seldane’s withdrawal was distinct from the withdrawals of the four other drugs at issue here. Seldane was withdrawn because a new, less dangerous alternative became available to allergy sufferers, namely the drug Allegra. The other four drugs were withdrawn due to unforeseen adverse reactions.

¹³In the 10-year period before Duract was withdrawn, only seven recalls had been announced by the FDA—including the four analyzed in this paper. See, e.g., Raja Mishra, *FDA Recalls Raise Questions on Its Speed of Approval*, SAN DIEGO UNION-TRIBUNE, June 24, 1998, at A21.

may not even be knowledgeable enough to be interested.

In short, this paper is a study of how the American people interact with and understand a complicated governmental agency. Part I examines the traditional role of media in providing information to people about government; Part II examines the FDA's role in government, and the public's overall perception of the FDA; Part III focuses on media coverage of the four drug recalls mentioned above; following this are a few concluding remarks.

By examining what information people received about a particular legal and political question—or, more generally, examining how people ordinarily receive information about the law (the primary product of government)—this paper provides insight into the relevance of today's legal controversies to average people. The issue of drug safety vs. the speed of drug approval may not employ thousands, or even hundreds, of lawyers, but it is indicative of the kind of questions lawyers dissect every day. The issue is particularly representative of the kind of questions asked by regulatory lawyers and government lawyers.

But the questions this paper raises about the profession's relevance to average people should be important to all attorneys. We come to law school because much of the law—perhaps regulatory law in particular—is Byzantine, obscure, and impenetrable to the untrained mind. You can't understand the law without law school; perhaps years ago people took the bar exam without obtaining a graduate degree, but certainly today that path is a very rare exception.

After law school, many lawyers work for the government in order to perform tasks they hope are important to people, tasks they hope will change people's lives for the better. And yet—perhaps, in part, due to the law's complexity—the public doesn't have enough information about the law to understand its operation. Average people are ignorant of the basic legal systems which are supposedly set up to protect them. They're

even ignorant of the policy dimensions on which those laws operate—such as the dimensions studied in this paper. Therefore, even the most well-meaning governmental lawyers may believe they’re doing what people would want them to do, but they cannot truly know. And for many people, the law remains just as arcane and useless, as much of a “leaden-headed old corporation” as it was for Charles Dickens in *Bleak House*. The right question for today’s public-minded lawyer isn’t “What do people think of the job I’m doing,” but “What do people even *know* about what I’m doing?”

We live under a government of men and morning newspapers.

Wendell Phillips¹⁴

Part I: The Role of the Media in Government

BEFORE ANALYZING THE MEDIA COVERAGE of any event, it is important to take a step back to examine the filter through which the analysis necessarily proceeds: the media itself. Part I of this paper is therefore concerned with providing a framework within which to view media coverage of the legal/political process.¹⁵ Most analyses of the American media focus on its vast power to influence government (and at least statutory, if not regulatory, law). The role of the press, the so-called “fourth branch” of government,¹⁶ may be an elusive one in constitutional terms, but it is obvious that such a political role does, in fact, exist. One might not even bother asking whether or how significantly the press influences policymaking; most observers concede that the influence of the press is substantial.¹⁷

It is important to clarify up front, however, that this paper does not attempt to explain or predict the role of the media in influencing FDA policy. Analyzing the media’s role in the U.S. government’s perception of popular opinion is a valid task, but it is not the task undertaken in this paper. Rather than analyzing

¹⁵Throughout this paper, I have intentionally blurred the line between the legal and the political process, in part because I agree with commentators who have successfully argued that law *is* politics, and in part because it is not important for the purposes of this paper to separate the two. Some people may wonder whether the lawyers who work inside the FDA—or any regulatory agency—are performing primarily “legal” or primarily “political” tasks. Regardless of the answer to that question, however, this paper focuses on what average people know about what these “lawyers” or “policy-makers” are doing, and not on whether their tasks are properly defined as “legal” or “political.”

¹⁶As George Boyce points out in his superb piece, George Boyce, *The Fourth Estate: The Reappraisal of a Concept, in* NEWSPAPER HISTORY FROM THE SEVENTEENTH CENTURY TO THE PRESENT DAY 1, 19-40 (George Boyce et al. eds., 1978), the “fourth branch” terminology is not quite apt as applied to the American press, since the term derives from the “fourth estate” metaphor often ascribed to Edmund Burke. In 1840, Thomas Carlyle wrote, “Burke said there were three estates in Parliament. But in the reporters’ gallery yonder there sat a fourth estate more important far than they all.” Thomas Carlyle, *The Hero as Man of Letters, in* ON HEROES, HERO WORSHIP, AND THE HEROIC IN HISTORY 152 (1840). Boyce emphasizes that 19th century British journalists were central in creating the “fourth estate” mythology, since they considered themselves to be taking on a legitimate political role. American journalists, on the other hand, have been much less enthusiastic about accepting a designation that would place them solidly *within* the governmental process.

¹⁷See, e.g., Gary R. Orren, *Foreword* to MARTIN LINSKY, IMPACT: HOW THE PRESS AFFECTS FEDERAL POLICYMAKING at 1, 20 (1986).

media coverage as an *input* to the governmental process, this paper analyzes media coverage as an *output* of governmental activity in general (and the FDA in particular).¹⁸ This is not to say that media coverage is an output of government; the American press would surely balk at the idea that it operates, even mildly, as an instrument of the state. But in order to report information about the government, the media must naturally be concerned about what the government, in fact, *does*: legislation, regulations, legal decisions, and their import. Media coverage of governmental activity is often aimed at communicating something about how our legal/political system is working—regardless of whether that information is coming from independent, governmental, or otherwise biased sources.

Thus, our task is to determine what the media’s coverage of a particular event (the recalls of Redux, Pondimin, Posicor, and Duract in 1997-98) tells us about what people know about the workings of the legal/political system—regardless of how responsively that system might be working, or how much the media’s coverage influences policy. In pursuit of that assignment, Part I discusses the traditional role of the media—not as the “fourth branch” performing some quasi-governmental task, but as the filter through which information about politics, government, and the law reaches average people.

The Media as Provider of Information

It should be clear from the discussion thus far that the communications media perform two important tasks: they help citizens tell their governments what they want government to do, and they help citizens reach informed decisions about what they want their government to do. It is this second task with which this

¹⁸This concept is drawn from SIDNEY VERBA & NORMAN H. NIE, PARTICIPATION IN AMERICA: POLITICAL DEMOCRACY AND SOCIAL EQUALITY 5-15 (1972). Verba and Nie were primarily concerned with investigating the inputs to governmental decisions.

paper is concerned: the task the media undertakes as a provider of information.

One of the central problems faced by all democratic citizens is that they need to obtain information—about the state of the world, about their governments’ policies, and about the interaction of the two—in order to determine how well their political preferences are being met. Without such basic information, people cannot engage in public deliberation, and governments cannot hope to be responsive to the popular will. Because one of the core ideas of democracy is that governments ought to do what their citizens prefer, the role the media play as information provider is critical to the operation of the democratic state—and the quality of information provided to the public is one of the core building blocks on which the legal/political system depends.

The fact that the media act as an intermediary between people and their government, however, raises some potentially difficult issues. As Benjamin Page asks:

... What if professional communicators purvey misleading information or fail to communicate ideas and information the public needs? Will citizens be deceived? Can the public be misled into supporting policies inconsistent with objective realities or with citizens’ basic values and interests?¹⁹

The reason we might be concerned about the answers to these questions is simple: even if we assume that the public is capable of rationality and high-level thinking, public opinion is bound to depend on the quality of information and ideas that reach people. If information is complete, balanced, and accurate, then the media has in essence “done its job” and we can assume that people have been given the basic building blocks they need to engage in democratic deliberation. But if the information people have at their disposal is biased, incomplete, misleading, inaccurate, or otherwise lacking, then a democratic government must choose between two impossible options: either pay attention to people’s wrong-headed preferences and do harm, or

ignore those preferences and violate basic notions of democratic sovereignty.²⁰

Ideally, people could communicate with those who work inside government (and with others who collect important political information) directly, and there would be no “middle-man” standing between citizens and the information they require. Some have argued that given modern technology, it may be possible either today or at some point in the future to build a more “direct democracy,” in which popular deliberation looks more like ancient Athens—where all citizens had equal rights to attend and speak their minds at meetings of the legislative body.²¹ Given the spread of e-mail, teleconferencing, and other forms of communication which bridge geographic space effectively, it could be possible (at least in theory) to construct a virtual town meeting at which information was directly shared with people, and to excise the media’s role entirely.

Yet—as Page points out—the real problem isn’t space but time: even assuming Americans can all become electronically connected with one another, we can’t all share information with one another simultaneously. “If each citizen got equal time to speak to the whole public, she or he would have a very small share of time or a very long wait before it came.”²² Moreover, it’s unlikely that every person would be interested in discussing every aspect of the arcane subject matter with which governments are often occupied. It’s one thing to listen to a presidential debate in which the candidates discuss—at the highest level—general issues like health care, social security, and education. It’s another thing entirely to be responsible for the re-drafting of corporate statutes, or bankruptcy laws, or to work through the uncertain mathematics of a basic fiscal budget.

²⁰See *id.* at 2.

²¹See, *e.g.*, S. SARA MONOSON, *PLATO AND ATHENIAN DEMOCRACY* (1996).

²²Page, *supra* note 6, at 4. As he further explains, “If . . . a nation of 250 million citizens devoted twenty-four hours to fully equal collective discussion of some political issue, each citizen would get less than 0.0004—less than four ten-thousandths—of one second to talk. If each citizen insisted, instead, upon a rather modest two minutes of speaking time, the discussion would take five hundred million minutes: that is, 347,222 days, or 950 years.” *Id.* Moreover, even in smaller communities like ancient Athens and in New England town meetings, time was “generally too scarce for everyone to talk. Already some division of labor and representation occurs informally; the hope (enforced, to a degree, by social norms) is that only those with something important to say and some minimal skill at saying it will speak up. The need for division of labor is much magnified in a huge collectivity like a modern nation, and specialization is more institutionalized as a result.” *Id.* at 14, n. 13.

Thus political communication takes place—today, and for the foreseeable future—within a division of labor, in which average citizens obtain information from others who have the requisite political expertise, policymaking acumen, and communications skills.²³ In other words, people obtain political information through the media, supplemented periodically by their own personal experiences and private conversations with friends and family. They pay attention to the issues which are important to them, and probably ignore a great deal of additional information which they consider extraneous.

