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THE GOALS OF FDA REGULATION AND THE CHALLENGES OF MEETING THEM

Ralph S. Tyler[†]

The subject of this article is regulation, specifically regulation of products within the jurisdiction of the United States Food and Drug Administration (FDA). My perspective is, of course, shaped by my former work as counsel to FDA.

For students of administrative law and for lawyers practicing before administrative agencies, terms such as “administrative law” or “regulatory law” bring to mind legal doctrines such as delegation of legislative authority from Congress, for example, or statutory principles such as notice and comment rulemaking. These doctrines and principles are certainly important to parties affected by agency actions, to counsel who practice before agencies, and to courts reviewing agency actions. I would argue, however, that these doctrines and principles provide very little insight into most of the substantive work in which regulatory agencies are engaged every day. In addition, these legal doctrines and principles do little to inform our ongoing national debate about the proper place of regulation in our economic system.

Two fundamental questions must be addressed to understand and to evaluate the work of an administrative agency. First, is there a need to regulate in a particular area? And second, how should an agency operate to solve the problem which was the reason for determining that a need for regulation existed? Obviously, one reaches the second question of “how to regulate” only if the answer to the first question is that there is a need or reason to regulate.

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Why, then, do we have an FDA? Put another way, do we need an FDA? The predecessor of the modern FDA had its origins in response to Upton Sinclair's classic novel, *The Jungle*, which was published in the early 1900's. *The Jungle* is remembered most often for its graphic depiction of the unsafe and insanitary conditions in the Chicago slaughterhouses of the time. The novel is about much more than that, however. *The Jungle* is the story of Jurgis Rudkis and his family, an immigrant family who are living a squalid, poverty-burdened existence in Chicago. This family is oppressed by all the institutional forces with which they are forced to interact, including employers, landlords, and financial institutions.

There is nothing subtle about the theme of *The Jungle*; the bluntly stated theme is that unchecked economic power acts in an oppressive fashion. For Jurgis Rudkis and his family, there is seemingly no prospect for relief from this oppression. In the final third or so of the novel, however, Upton Sinclair gives his answer to how the crushing burdens of the Rudkis family and others like them will be relieved. For Upton Sinclair, speaking through Jurgis Rudkis, socialism is the answer.

The Jungle had a huge impact. The United States, starting with its then President, Theodore Roosevelt, took to heart the social and economic problems which Upton Sinclair portrayed so effectively, *but* rejected Sinclair's solution. The American model -- the public policy response to *The Jungle* -- was not socialism, as Sinclair proposed, but the establishment of institutions of public power to balance, if not control, the major institutions of private power. The United States Food and Drug Administration is perhaps the most prominent example of this model.

FDA exists because of the belief that without regulation -- meaning governmentally established and enforced rules and standards -- life-essential goods such as safe food and safe and effective drugs and medical devices are less likely to be available. I submit that this belief is rooted in fact. Consumers lack the information and the ability to monitor the safety of the food supply chain once the world changes from a place where people grow their own food or obtain it from their neighbors to a world in which food is grown and packaged far from where it is consumed, now often in other countries. Similarly, with respect drugs, there is no substitute for a well-controlled clinical trial to establish a drug's safety and effectiveness and conducting such a trial is beyond the competence of individual consumers. Consumers, unprotected by regulations requiring such trials, are unable to judge the safety and effectiveness of a drug.

The alternative to regulation in the areas of food, drugs, and medical devices is a marketplace flooded with products which carry no

greater assurance of safety, efficacy, and purity than the unverified and self-interested representations of those producing the products. Because of the risks inherent in that alternative, there is a strong consensus in our country and, indeed, across much of the world that regulation in the areas of food and medical products is necessary.

There are many complaints about how FDA operates. These complaints focus on the agency's fairness, including the perception of some that it is too close to the industries it regulates, its effectiveness, its slowness, and the costs of compliance. What is notable, however, is that few people, even FDA's severest critics, suggest that consumers would be protected adequately, let alone better protected, if there were no FDA and, instead, we had a system which permitted the unrestricted marketing, distribution, and sale of food and medical products. This is because not many people believe that the marketplace alone or the marketplace supplemented by the civil tort system would police the marketplace sufficiently to assure a reasonable level of safety and protection. The food and drug regulatory system has its weaknesses and most certainly it has its critics, but regulation in these areas is generally recognized as far preferable to no regulation.