Not only does this state of affairs present a theoretical principal-agent problem (since the people gathering information are not the same people as those who are consuming it), but the problem is likely exacerbated by the economic structure of the media industry. Professional journalists in the 21st century are employees of a business, and although they may operate under more modest profit goals than the employees of a drug company or an auto manufacturer, the bottom line is relevant in considering how (and how expensively) they approach the job of information collecting. Companies—even media companies—must be concerned about making profits. While profit-making and information-gathering may go hand-in-hand for some media companies, it is not necessarily so, since professional journalists may be hired for reasons *aside from* their ability to clearly inform the average citizen.²⁴ Moreover, average people may not crave a great deal of political information; as discussed above, they may prefer to focus their energies on a selective amount of information. Or (as many within the media complain), people may prefer to consume sensationalized, opinionated, personality-driven quasi-news which serves more to entertain than to inform.²⁵ Any profit-minded company will at least be affected by these preferences, if not driven by them. And given the well-documented trend of concentration within the media industry, we may have more reason than ever today to worry about the

²³See *id.* at 3-6.

²⁴See *id.* at 6.

²⁵Within the ambit of “entertainment and not information,” I should mention the rise of commentators like Rush Limbaugh and, more generally, Rupert Murdoch’s FOX News organization whose presentation of political news barely bother to justify their reporting as bare, unbiased information, but rather admit that they selectively gather data in order to support certain political views. Some have argued the rise of the Internet has exacerbated the problem. See, e.g., Mark Jurkowitz, *Up in Flames*, THE BOSTON GLOBE MAGAZINE, March 25, 2001, at 5.

influence of corporate profits over the process of collecting political information.²⁶

Perhaps this complaint proves too much: it shows that journalists operate *too* democratically, that they are *too* responsive to people's wants and needs, and that the principal-agent problem one might expect in American journalism is, in fact, lacking. Moreover, detailed political information is surely gathered by many news organizations and is readily available "on CNN or PBS or C-Span or in specialized publications when people want it."²⁷ If people choose not to access such information, it is a choice they make by their own free will, and no one else should put himself in a position to paternalistically second-guess their judgments.

All this may be true. Part III of this paper will show that most people don't have access to a great deal of nuanced information about the legal/political issues that engulf the specialists who work at the FDA, but perhaps most people don't want such information. Perhaps the market for news is working perfectly. This paper does not purport to fully examine the consequences of the fact that people may not have access to particular kinds of specialized information. Yet I submit that a dearth of information about complex legal/political issues can be problematic in at least two ways: (1) It doesn't mean that the news market is working perfectly, or prove the absence of the principal-agent problem, and (2) It has serious consequences for a government which proposes to remain democratically responsive.

First, the fact that journalists select certain stories rather than others, and that those choices are affected by market forces, simply means that journalists cater to the majority of their most vocal, wealthy, or otherwise powerful readers.²⁸ It doesn't mean that everyone is getting what they want. Markets don't automatically provide people with everything their hearts desire; they provide certain people with certain goods based on their ability to pay for them. Others (the less wealthy, the disenfranchised) are easy to leave behind—and there's no guarantee that CNN, PBS, or anyone else will pick up the slack. Moreover, even if most people are

²⁶See, e.g., BEN H. BAGDIKIAN, *THE MEDIA MONOPOLY* 18-26 (4th ed. 1992). Bagdikian calculated that at the beginning of the 1990s, 23 corporations dominated every type of major media, doing half or more of business in the field.

²⁷Page, *supra* note 6, at 6.

²⁸See, e.g., TIMOTHY E. COOK, *GOVERNING WITH THE NEWS: THE NEWS MEDIA AS A POLITICAL INSTITUTION*, 87-91 (1998).

satisfied with having journalists obtain their news for them, they still face a principal-agent problem. Clients are happy to hire attorneys to advise them on specialized matters, but that doesn't remove the principal-agent problem. People may depend on the judgment of medical doctors for advice about their health, but that doesn't remove the principal-agent problem. The existence of a functioning market for news, similarly, doesn't prove the absence of the principal-agent problem.

Second, we may have particular reasons to be concerned about our reliance on specialists—like journalists—in a representative democracy. If legal/political actors expect to be directed by people's preferences, then it is problematic that they may often be working on certain issues about which people don't have enough information to have any particular preferences. Certainly American politics is full of people who lead, rather than follow, public opinion; and certainly there are times citizens would rather delegate their democratic power than spend their time exercising it. But the smaller the number of people armed with basic facts—about the world, about their legal/political system, and about that system's efficacy—the less responsive our government is required to be. For a government (and a regulatory agency like the FDA) which relies on its democratic pedigree for legitimacy, the dearth of information-exchange can be a problem.

Specialists on Both Sides

If we are concerned about the problems created by citizens' reliance on the media to obtain political information, then we might be even more concerned about our reliance on specialists within government itself. In fact, the division of labor on which citizens depend in their pursuit of political information may be small compared to the division of labor within modern government—which has particularly accelerated in recent

years.

Before World War II, the total number of appointed civilian officials employed by the federal government grew at a relatively modest pace: from 3,000 at the end of the 18th century, to 95,000 by 1881, to nearly 500,000 by 1925.²⁹ By 1999, the latest year for which census data is currently available, the federal government employed approximately 2.8 million civilians.³⁰ Meanwhile, the responsibilities of the federal government have proliferated beyond anyone's prediction—in areas such as health, civil rights, education, housing, consumer protection, the environment, energy, defense, transportation, and agriculture.³¹

The history of the FDA is instructive in this regard; the agency's function has evolved significantly over the years. Food regulation remained largely in the hands of the states during America's early history, and while Lemuel Shattuck's 1850 report on the nation's public health and sanitation accelerated the enactment of local laws, the laws remained quite local in character and naturally narrow in scope.³² Not until the beginning of the 19th century did the federal government expand its role in regulating the food and drug supply, after Dr. Harvey W. Wiley formed a "poison squad" consisting of the 12 youngest members of the Department of Agriculture, and fed them foods containing the five leading preservatives in order to test their safety.³³ Dr. Wiley's reports, perhaps combined with the publication of Upton Sinclair's *The Jungle* in 1906, highlighted the need for Congressional action. Congress responded that same year with the Food and Drugs Act.

The Food and Drugs Act required a large group of specialists—scientists, bureaucrats, and lawyers—to administer the new regulatory agency. The 1906 law was strong for its time, and by 1927 the law even

²⁹See James Q. Wilson, *The Rise of the Bureaucratic State*, 10 THE PUB. INTEREST 77 (1975).

³⁰See U.S. Census Bureau, *Federal Government Civilian Employment*, <<http://www.census.gov/govs/apes/99fedfun.txt>>

³¹See Gary R. Orren, *Foreword* to MARTIN LINSKY, *IMPACT: HOW THE PRESS AFFECTS FEDERAL POLICYMAKING* at 1, 2 (1986).

³²This review of the history of the FDA relies on Peter Barton Hutt, *Government Regulation of the Integrity of the Food Supply*, 4 ANNUAL REVIEW OF NUTRITION 1 (1984).

³³Peter Barton Hutt, Lecture for Harvard Law School Class on *Food and Drug Law* (January 3, 2000).

gave birth to a new bureaucracy: the Food, Drug, and Insecticide Administration (renamed the Food and Drug Administration in 1931). Yet the early legislation was also full of loopholes.³⁴ False medicinal claims were rarely prosecuted because the burden of proof fell on the government to show that the manufacturer intended to defraud people, and because “judges could find no specific authority in the law for the standards of purity and content that the FDA had established.”³⁵

The impetus to close such loopholes came after the sale and marketing of the supposedly therapeutic product “Elixir Sulphanilamide” killed 107 people in 1937. In June, 1938, Congress passed the Federal Food, Drug, and Cosmetic Act (FFDC)³⁶ to replace the original legislation and provide new authority for the FDA. The new legislation expanded the FDA’s workload significantly.

Since the enactment of the FFDC, the statute has been amended more than 100 times, but has never been entirely recodified.³⁷ Consonant with trends in the U.S. federal government, the FDA’s authority and size have grown significantly, but the agency’s recent growth has been particularly significant. The agency’s budget in 1962 was \$23.0 million. Just 10 years later the FDA’s budget had almost quintupled to \$112.4 million, and by 1998 Congressional appropriations passed the \$1 billion mark.³⁸ As this paper will later discuss, recent pressures to speed up the process of drug approval have demanded further increases in the agency’s size and staffing.

Such expansion naturally calls for the rise of specialists to operate particular programs with expertise and skill. As a result, today it is almost impossible to understand either the politics, the science, or the legal technicalities of an agency like the FDA without talking to someone who can translate the terminology used on the “inside” into general terms. In turn, this specialization in government requires a certain amount

³⁴See HERBERT BURKHOLZ, THE FDA FOLLIES 8-9 (1994).

³⁵*Id.* at 9.

³⁶52 Stat. 1040 (1938).

³⁷See Covington & Burling, Food and Drug Administration Modernization Act of 1997 5 (Dec. 12, 1997) (unpublished document on file with author).

³⁸See Budget of the United States, various years.

of specialization within the press.³⁹ Beat reporters focus on particular topics of interest, or on particular agencies, and serve as full-time watchdogs. Specialty newspapers and periodicals proliferate. Meanwhile, the advent of “narrowcasting” over the Internet (so-called because the medium allows news to be disseminated in pieces to particular subscribers rather than “broadcast” to all people regardless of their interests) indicates that even today’s news consumers may be morphing into specialists.

The Shape of Principal-Agent Bias: Crisis Is King

The import of all this specialization is not exactly clear, but critics have highlighted the trend of specialization as a way of pointing out that they don’t believe the media is surmounting the basic principal-agent problem created by relying on others to provide us with legal/political information. On the contrary: the media have natural incentives to overlay their own biases on top of the information they report, and do so.

Paul Weaver describes the problem in terms of barter.⁴⁰ The specialist press exists to cover only certain kinds of topics, and specialist government workers spend their time working on only certain kinds of issues. Yet each group is preoccupied with reaching out to an audience which is as broad as possible. The legal/political actor’s motivations are mainly political (to appeal to a wide voting constituency), and the journalist’s may be economic (to appeal to a wide consumer base), but regardless, the two share an interest in serving a target group which is as large as possible. Because of this shared interest, there exists an opportunity for what economists might call “value creation.” Essentially, journalists and governmental officials

³⁹ See, e.g., Orren *supra* note 16, at 1-4.

⁴⁰ See PAUL H. WEAVER, NEWS AND THE CULTURE OF LYING 1-31 (1994).

...engage in barter: Information, access, and events are given in exchange for news coverage, and vice versa. The trade leaves everyone involved seemingly better off. Officials get publicity, journalists get the raw materials of news, and the public learns what officials and institutions are up to.⁴¹

The problem with this exchange, as Weaver explains, is that the news becomes much more than simply a “report of what happened yesterday.”⁴² If what’s actually going on in the world is the slow process of bureaucratic institutional activity, that’s not news. It’s not fodder for editorial pages, and it’s not material for a feature article. Why? Because both journalists and governmental officials are trying to reach out to broad constituencies, and to do so, they need to simplify the story. The central figures involved in a particular situation must be made into characters; people’s actions must be given a narrative; mundane terminology must be translated into the language of movement; the need for response must be made urgent. “Officials in search of publicity and journalists in search of news don’t converge on just any sort of news event...they translate themselves and their projects into the language—and theater—of crisis.”⁴³

This isn’t to say, of course, that crises within government don’t truly exist. But when each politician’s character flaws become scandals, when even the threat of a short recession seems like a shout of “national emergency,” when our news agencies only respond to clarion calls of distress—that distracts people from understanding the day-to-day work that governments actually perform. It places an artificial lens over our own views of government and prevents us from engaging in the kind of deliberate, stately, time-consuming discourse that many (if not most) political problems demand. Normal democratic government is messy and oftentimes loud, but it also takes place within an atmosphere in which people and institutions play particular roles. The central assumption girding the system is that legal/political actors are servants of the “public interest,” and that even though it’s difficult to understand what the “public interest” may be, government officials should make every effort to recognize it and be responsive to it.

In a crisis atmosphere, “representation and deliberation are put on hold since there isn’t time to hear

⁴²*Id.*

⁴³*Id.* at 2.

everyone out and anyway the objective isn't to formulate general rules generally applicable, it's just to get past the present disaster in one piece."⁴⁴ The legal/political system transforms into one of executive decree. Regulators like those at the FDA need not worry about the precedents they set; they just need to make sure that they solve whatever dire problem has recently threatened the public health—and do it quick, before we risk any more lives. Meanwhile, the bulk of mundane and less crisis-laden tasks with which the agency is concerned fly safely under the radar screen, free from public scrutiny.

This is the central problem with relying on specialist journalists (who, in turn, rely on specialist legal/political workers) for the news: journalists engage in trade with public officials and converge on crises, not real events.

As Weaver describes the situation:

The news stops representing the real world and begins to falsify it. The barter transaction between newsmaker and journalist degenerates into an exercise in deceit, manipulation, and exploitation... The public discourse degenerates into a farrago of invented crises, illusory programs, government interventions that make matters worse, benefits to the undeserving, punishment of the innocent, sneaky heroes, villains whose only offense is to be on the losing side, and lies of every size and description.⁴⁵

Some have suggested that this preoccupation with crisis is simply a situation created by over-zealous journalists, by “junk-yard-dog journalism.”⁴⁶ But it's likely that the problem has nothing to do with the biases or personality of any particular journalist; rather, this is a structural problem stemming from the fact that (a) people rely on journalists for information, (b) government has become quite specialized, and (c) there's little money to be made by producing information about government because such information is a public good. Once information has been produced, it's difficult to selectively prevent people from obtaining it (and therefore to require them to pay for it); this is particularly true of information which is relevant to large, dispersed groups of people.⁴⁷ Therefore, the media *don't* work very hard at producing raw information;

⁴⁴*Id.* at 3.

⁴⁶Page, *supra* note 6, at 7.

⁴⁷This idea is particularly well-explained by Page, *id.*, at 9.

rather, they engage in “barter” with government officials—relying largely on official sources for the stories they write—and average people receive different kinds of information than they would if they never relied on journalists to collect it in the first place. This happens because it is unprofitable for news agencies to deliver the so-called “straight news” story; rather, it is more profitable for media companies to focus on the kind of information which is relevant to a government operating in constant crisis mode. These are the stories which attract large audiences (read: advertising revenues for newspapers; votes for public officials), and these are the stories that end up in the popular consciousness.

Not everyone agrees, of course, that the existence of the news media as “middleman” between average people and their government creates this sort of bias. Some might re-cast the story I’ve told above as a paranoid vision about a conspiracy between public officials and the media to keep the “truth” (whatever that might be) from the American people.

I don’t believe such a conspiracy exists, or even that it could possibly exist given the diversity of media outlets and the diversity of issues that concern the journalists who work for them. But I do believe that it is true, as Timothy Cook argues, “that governmental processes provide the stages, the actors, and the lines for the accounts that journalists create.”⁴⁸ Certainly the media takes these elements and mixes them together with its own opinions and thoughts. This mixture results in accounts—news accounts, editorial opinions, or feature pieces—which the legal/political actors themselves often dislike and openly argue against. So the modern American media can hardly be said to be in anyone’s pocket, exactly.

Nevertheless, these two groups—the media and the public officials they cover—have worked out an odd “bargain of sorts...in the words of a plaque [which sat] on the desk of President Reagan’s White House

⁴⁸TIMOTHY E. COOK, *GOVERNING WITH THE NEWS: THE NEWS MEDIA AS A POLITICAL INSTITUTION* 15 (1998).

spokesman Larry Speakes, ‘You don’t tell us how to stage the news and we don’t tell you how to cover it.’⁴⁹ Moreover, given the fact that people don’t have the time or inclination to gather most of their political information by themselves, and given the fact that the work governments do today is more specialized and complicated than ever before, we do have reason to worry about the quality of information with which our citizenry is provided. In particular, if the media are pre-occupied with covering emergencies and crises, then not only the amount of information but the quality of information people receive about government on a daily basis may be too low for people to make informed judgments about what their governments *should* be doing for them.

Thus we arrive at a hypothesis, which will be tested in Parts II and III of this paper: the media tend to focus on crisis-driven events, and absent a crisis, people receive very little information about government from the media. To focus this inquiry, Part II will discuss the popular image of one regulatory agency—the FDA. Part III will undertake a more in-depth analysis of how the media covered a particular legal/political issue within the FDA.

⁴⁹ *Id.*

Cynicism about government has become the new conventional wisdom.

Joseph S. Nye⁵⁰

Part II: Public Perception of the FDA

THE PUBLIC'S PERCEPTION OF THE FDA is complicated by the fact that the FDA's ideal democratic relationship with "the public" is unclear. As a health-related regulatory agency, the FDA is just one of many regulatory bodies in Washington, D.C., some more independent from public opinion than others.⁵¹ The executive agencies have been traditionally insulated from popular opinion, given the fact that most of their employees are unelected⁵² and their work is quite specific. On the other hand, as Peter Hutt and Richard Merrill have argued:

even by Washington standards [the] FDA has been an intensely watched agency...The number of studies of FDA's performance is certainly evidence of the high degree of public interest in its work, but it also betrays the persistence of a belief among some in Washington that the agency is not doing its job well enough or fast enough, a skepticism that contributes to the self-doubt that has periodically beset agency employees.⁵³

In theory, independence from the political process is quite desirable for the regulatory agencies, and "may even be a requisite for successful accomplishment of regulatory goals."⁵⁴ Without political pressures to worry about, the regulatory agencies may focus on their task in a purely professional manner, and avoid charges that the results of their scientific and/or legal opinions are "subject to substantial political influence."⁵⁵ Of

⁵¹See Edward J. Burger, Jr., *Introduction* to EDWARD J. BURGER, JR., PROTECTING THE NATION'S HEALTH: THE PROBLEMS OF REGULATION 1, 1-7 (1976).

⁵²The Commissioner of the FDA and the Deputy Commissioner are appointed by the President and confirmed by the Senate, but changes in the executive have not usually resulted in large-scale personnel changes at the FDA. See PETER BARTON HUTT & RICHARD A. MERRILL, FOOD AND DRUG LAW 16 (2d ed. 1991).

⁵⁴Burger, *supra* note 2, at 1.

⁵⁵Hutt & Merrill, *supra* note 3.

course, there are many critics who remain skeptical of this theory, and who have repeatedly charged that in the absence of democratic influence the agencies “have been ‘captured’ by the very industries or segments of national life they are supposed to regulate.”⁵⁶

The relevant question for the FDA and other health-related organizations in Washington is who they should and actually do represent. The agency employs over 9,000 personnel, and Congress appropriated approximately \$1.3 billion to the FDA for fiscal year 2001.⁵⁷ On the surface, it seems obvious that the FDA’s personnel and their activities represent money and time well-spent: they help protect and preserve the public health, at a cost to taxpayers of about \$3 per person.⁵⁸ But the FDA engages in a series of balancing acts on any number of issues, which make its decisions disparately important to particular groups of people. How safe should we require our food and drug supply to be? For whom should we measure safety: the elderly, the most vulnerable, the average? How heavily should we rely on the labels of drug products which can be dangerous if used for “off-label” purposes? Or, as Part III of this paper examines, how do we trade off the speed of new drug approval against drug safety? These and many other questions make it important for many people to determine whom the FDA represents and from whom it seeks advice.

Without listing the litany of complaints which critics have lodged against the FDA, it is sufficient to stipulate that the FDA’s role in protecting the “public interest” is somewhat controversial. For the purposes of providing background to the press coverage examined in Part III of this paper, we will examine here the three most frequent charges aimed against the FDA: (1) the FDA is a arrogant bureaucracy which is unresponsive to the public interest, (2) the FDA makes decisions on the basis of fundamentally flawed scientific data, and (3) the FDA’s drug approval process does little to improve our safety but does significantly increase the cost of drugs.

⁵⁶Burger, *supra* note 2, at 2.

⁵⁷See U.S. Food and Drug Administration, *Frequently Asked Questions*, <<http://www.fda.gov/opacom/faq/faq.html>>; see U.S. Food and Drug Administration, *FY 2001 Final Appropriations Action*, <<http://www.fda.gov/oc/oms/ofm/budget/2001/CONF01.htm>>.

⁵⁸See U.S. Food and Drug Administration, *Frequently Asked Questions*, <<http://www.fda.gov/opacom/faq/faq.html>>.

The FDA as Arrogant Bureaucracy

In the camp of those who accuse the FDA of being little more than an arrogant bureaucracy, we find Edward Burger, who argues that the FDA makes systematic mistakes in both over-estimating and under-estimating the amount of protection the public requires.⁵⁹ Because the FDA is composed of mostly unelected officials who have little incentive to act for the *entire* public interest, the agency doesn't pursue balanced, well-reasoned, totally representative answers to the questions posed to it.