If the answer to the question of "why do we have an FDA?" is clear and widely accepted, the answer to the question of how FDA should operate is far less clear and is considerably more controversial. Even after a century of food and drug regulation, there is no consensus in our country on many central questions. These questions include how should FDA be organized to do its work most effectively; what resources FDA needs to meet its responsibilities; and what percentage of FDA's funding should be general tax revenues and what percentage should be industry paid user fees. And perhaps most significantly, in the medical products area, there is little agreement on the core policy question of how much risk FDA should tolerate when, for example, it reviews products to allow them onto the market or when FDA acts to remove approved products from the market.

Since the adoption of the first version of the federal Food and Drug Act in 1906, Congress has enacted more than 200 laws related to the manufacture, distribution, and sale of food, health products, and most recently tobacco products. The agency, in turn, has adopted hundreds of implementing regulations and issued many guidance documents. Nevertheless, the regulatory framework is unsettled and there are now, as there have been in the past, demands in Congress and elsewhere to change the laws under which FDA operates.

The medical device industry, for example, is vocal in expressing the view that FDA is too risk adverse, too slow, is a barrier to innovation and job creation, and that the solution is removal of some of the regulators, or modification of the device approval process, or both.

Another example involves the issues of cost and access to medical products. Cost is not part of FDA's current statutory calculus. When escalating health care costs are one of the greatest challenges facing our country, a fair question is whether it makes sense to divorce drug and device approval decisions from questions of their cost and access to these products.

There are also questions about whether the agency's method of regulating is the most effective use of its limited resources. For many years, rulemaking has been the agency's overwhelmingly dominant mode of regulation. A preference for rules over adjudication is perhaps inevitable given that the Food, Drug and Cosmetic Act is not a model of clarity, an inevitable consequence of numerous legislative compromises and piecemeal enactments. In addition, the sweep of FDA's regulatory reach favors rulemaking over adjudication. The oft cited figure is that FDA regulates 20-25% of the US economy. It is not practical and it is potentially unfair to regulate that much activity one case at a time via adjudication.

The question remains, however, whether FDA has been too rule reliant and failed to bring a sufficient number of enforcement cases to make its rules credible. Over the years, while FDA's responsibilities have grown and the number of FDA regulated products has increased while the level of enforcement activity has declined. In 1975, for example, the agency brought 435 seizure actions (those being actions to seize unsafe or insanitary food or health products) and 29 injunction cases (cases against firms to stop unsafe or insanitary manufacturing, production, or distribution practices). Twenty years later in 1995, the numbers were 73 seizures and 8 injunctions; by 2008, it was 8 seizures and 5 injunctions. There has been an increase in the level of enforcement activity in the past couple of years, but the level of enforcement activity is still quite modest as an absolute matter and is particularly so when compared to the agency's overall regulatory output and the number of firms subject to its jurisdiction.

FDA was conceived, structured, and has operated as a domestic regulatory agency, on the assumption that it could do its job by regulating industries making or growing products in the United States. The world has changed, however, and the marketplace of FDA regulated products is now global. In 2011, nearly 24 million shipments of FDA regulated products, food, medical devices, drugs, cosmetics, radiation emitting devices, and tobacco products, will arrive at US ports of entry. These millions of shipments come from more than 150 countries, from more than 300,000 facilities, and involve 130,000 importers of record. Imports of FDA regulated products have quadrupled over the past decade.

Our nation's heavy reliance on imported food, medical products, and other FDA regulated products poses new public health risks and requires major changes in how regulation is conducted. When, for example, we experience an outbreak of food-caused deaths or illness in the United States, as occurred not long ago with cantaloupes, tracing the outbreak back to its root cause is essential to limit exposure and to prevent recurrence. This trace back task is difficult enough when the product is produced domestically. The problem becomes considerably more complex, but no less important, when the potential source of the offending product is a farm or processing facility on the other side of the world.

Increasingly, active pharmaceutical ingredients and components of medical devices are manufactured outside the United States. A central tenet of FDA's regulatory regime is that these products are to be manufactured in accordance with current good manufacturing practices. The rules governing these practices require that a manufacturer has control over its manufacturing processes and is able to document that control. FDA's ability to enforce these rules through inspection of non-US facilities is limited. Imported products also pose risks from economically motivated intentional adulteration or counterfeiting. This has occurred with pharmaceuticals, human food, and pet food.