Rather, the FDA pursues policy in the absence of much of the information it would need if the agency were to be responsive to a broad-based constituency. Only selective political pressures affect the FDA, because only narrow interest groups can gather the necessary political will to communicate with an “overwhelmingly complex administrative bureaucracy of regulation.”⁶⁰ As a result, the FDA has little enthusiasm for taking the time to understand the broad view of issues. “Simply fulfilling the regulatory law is thought to be sufficient to accommodate or serve the public's interest.”⁶¹

This view of the FDA is echoed by some reporters who have covered the FDA, like Herbert Burkholz, who writes:

Aside from the routine handouts, getting information from an FDA press officer was an exercise in futility. Calls were rarely returned, off-the-record comments were discouraged, and known critics of the agency were treated as pariahs. Most of this was prompted by nothing darker than a deep sense of loyalty and a conviction that the agency was being poorly used, but the attitude came across as an arrogant, damn-your-eyes indifference to public opinion. Working under those conditions, it is not surprising that the FDA was presented to the public by the printed and the electronic media as the ultimate bureaucracy. And not without reason if a bureaucracy is to be defined as a system of administration marked by officialism, red tape, and self-serving job protection.⁶²

⁵⁹ See Burger, *supra* note 2, at 4-5.

⁶⁰ *Id.* at 118.

⁶¹ *Id.*

The “arrogant” bureaucracy described by Burkholz lies but one step away from the “bumbling bureaucracy” that many associate with official Washington D.C., and which many impute to the FDA. It has been to the advantage of some within official Washington⁶³ to perpetuate an image of the FDA as an incompetent agency which can’t work properly without constant oversight. Between September 1971 and July 1977, FDA officials were called to testify before congressional committees 198 times,⁶⁴ and this was during an era in which Burkholz notes the “agency enjoyed a worldwide respect as the finest regulatory body of its kind.”⁶⁵ At the very least, one should conclude from such figures that the FDA is controversial, and that many people feel the agency’s activities should be more closely monitored.

It is important to recognize both that this view of the FDA is not entirely unnatural, and also that this view is not shared by everyone. Consumer groups often distrust the decisions that government agencies make for us; they particularly attack agencies when they are frustrated over the fact that they don’t know what information goes into decisions, or they don’t know how decisions have been made.⁶⁶ It is impossible for most agencies to obtain credibility in the eyes of such groups and yet to maintain enough professional distance to engage in an orderly administration of the law. It is part of the nature of working in an agency to face criticism that you are not doing your job with enough attention toward the public interest, or that there is some important variable you’ve forgotten. At the same time, in opinion polls the FDA “seems generally perceived as not only performing an important function but as doing it well.”⁶⁷ If Americans’ confidence in their government has been generally decreasing over time,⁶⁸ and if people hold a particularly low opinion

⁶³Certain congressmen in particular have built careers attacking the FDA, notably Rep. John Dingell (D-Mich.). *See, e.g., id.* at 13-14.

⁶⁴*See* Hutt & Merrill, *supra* note 3, at 19.

⁶⁵Burkholz, *supra* note 13, at 13.

⁶⁶*See* Burger, *supra* note 2, at 7.

⁶⁷Louis Lasagna, *Congress, the FDA, and New Drug Development: Before and After 1962*, 32 PERSP. IN BIOLOGY AND MED. 322 (1989).

⁶⁸*See, e.g.,* PATRICIA MOY & MICHAEL PFAU, WITH MALICE TOWARD ALL?: THE MEDIA AND PUBLIC CONFIDENCE IN DEMOCRATIC INSTITUTIONS 9-29 (2000). Moy and Pfau posit two explanations for the spiraling confidence Americans have in government generally: (1) that there have been substantive failings of American institutions, and (2) that the negative tone of the mass media is to blame. They agree that both explanations contain some kernel of truth.

of the executive branch,⁶⁹ the FDA has often enjoyed a good reputation and high approval ratings.⁷⁰ Thus we should not over-emphasize the extent to which public opinion stands generally against the FDA as a bureaucracy.

Flawed Scientific Data

Certain analysts, however, have come forward with more specific criticisms, notably that the agency makes its decisions on the basis of fundamentally flawed scientific data. This criticism is related to the general critique of the FDA as an indifferent bureaucratic agency, because one might assume that if the FDA were a representative body, its science would be appropriately geared to the task of saving as many lives as possible, or improving the public health as much as possible.⁷¹ However, this accusation is more specific. Critics who lead this charge argue that the approval process for new drugs fails to take account of a number of relevant variables. Most pre-approval drug testing takes place within a limited population—often focusing on white, middle-aged men⁷²—and all clinical trials are paid for by drug manufacturers themselves, not by the FDA. Women and ethnic/minority groups don't often participate in clinical trials, and the fact that the trials themselves are paid for by drug manufacturers may indicate an inherent bias. Critics argue that the FDA's decisions on new drug approval are therefore often based on insufficient evidence, and we should not be surprised when the FDA's conclusions turn out to be wrong.⁷³

⁶⁹See *id.* at 13-14.

⁷⁰See, e.g., Robert Higgs, *Introduction*, in *HAZARDOUS TO OUR HEALTH? FDA REGULATION OF HEALTH CARE PRODUCTS* 1 (Robert Higgs, ed., 1995).

⁷¹See, e.g., *Burger*, *supra* note 2, at 4.

⁷²*Id.*

⁷³See Ronald W. Hansen, *FDA Regulation of the Pharmaceutical Industry*, in *HAZARDOUS TO OUR HEALTH? FDA REGULATION OF HEALTH CARE PRODUCTS* 13, 21 (Robert Higgs, ed., 1995).

Of course, even if the FDA's regulations were originally designed to protect 100% of the population,⁷⁴ today's harshest critics of the FDA would probably agree that such standards are impossible to apply, given the variability in human behavior and in human genetics. Some of the FDA's errors in judgment are due to the occurrence of rare adverse effects which will not be evident in limited clinical trials, and few people would advocate extending the pre-approval period to account for such rarities.⁷⁵

Still, the criticism persists that the FDA is under-concerned about the public health, and that the agency doesn't engage in the kind of unbiased, thorough, independent scientific review that would be needed to provide an objective measure of drug safety.

Increasing Drug Costs

Compounding this accusation is the argument that the FDA not only does little to protect the public health, but also that its procedures have served simply to inflate the cost of drugs for average Americans, who are paying more for their health care today than ever before. In this view, the FDA is doing more harm than good, and the agency has perhaps been "captured" by the very interests it is supposed to be monitoring. While it is far beyond the scope of this paper to either prove or disprove the truth of this argument, for our purposes it is important to understand the argument's basic structure.

Drug companies have traditionally tried to excuse high prices for drugs by focusing on the high cost of research. Many drugs on which corporations spend millions end up being ineffective and never make it to market. For those drugs which do make it, the process from research to marketing approval can cost an

⁷⁴See Peter Barton Hutt, Lecture for Harvard Law School Class on *Food and Drug Law* (January 10, 2000).

⁷⁵See Hansen, *supra* note 24.

average of \$500 million,⁷⁶ and at such costs, any delay a drug manufacturer may experience in recouping R&D costs can seem huge. The FDA drug approval process in particular, by increasing the time-to-market for new drugs, increases the costs of developing them.

On the other hand, the revenues at stake for drug companies can be so astronomical that numbers like \$500 million pale in comparison. For example: Schering's #1 allergy drug, Claritin, garnered total U.S. sales of \$3.0 billion in 2000. That's \$250 million each month, or \$8.2 million per day.⁷⁷ Claritin isn't even one of the most profitable recent drug launches; Pfizer made \$4 billion from U.S. sales of Lipitor in 1999, instantly capturing 41% of the market share for cholesterol-lowering drugs.⁷⁸ It is also notable that by the end of the 1980s, the drug industry "was spending more on the promotion and marketing of its products than it was on research,"⁷⁹ indicating the robust confidence they had in their profitability. Recently, the drug manufacturers have enjoyed the highest profitability of any industry in the U.S.⁸⁰

Additionally, the U.S. government recognizes that because it takes so much time and energy for a company to produce even one drug which has the potential to be profitable, drug manufacturers require huge incentives to invest in the industry. The need for additional incentives for scientific research generally⁸¹ come in the form of patent protection, which currently extends 20 years from the date of application for the patent, or 17 years from the issuance of the patent, whichever is longer.⁸² For the duration of the patent, no other company is permitted to produce the same or substantially similar substance—and the company which holds the patent can charge monopoly rents to people who wish to purchase the drug. One might argue that high

⁷⁶ See, e.g., Tom Abate, *Drugmakers Yield to Pressure; Multinational Firms Offer Tiered Pricing for Life-saving Medications* S.F. CHRONICLE, March 25, 2001, at A15.

⁷⁷ See Schering-Plough, *Schering-Plough Reports Sales, Earnings for 2000 Fourth Quarter and Full Year*, <<http://www.sgp.com/news/financial/earnings/01-25-01.html>>.

⁷⁸ See Pfizer, Inc. *About Pfizer: Pfizer Pharmaceuticals Group*, <<http://www.pfizer.com/pfizerinc/about/focus/pharmaceuticals.htm>>.

⁷⁹ Burkholz, *supra* note 13, at 19-20.

⁸⁰ See, e.g., *The Fortune 500: How the Industries Stack up*, 141 FORTUNE MAGAZINE, April 17, 2000.

⁸¹ Patent protection extends to "any new and useful process, machine, manufacture, or composition of matter." 35 U.S.C. § 101 (2001).

⁸² 35 U.S.C. § 154 (2001).

drug prices result from our patent policy, and not from the FDA's drug approval process.

Still, the high cost of drugs is an important issue for the FDA. Even if the FDA does not directly regulate drug prices, and even if the FDA says that rising drug prices are irrelevant to its judgments, the agency faces a difficult legal/political challenge justifying any added expense its drug approval process tacks onto drug development because Americans are concerned about the high cost of prescription drugs. One unintended consequence of a longer drug approval period is the reduction of the effective patent life,⁸³ and even if we assume that patent protection is the main source of high drug prices, the FDA might be exacerbating the problem. After all, the shorter the effective patent life, the more quickly drug manufacturers must make up the money they spend in R&D, and therefore the higher the prices. The FDA's policy of patent term restoration ameliorates, but does not eliminate, the problem.⁸⁴

High drug prices have become particularly problematic in the face of the AIDS epidemic, which has disproportionately affected a third world population that has difficulty paying for new medications—medications which are usually developed and patented in the United States before going abroad.⁸⁵ Human rights group flatly accuse drug companies of gorging on profits and the FDA of dragging its feet while “some of the poorest people on Earth live in torment and die long before their time.”⁸⁶ The most potent criticism of the

⁸³See Hansen, *supra* note 24, at 19.

⁸⁴Congress in 1984 enacted Title II of the Drug Price Competition and Patent Term Restoration Act, P.L. 98-417, to compensate drug companies for the period during which their drugs were under FDA review. Under the Act, patent holders can recoup some of this lost time. Yet patent restoration has its limits; a maximum of five years can be restored to the patent, and in no case shall the patent duration extend for more than 14 years of useful marketing time. The patent term for many drugs, therefore, will be shorter than the 20-year duration of patented items generally. See 21 C.F.R. 60.

⁸⁵See, e.g., Lynda Hurst, *Life and Death of AIDS Victims on the Docket*, TORONTO STAR, March 25, 2001, at NE1. According to Hurst's estimate, the average cost of AIDS drugs today is \$6,000 per person per year. In comparison, South Africa—one of the more prosperous African countries with a significant AIDS-infected population—has an annual health care budget of \$50 per person.

⁸⁶*Id.*

FDA's drug approval policy is perhaps best summed up by Higgs, who writes:

People in general are made worse off; the only ones who systematically benefit [from drug approval] are those who wield the powers... 'The result is impressive: expensive drugs, lack of innovation, and no improvement in drug safety.' Thanks to the FDA, hundreds of thousands of Americans have died prematurely and far more have suffered unnecessarily. Multitudes have been denied opportunities to assume a risk they considered worth bearing, given the expected benefits. With a paternalistic 'father' like the FDA, orphanhood would be a blessing.⁸⁷

By mentioning these criticisms of the FDA, I do not mean to justify them, or to otherwise argue their validity. There are, of course, counter-arguments that proponents of FDA policy would offer, which may be much more valid than the criticisms offered here.

The reason for exploring these criticisms is to provide a sense of the arguments critics *might* have presented during the recalls of Redux, Pondimin, Posicor, and Duract in 1997-98. The fact that these recalls occurred so immediately after one another, combined with the fact that they occurred so close to the timing of the Modernization Act, should have formed a natural connection in the minds of those who usually speak up when something at the FDA goes wrong. We might have expected to hear that: (1) the recalls provided further evidence of the FDA's lack of attention to the "public interest," because any agency truly concerned about the public interest wouldn't have let these drugs come on the market in the first place, or (2) the recalls show one example of the scientific problems with the FDA's pre-approval testing process, or (3) the recalls show how deeply the FDA has been co-opted by the drug companies, because even given FDA concerns about safety, the agency was willing to approve these drugs and permit the manufacturers to profit so long as there weren't *too many* visible deaths or injuries. Thus this portion of the paper provides us with a second hypothesis, explaining the kind of criticism one would expect to hear about the FDA upon learning that

four drugs have been recalled from the market within 12 months.

The recall of these four drugs each formed a distinct news event, and it is certainly possible that the media would have simply reported the event, without editorial judgment. The journalist's commitment to high standards of impartiality and objectivity⁸⁸ might prevent certain members of the media from linking each drug's withdrawal to anything beyond the simple facts of the particular recall at issue. But the "twin concerns that news should be important and it should be interesting"⁸⁹ should also have led even an average journalist to investigate whether four drug recalls—again, clustered so closely together, and so near in time to the passage of the Modernization Act—caused any concern among those who spend their time watching very closely over and often criticizing the FDA. To the agency's critics, these recalls would have been a big story.

⁸⁸*See, e.g.*, TIMOTHY E. COOK, GOVERNING WITH THE NEWS: THE NEWS MEDIA AS A POLITICAL INSTITUTION, 5 (1998).

⁸⁹*Id.*

News is necessarily selective... but journalists can and do credibly respond that they have come up with the most important occurrences and persons to include in the news.

Timothy Cook⁹⁰

Part III: Media Coverage of Drug Recalls

AFTER THE 1996 ELECTIONS, members of the U.S. Congress turned their attention to an issue that had remained on the legislative radar screen for quite some time: reform of the Food and Drug Administration. For years, the FDA's critics had argued that the agency's drug approval process worked too slowly; in 1992 the average time required for a drug review was two and a half years.⁹¹ To speed up the process both piecemeal and wholesale, FDA had regularly expedited the new drug applications for "important new medicines,"⁹² and in 1992 Congress had enacted the PDUFA.⁹³ Due to the additional funding brought in under the PDUFA, the FDA increased its drug and biological review staff by almost 60% (or over 600 reviewers) between 1993 and 1997, cutting drug review times in half.⁹⁴

But the PDUFA would expire at the end of September 1997, and the issue of FDA reform took on a new urgency for the 105th Congress.⁹⁵ By October 1997, FDA reform bills had passed both the House and Senate.⁹⁶ Following a reconciliation of the Senate and House versions of the bills, both houses approved the Modernization Act (which included a re-authorization of PDUFA), and President Clinton signed the legislation into law on November 21, 1997.⁹⁷

⁹¹Food and Drug Administration, *Background to the FDA Modernization Act of 1997*, <<http://www.fda.gov/opacom/backgrounders/modact.htm>>.

⁹²PETER BARTON HUTT & RICHARD A. MERRILL, *FOOD AND DRUG LAW* 529 (2d ed. 1991).

⁹³106 Stat. 4491 (1992), 21 U.S.C. 379(g), § 735 of the FD&C Act.

⁹⁴See Food and Drug Administration, *supra* note 2.

⁹⁵See Covington & Burling, *Food and Drug Administration Modernization Act of 1997* 6 (Dec. 12, 1997) (unpublished document on file with author).

⁹⁶See S. 830, 105th Cong., 1st Sess. (1997); H.R. 1411, 105th Cong., 1st Sess. (1997); H.R. 1710, 105th Cong., 1st Sess. (1997), and H.R. 2469, 105th Cong., 1st Sess. (1997).

⁹⁷See 111 Stat. 2296 (1997).

Signs of potential problems for the FDA, however, had already begun to surface. On September 15, before the House had even reported its Modernization Act bills out of committee, the FDA recalled two drugs which were being prescribed for the treatment of obesity: Redux and Pondimin. The FDA's experience with the two drugs had been vastly different, although the two are pharmaceutical cousins:⁹⁸ Pondimin had been safely marketed and consumed in the U.S. since 1973, while Redux was recalled less than 1-1/2 years after it had first been approved. Both drugs had been approved by the FDA as short-term diet aids.

Problems occurred when consumers began taking either Pondimin or Redux (known chemically as fenfluramine and dexfenfluramine, respectively) in combination with a second drug, phentermine. This drug concoction, known as "fen-phen," was never specifically approved by the FDA, but the so-called "fen-phen craze" had started as early as 1992,⁹⁹ and thus the combination was well-known by the FDA by the time the agency approved Redux. Moreover, FDA approval of Redux had been delayed due to concerns about fenfluramine's link with primary pulmonary hypertension (PPH), a fatal heart disease which had been associated with another weight-loss drug, Menocil, sold in Europe from 1967 to 1973. The FDA's advisory committee initially voted against the approval of Redux, but in late 1995 the committee reversed course and approved it by a vote of 6-5.¹⁰⁰

Then in early 1997, a study in the *New England Journal of Medicine* found that 32 percent of the surveyed people who had taken the "fen-phen" combination for an average of 12 months developed heart abnormalities.¹⁰¹ The study was considered so important that its details were released to the public before publication, "breaking a long-standing tradition of embargoing news about medical research until it is published."¹⁰² In response the FDA issued a letter to doctors, putting them on notice about the potential for damage and

⁹⁸Pondimin is known chemically as fenfluramine while Redux is known as dexfenfluramine.

⁹⁹See Paul D. Rheingold, *Fen-phen and Redux: A Tale of Three Drugs*, TRIAL-MAG. Jan. 1, 1998, available in 1998 WL 30769879.

¹⁰⁰See *id.*

¹⁰¹See Heidi M. Connolly et al., *Valvular Heart Disease Associated With Fenfluramine-Phentermine*, 337 NEW ENG. J. MED. 581 (Aug. 28, 1997).

¹⁰²Rheingold, *supra* note 10.

cautioning against the use of Redux or Pondimin for cosmetic weight loss. The agency did not, however, make any specific statement warning against the prescription of fenfluramine and phentermine in combination.¹⁰³ By September 15, it was clear that more significant action was required; the FDA announced its own findings about patients taking Redux or Pondimin, reporting that 30 percent of those who had been evaluated for heart valve function had abnormal readings.¹⁰⁴ The drug manufacturers agreed with the FDA to recall both drugs from the market.

The recalls of Pondimin and Redux were widely publicized, and a number of plaintiffs filed products liability lawsuits against the drugs' manufacturers.¹⁰⁵ Putting aside the question of who was at fault for the health risks resulting from the use of Pondimin and Redux, however, the recalls still had come as a surprise to many since drug recalls initiated by the FDA are so rare. According to the *Journal of the American Medical Association* article on which the FDA relied in a recent report on managing risks from medical product use, from 1980 until the recall of Pondimin and Redux, only 8 drugs had been recalled because they had proven to be unsafe.¹⁰⁶ Yet during the summer of 1997—while Congress was debating the Modernization Act—the FDA approved two more drugs which it would recall less than a year later.

The first drug approved (and the first recalled) was sold by Roche Laboratories under the name Posicor. The FDA approved Posicor, a calcium-channel blocker, for the treatment of high blood pressure and chronic stable angina on June 20, 1997. When the drug was first marketed, the FDA required that its label note the

¹⁰³See Food and Drug Administration, *Updates*, 31 FDA CONSUMER, Sept. – Oct., 1997, <http://www.fda.gov/fdac/departs/1997/697_upd.html>.

¹⁰⁴See Food and Drug Administration, *Updates*, 31 FDA CONSUMER, Nov. – Dec., 1997, <http://www.fda.gov/fdac/departs/1997/797_upd.html>.

¹⁰⁵See Rheingold, *supra* note 10.

¹⁰⁶See Michael A. Friedman et al., *The Safety of Newly Approved Medicines: Do Recent Market Removals Mean There is a Problem?*, 281 JAMA 1728, 1730 (May 12, 1999). See also Food and Drug Administration, *Managing the Risks from Medical Product Use: Creating a Risk Management Framework*, <<http://www.fda.gov/oc/tfrm/riskmanagement.pdf>>.

risk of interactions with the ulcer medication Propulsid and allergy medications Hismanal and Seldane.¹⁰⁷ In December, two more drugs (Zocor and Mevacor) were added to the label warning.¹⁰⁸ But in the ensuing months, both Roche and the FDA continued to learn of adverse reactions related to the co-administration of Posicor with other drugs.¹⁰⁹ By the time the FDA asked Roche to withdraw the drug from the market on June 9, 1998, the agency had over 400 reports of health problems in patients taking Posicor, including 24 deaths.¹¹⁰ The time period from FDA approval to FDA recall had totaled 354 days.