American consumers do not have one standard for domestic products and another standard for imported products. The American people expect their food to be safe and their medical products to be safe and effective irrespective of the product's country of origin. FDA's challenge, therefore, is how to meet that expectation in a world in which increasingly these regulated products are imported from other countries. The realistic options are limited.

Scale and resources make it impractical to inspect with regularity all the non-US production facilities, farms, and manufacturing facilities producing for the US market. There are also serious limitations to using inspections at the border as the principal means of identifying unsafe or otherwise violative products. These limitations include the mismatch between inspection resources and the volume of imports and the need for expedited review of many products to avoid spoilage.

Necessity dictates that importers be responsible for assuring the integrity of their products. The framework has to be that those bringing products into this country are responsible for ensuring that their products are produced, packaged, and transported in accordance with science-based, prevention-based standards. The agency's regulatory responsibility is to articulate clear standards, while industry bears the burden and the responsibility of compliance. The Food Safety Modernization Act, which became law in January 2011, reflects this ap-

proach. The Act requires that each importer of food “perform risk-based foreign supplier verification activities,” the nature of which FDA is to define by regulations.

The global supply chain of regulated products means that FDA will increasingly need to rely on the regulatory regimes of the countries in which products originate and the countries through which products pass enroute to the United States. This need to rely on the regulatory regimes of other countries is a cause for concern, but is unavoidable. The new food safety law requires FDA to develop within two years “a comprehensive plan to expand the technical, scientific, and regulatory food safety capacity of foreign governments, and their respective food industries, from which foods are exported to the United States.” That is a tall order. Moreover, this is a task which must be approached with humility because no one can legitimately claim that the food safety system in the U.S. is free of weaknesses.

The case for strengthening regulatory regimes in other countries must be made on the ground that it is good for the exporting country. Exporting countries have a strong brand interest in having US consumers trust the safety of their products. That trust will grow and be maintained by developing the regulatory regimes of those countries. The force of this argument is undercut, however, by competing demands for scarce public resources. Again, this is as true in the United States as it is elsewhere. The United States Congress is far more likely to give FDA new regulatory responsibilities than it is to give FDA additional budget resources to meet those responsibilities.

As I believe these various examples illustrate, FDA faces the tension of the difference between the strong consensus around the question of the need for FDA and the lack of a consensus around the questions of how FDA should operate and what it should do to meet that agreed-to need. The gap between these two is not a trivial matter.

In the end, governing and regulating are not primarily about vision or theory; they are about execution; they involve managing complex organizations comprised of a large number of people of varying backgrounds and skills and having them perform day in and day out to solve tough problems like assuring the safety of the food supply and assuring that safe and effective drugs and medical devices get to the market while preventing unsafe and ineffective ones from reaching the market. Successful execution of these important and difficult tasks virtually presupposes agreement about how what needs to be done is done. The absence of agreement regarding the “how” of regulation inevitably diminishes regulatory effectiveness.

We in this country are not alone in our concern about the effectiveness of our administrative agencies. I had the opportunity to visit Beijing and Shanghai on behalf of FDA. In Beijing, I met with a

group of faculty and graduate students at Peking University Law School for a discussion about FDA and food and drug regulatory issues more generally. A young woman in the group asked the perceptive question of “how do you know if an administrative agency is actually making a difference?” This is a question which is not asked as frequently as it should be. How, then, does one know?

The starting point must be for an agency to articulate clearly what constitutes success. If an agency does not begin by defining success, it can never be said to have failed or succeeded because no one, including the agency, knows what constitutes success or failure. To be meaningful, an agency needs to define success with precision. An amorphous goal such as protecting the public health is too general a definition of success to be meaningful because it is not measurable. Specific public health metrics must be identified so progress against those metrics can be measured.

Consider, for example, FDA’s new responsibility to regulate, but not outlaw, tobacco products. The Center for Disease Control estimates that 46 million adult Americans smoke. An enormous amount of data has been accumulated over many years confirming the health risks and costs of smoking. These data show that smoking is the largest cause of preventable deaths in our country, and that there are enormous costs associated with treating people with smoking caused illnesses. The public health case for reducing the number of smokers is stated rather easily: reducing the number of smokers will prevent premature deaths; it will improve the health of those who quit or never start; and it will result in lower costs for the health care system overall.