The FDA's final drug recall during this period hadn't even been on the market that long. The drug, Duract, was approved on July 13, 1997 for short-term treatment of acute pain. The FDA recommended that patients only take Duract for a period of 10 days or less because "clinical trials revealed a higher incidence of elevated liver enzymes [with higher usage]."¹¹¹ By February, 1998, Duract's manufacturer became concerned about reports that patients who had taken the drug for longer periods experienced severe hepatitis and liver failure, and added a black-box warning to the labeling.¹¹² On June 22—just 13 days after the recall of Posicor—the agency announced the recall of Duract, amid reports that four patients who took the drug had died and eight required liver transplants.¹¹³ Duract had been on the market for only 344 days.

These are short versions of the stories about the four drug recalls. Each story has its own particular arc, and each story can easily be told without a great deal of background about the FDA approval process, or even a single reference to the Modernization Act. There are many ways for a responsible journalist to gather facts,

¹⁰⁷ See Robert Langreth, *Recall of a Popular Roche Drug Raises Questions on Testing, Approval Process*, WALL ST. J. Jun. 10, 1998, at B16.

¹⁰⁸ See Food and Drug Administration, *Updates*, 31 FDA CONSUMER, Sept. – Oct., 1998, <http://www.fda.gov/fdac/departs/1998/598_upd.html>.

¹⁰⁹ *Id.*

¹¹⁰ See Langreth, *supra* note 18.

¹¹¹ Food and Drug Administration, *Updates*, 31 FDA CONSUMER, Sept. – Oct., 1998, <http://www.fda.gov/fdac/departs/1998/598_upd.html>.

¹¹² See *id.*

¹¹³ See, e.g., John Hendren, *Pain Reliever Recalled After 4 Die*, AP ONLINE, June 22, 1998, available at 1998 WL 6684924.

and many ways to tell a story.

I do not wish to argue that it was irresponsible or unprofessional for journalists to write about the FDA recalls of Redux, Pondimin, Posicor, and Duract in 1997-98 without mentioning the Modernization Act, or without mentioning recent reforms at the FDA. However, without belaboring the point any more than I already have in this paper, I would argue that when four prescription drugs are recalled—three of them without even having been on the market for a year and a half—it is reasonable for inquisitive journalists to ask whether average people should be concerned about the FDA’s drug approval process. Perhaps, as the FDA might argue, these four recalls simply constituted a “cluster” of events, a fluke of timing which was not statistically significant enough to indicate anything about the FDA. Yet it was reasonable for journalists to investigate whether or not these four recalls *were* simply a cluster. This is particularly true when any reporter covering the FDA during the relevant period would have recently learned about the FDA’s attempts to improve that approval process, while covering the enactment of the Modernization Act.

In order to determine how the media *did* cover the FDA recalls of Redux, Pondimin, Posicor, and Duract, I performed a media study concerning a sample of reports which were written in 1997-98. The study reveals that most accounts of these drug recalls failed to provide any context about the FDA approval process.

General Caveats

Before discussing the quantitative and qualitative results of this media study, it is important to describe the study’s limits. First, the study was limited in time frame. Only reports which appeared between November 21, 1997 (the day the Modernization Act was signed into law) and November 21, 1998 were included in the

scope of the study. Second, the study was limited in subject matter. Only reports which included the names of any of the four drugs (either brand-name or chemical), and which also mentioned the word “drug” and some form of the word “recall” were included in the scope of the study. This second boundary was placed on the study in order to eliminate articles which included relevant words (like “Redux”) but were irrelevant to the issue at hand (e.g., “George Bush, Redux”).

Both boundaries are, perhaps, controversial, because it is possible that the choice of time frame and/or search terms artificially and incorrectly limited the sample under study. On the other hand, one must admit that any study is, by its nature, limited. I believe the limits set for this media study were appropriate to the subject matter. The main question at issue in this paper is whether journalists made the basic connection between these four recalls and the Modernization Act—or, at least, between these four recalls and the issues at the heart of the Modernization Act, like the FDA’s drug approval policy. This paper cannot comprehensively answer that question, in part due to limited time and resources. But it can provide a good start, and in order to begin answering that question, this paper examines what a *portion* of the journalistic landscape looked like during the Modernization Act’s first year.

Quantitative Results

This study concerns 535 articles, broadcast transcriptions, or other accounts of the FDA recalls of Redux, Pondimin, Posicor, or Duract.¹¹⁴ That is, during the relevant period, searches of a major news database¹¹⁵ revealed 222 separate sources reporting on Redux, 198 reporting on Pondimin, 49 reporting on Posicor, and 66 reporting on Duract. Of course, there was a great deal of overlap among these sources; many reports showed

¹¹⁴See Appendix 1.

¹¹⁵Westlaw’s ALLNEWS database

up in more than one search, and many reports actually derived from the same source (e.g., the Associated Press).¹¹⁶ Thus of the 535 stories studied for this paper, only 290 reports were published as distinct stories in distinct publications, and only 161 reports were distinct from one another—that is, written by different authors, containing different language, and appearing in different publications on different dates.

It is difficult to put these numbers in perspective without comparison, but it is striking that over a 365-day period, only 161 distinct stories appeared in major news outlets mentioning the recall of these four drugs in any context—regardless of whether those stories appeared in a news brief or a feature, and regardless of whether those stories mentioned the FDA drug approval process at all. Yet it is important to keep in mind the caveats mentioned above. This study does not claim that—even in the relevant time period—no more than 161 stories were written to chronicle the recall of Redux, Pondimin, Posicor, or Duract. Searches of different databases would certainly yield additional articles, as would searches of the same database using slightly different terms. In fact, for the purposes of this media study it might be wise to avoid reaching conclusions about the quality of media coverage based on the number 161. Yet certain qualities of those 161 articles provide a relevant sample of the media’s coverage.

One measure of the media’s coverage depends on which sources are independently covering the industry. The most voluminous coverage of these recalls came from the *Wall Street Journal*, which originated 30 of the 161 distinct articles under study. The Associated Press was ultimately responsible for another 19 articles. No other single source even came close to that kind of in-depth coverage. This is not to say that other publications didn’t cover the recalls of Redux, Pondimin, Posicor, and Duract.¹¹⁷ But most publications weren’t *independently* covering the recalls; they relied on outside sources (such as the Associated Press, or

¹¹⁶Much of the overlap among articles comes from the fact that an article written by a single author was published within 1-2 days by multiple sources. For example, the *Wall Street Journal* would often provide the same text to the *Wall Street Journal* and the *Asian Wall Street Journal*, and the *Wall Street Journal* edition published in Europe.

¹¹⁷Other news sources which initiated significant coverage during the relevant period were the *Star-Ledger* of Newark, New Jersey (7 articles); the *Record of Northern New Jersey* (5 articles), and the *American Political Network* (5 articles).

Knight-Ridder News Service) for the content of their reports.¹¹⁸ This fact is, perhaps, unsurprising: given the low profit margins in the media industry, one might expect smaller media outlets to rely on a national news service for information about an agency as specialized as the FDA.

It might be more surprising to learn how “small” a story most news outlets judged these recalls to be, however:

¹¹⁸The fact that some of the nation’s most prestigious newspapers, like the *New York Times* and the *Washington Post*, didn’t show up more often in the course of this research points to one of the weaknesses of this media study: by design, the database search produced only those articles which contained particular search terms, like articles which contained a version of the word “recall.” The use of this search term artificially limited the set of articles under study. Given limited time and limited resources, however, it would have been impossible to read through every article written on the subject of study here. Thus, once more, I should reiterate that this study examines only a *sample* of the articles that were written on the relevant subject matter during the relevant time period.

In order to verify certain conclusions of this study, however, I performed targeted search within the archives of certain publications for the names of any of the four drugs (and the word “drug,” just to eliminate articles which used the word “redux” in a different context). These searches generally verified the conclusions of this study. For example, a search of the *Washington Post* yielded only 25 articles, 10 of which were written by either the Associated Press or Reuters. Only two articles contained any significant analysis of the FDA drug approval process. Of those two articles, one was an editorial, and it was written by an author who had just published a book on the FDA. He barely mentioned the drug recalls on 1997-98. Thus even the *Post*—the bible of the Washington “insider”—didn’t tie its coverage of the Redux, Pondimin, Posicor, and Duract recalls to the FDA’s approval process.

Table 1: Placement of Stories Within Publication

Placement	Number of Stories
Front Section, Front page	21
Front Section, inside page	69
Other sections, Front page	28
Other section, inside page	96
Unknown placement	76
Total	290 ¹¹⁹

Only 10% (21 of 214) of the stories for which the publication’s pagination information was known were published as front-page news. Only 23% (49 of 214) of those stories were published on the front page of *any* section. Most often, stories about the recalls of Redux, Pondimin, Posicor, or Duract were published on the inside pages of an inside section—where many fewer people would find them.

Another relevant statistic in determining the depth of coverage is the length of the average piece. Over the relevant period, the median article length was approximately 680 words. Table 2 contains an abbreviated summary of each story’s length:

Table 2: Length of Stories

Placement	Number of Stories
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¹¹⁹Note that the relevant total number of stories here is 290, which consists of the 161 distinct pieces written in the relevant time frame, but includes each duplicate publication of those 161 pieces. This larger set of articles thus takes into account the fact that a particular piece by the Associated Press may have run in 7 different publications, in 7 different places.

Under 100 words	4
100-250 words	6
250-500 words	37
500-750 words	47
750-1000 words	25
1000+ words	35

Unknown word count	7
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Total	161
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An article of 680 words is probably about average for a news story, but certainly doesn't provide the author with a great deal of room to enter into significant analysis. Additionally, given the fact that many of these stories were written as portions of a larger "news briefs" section of significant size, it is likely that the "average" article about any of these four recalls was much shorter than 680 words.

Perhaps more strikingly, only 30 articles—or 19% of the relevant sample size—contained any analysis, no matter how bare, of the FDA's drug approval policy. Thus regardless of the quality of their coverage, it is fair to say that most media outlets provided little context for the stories they wrote about the recalls of these four drugs.

In summary, a bare quantitative analysis reveals that most media outlets considered these four drug recalls to be a minor story. When the media covered the story they did so by publishing a relatively short story on inside pages, and only rarely did that article present any background information on the drug approval process.

Qualitative Results

The real tenor of media coverage comes alive when one analyzes these articles' content. Consider the text of a typical story about one of these drugs' recall, which ran on June 23, 1998 in the *San Diego Union-Tribune*:

The potent painkiller Duract was recalled by the manufacturer Monday after four people who had been taking it died and eight others required liver transplants.

All but one of the patients had been using Duract for longer than the government-recommended maximum of 10 days, Wyeth-Ayerst said. The person who used it for a shorter time already had significant liver disease.

'While we continue to believe that Duract is safe and effective when used for 10 days or less, rare but serious adverse events have been associated with Duract when used for longer periods,' Dr. Philip de Vane, head of clinical affairs for Wyeth-Ayerst's parent, American Home Products Corp., said in a statement.

The company concluded that keeping the product on the market with a stronger warning against using it for more than 10 days 'would not be feasible or effective,' de Vane said.

Doctors have written 2.5 million prescriptions for Duract since it hit the market in July 1997 as an alternative to narcotics for short-term pain relief after surgery and for other acute pain.

Duract isn't intended for arthritis or other chronic pain.

The Food and Drug Administration approved Duract for use up to 10 days, but doctors are free to prescribe it for longer periods. The agency warned that the drug can lead to potentially fatal liver damage in patients who use it for longer than 10 days. Wyeth-Ayerst sent letters to more than 600,000 doctors in the United States, urging them to stop prescribing the drug immediately and suggesting that they contact patients who may be using Duract for longer than 10 days or have a history of liver disease.

American Home has already been dazed by lawsuits from thousands of dieters who claim they were harmed by the anti-obesity drugs Redux and fenfluramine—half of the popular 'fen-phen' diet cocktail. The company recalled the two drugs last August.¹²⁰

Notice a few facts. First, the story is rather short. Second, it ran on page 6 of the front section. Thus, while the story was placed within the "news" section of the paper, it wasn't even considered significant enough to run on the right-hand side of the page.¹²¹ Third, the story was written by John Hendren of

¹²¹It is common knowledge among those who specialize in newspaper layout and design that although people read from left to right, they usually scan the upper-right hand side of a page before reading from left to right. Thus the "lead" story in a newspaper, often referred to as the "C6" story in a traditional 6-column newspaper, will always be placed on the upper-right hand side of the front page. On inside pages, the more important stories usually fall on odd-numbered pages in order to attract

the Associated Press (AP), whose coverage of the FDA is probably more widely-read than any other single reporter's because the AP's stories are published in so many news outlets. Fourth and most significantly, the FDA is barely mentioned.

This last attribute is representative of most articles about Redux, Pondimin, Posicor, and Duract in the relevant period. Where the FDA does make an appearance, analysis is extremely bare, as revealed by the additional paragraphs Hendren wrote in his original wire story (but which were not published in the *San Diego Union-Tribune*):

The FDA could not have given a clearer warning to doctors who continued to prescribe the drug for longer use, said Dr. Murray Lumpkin, deputy director for the agency's Center for Drug Evaluation and Research. 'Given the alternatives... it made no sense to accept death and liver transplants when there are alternatives available,' he said.

Critics say the drug should never have been approved.

'You have 19 or 20 other drugs in the same class, and one comes along with a unique ability to cause liver damage. Why should a drug like that be approved?' said Larry Sasich, a pharmacist who is a spokesman for the consumer group Public Citizen.¹²²

Even assuming these paragraphs of the AP story had remained intact everywhere the story was published, they provide no insight into how the FDA's drug approval process works. They ask a rhetorical question ("Why should a drug like that be approved?") without bothering to research the answer, and they cut off dialogue between critics and proponents of the agency before it has time to develop.

Notice also that the only reason this story connects the Duract recall to the recalls of any of the other three drugs is that Duract was manufactured by the same company, American Home Products (AHP), which was responsible for Redux and Pondimin. This hints at the reason for the *Wall Street Journal's* rather thorough coverage of the drug recalls: each of the AHP recalls had a significant and lasting effect on AHP's stock price. Every time AHP entered into merger discussions, or dropped merger discussions, or its president readers' attention as they're thumbing through the rest of the section (page 3, page 5, page 7, etc.).

made a statement, the *Wall Street Journal* ran a story about it. This isn't so surprising; after all, such activities are significant news in the world of business. But the reason we find 30 stories in the *Wall Street Journal* mentioning the "recall" of Redux, Pondimin, or Duract is that every one of those business stories includes a small paragraph about how AHP's "growth prospects were hurt by the recall of..."¹²³ These stories weren't primarily about the recalls, or about FDA policy, or really even about medicine; they were about Wall Street.

Even those articles which *did* provide some coverage of FDA policy on drug approval varied greatly in scope and tenor. They ranged from a 291-word news article in *USA TODAY*¹²⁴ to a feature-length piece about FDA approval in the *Wall Street Journal*.¹²⁵ A handful of publications even ran editorials about the FDA's drug approval process in response to the recalls (though editorials were few and far between, representing only 4% of the 161 unique articles in this media study).

A few key observations about these articles are relevant: First, the existence of such stories validates the theory that it was natural to consider the connection between the recalls of Redux, Pondimin, Posicor, or Duract and the FDA's drug approval policy. Reporters at publications ranging from the *Wall Street Journal* to the *Palm Beach Post*¹²⁶ thought the connection was relevant, and wrote about it.

Second, with a few exceptions the most well-conceived and thorough pieces appeared in specialty publications.

A good example is provided by J.D. Kleinke and Scott Gottlieb's article in the *British Medical Journal*.¹²⁷

While the piece is quite short, it was the only one which provided deep historical background, mentioned both the PDUFA and fast track legislation, and provided mathematical analysis to put the "adverse events

¹²³See, e.g., Elyse Tanouye & James P. Miller, *American Home, Monsanto to Combine in a Stock Swap Valued at \$35.08 Billion*, THE WALL ST. J., June 2, 1998, at A3.

¹²⁴See Robert Davis, *Painkiller Duract Recalled After Transplants, 4 Deaths*, USA TODAY, June 23, 1998, at A1.

¹²⁵See Rochelle Sharpe, *Painkiller: How a Drug Approved By the FDA Turned Into a Lethal Failure*, THE WALL ST. J., Sept. 30, 1998, at A1.

¹²⁶See *Second Opinion on FDA*, PALM BEACH POST, July 17, 1998, at A10.

¹²⁷J.D. Kleinke & Scott Gottlieb, *Is the FDA Approving Drugs Too Fast? Probably Not—But Drug Recalls Have Sparked Debate*, 317 BRIT. MED. J. 899 (Oct. 3, 1998).

that prompted each of the... drug recalls”¹²⁸ into perspective. Other examples of more complete, in-depth reporting were found in publications like *American Druggist*¹²⁹ and *The European*,¹³⁰ which can hardly be said to reach either a large audience or the “average” American.

More typical among those stories which appeared in daily newspapers was the editorial written by Joe and Teresa Graedon which ran in the *Star Ledger* of Newark, N.J., the *News & Observer* of Raleigh, NC, and *Newsday*.¹³¹ The editorial begins by noting that “the Food and Drug Administration has accelerated its drug approval process,” and then asks, rhetorically, “Have we traded speed for safety?”¹³² But the piece offers precious few facts—only mentioning the recalls of Redux, Duract, and Posicor in passing, along with recent reports of difficulties with prescription drugs Viagra and Propulsid. The authors offer no insight into the drug approval process, no statistics about how many drugs have been approved recently, and no analysis of how the FDA determines whether a drug should be removed from the market. The piece concludes rather abruptly with the message that “patients need to realize that they cannot depend on the FDA to protect them from life-threatening side effects or drug interactions,”¹³³ but fails to provide any suggestion to the FDA on how to do its job better, or any advice to individual people about what information they would need to protect themselves. Therefore, even among the articles which do provide context for the recalls of these four drugs, it was difficult to find basic information. It was even more difficult to find high-level, sophisticated analysis.

¹²⁸ *Id.*

¹²⁹ See Russ Colchamiro, *Patient Deaths Lead to Duract Withdrawal*, 215AM. DRUGGIST 26 (Aug. 1, 1998).

¹³⁰ See Cath Blackledge, *Drug Firms’ Multi-billion Dollar Headache: Pharmaceuticals*, EUROPEAN (June 29, 1998), available at 6/29/98 European 271998 WL 8699991.

¹³¹ See Joe Graedon & Teresea Graedon, *Is the FDA’s Drug-Approval Process a Disaster?*, STAR-LEDGER (NEWARK, N.J.), Aug. 11, 1998, available at 0091998 WL 16950686; Joe & Terry Graedon, *FDA Fails Us in Too-Swift Approval of Drugs*, NEWS & OBSERVER (RALEIGH, N.C.), July 19, 1998, at D6; Joseph & Teresea Graedon, *The People’s Pharmacy; Drug Approval: Is It Safe at Any Speed?*, NEWSDAY, July 21, 1998, at C4.

¹³² *Id.*

¹³³ *Id.*

Third, a few publications deserve mention as having paid particular attention to the problem of these four drug recalls and, generally, the FDA's drug approval policy. The best, most timely and in-depth article on the subject was probably written by Rochelle Sharpe of the *Wall Street Journal*,¹³⁴ and one could easily hazard a guess that the well-to-do readers of the *Journal* are well-informed regarding the drug approval process given the depth and breadth of FDA coverage.¹³⁵ Other publications which consistently cover issues relevant to the subject matter of this media study include the *Star-Ledger* of Newark, N.J. and the *Record of Northern New Jersey*.¹³⁶ The fact that two small New Jersey papers would cover the drug approval process so thoroughly shouldn't be entirely surprising; most drug companies have either manufacturing or office facilities in New Jersey.¹³⁷

Outside New Jersey, however, it was difficult for people to either (a) consistently obtain information about drug recalls or (b) obtain the context within which the FDA might have approved those drugs.¹³⁸ Such stories aren't hard to write for a broad audience; *USA TODAY* (which is often referred to as "McPaper" because it is written for a broad audience with a low reading level) provided an excellent news feature on the issue of drug approval.¹³⁹ But the *USA TODAY* piece was hardly timely (it ran almost three weeks after Duract—the last of the four drugs—was recalled), and it wasn't re-printed in any of the other newspapers

¹³⁴See Rochelle Sharpe, *FDA Defends Drug Monitoring as Physicians, Advocates Are Cautious*, WALL ST. J., June 24, 1998, at B5.

¹³⁵See also Robert Langreth, *Recall of a Popular Roche Drug Raises Questions on Testing, Approval Process*, WALL ST. J., June 10, 1998, at B16.