As an example of what FDA is to do by way of regulating while not outlawing tobacco products, Congress directed FDA to promulgate a rule requiring cigarette manufacturers to put graphic images on cigarette packages depicting the health risks of smoking. The rationale of the proposed warnings is that having graphic images on cigarette packages will affect behavior by discouraging people from starting to smoke and encouraging current smokers to quit. Predictably, the tobacco industry has challenged these warnings on First Amendment and other grounds and, as of this writing, the courts have enjoined the implementation of the warnings. Assuming the warnings are upheld and ultimately implemented, the proof of whether the images make a difference is whether the number of smokers declines. That is, after all, the point of the warnings and, indeed, is the point of FDA’s having jurisdiction over tobacco products. The purpose of regulation is to make a difference, not to add to the volume of legally valid regulations. Promulgating regulations is only a means, not an

end, and it is certainly not the reason Congress gave FDA regulatory authority over tobacco.

Food safety is another example. CDC publishes data on food related illnesses and deaths of which there are approximately 3,000 in the United States each year. A relevant measure of the effectiveness of the FDA's increased regulatory activity in the food safety area is whether those numbers, adjusted for changes in population, decline.

Fairness requires recognizing that there are complexities associated with assessing accurately FDA's effectiveness. A critical part of FDA's work involves acting to prevent bad things from happening. The most famous example of this is FDA's failure to approve the drug thalidomide when the drug was approved in Europe. FDA's failure to follow Europe's lead prevented untold numbers of American children from being born with serious birth defects. Success here meant injuries were avoided because a product was not approved, a type of regulatory success which is difficult to measure.

Nevertheless, and recognizing the difficulties, those who believe in the importance of regulation as an essential tool in protecting consumers by preventing those with market power from abusing that power, and I count myself in that group, must take seriously the task of setting and transparently disclosing objective metrics against which regulatory performance can be judged. There is great truth to the statement that "if it is not measured, it won't get done." That statement applies to the wide spectrum of administrative agencies, from an agency responsible for food and drug safety to one responsible for filling pot holes.

FDA has made a start in this area. FDA publishes on its FDA Track website data for the various offices and centers so the public can see what the agency says it is going to do, what its goals are, and how the agency is performing against those goals. This effort is only a start, however, because the data tracked currently focuses on things like timely completion of regulatory or administrative actions, as distinguished from measuring the agency's performance in accomplishing its major public health objectives of, for example, reducing the number of smokers, or reducing the number of food related illnesses, or reducing the obesity epidemic which plagues our nation. FDA's timely accomplishment of its smaller regulatory tasks is not unimportant, but, in all fairness, those tasks are not the reason Congress created and funds FDA, nor are these smaller tasks of much interest to the American public.

The most basic principles of administrative law hold that administrative agencies are required to comply with the statutes pursuant to which they are authorized and agencies are bound to comply with their own rules. In other words, an agency must not violate the law.

While that much is to be expected, it is not sufficient. The law's equivalent of the Hippocratic Oath's "first, do no harm" is not a reason to create an administrative agency nor does it provide a rational basis for evaluating an agency's performance.

In the century since *The Jungle* was published, there has been a proliferation of regulatory agencies at all levels of government in the United States. Despite this, we know too little about how well these agencies actually perform. We need to demand greater clarity of agencies in stating how their performance is to be judged and more data about how, in fact, agencies are performing against those stated criteria.

FDA operates in the sensitive space of public health, balancing safety, risk, and benefit, and often it must make decisions based on imperfect or incomplete information. FDA will always be the subject of substantial criticism, some fair and some not. Unfair criticisms are best answered and the larger case for regulation is made most effectively by FDA's articulating clearly the criteria against which agency performance should be judged and disclosing in real time actual agency performance data. The need for an effective FDA is every bit as great now as it was at the time of *The Jungle* and, arguably, the task of protecting Americans is more complicated now than it was then.

Disparaging government is currently highly fashionable in our country. We should be cautious about this tendency and remember that we need our governmental institutions and we need them to work. The wholesale trashing of public institutions and those who work to maintain those institutions weakens the institutions, and thereby weakens their ability to protect the public. We need to return to a time when public service is honored, respected and, yes, encouraged.

The active debates in this country about regulation are close to the core of our never ending national debate about the proper role of government, including the role of the federal government as compared to that of state and local governments. Demonstrated agency performance will increase public support for the critically important work which administrative agencies, like FDA, do and ultimately provides the best answer to the question of why we need these agencies and, indeed, why we need an effective government.