¹³⁶See, e.g., Edward R. Silverman, *Prescription for Danger? Suicide Raises Questions About Drug Monitoring*, STAR-LEDGER (NEWARK, N.J.), June 29, 1998, available at 6/29/98 Star-Ledger (Newark N.J.) 0011998 WL 3426988; Rafael Genera-Morales, *Putting Drugs to the Test: Clinical Trials Often Fail to Identify Side Effects*, REC. N. N.J., July 5, 1998, at B11.

¹³⁷See, e.g., Linda A. Johnson, *N.J. Drug Companies Attract Each Other*, AP ONLINE, March 25, 2001, available at 2001 WL 16547411

¹³⁸It is notable in this regard that the U.S. Newswire, which tracks the major television news networks' evening news programs, found that only one of the networks (ABC) reported on Posicor's withdrawal when the FDA's announcement was made. See U.S. Newswire, *Network TV Headlines from Monday, June 8, 1998*, available at 6/8/98 U.S. Newswire 1998 WL 5686499.

¹³⁹See Rita Rubin, *Rush to Judgment?: Policy Speeds Approvals, But Some Say It's Risky*, USA TODAY, July 10, 1998, at A1.

owned by Gannett News Service, thus limiting its audience.

Generally the quality of the news, feature, and editorial articles about the recalls of Redux, Pondimin, Posicor, and Duract was low. Pieces were short, buried deep inside, and—most strikingly—failed to provide any context for the FDA’s findings that the drugs should have been withdrawn. After reading so many different accounts of these four drugs’ withdrawals, one cannot help but be struck by the *lack* of information most people would have gathered about the FDA in the year following the Modernization Act. The careful reader might have noticed that four drugs had been withdrawn from the market, but might not have known that there was anything unusual about that fact. Only the vigilant reader would have thought that these drug withdrawals presented any legal/political problems for the FDA.

These conclusions point to a startling problem: if most people obtain most of their information about regulatory agencies like the FDA from the mass media, then absent a crisis people do not know much about the executive agencies. The public does not obtain enough raw information on a regular basis about legal questions, regulatory debates, or the effectiveness of particular governmental policies to provide any guidance to even the most democratic, public-minded person who works inside the FDA.

Government is a contrivance of human wisdom to provide for human wants. Men have a right that these wants should be provided for by their wisdom.

Edmund Burke¹⁴⁰

Conclusion

FOR THE AVERAGE NON-LAWYER, the work of a lawyer is almost beyond comprehension. Lawyers seem to do a lot of paper-pushing. They draft a lot of documents. They use incomprehensible language, never seem to reach a conclusion when you ask a seemingly simple question, and they charge astronomically high fees. They gather information from these huge, encyclopedic volumes of books which stand impressively behind their desks in order to remind their clients just how daunting a task it is to figure out what the law really is. But for the lawyer who works inside government, the law should be more accessible to average people than this. This lawyer's client is the "public interest," and the public has a right to know what its lawyers are doing for them. Moreover, the public has a right to re-direct its lawyers' energies when they are being spent unwisely. Any client should have that right, but in a democracy, the responsibilities of the government lawyer toward his client are even stronger.

This is why responsible, right-minded attorneys who work inside government often ask themselves how well they're serving the "public interest." They pore over poll numbers; they take telephone calls from people who wish to voice their opinion; they read the daily newspaper thoroughly, down to the "Letters to the Editor," seeking to determine how well they're doing their job.

If the media study discussed in this paper is even directionally correct, then we all face a serious problem: no matter how many well-meaning, right-minded attorneys we hire to work inside our government agencies, absent a crisis they cannot know how well they're doing. Additionally, perhaps many government attorneys

do not care what the public knows or thinks. They have their own sense of mission and are only interested in performing their job as they see fit. If these attorneys do not respond to the public interest, and if they are performing their job in a manner that the public believes is inappropriate, then it might be reasonable to expect that they would at least receive some negative feedback. Yet as this paper shows, the public doesn't have enough raw information about the law to evaluate its lawyers, to provide feedback, to minimize the principal-agent problem, or to provide a check on their activities.

Part I of this paper discussed the importance of the media in communicating legal/political information to people, and provided a hypothesis: absent a crisis, people receive very little information about government from the media. Part II of this paper discussed the popular criticisms of the FDA and provided a hypothesis about the kind of critiques which might have been raised about the agency during a crisis. Part III analyzed the information available to people during an event which *might* have been classified as a crisis, given the fact that the FDA recalled an unprecedented number of drugs from the market, and that people had died due to the drugs' initial approval. Yet having read a sample of the media coverage of those events, one must conclude that these four drug recalls did not constitute a crisis, since the media barely connected the events to FDA policy. Needless to say, the media's coverage didn't approach the level of principled discussion of FDA policy discussed in Part II of this paper.

This study, then, confirms the hypothesis it laid out in Part I: the amount of information available on a daily basis to people about the regulatory activities of their government is quite low.

For many people, this conclusion will not be very troubling. Those who work in government are faced with a dual task: representing, and leading. At times, people prefer that the "public servant" serve whatever interest the public seems to be clamoring for, and that he demonstrate no independent mind of his own. At other times, people are all too happy to delegate their judgment and their power to someone with more time, energy, and perhaps interest in a particular topic. If legal/political issues at a regulatory agency like

the FDA are often left to the judgment of the regulators who work at the FDA, perhaps that is what we prefer.

For me, however, this paper raises troubling questions about the relevance of lawyering in general. The issue under study here—drug safety vs. the speed of drug approval—provides one small example of the kind of issue which employs lawyers every day. To some people, it is a vitally important issue. For anyone with a life-threatening illness, it is a deeply personal and gut-wrenching issue. In order to work through the particulars of FDA policy—which are written in language which is just as technical, stilted, and difficult to access as the rest of the regulatory landscape—people need lawyers. In order to voice their objections, or suggestions to FDA policy, people need lawyers.

Any layman who hires a lawyer does so knowing that he will face a basic monitoring problem: his lawyer is doing work that he, the client, doesn't have the expertise to evaluate. So most clients need to trust that their lawyers are working in their own interest. This is a structural problem based on the fact that lawyers are members of a profession employing people who obtain specialized knowledge and aptitude through years of training.

But as this paper has shown, the problem for many clients is even deeper than that: they must depend on lawyers to initiate the legal discussion in the first place. Policy discussions aren't part of the daily discourse in today's newspapers, absent a crisis. When people lack information about what their government and what "their" lawyers are doing, how can they object? When people are unaware of the basic shape of FDA policy, how can they provide meaningful direction for those who work within the FDA? Government begins to feel invisible to people, and the law is something outside their daily experience. It's not a tool they can direct; it's something the lawyers take care of. They'd never think to voice their objection, or write a letter to the editor; they don't have enough basic information to form a learned opinion—much less ask that "their lawyers" change direction.

On the other hand, it is true that legislators provide valuable substitutes for their constituents. Congress holds endless hearings on the FDA, and often becomes both knowledgeable and vocal about the FDA's work. In addition, many consumer and business groups provide surrogates for direct popular involvement in FDA policy. The danger is that these surrogates do not reflect the actual shape of the American electorate's policy preferences. Elected representatives surely must pay attention to their constituents' wishes on the most visible and controversial issues, or they risk being defeated in the next election. But regarding less visible issues like the FDA's daily activities, representatives can often safely vote their conscience regardless of their constituents' actual wishes. Interest groups may fill the gap between congressional voting patterns and the preferences of the electorate, but they may not, whether because of basic collective action problems, or because of the socio-economics of lobbying. Thus public agencies like the FDA may be led astray about what the public interest really is. Moreover, since the public has extremely little information about the agency, even the public itself cannot correct the error.

If Charles Dickens' description of the High Court of Chancery in *Bleak House* still seems relevant to people, then this study points to one of the reasons. The law isn't their tool any more. It belongs to the lawyers, and it has become so technical, so complex, so incomprehensible that they banish it from their daily lives. The media have a great deal of information to impart, and they must communicate it using package with limited space. Journalists must naturally be selective in what they convey. Absent a crisis—in a situation like FDA's recalls of these four drugs—journalists selectively ignore the legal dimensions of the story. Why? Perhaps because the law is so disconnected from the experience of average people, and it is so difficult to explain, that it is hardly worth the effort.

On a daily basis, therefore, people will make do with the basic facts. They might notice a 600-word news item which doesn't dig far beneath the surface, but they won't be able to obtain enough data to suggest that anything else *exists* beneath the surface. Some might argue that this state of affairs is appropriate,

that people do not need to be constantly aware of every activity which is being pursued inside the federal government. Particularly at the FDA—where legal/political questions are necessarily complex because they not only contain a legal dimension and a political dimension, but also a scientific dimension—we might be better off delegating our judgment to a group of specialists who are qualified to make better decisions about our personal welfare than we are able to make ourselves.

The problem with this argument is that it fails to understand the value of maintaining responsiveness in our democratic institutions. Representative democracies are by nature quite fragile, since they must govern in a de-centralized, often messy and complicated way. They are rife with inefficiency, and vulnerable to the feelings of frustration they elicit from those who would prefer a government run more pragmatically, leaving important judgments to experts and avoiding lengthy legal/political battles which do little but waste out time. Taking time to understand other people's preferences is never a waste of time. Both good democratic governments and good businesses know this; the White House and the CEOs of America's Fortune 500 companies constantly hire pollsters to find out how better to serve their constituencies. Good lawyers know this as well. They meet with their clients as often as possible in order to ensure that they are performing the work their clients would have them do. For the regulatory lawyer who spends most of his day toiling away in a dank, lonely office trying to draft the latest code language, even a short telephone call from an average person about what value his work has created can provide a great deal of motivation. Such conversations help us build communities, feel connected to one another, and engaged in what we do. People who complain about corruption within government are asking people like regulatory lawyers to be more responsive to the public interest. They are looking for a stronger sense of community within government. This is not only a reasonable, but a laudable request.

But forget asking the regulatory lawyers to be more responsive to the public interest. The public doesn't have enough information. Without information, people cannot form knowledgeable opinions about regulation.

The public can't express its own interest. So whose interests do these lawyers represent? Until the media provides people with enough data to make informed decisions, the answer to that question will remain as steeped in fog and mud as Charles Dickens' High Court.

Appendix 1: Relevant News Accounts

Each of the following four tables lists information about the articles under study for this paper. Each article was assigned an ID Number in order to indicate which articles—although they carried separate headlines and appeared in different formats—were, in fact, the same. Byline, section, page number, and word count information was gathered where possible. Certain duplicate articles, such as articles placed on the AP wire multiple times in a particular day, have been removed from these tables.